

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL LOAN DIVISION

LOAN PRESENTATION TO THE BOARD OF AGRICULTURE

Please review the attached loan presentation prior to the meeting of the Board.

To protect the privacy of the applicant, all confidential/proprietary information has been placed in EXHIBIT A. Please be aware that certain confidential/proprietary information cannot be discussed at the board meeting without the expressed prior consent of the applicant. Any discussion or reference to this information at the meeting may potentially result in all of the information becoming public record. Should you have any questions pertaining to any information contained in EXHIBIT A, please call Dean Matsukawa, Administrator, at (808) 973-9460, prior to the scheduled board meeting.

Please return all hard copies of each loan presentation to the Board Secretary prior to or at the adjournment of the meeting. Your cooperation is greatly appreciated.

TERMS:

Amount: \$100,000
 Term: Ten (10) Years
 Interest Rate: 3.0% per annum
 Repayment: No payment for six (6) months, then interest payments of \$500 per month for six (6) months Followed by monthly principal and interest payments of \$1,058.00 until maturity.

SECURITY:

This loan will be secured as follows:

- A first position blanket security interest in crops, accounts receivable, farm and coffee roasting equipment. The accounts receivables total \$105,000 and farm equipment is valued at \$280,000. A specific security interest will be taken on \$100,000 worth of equipment which includes 2 Kubota tractors with loaders and a Diedrich Coffee Roaster. Other farm equipment consists of cultivators, disc, rototillers, mowers, forklift, fuel storage tank, greenhouse, kilns, canopies, curing tents, shipping storage containers, trailers, etc.

GUARANTORS:

None

**FINANCIAL
CONDITION:**

SEE EXHIBIT A (CONFIDENTIAL)

**REPAYMENT
ABILITY:**

SEE EXHIBIT A (CONFIDENTIAL)

INSURANCE:

Liability insurance with SALD as certificate holder.

BACKGROUND:

Originally from New Hampshire, Mr. Drent is a long time resident of Hawaii, is married to Gigi Thru Drent and they have 2 children,

ages twelve and fifteen. In 1991, he received his B.A. in English from the College of Wooster, Wooster, Ohio. Mr. Drent then moved to the Big Island of Hawaii in 1991 and established his business in 1993.

Mrs. Drent has been a resident of Hawaii since mid-2003, when she relocated from California for an employment opportunity on the island of Kauai. In 1999, Mrs. Drent received her B.A. with CA Single Subject Credential in Mathematics and a minor in Business Administration from California State University at Fullerton and in 2002 received her M.A. in Mathematics with a Concentration in Teaching. Mrs. Drent began her career as a Math Instructor at La Serna High School in Whittier, CA from September 1999 to June 2003; and was also a Math Lecturer at the California State Polytechnic University at Pomona, CA from January of 2003 to June 2003. In August 2003, Mrs. Drent secured the position of Professor of Mathematics at the Kauai Community College in Lihue, island of Kauai, Hawaii where she continues to hold this position.

LBD Coffee, LLC ("LBD Coffee") is a Limited Liability Company that was originally established in the State of New Hampshire on December 31, 2002, and was registered in the State of Hawaii on August 4, 2006. Leslie B. Drent is the sole member of LBD Coffee. The Applicant currently farms a total of about 23 acres of coffee, tobacco, cacao and added corn to their crop production in 2014. On a smaller scale they raise bees for honey and farm pollination and grow a wide variety of fruits including but not limited to mango, lychee, avocado, breadfruit and bananas.

The Applicant operates Hawaii grown value added agricultural ventures "doing business as" Coffee Times, Blair Estate Coffee, Kauai Cigar Company and Kauai Distilling Company. Coffee Times is the name of Mr. Drent's publication started on the Big Island in 1993 as a tourist guide and coffee industry promotional magazine.

The coffee business was Mr. Drent's first line of agricultural activity after he arrived in Hawaii in 1991, and he started off by roasting and selling 100% Kona grown coffee on the Big Island. Mr. Drent's interest expanded to "roasting services" and he decided to move his businesses to Kauai in 1998. In 2001 he purchased a 2.5 acre agriculture parcel and began growing Certified Organic Kauai coffee on this parcel and built his residence that included their roasting facility on the ground level of his family farm called Blair Estate. In 2002, LBD Coffee was created and he started the Blair Estate Coffee business and trademark and started growing, roasting and retailing its own

Kauai grown coffee as well as beans from other farms around Hawaii. In 2005, their business increased further when a Kauai roaster stopped servicing the local wholesale buyers so the company started roasting and selling international coffee. The company, today, retails its own brand of Blair Estate 100% Kauai Organic Coffee, Coffee Times 100% Kona Coffee. Due to their high price these coffee products are sold almost exclusively online and by phone order. The company also retails Hawaii grown macadamia nut and coffee chocolates, Blair Estate honey, lychee and various other locally grown fruits and vegetables.

Mr. Drent experimented with small tobacco crops for many years then in 2004, he acquired a 2-acre portion of a 4.11-acre parcel in Kapaa through a 30-year joint venture Lease from the State of Hawaii, Department of Land and Natural Resources. His interest in tobacco is due partly from his fondness for Cigars and his recognition of the similarities in the weather and soil conditions between Kauai and the traditional tobacco growing regions. This interest and experimentation created Kauai Cigar Company in 2005. After an extensive search, Mr. Drent obtained an old generation Cuban Pinar del Rio seed that is valued in Cuban cigar production. He also acquired Cuban originated Habano, Corojo, and Criollo seed, as well as Connecticut Shade and Broadleaf seed. Planting tobacco seeds properly can be a challenge, but Kauai's summer climate is similar to Cuba and their tobacco plants thrive in this perfect tropical environment. The almost year-round growing season begins in March and runs through December, allowing the company to plant and harvest several crops of tobacco per year. The mineral rich deep volcanic soil fed by natural water from mountain waterfalls plays an important role in the healthy growth of their tobacco. During the growing months their tobacco is suckered and the flowers are removed so that the leaf production on the plant is maximized. During harvests, leaves that are at peak ripeness are selectively chosen from different parts of the plant. Leaf picking begins at the bottom of the plant and works upwards at a rate of 3 leaves per week. The Volado (bottom leaves) serve as mild filler for the cigars; the Seco (from the middle) provides texture and taste; and the strongest tobacco is the Ligerero (from the top of the plant). Each leaf must be mature and intact at the time of harvest and a total of 18-21 leaves per plant is harvested over an estimated 6-7 rounds of picking. The dark wrapper cigars contain mostly Ligerero tobacco while their light wrapper cigars contain mostly Seco and Volado leaves. After harvesting, the tobacco leaves are then cured, transforming the tobacco's chlorophyll into starches. The company has chosen this technique of slow-drying the leaves in a climate controlled barns to preserve nearly all of the essence of the leaf. This slow air-curing and drying of the leaves lasts four to eight weeks making sure the tobacco never completely

dries out. Special attention must be given to both heat and humidity so that the leaves remain pliable before being moved to the next step of production. The tobacco leaves are loosened and baled, and then goes through a 40-day fermenting period to stabilize the leaf. It took the company nearly 6 months to obtain a federal permit to manufacture and sell cigars. The reporting requirements, bi-monthly federal taxes and a substantial monthly 50% Hawaii wholesale tax made it financially impossible to hand produce these cigars in Hawaii. While looking for a solution to this problem, they were introduced to a contact based in Nicaragua that would be able to manufacture their premium tobacco into cigars. This aromatic Kauai tobacco is shipped to Nicaragua where it is fermented in bulk and transforms starches into sugars that allows the tobacco to become sweeter and finer in flavor. With the careful regulation of humidity and temperature, the fermentation process "sweats out" impurities that can cause harshness in flavor and scent. Following fermentation, the leaves are aged allowing the tobacco to take on character, a smoother scent and richer flavor. At a small factory in Esteli, Nicaragua the tobacco is hand rolled into cigars, draw tested, hand inspected and carefully packed into handmade wood cigar boxes. Once these cigars have rested, they are imported back to Kauai. The company started with growing tobacco on the 2-acre parcel and has expanded to 20 acres with the addition of a 16-acre parcel in Lihue obtained in October 2011 through a License Agreement with the Grove Farm Company, and an additional 2 acre agricultural parcel that was purchased near the coffee farm and original tobacco farm.

The fourth and final brand, Kauai Distilling Company, was created in 2014. While searching for a viable cover crop for tobacco, Les considered planting triticale, a crop that would benefit the organic matter in the soil between tobacco seasons. Before that cover crop failed, Les realized that triticale could be used to produce whisky. Unfortunately, without a harvest, making whisky from triticale was not possible. But his dream to make whisky endured and he turned to another grain, corn, that flourishes on Kauai. After four long years of growing various varieties of corn, and serious research and development at a partner distillery in Spokane, Washington, he was able to produce small batch bourbon. Kauai Distilling Company was born and it's brands of Kapahi Bourbon, and Virgin Kea moonshine are currently sold in Hawaii stores. Kauai grown corn production has increased over the last two years and the company currently partners with Beck's Hybrid in Kekaha, Kauai to grow, combine, and dry its corn before shipment to the mainland.

COMMENTS:

Mr. Drent is an experienced farmer and an innovative businessman. The company believes that to be successful, farming today requires the ability to grow, produce, fabricate, brand and distribute high end crops into value added goods, while also sustaining the environment for tomorrow's farmers. The company has been successful in its endeavors and found ways to succeed despite many challenges.

The COVID-19 pandemic has caused a significant decline in the company's sales and the proposed loan will provide the necessary funds to continue the farm operations.

The loan will be well secured with the farm equipment and accounts. Mr. Drent has excellent credit and the financial strength to support the loan. The company's historical performance demonstrates more than sufficient repayment ability for the proposed loan.

TURNDOWNS:

Turndowns for emergency loans of \$100,000 and under have been waived by the Board of Agriculture.

RECOMMENDATION:

Approval of this request is recommended based on LBD's positive historical performance, the collateral offered and Mr. Drent's excellent credit history.

Date

Recommended by:

6/12/20

Dean M. Matsukawa
Dean M. Matsukawa
Division Administrator

Date

Approved for Submission:

6/16/20

Phyllis Shimabukuro-Geiser
Phyllis Shimabukuro-Geiser, Chairperson
Board of Agriculture

in Kona, Hawaii. The loan is secured by first position leasehold mortgages on three parcels totaling 28.9 acres and a first position financing statement on farm assets. The 2010 appraised value of the three leaseholds securing the SALD loans was \$1,000,000. The Batemans have handled their SALD loan responsibly

LOAN REQUEST & PURPOSE:

<u>AMOUNT</u>	<u>CLASS</u>
\$100,000	Class D Direct Emergency Loan

Shown below is a breakdown of the loan request.

\$82,000	Operating Funds
<u>\$18,000</u>	Repair Water System
\$100,000	TOTAL LOAN REQUEST

Operating loan funds will used to maintain the coffee orchard including fertilizing, spraying for CBB and labor costs etc. The repair of the water system is critical as it supplies water to their seedling nursery and the coffee processing facility.

TERMS:

Amount: \$100,000
Term: Ten (10) Years
Interest Rate: 3.0% per annum
Repayment: No payment for six (6) months, then interest payments of \$500 per month for six (6) months Followed by monthly principal and interest payments of \$1,058.00 until maturity.

The no payment and interest payments are scheduled to assist with cash flow during the pandemic. If additional time is needed SALD will work with the borrower to adjust the payment.

SECURITY:

The loan will be secured by a second lien blanket Financing Statement covering crops, equipment, and accounts on Heavenly Hawaiian, Ltd. and the Other Farm, Ltd. The farm and coffee roasting equipment including a Satake Color Sorter is valued at \$123,000. The current coffee inventory is valued at \$263,000. The first position Financing Statement is held by the SALD for its prior loan to Heavenly Hawaiian, Ltd. and the Other Farm, Ltd.

GUARANTORS:

David A. Bateman and Trudy A. Bateman, husband and wife, will be required to personally guaranty the loan.

**FINANCIAL
CONDITION:**

SEE EXHIBIT A (CONFIDENTIAL)

**REPAYMENT
ABILITY:**

SEE EXHIBIT A (CONFIDENTIAL)

INSURANCE:

Liability insurance with SALD as certificate holder.

BACKGROUND:

In 2005, Mr. Bateman bought a coffee farm on 3 adjoining leasehold parcels from Kraig Lee and Ray Young. In addition, he purchased a 4th parcel which had a coffee and macadamia nut farm on the adjacent leasehold property consisting of 11.2 acres from Earl Serry. The macadamia nut/coffee farm needed a lot of work including removal of macadamia nut trees that were shading out the coffee trees and renovation of an unfinished dwelling for labor housing. The total farm acreage is now 38 acres with 32 acres in coffee plantings. They also purchase coffee from Mr. Bateman's 7-acre coffee farm and residence in Keauhou Mauka.

Since buying the farms, Mr. Bateman has made major improvements with a focus on increasing yields and profitability. Improvements included planting coffee trees in open areas to increase production and vertically integrating the operation. The farms are all fully irrigated which helps ensure steady production and helps the quality of the beans as it reduces the number of "floaters" during the periods of drought. The farm is vertically integrated and has the ability to fully process the coffee from cherry stage to green bean and to roasted coffee.

Initially the farm sold most of the crop via wholesaling green bean and the balance retailed as roasted coffee. In order to increase profits, they focused on increasing roasted coffee sales and began offering tours of the farm. Initially they had 20-30 visitors daily and before the shutdown it had grown to over 200 participants a day who would also frequent their gift shop and join their mailing lists. As their agri-tourism business increased they improved their web presence with an online store and a coffee subscription service. The farm now has 6 full-time employees and 20 seasonal hires for coffee harvesting. The farm also utilizes volunteer labor to assist with the farm work in exchange for learning about coffee growing and housing.

COMMENTS:

The Bateman's are experienced coffee farmers and continually seek to improve their coffee farm and operation. The farm is vertically integrated and has the capacity to take coffee grown on their farms from cherry to roasted coffee. They have a steady clientele and developed a good reputation with tourists.

A farm inspection shows that the farm is very efficient and productive. Coffee is healthy and well maintained. The operation has suffered a significant reduction in sales due to the COVID-19 pandemic. Once quarantine is lifted, it is expected that sales for the farm will slowly recover. If the quarantine is prolonged they will concentrate on increasing coffee club sales and resume wholesaling of green bean coffee.

The proposed loan will be well secured by the farm equipment and coffee inventory. The proposed loan along with the company's cash on hand should provide sufficient liquidity to maintain operations until full sales can resume.

TURNDOWNS:

Turndowns for emergency loans of \$100,000 and under has been waived by the Board of Agriculture.

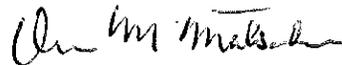
RECOMMENDATION:

Approval of this request is recommended based on HH and TOF positive historical performance, the company's credit history with SALD and the collateral offered.

Date

6/12/20

Recommended by:

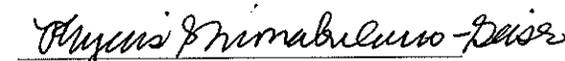


Dean M. Matsukawa
Division Administrator

Date

6/16/2020

Approved for Submission



Phyllis Shimabukuro-Geiser, Chairperson
Board of Agriculture

TERMS: Amount: \$100,000
 Term: Ten (10) Years
 Interest Rate: 3.0% per annum
 Repayment: No payment for six (6) months, then interest payments of \$500 per month for six (6) months Followed by monthly principal and interest payments of \$1,058.00 until maturity.

SECURITY: This loan will be secured as follows:

- First position on horse herd valued at \$135,000.
- A second position blanket security interest in livestock, accounts receivable and ranch equipment. Ranch equipment is valued \$165,500 and consists of a flat track skidsteer, mowers, trailers, ATVs, compressors and welding machine. The cattle herd including cows and bulls are valued \$1,050,000. The first position is held the USDA Farm Services Agency for their loan with a balance of \$235,418.87.

GUARANTORS: None

FINANCIAL CONDITION: SEE EXHIBIT A (CONFIDENTIAL)

REPAYMENT ABILITY: SEE EXHIBIT A (CONFIDENTIAL)

INSURANCE: None

BACKGROUND:

Zanga Schutte grew up on homestead land on the Big Island after his family moved from Oahu in 1965. Growing up he competed in roping events at rodeos and is well known on the rodeo circuit. He grew up ranching cattle with his father Spencer Kalani Schutte. In 1986, he began work as a range manager for Hale Kea Farms. In the 2000s he left Hale Kea Farms to started ranching full-time as ZBAR. He initially purchased 100 head of cattle as seed stock from Colorado and has grown the herd to 700 mother cows with a cycle of spring and fall calving divided evenly with approximately 350 per season. The ranch has 2,500 acres of pasture lands spread throughout Kamuela. The ranch land consists of 8 Department of Hawaiian Home Lands (DHHL) parcels and a lease from James Walker Trust. The 8 DHHL parcels are under Third Party Planting/Grazing Agreements, all of which have been approved by DHHL.

The ranch employs two workers not including Mr. Schutte and takes a holistic approach to cattle ranching. This includes good stewardship and management of the land to ensure well maintained pastures and making sure there is easy access to adequate feed and water for the herd. Taking care of the herd includes being attentive to their needs and not chasing or stressing the animals to create better temperament and more tender beef. The ranch is also GAPs certified, the animals are hormone and antibiotic free. The ranch is audited on an annual basis to check the condition of the herd as part of the certification. In addition, there are other provisions including records maintained on treatments, corralling and transportation. The certification allows his meat to marketed to stores such as Whole Foods.

Mr. Schutte also works with Hawaii Meats as a broker for the local area with the ultimate goal to allow cattle ranchers to be less price takers and receive higher prices. He has used his own funds to build a scale and receiving corral that allows ranchers to accurately know the live weight of the cattle being sold. The ranchers are paid a set price based on the live weight of the cattle and if the quality of the beef is better than anticipated they are paid a higher price.

COMMENTS:

Zanga Schutte is an experienced rancher who provides quality grass-fed beef to Hawaii consumers. The ranch is operates in a humane and sustainable manner. The field visit to the ranch confirmed that the pastures are well managed and that the animals are in good condition, healthy and have a gentle temperament.

The ranch has suffered a significant drop in income as a result of the Corona virus which has affected prices and shipping of animals. The

proposed loan will provide assistance in paying for necessary operational expenses to keep the long-time ranch in operation.

The loan will be well secured with horse herd and a second lien position on the cow herd and ranch equipment. The ranch has sufficient historical cash flow to service the proposed debt. The loan is supported by the overall strength of the LLC and Zanga Shutte personally.

TURNDOWNS:

Turndowns for emergency loans of \$100,000 and under have been waived by the Board of Agriculture.

RECOMMENDATION:

Approval of this request is recommended based on Mr. Schutte's ranching experience, the historical performance of the ranch, collateral offered and good credit rating.

Date

Recommended by:

6/12/20

Dean M. Matsukawa
Dean M. Matsukawa
Division Administrator

Date

Approved for Submission:

6/16/2020

Phyllis Shimabukuro-Geiser
Phyllis Shimabukuro-Geiser, Chairperson
Board of Agriculture

**State of Hawaii
Department of Agriculture
Agricultural Loan Division**

June 23, 2020

**Board of Agriculture
Honolulu, Hawaii**

Subject: Loan Presentation

APPLICANT: Dutch-Hawaiian Dairy Farms, LLC
P.O. Box 461
Papaikou, HI 96781

**CLASSIFICATION
& ELIGIBILITY** The applicant meets the eligibility requirements of Chapter 155, Hawaii Revised Statutes. Dutch-Hawaiian Dairy Farms, LLC (DHDF) was registered as a limited liability company (LLC) with the Department of Commerce & Consumer Affairs (DCCA) on 12/16/19 and is owned 50% by Kees Kea, 25% by Malena Kea, and 25% by their son Cornel Kea. Kees Kea and Malena Kea are qualified farmers and have owned and operated farms in Hawaii and on the Mainland. They currently own Mauna Kea Moo, LLC which is owned 50% each by Kees and Malena which was registered by the DCCA on 4/19/05. Malena and Cornel are US citizens and have been residents of Hawaii for the past 17 years. Kees is a permanent resident alien and a Hawaii resident for the past 17 years.

COMMODITY: Dairy

CREDIT HISTORY: SEE EXHIBIT A (CONFIDENTIAL)

**OTHER STATE
AGRICULTURAL
LOANS:**

None

**LOAN REQUEST
& PURPOSE:**

<u>Amount</u>	<u>Class A Direct Ownership/Improvement</u>
\$495,000	Purchase dairy infrastructure
\$105,000	<u>Install feed lane</u>
\$600,000	Total Request

The requested loan will purchase the leases and farm infrastructure from Cloverleaf Dairy in Kohala on the Big Island. The purchase includes eight leasehold parcels totaling 879.549 acres. The Keas have already contributed \$5,000 to the transaction and the loan request will provide the remaining \$495,000 for purchase of the infrastructure. The loan will also provide \$105,000 to construct a cement feed lane by the milking barn in order to efficiently feed the milking cows and eliminate feed waste.

<u>Amount</u>	<u>Class C Direct Operating</u>
\$200,000	Purchase dairy herd and equipment
\$200,000	Operating funds
\$200,000	<u>Equipment purchase</u>
\$600,000	Total

This loan is to purchase the existing dairy herd and equipment, provide operating funds and purchase additional equipment. The herd as of 11/10/19 consists of 513 cows of which 319 are milking, 194 are dry cows and 600 heifers. The Keas will be contributing an additional 120 heifers many of which already been bred and expected to be producing milk within the next few months adding to production. The purchase will also include all of the dairy's equipment that is sufficient to fully operate the dairy.

The loan also provides funds to purchase additional equipment to grow and produce forage for their dairy. The equipment includes a baler, a feed wagon, a skid steer, a mower, and a slurry tanker. The slurry tank will be used to hold animal waste and wash water that can then be used to fertilizer pasture land. The baler will be used to compress

forage that allows them to cut and store grass when forage is abundant and then supplement feed for the livestock during the dry months. This would reduce the amount of feed that they would need to purchase from the Mainland which should substantially reduce their feed costs. In addition, they have access to additional grass from the O'okala lease which can supplement feed during the dry months.

TERMS:

Class A – Direct Farm Ownership Loan

Amount: \$600,000
Period: 18 years
Interest rate: 3.75% per annum, fixed.
Repayment: Interest only for the first six months followed by principal and interest payments of \$3,901 per month until maturity.

Class C – Direct Operating Loan

Amount: \$600,000
Period: 10 years
Interest rate: 3.75% per annum, fixed.
Repayment: Interest only for the first six months followed by principal and interest payments of \$6,265 per month until maturity.

SECURITY:

The Class-A loan and Class C loan will be secured by the following:

- First leasehold mortgages on the following eight parcels: TMKs (3) 5-5-003-004, 5-5-003-005, 5-5-003-006, 5-5-005-001, 5-5-006-002, 5-5-006-003, 5-5-006-004, 5-5-006-015. The properties are located in Hawaii on the island of Hawaii and total 879.549 acres. The properties are under the management of the Agricultural Resource Management Division (ARMD) of the Hawaii Department of Agriculture with a term that extends to 6/22/41. Parcel 5-5-006-002 has three-3bdrm 1 ½ bath 1,056 sq. ft. labor houses. Parcel 5-5-006-003 has one-3bdrm 2 1/2 bath 1,800 sq. ft., one-3bdrm 2bath 1,224 sq. ft., one-3bdrm 2 bath 1,380 sq.ft. The properties also contain a dairy milking barn, a feed storage shed

and pasture infrastructure such as fences, water lines, and water troughs. The leasehold properties and improvements had an appraised market value of \$1,150,000 as of March 30, 2020. The properties and improvements were appraised by State certified appraiser Ted Yamamura of ACM Consultants Inc.

- A first lien blanket Financing Statement and Security Agreement on livestock, accounts, inventory, and equipment. A specific interest will be taken in the equipment and livestock being purchased with the dairy and in the equipment that will be purchased with a portion of the loan funds. The dairy's existing equipment includes tractors, milking equipment, compressors, chillers, milk storage tank, feed wagons, milking stalls, generators, and sprinkler guns. The estimated value of the dairy's equipment is \$450,000 and the herd is \$400,000. The value is based on a review of similar equipment being listed for sale and the condition of the equipment. The additional 120 heifers contributed by the Keas is valued at \$100,000. The total value of the livestock and equipment is \$950,000.

Class A

$$\frac{\text{Loan to Value Ratio}}{\text{Value Ratio}} = \frac{\$600,000}{\$1,150,000 \text{ (RE Appraised Value)}} = 52.2\%$$

The loan to value meets the statutory requirement of a maximum 85% loan to value. For informational purposes shown below is the overall loan to value ratio indicating that the loans are well secured. It should be noted that some of the valued collateral have limited life.

$$\frac{\text{Loan to Value Ratio}}{\text{Value Ratio}} = \frac{\$600,000 \text{ (Class A)} + \$600,000 \text{ (Class C)}}{\$1,150,000 \text{ (RE)} + \$950,000 \text{ (Chattels)}} = 57.1\%$$

GUARANTORS:

The following are required to personally guarantee the loan:

- Kees Kea
- Malena Kea
- Cornel Kea

**FINANCIAL
CONDITION:**

SEE EXHIBIT A (CONFIDENTIAL)

**REPAYMENT
ABILITY:**

SEE EXHIBIT A (CONFIDENTIAL)

INSURANCE:

Property insurance on the residences and dairy infrastructure with SALD named as mortgagee and commercial general liability insurance.

**BACKGROUND/
MANAGEMENT
ABILITY:**

Kees Kea is a multi-generation dairyman originally from the Netherlands. He also had a general contractor's license in the Netherlands and California and owned a construction business in both places. Malena was raised on a dairy in Southern California. She lived in the Netherlands for three years and learned the art of cheese making. When her parents retired in Tillamook, Oregon, Kees and Malena purchased and managed the family's dairy farm for 13 years. In 2003, they moved to the island of Hawaii and Kees became a partner and manager of Island Dairy. The partnership did not work out, but he realized that he wanted to eventually own and operate a dairy in Hawaii. Kees and Malena currently operate a cattle operation under Mauna Kea Moo, LLC in O'okala, Hawaii on 1,400 acres under a Department of Land and Natural Resources (DLNR) long-term lease. The Keas acquired the lease with the objective of developing a dairy. The property was overgrown with weeds and brush, and they were able to obtain a USDA grant to clear land, put in roadways, and install fencing, water lines, and water troughs. They acquired dairy and beef cattle to help clear the lands through grazing and have been selling some of the beef cattle to generate income. The Keas have been attempting to secure funding to start a dairy at the site, but it will be expensive and time consuming to develop the dairy's infrastructure from the ground up. Currently there is no access to electricity and potable water which would make dairy operation more costly.

The opportunity to purchase Boteilho's dairy presents a rare one-time opportunity to acquire a turnkey farm that has all the infrastructure and equipment in place, as well as an existing market for fluid milk. Purchasing the operating dairy would be less costly than developing the infrastructure from scratch and would allow the Keas to start farming and generating income immediately. The dairy has two separate milking lines which provides redundancy and backup should one line need to be shutdown. The operation also has two tanks to hold and chill milk on site and a tanker vehicle to transport the milk to the processor. The property also has six dwellings that can be used for labor housing and for the Keas to live in. In addition, the farm has numerous tractors and farm machinery to operate the dairy and sprinkler guns to water a portion of the pastures. The construction of a cement feed alley will reduce feed waste and the Keas' access to the 1,400-acre parcel allows them to cut down substantially on feed costs as they would be able to grow, bale, and store feed to reduce the reliance of shipping feed in from the Mainland. Since feed costs are typically the major cost of operating a dairy in Hawaii, reducing this expense would have a major impact on the dairy's bottomline.

In addition to Kees and Malena, two of their four children plan to help operate the dairy. They were raised in Hawaii and acquired complementary backgrounds and education. Cornel Kea obtained a degree in agriculture from the University of Hawaii at Hilo focusing on Animal Science. He spent his junior year as an exchange student at the University of Wisconsin, River Falls, studying dairy science. He worked at the university's dairy in Wisconsin as well as their production center where value-added dairy products such as cheese, cheese curds, and ice cream were made. To prepare for the family's dairy, he obtained his pasteurizing certification. Their daughter, Alida, majored in business at Portland State. She and Malena will be responsible for marketing and sales of the value-added products once they are produced.

SUMMARY:

The severe drought in 2019 resulted in poor milk production and increased feed costs which put Cloverleaf Dairy in poor financial condition. Despite the recent rains and much improved milk production the operation's financial condition remains poor and with pressure from

creditors is on the verge of shutting down. The shutdown of the dairy will result in significant problems including the health and welfare of the animals which need to be watered, fed and milked, long time employees familiar with the herd would be lost and idle dairy equipment would deteriorate.

Cloverleaf Dairy is the only dairy remaining in Hawaii. The farm has all the necessary infrastructure and equipment in place to continue operating including grazing land, a milking barn, a feed storage facility, equipment, labor housing, and a waste system. The Keas have the opportunity to take over an operating dairy that would have more favorable conditions and be cheaper than starting their own dairy in O'okala. Kees and Malena have years of experience operating dairies including one on Hawaii Island. Malena has experience in making cheese which could lead to value-added opportunities to increase profits. Their children have also been obtaining education and training in complementary areas to assist the family's dairy and also help reduce labor costs. Kees' background in construction will be beneficial to make renovations and repairs that will be needed.

The Keas are experienced dairy operators and the loans will be well-secured. The requested loans will allow the State's last dairy to continue operating under new ownership and will help the State to supply some of its own milk to contribute toward food self-sufficiency.

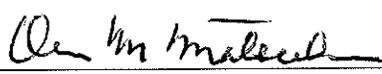
TURNDOWNS:

Bank of Hawaii and Home Street Bank denied the loan request for the following reasons:

- Insufficient collateral
- Lender lacks sufficient knowledge financing a dairy
- Lack of established earning record
- Insufficient income for amount requested

RECOMMENDATIONS: This loan request is recommended for approval based on the Keas' dairy farming experience, credit history. collateral offered, projected debt servicing ability.

Disbursal of loan funds are subject to transfer of milk quota and leases from Boteilo Hawaii Enterprises to Kees Kea or Dutch Hawaiian Dairy Farms, LLC.

Date
6/12/20
Recommended by:


Dean M. Matsukawa
Division Administrator

Date
6/17/2020
Approved for submission:


Phyllis Shimabukuro-Geiser
Chairperson, Board of Agriculture

them with wean offs that typically receive \$0.40/lb more than market. The ranch also pastures their bulls and in exchange is able to use the bulls for the ranch's breeding program.

The ranch main focus is raising grass-fed beef which takes significantly longer finish compared to utilizing a feed lot. The ranch markets the grass-fed cattle to Hawaii Meats. The decline in income in 2018 is primarily due to an attempt to try breeding heifers with Wagyu bulls in order to produce a smaller but higher price per weight calf but unfortunately this is not go as planned and the calves were about a month behind in growth and conception rate was lower than anticipated.

The three average ranch income totals \$496,374 with an average annual net of \$116,568. Annual debt service for the ranch's existing debts totals \$69,852 and along with the proposed SALD debt service of \$12,696 totals \$82,548 annually. The ranch's average annual net income of \$116,568 over the recent three-year period is sufficient to service existing debts along with proposed loan.

**OTHER STATE
AGRICULTURAL
LOANS:**

None

**LOAN REQUEST
& PURPOSE:**

<u>Amount</u>	<u>Class A Direct Ownership/Improvement</u>
\$495,000	Purchase dairy infrastructure
<u>\$105,000</u>	<u>Install feed lane</u>
\$600,000	Total Request

The requested loan will purchase the leases and farm infrastructure from Cloverleaf Dairy in Kohala on the Big Island. The purchase includes eight leasehold parcels totaling 879.549 acres. The Keas have already contributed \$5,000 to the transaction and the loan request will provide the remaining \$495,000 for purchase of the infrastructure. The loan will also provide \$105,000 to construct a cement feed lane by the milking barn in order to efficiently feed the milking cows and eliminate feed waste.

<u>Amount</u>	<u>Class C Direct Operating</u>
\$200,000	Purchase dairy herd and equipment
\$200,000	Operating funds
<u>\$200,000</u>	<u>Equipment purchase</u>
\$600,000	Total

This loan is to purchase the existing dairy herd and equipment, provide operating funds and purchase additional equipment. The herd as of 11/10/19 consists of 513 cows of which 319 are milking, 194 are dry cows and 600 heifers. The Keas will be contributing an additional 120 heifers many of which already been bred and expected to be producing milk within the next few months adding to production. The purchase will also include all of the dairy's equipment that is sufficient to fully operate the dairy.

The loan also provides funds to purchase additional equipment to grow and produce forage for their dairy. The equipment includes a baler, a feed wagon, a skid steer, a mower, and a slurry tanker. The slurry tank will be used to hold animal waste and wash water that can then be used to fertilizer pasture land. The baler will be used to compress

forage that allows them to cut and store grass when forage is abundant and then supplement feed for the livestock during the dry months. This would reduce the amount of feed that they would need to purchase from the Mainland which should substantially reduce their feed costs. In addition, they have access to additional grass from the O'okala lease which can supplement feed during the dry months.

TERMS:

Class A – Direct Farm Ownership Loan

Amount: \$600,000
Period: 18 years
Interest rate: 3.75% per annum, fixed.
Repayment: Interest only for the first six months followed by principal and interest payments of \$3,901 per month until maturity.

Class C – Direct Operating Loan

Amount: \$600,000
Period: 10 years
Interest rate: 3.75% per annum, fixed.
Repayment: Interest only for the first six months followed by principal and interest payments of \$6,265 per month until maturity.

SECURITY:

The Class-A loan and Class C loan will be secured by the following:

- First leasehold mortgages on the following eight parcels: TMKs (3) 5-5-003-004, 5-5-003-005, 5-5-003-006, 5-5-005-001, 5-5-006-002, 5-5-006-003, 5-5-006-004, 5-5-006-015. The properties are located in Hawaii on the island of Hawaii and total 879.549 acres. The properties are under the management of the Agricultural Resource Management Division (ARMD) of the Hawaii Department of Agriculture with a term that extends to 6/22/41. Parcel 5-5-006-002 has three-3bdrm 1 ½ bath 1,056 sq. ft. labor houses. Parcel 5-5-006-003 has one-3bdrm 2 1/2 bath 1,800 sq. ft., one-3bdrm 2bath 1,224 sq. ft., one-3bdrm 2 bath 1,380 sq.ft. The properties also contain a dairy milking barn, a feed storage shed

and pasture infrastructure such as fences, water lines, and water troughs. The leasehold properties and improvements had an appraised market value of \$1,150,000 as of March 30, 2020. The properties and improvements were appraised by State certified appraiser Ted Yamamura of ACM Consultants Inc.

- A first lien blanket Financing Statement and Security Agreement on livestock, accounts, inventory, and equipment. A specific interest will be taken in the equipment and livestock being purchased with the dairy and in the equipment that will be purchased with a portion of the loan funds. The dairy's existing equipment includes tractors, milking equipment, compressors, chillers, milk storage tank, feed wagons, milking stalls, generators, and sprinkler guns. The estimated value of the dairy's equipment is \$450,000 and the herd is \$400,000. The value is based on a review of similar equipment being listed for sale and the condition of the equipment. The additional 120 heifers contributed by the Keas is valued at \$100,000. The total value of the livestock and equipment is \$950,000.

Class A

$$\begin{array}{l} \text{Loan to} \\ \text{Value Ratio} \end{array} = \frac{\$600,000}{\$1,150,000 \text{ (RE Appraised Value)}} = 52.2\%$$

The loan to value meets the statutory requirement of a maximum 85% loan to value. For informational purposes shown below is the overall loan to value ratio indicating that the loans are well secured. It should be noted that some of the valued collateral have limited life.

$$\begin{array}{l} \text{Loan to} \\ \text{Value Ratio} \end{array} = \frac{\$600,000 \text{ (Class A)} + \$600,000 \text{ (Class C)}}{\$1,150,000 \text{ (RE)} + \$950,000 \text{ (Chattels)}} = 57.1\%$$

GUARANTORS:

The following are required to personally guarantee the loan:

Kees Kea
Malena Kea
Cornel Kea

**FINANCIAL
CONDITION:**

SEE EXHIBIT A (CONFIDENTIAL)

**REPAYMENT
ABILITY:**

SEE EXHIBIT A (CONFIDENTIAL)

INSURANCE:

Property insurance on the residences and dairy infrastructure with SALD named as mortgagee and commercial general liability insurance.

**BACKGROUND/
MANAGEMENT
ABILITY:**

Kees Kea is a multi-generation dairyman originally from the Netherlands. He also had a general contractor's license in the Netherlands and California and owned a construction business in both places. Malena was raised on a dairy in Southern California. She lived in the Netherlands for three years and learned the art of cheese making. When her parents retired in Tillamook, Oregon, Kees and Malena purchased and managed the family's dairy farm for 13 years. In 2003, they moved to the island of Hawaii and Kees became a partner and manager of Island Dairy. The partnership did not work out, but he realized that he wanted to eventually own and operate a dairy in Hawaii. Kees and Malena currently operate a cattle operation under Mauna Kea Moo, LLC in O'okala, Hawaii on 1,400 acres under a Department of Land and Natural Resources (DLNR) long-term lease. The Keas acquired the lease with the objective of developing a dairy. The property was overgrown with weeds and brush, and they were able to obtain a USDA grant to clear land, put in roadways, and install fencing, water lines, and water troughs. They acquired dairy and beef cattle to help clear the lands through grazing and have been selling some of the beef cattle to generate income. The Keas have been attempting to secure funding to start a dairy at the site, but it will be expensive and time consuming to develop the dairy's infrastructure from the ground up. Currently there is no access to electricity and potable water which would make dairy operation more costly.

The opportunity to purchase Boteilho's dairy presents a rare one-time opportunity to acquire a turnkey farm that has all the infrastructure and equipment in place, as well as an existing market for fluid milk. Purchasing the operating dairy would be less costly than developing the infrastructure from scratch and would allow the Keas to start farming and generating income immediately. The dairy has two separate milking lines which provides redundancy and backup should one line need to be shutdown. The operation also has two tanks to hold and chill milk on site and a tanker vehicle to transport the milk to the processor. The property also has six dwellings that can be used for labor housing and for the Keas to live in. In addition, the farm has numerous tractors and farm machinery to operate the dairy and sprinkler guns to water a portion of the pastures. The construction of a cement feed alley will reduce feed waste and the Keas' access to the 1,400-acre parcel allows them to cut down substantially on feed costs as they would be able to grow, bale, and store feed to reduce the reliance of shipping feed in from the Mainland. Since feed costs are typically the major cost of operating a dairy in Hawaii, reducing this expense would have a major impact on the dairy's bottomline.

In addition to Kees and Malena, two of their four children plan to help operate the dairy. They were raised in Hawaii and acquired complementary backgrounds and education. Cornel Kea obtained a degree in agriculture from the University of Hawaii at Hilo focusing on Animal Science. He spent his junior year as an exchange student at the University of Wisconsin, River Falls, studying dairy science. He worked at the university's dairy in Wisconsin as well as their production center where value-added dairy products such as cheese, cheese curds, and ice cream were made. To prepare for the family's dairy, he obtained his pasteurizing certification. Their daughter, Alida, majored in business at Portland State. She and Malena will be responsible for marketing and sales of the value-added products once they are produced.

SUMMARY:

The severe drought in 2019 resulted in poor milk production and increased feed costs which put Cloverleaf Dairy in poor financial condition. Despite the recent rains and much improved milk production the operation's financial condition remains poor and with pressure from

creditors is on the verge of shutting down. The shutdown of the dairy will result in significant problems including the health and welfare of the animals which need to be watered, fed and milked, long time employees familiar with the herd would be lost and idle dairy equipment would deteriorate.

Cloverleaf Dairy is the only dairy remaining in Hawaii. The farm has all the necessary infrastructure and equipment in place to continue operating including grazing land, a milking barn, a feed storage facility, equipment, labor housing, and a waste system. The Keas have the opportunity to take over an operating dairy that would have more favorable conditions and be cheaper than starting their own dairy in O'okala. Kees and Malena have years of experience operating dairies including one on Hawaii Island. Malena has experience in making cheese which could lead to value-added opportunities to increase profits. Their children have also been obtaining education and training in complementary areas to assist the family's dairy and also help reduce labor costs. Kees' background in construction will be beneficial to make renovations and repairs that will be needed.

The Keas are experienced dairy operators and the loans will be well-secured. The requested loans will allow the State's last dairy to continue operating under new ownership and will help the State to supply some of its own milk to contribute toward food self-sufficiency.

TURNDOWNS:

Bank of Hawaii and Home Street Bank denied the loan request for the following reasons:

- Insufficient collateral
- Lender lacks sufficient knowledge financing a dairy
- Lack of established earning record
- Insufficient income for amount requested

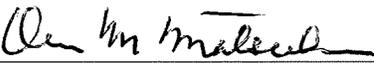
RECOMMENDATIONS: This loan request is recommended for approval based on the Keas' dairy farming experience, credit history. collateral offered, projected debt servicing ability.

Disbursal of loan funds are subject to transfer of milk quota and leases from Boteilo Hawaii Enterprises to Kees Kea or Dutch Hawaiian Dairy Farms, LLC.

Date

Recommended by:

6/12/20


Dean M. Matsukawa
Division Administrator

Date

Approved for submission:

6/17/2020


Phyllis Shimabukuro-Geiser
Chairperson, Board of Agriculture

EXHIBIT A
CONFIDENTIAL

CREDIT HISTORY:

Due to relative newness of Dutch-Hawaiian Dairy Farms, LLC it was decided that a Dun and Bradstreet report would provide little information. Overall, the Keas provide support as guarantors with good credit histories as noted below.

A TransUnion credit report dated 2/10/20 was obtained on Kees C.J. Kea. The FICO credit of 769 is considered very good. There were no public records or collection accounts. All loans were current and being paid as agreed.

A TransUnions report dated 2/10/20 was obtained on Malena A. Kea. The FICO score of 694 is considered good. There were no public records or collection accounts. All loans were current and being paid as agreed.

A TransUnions report dated 2/10/20 was obtained on Cornel A. Kea. The FICO score of 735 is considered good. There were no public records or collection accounts. All loans were current and being paid as agreed.

**FINANCIAL
CONDITION:**

Dutch-Hawaiian Dairy Farms, LLC due to its recent startup does not have a balance sheet. Shown below is a summary of the financial statement dated 2/1/20 for Kees and Malena Kea which include assets and liabilities for Mauna Kea Moo, LLC. The statement was adjusted based on their latest bank account statements and the credit reports.

ASSETS		LIABILITIES	
Cash	39,318	Credit Cards	8,500
Grant	30,000	RV #1 Loan	62,911
Cattle	320,000	RV#2 Loan	37,179
Cheese Proc. Equip.	125,000	Student Loan	64,390
Mohala Pua Building	200,000	ATV Loan	993
Fencing, Roadways	120,400	Car Loan	15,238
Farm Equipment	159,800	CPB Loan	5,375
2 RV Trailers	120,000	Account Payable	1,000
Vehicles	42,500		
1,400-Acre Lease	750,000		
Residence-Oregon	150,000	TOTAL LIABILITIES	195,586
		NET WORTH	1,933,504
Other	72,072		
TOTAL ASSETS	2,129,090	NET WORTH & LIABILITIES	2,129,090

The assets are primarily tied to their farm operation. This includes beef and dairy heifers, farm equipment, a long-term lease for 1,400 acres of agricultural lands with DLNR, and land improvements (e.g., fencing, roadways). The Keas also own cheese processing equipment and a glass building. The major debts are for loans for two RV's used as their residence and for student loans.

The Keas have \$21,818 in cash and a \$30,000 grant. They also own a residence in Oregon, which they have listed for sale at \$150,000 with the intention to provide more liquidity for the proposed dairy.

The net worth may be overstated as it is uncertain whether the 1,400-acre leasehold can be sold for \$750,000. The Keas, however, are in good financial condition and have considerably more assets than liabilities.

Shown below is a summary of the financial statement dated 2/11/20 for Cornel Kea. Some of the liabilities were adjusted with information from the credit report.

ASSETS		LIABILITIES	
Cash	\$1,400	Credit Cards	933
Vehicles (2)	36,000	Auto Loan	11,947
ATV	8,000	Student Loan	11,500
Household Effects	5,000	ATV Loan	6,141
		Personal Loan	8,848
		TOTAL LIABILITIES	39,369
		NET WORTH	11,031
TOTAL ASSETS	50,400	NET WORTH & LIABILITIES	50,400

Cornel's major assets are a GMC truck, a Jeep SUV, and a Honda ATV. His major liabilities are an auto loan and student loan. Cornel graduated from college a couple of years ago and his net worth is minimal at \$11,031. Since graduation he has been spending most of his time assisting with Mauna Kea Moo LLC.

REPAYMENT ABILITY:

Shown below are Mauna Kea Moo, LLC's income and expenses from the federal tax returns from 2016 to 2018:

	2016	2017	2018
Income	13,950	170,520	153,606
Expenses (a)	34,967	99,006	105,309
Net Cash	<21,017>	71,514	48,297
(a) Excludes depreciation expenses.			

Although Mauna Kea Moo is not part of this transaction, the information shows their recent activity and documents their farming experience. The Keas have been in the process of setting up a pasture at the 1,400-acre O'okala site. All of the income in 2016 and 2017 are from federal grants used to set up the operation. In 2018, most of the income is from the grant with \$7,200 obtained from sale of cattle. The cost over the period shown were primarily to set up the ranch such as land clearing, seeds, and, repairs and maintenance. Other costs were to operate including utilities, supplies, rent, fuel, feed, etc.

Show below are the projections for DHDF for the next three years:

	Year 1	Year 2	Year 3
Farm Income	1,663,922	1,920,576	1,920,576
Operating Loan Funds	<u>200,000</u>	<u>0</u>	<u>0</u>
Total Income	1,863,922	1,920,576	1,920,576
EXPENSES			
Feed	663,662	711,011	711,011
Labor	193,296	193,296	193,296
Payroll Taxes	23,196	23,196	23,196
Employee Benefits	67,512	67,512	67,512
Utilities	207,600	207,600	207,600
Repairs & Maint.	120,000	120,000	120,000
Milk Hauling	128,890	134,280	134,280
Supplies & Chemicals	77,700	77,700	77,700
Fuel & Oil	42,000	42,000	42,000
Insurance	36,000	36,000	36,000
Rent	41,400	41,400	41,400
Taxes & Licenses	21,600	21,600	21,600
Legal & Accounting	9,600	9,600	9,600
Truck	14,400	14,400	14,400
Veterinary	12,000	12,000	12,000
Miscellaneous	12,000	12,000	12,000
Industry assessment	<u>7,200</u>	<u>7,200</u>	<u>7,200</u>
Total Expenses	<u>1,678,056</u>	<u>1,730,795</u>	<u>1,730,795</u>
Net Cash	<u>185,867</u>	<u>189,781</u>	<u>189,781</u>
Class A Loan proposed	34,656	46,812	46,812
Class C Loan proposed	<u>48,840</u>	<u>75,180</u>	<u>75,180</u>
Net	102,371	67,789	67,789

The projections were prepared for DHDF with the assistance of Gary Genske a recognized dairy expert. Mr. Genske is a certified public accountant in Costa Mesa, California and is the founder and manager of the accounting firm Genske, Mulder, and Company, LLP. The company specializes in dairy farm accounting and works with about 500 dairy farms that produce about 15% of the country's milk in 33 states from Hawaii to New York. Mr. Genske is also a partner in a 2,000 head milking cow dairy in New Mexico and is a board member of the National Dairy Producers Organization, Inc.

The projections for the first year are based on milking 330 cows in the first two months. Starting from the third month the projections are based on milking 400 cows. The milk output per cow starts at 24/lbs. per day in the first month and increases to 30 lbs. in the second month and 35 lbs. by the third month. Starting from the fourth month the projections are based on 40 lbs. of milk per cow. The price is based on \$40 per cwt., which is the price currently being paid to Boteilho's dairy. To be conservative we adjusted the projections by reducing farm income by 25% in year one and by 20% in the following years. Income was reduced more for the first year as Boteilho's dairy cows are recovering from a severe drought and will need time to become fully productive. Also, it may take the new owners time to adjust to the dairy farm after taking over the operation. Because Boteilho's dairy has 500 cows and 600 heifers of various ages, and since the Keas have 120 heifers, it is possible to have sufficient livestock to milk 400 cows per day. Since Boteilho's dairy was able to obtain 46–50 lbs. of milk per cow, the projected volume of milk appears attainable. The Division did review the recent performance and has confirmed the significant increase in milk production with the return of the good grass growth due to the rainy season.

The projections also did not factor in value-added products, such as yogurt and cheese, that have higher margins than selling raw milk to a processor. The Keas plan to initially sell milk as it would generate income immediately and eventually start producing value-added products after they had time to become more familiar with operating the dairy.

As typical of dairies, the projections show feed as the major cost. Other major costs are utilities, labor, repairs and maintenance, and milk hauling. A major difference between Boteilho's dairy and DHDF is that the Keas have access to another 1,400 acre parcel where they have plans for a forage program to grow, bale, and store feed. As indicated, this is expected to reduce feed costs significantly and reduce the need to ship feed in from the Mainland.

The operating funds are provided to assist the dairy during the first year as the cows recover from drought conditions. The loans are also provided with an initial six-month interest only payment period to reduce loan payments as

A37

DHDF transitions into operating the dairy. The projections show repayment ability for the requested loans.

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII 96814

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR APPROVAL FOR THE TRANSFER OF PUBLIC LANDS AT KULA ON THE ISLAND OF MAUI FROM THE DEPARTMENT OF LAND AND NATURAL RESOURCES TO THE DEPARTMENT OF AGRICULTURE PURSUANT TO ACT 90, SLH 2003, CODIFIED AS CHAPTER 166E, HAWAII REVISED STATUTES

Authority: Section 166E-3, Hawaii Revised Statutes (HRS)

Tax Map Keys: See Exhibit "A" – Attachment

BACKGROUND:

Act 90, sessions Laws of Hawaii ("SLH") 2003 established the Non-Agricultural Park lands program within the Hawaii Department of Agriculture ("HDOA"), and was codified as Chapter 166 E, Hawaii Revised Statutes ("HRS"). Under this program, the legislature found that certain public lands classified for agricultural use by the Department of Land and Natural Resources ("DLNR") should be transferred to the HDOA for purposes and in a manner consistent with Article XI, section 10, of the State Constitution.

The purpose of this chapter is to ensure the long-term productive use of public lands leased or available to be leased by the DLNR for agricultural purposes by allowing these lands to be transferred to the HDOA for leasing and management.

At its meeting of October 11, 2019, the Board of Land and Natural Resources had approved transfer of seven (7) land parcels on the Island of Maui subject to staff's review of the DLNR file records and a physical site visit to verify compliance with Act 90, SLH 2003. Staff verified compliance of seven (7) vacant, unencumbered parcels for approval by BOA as listed on Exhibit "A."

B2

RECOMMENDATION:

Staff has reviewed the list of proposed vacant and unencumbered land parcels located at Kula on the Island of Maui and performed its due diligence; and, therefore, recommends that the BOA approve the transfer of the seven (7) vacant and unencumbered parcels as listed on Exhibit "A."

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer
Agricultural Resource Management Division

Attachment – Exhibits "A" and "B"

APPROVED FOR SUBMISSION



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

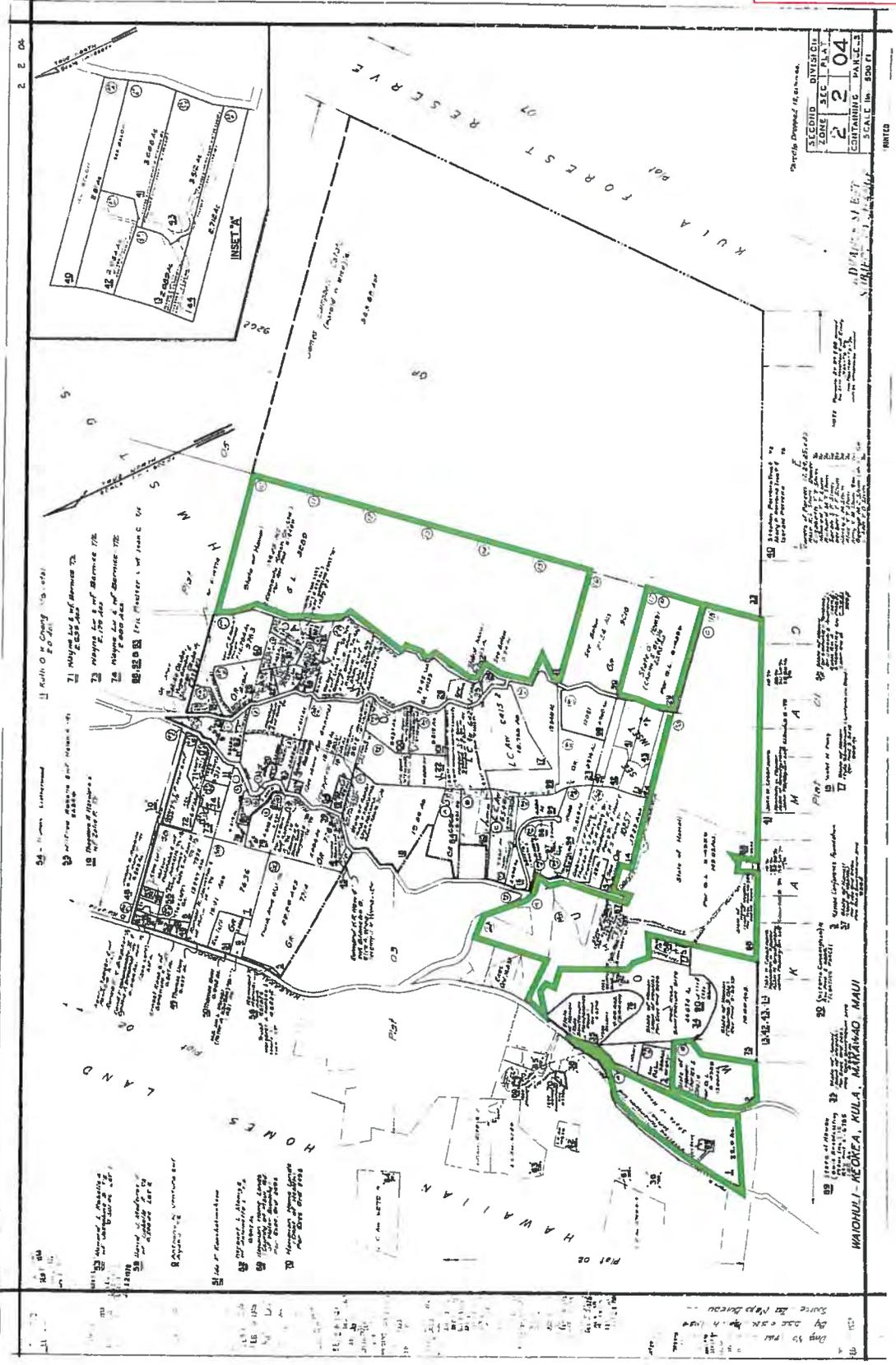
EXHIBIT "A"

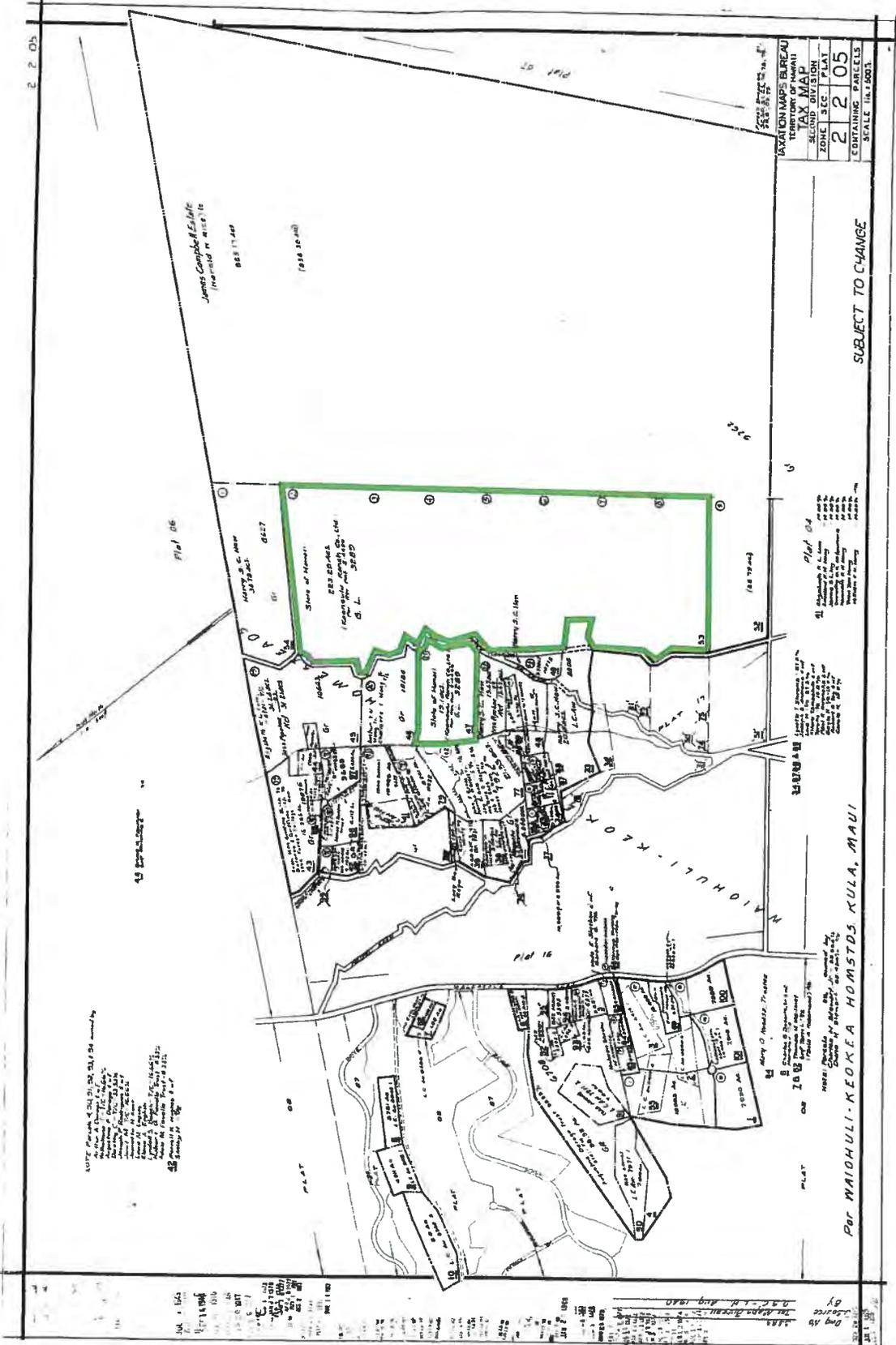
Act 90 Transfers - Maui

Doc. No.	Lessee Name	TMK	Char of Use	Land Area (Acres)
Vacant	Vacant	(2)2-2-004:001	Pasture	22
Vacant	Vacant	(2)2-2-004:002	Pasture	13
Vacant	Vacant	(2)2-2-004:029	Pasture	20.98
Vacant	Vacant	(2)2-2-004:031	Pasture	139.28
Vacant	Vacant	(2)2-2-004:066	Pasture	149.03
Vacant	Vacant	(2)2-2-005:047	Pasture	19.1
Vacant	Vacant	(2)2-2-005:053	Pasture	223.29

BA

EXHIBIT "B"
Page 1 of 2





SUBJECT TO CHANGE

TAXATION MAPS BUREAU
COUNTY OF MAUI
SECOND DIVISION
ZONE 2
SEC. 2
PLAT 05
SCALE 1 IN. = 100 FT.

Per MAIHOULI-KEOKEA HOMSTDS KULA, MAUI

BS

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII 96814

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR ACCEPTANCE OF ANNUAL LEASE RENTS AS DETERMINED BY INDEPENDENT APPRAISAL FOR RENT REOPENINGS AND NEW LEASES FOR TMK: (1) 4-1-009:269; (1) 4-1-027:004; (1) 8-5-034:001; (1) 8-5-034:003; (1) 8-5-034:004; (1) 8-5-034:006; (1) 8-5-034:008; (1) 8-5-034:010; (1) 8-5-034:011; (1) 8-5-034:012; (1) 8-5-034:015; (3) 1-2-006:019; (3) 2-1-016:001; (3) 2-4-049:011; (3) 5-8-002:002; (3) 5-9-001:004, (3) 5-9-003:002 & 004, (3) 5-9-004:001 & 008; (3) 1-5-116:001; (3) 1-5-116:003; (3) 1-5-116:007; (3) 1-5-116:011; (3) 1-5-116:012; (3) 1-5-116:013; (3) 1-5-116:015; (3) 1-5-116:017; (3) 1-5-116:018; (3) 1-5-116:020; (3) 1-5-116:034; (3) 1-5-116:062; (4) 1-9-002:001; (4) 1-9-002:013; (4) 1-9-002:019; (4) 1-9-002:020; (4) 1-9-002:045; (4) 1-9-003:006; (4) 1-9-003:010; (4) 4-1-001:007; (4) 4-1-001:012; (4) 4-1-009:005 & 006; (4) 4-4-002:031.

Authority: Section 166-9 and Section 166E-9, Hawaii Revised Statutes (HRS) Sections 4-153-3(a)(10) & 18, and Sections 4-158-2(a)(11) and 21, Hawaii Administrative Rules (HAR)

Lease: Various as shown on the table below

Lessee: Various

Land Status: Properties set aside to the Department of Agriculture by various Governor's Executive Orders.

Character of Use: Diversified Agriculture or Intensive Agriculture Purposes

REMARKS:

Pursuant to the provisions of sections 4-153-3(b)(10) and 18, 4-158-2(a)(11) and 21, and 4-158-8(b)(1), HAR, the Board of Agriculture (BOA) is required to establish and approve annual lease rentals by independent appraisal for issuance of new leases, conversions of leases, and reopenings of base and additional rentals for existing leases in the Agricultural Park and Non-Agricultural Lands programs.

The DOA contracted ACM Consultants, Inc. to determine the fair market rents of various agricultural park and non-agricultural park lands leases for rents reopened on various dates, lease conversions, and dispositions of new leases. ACM Consultants, Inc. recently completed the appraisal and the new lease rents are presented in the following tables:

B6

B1

SUMMARY OF VALUE CONCLUSIONS

<u>Parcel TMK</u>	<u>Lease</u>	<u>Land Area in Acres</u>	<u>Appraised Fair Market Rental</u>	<u>Percentage Rent on Gross Proceeds</u>	<u>Purpose</u>
<u>NON-AGRICULTURAL PARK LANDS, ISLAND OF OAHU</u>					
(1) 4-1-009:269	S-5592	13.888	\$9,075.00	1.5%	reopening
(1) 4-1-027:004	S-4011	1.032	\$4,320.00	1.5%	conversion
<u>WAIANA E AGRICULTURAL PARK, ISLAND OF OAHU</u>					
(1) 8-5-034:001	S-1001	5.042	\$2,303.00	1.5%	disposition
(1) 8-5-034:003	S-1003	6.694	\$4,043.00	1.5%	reopening
(1) 8-5-034:004	S-1004	7.484	\$2,985.00	1.5%	reopening
(1) 8-5-034:006	S-1006	12.566	\$4,680.00	1.5%	reopening
(1) 8-5-034:008	S-1008	9.668	\$3,360.00	1.5%	reopening
(1) 8-5-034:010	S-1010	10.940	\$3,638.00	1.5%	reopening
(1) 8-5-034:011	S-1011	6.964	\$2,880.00	1.5%	reopening
(1) 8-5-034:012	S-1012	10.690	\$3,525.00	1.5%	reopening
(1) 8-5-034:015	S-1015	6.040	\$3,008.00	1.5%	reopening
<u>NON-AGRICULTURAL PARK LANDS, ISLAND OF HAWAII</u>					
(3) 1-2-006:019	vacant	816.000	\$1,910.00	0%	disposition
(3) 2-1-016:001	S-5510	50.887	\$2,528.00	1.5%	reopening
(3) 2-4-049:011	S-4225	10.021	\$4,910.00	1.5%	reopening
(3) 5-8-002:002	RP-7496	73.000	\$1,030.00	0%	
(3) 5-9-001:004, (3) 5-9-003:002 & 004, (3) 5-9-004:001 & 008	S-5599	5,684.000	\$15,700.00	0%	reopening
<u>PAHOA AGRICULTURAL PARK, ISLAND OF HAWAII</u>					
(3) 1-5-116:001	vacant	10.193	\$940.00	1.5%	disposition
(3) 1-5-116:003	vacant	10.000	\$930.00	1.5%	disposition
(3) 1-5-116:007	vacant	10.000	\$930.00	1.5%	disposition
(3) 1-5-116:011	vacant	30.000	\$2,350.00	1.5%	disposition
(3) 1-5-116:012	vacant	29.166	\$2,300.00	1.5%	disposition
(3) 1-5-116:013	vacant	25.000	\$2,020.00	1.5%	disposition
(3) 1-5-116:015	vacant	19.596	\$1,640.00	1.5%	disposition
(3) 1-5-116:017	vacant	15.000	\$1,310.00	1.5%	disposition
(3) 1-5-116:018	vacant	5.371	\$680.00	1.5%	disposition
(3) 1-5-116:020	vacant	10.000	\$930.00	1.5%	disposition
(3) 1-5-116:034	S-4829	5.002	\$660.00	1.5%	reopening
(3) 1-5-116:062	vacant	13.428	\$1,190.00	1.5%	disposition

<u>Parcel TMK</u>	<u>Lease</u>	<u>Land Area in Acres</u>	<u>Appraised Fair Market Rental</u>	<u>Percentage Rent on Gross Proceeds</u>	<u>Purpose</u>
NON-AGRICULTURAL PARK LANDS, ISLAND OF KAUAI					
(4) 1-9-002:001	vacant	2.396	\$1,073.00	1.5%	disposition
(4) 1-9-002:013	vacant	4.246	\$1,830.00	1.5%	disposition
(4) 1-9-002:019	RP-7317	1.140	\$608.00	1.5%	reopening
(4) 1-9-002:020	vacant	0.930	\$518.00	1.5%	disposition
(4) 1-9-002:045	vacant	6.730	\$2,363.00	1.5%	disposition
(4) 1-9-003:006	RP-7045	7.826	\$2,235.00	1.5%	reopening
(4) 1-9-003:010	RP-7794	4.037	\$1,275.00	1.5%	reopening
(4) 4-1-001:007	RP-7738	19.980	\$320.00	0%	reopening
(4) 4-1-001:012	RP-7771	6.130	\$608.00	0%	reopening
(4) 4-1-009:005 & 006	RP-2102	10.444	\$170.00	0%	reopening
(4) 4-4-002:031	S-5480	19.162	\$2,347.00	1.5%	reopening

Staff believes the new rental rates are fair and reflect the current market conditions for the agricultural leases. Accordingly, staff recommends that the Board accept the new rental values as determined by ACM Consultants, Inc.

RECOMMENDATION:

That the Board accept the fair market rentals for the various non-agricultural park land leases as presented in the tables above. The new rental rates will take effect upon the stated rent reopening dates or upon issuance of a new lease, as may be appropriate for each lease identified above. Any reopened rental whose current rate exceeds the appraised rate shall remain at the current rate pursuant to the terms of each such lease.

Respectfully submitted,



BRIAN KAU, P.E.
 Administrator & Chief Engineer
 Agricultural Resource Management Division

ATTACHMENT: EXHIBIT "A"

APPROVED FOR SUBMISSION:

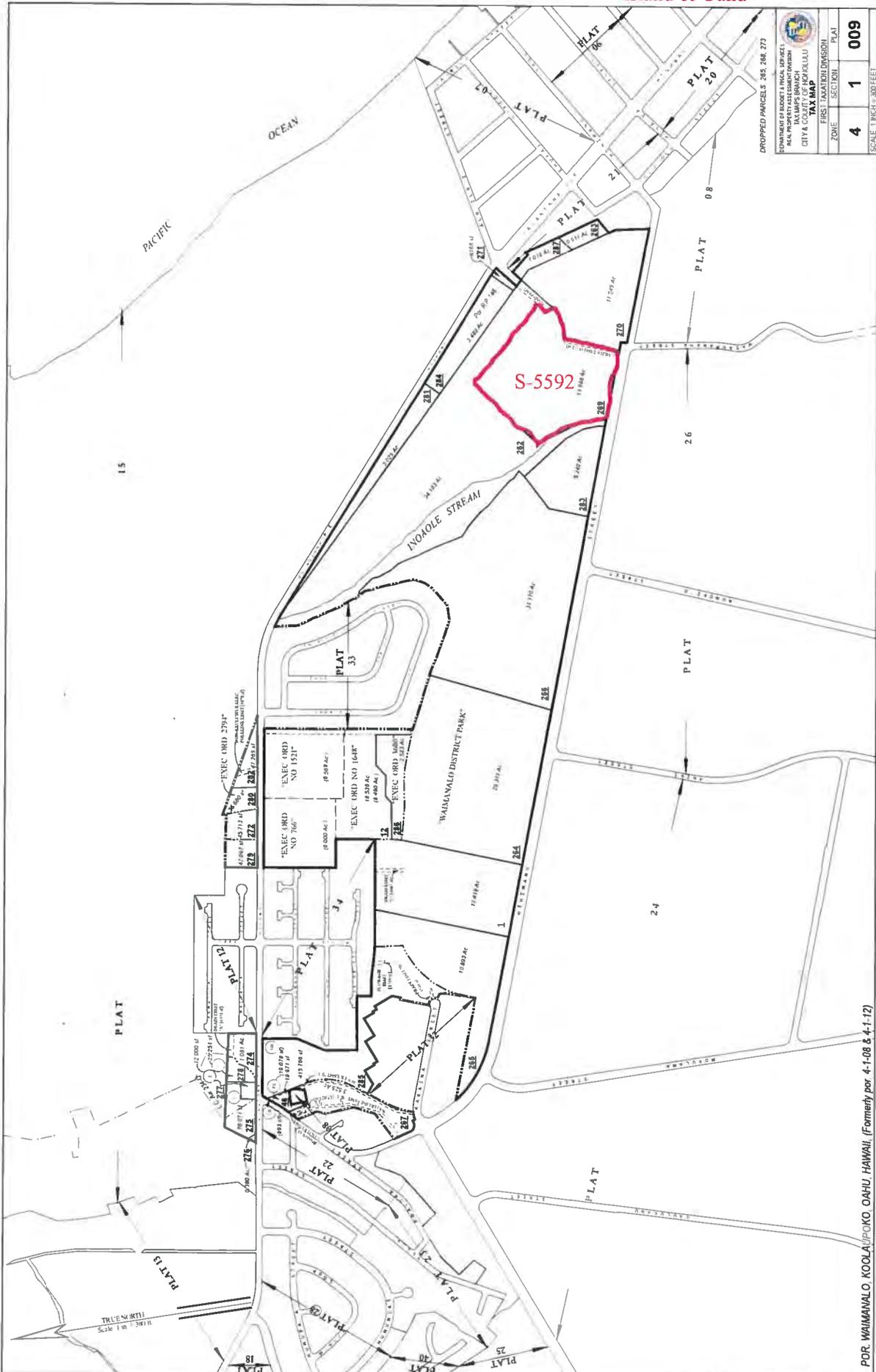


PHYLLIS SHIMABUKURO-GEISER
 Chairperson, Board of Agriculture

BB

Exhibit "A"
Island of Oahu

B9



DROPPED PARCELS: 265, 266, 273

DEPARTMENT OF REVENUE & FINANCIAL SERVICES
HAWAIIAN PROPERTY TAX ADMINISTRATION
CITY & COUNTY OF HONOLULU
TAX MAP

ZONE	SECTION	PLAT
4	1	009

SCALE: 1 INCH = 100 FEET

PDR, WAIMANALO, KOOLAUPUO KO, OAHU, HAWAII, (Formerly par. 4-1-08 & 4-1-12)

Exhibit "A"
Island of Oahu

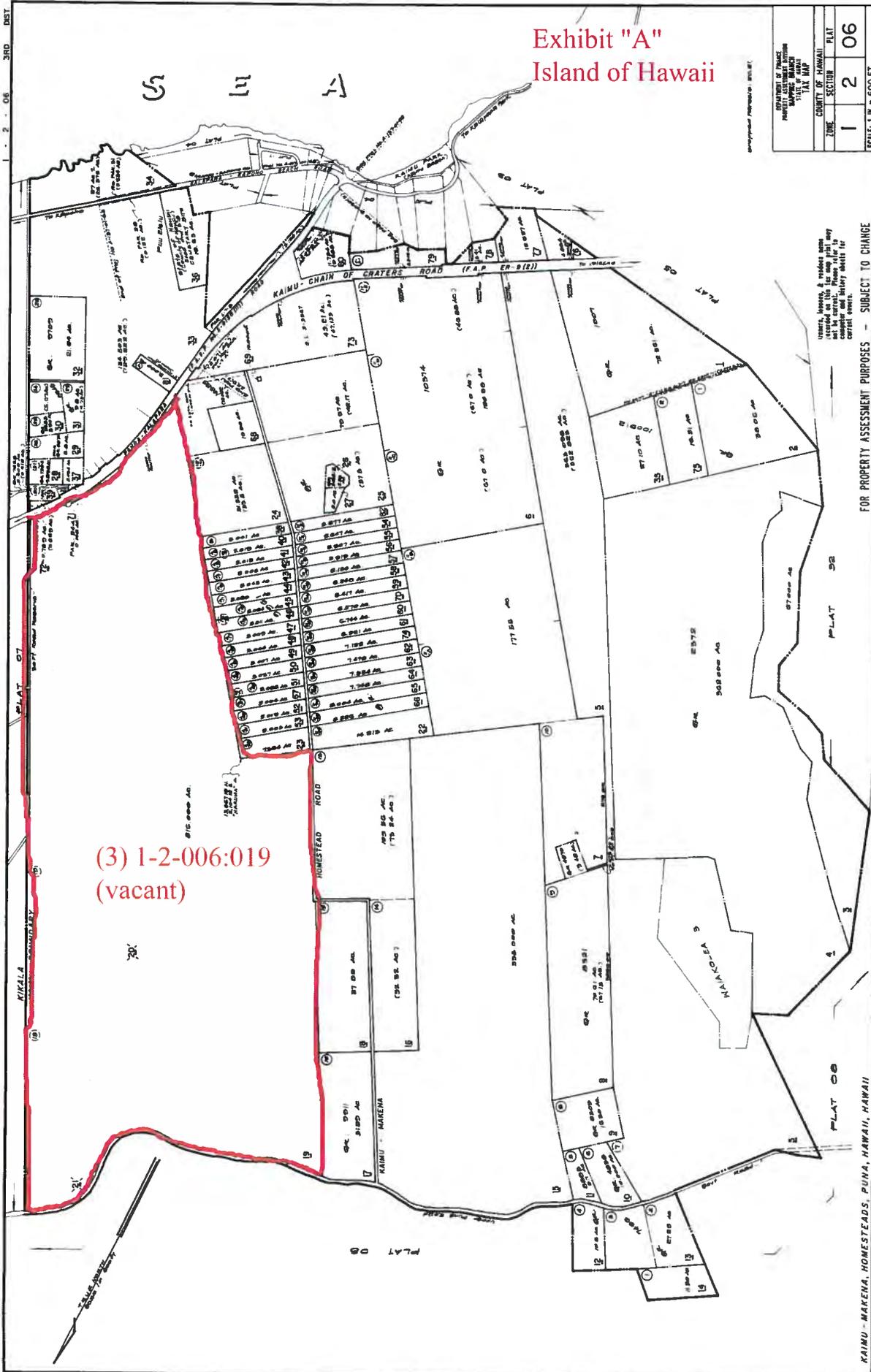


 DEPARTMENT OF BUDGET & FISCAL SERVICES REAL ESTATE TAX ADMINISTRATION TAX MAPS BRANCH CITY & COUNTY OF HONOLULU			
PLAT	SECTION	ZONE	FIRST TRACT DIVISION
027	1	4	4

PDR, WAIMANALO AGRICULTURAL SUBD., WAIMANALO, KOOLAUPOKO, OAHU, HAWAII (Formerly por 4-1-08)

B10

Exhibit "A" Island of Hawaii



(3) 1-2-006:019
(vacant)

DEPARTMENT OF PUBLIC PROPERTY ADMINISTRATION STATE OF HAWAII TAX MAP		
COUNTY OF HAWAII		
ZONE	SECTION	PLAT
1	2	06

UNSATURATED, MOIST, & WETLAND AREAS
SHOWN ON THIS MAP MAY NOT BE
COMPLETELY ACCURATE FOR
CERTAIN PURPOSES.

FOR PROPERTY ASSESSMENT PURPOSES - SUBJECT TO CHANGE

KAIMU - MAKENA, HOMESTEADS, PUNA, HAWAII, HAWAII

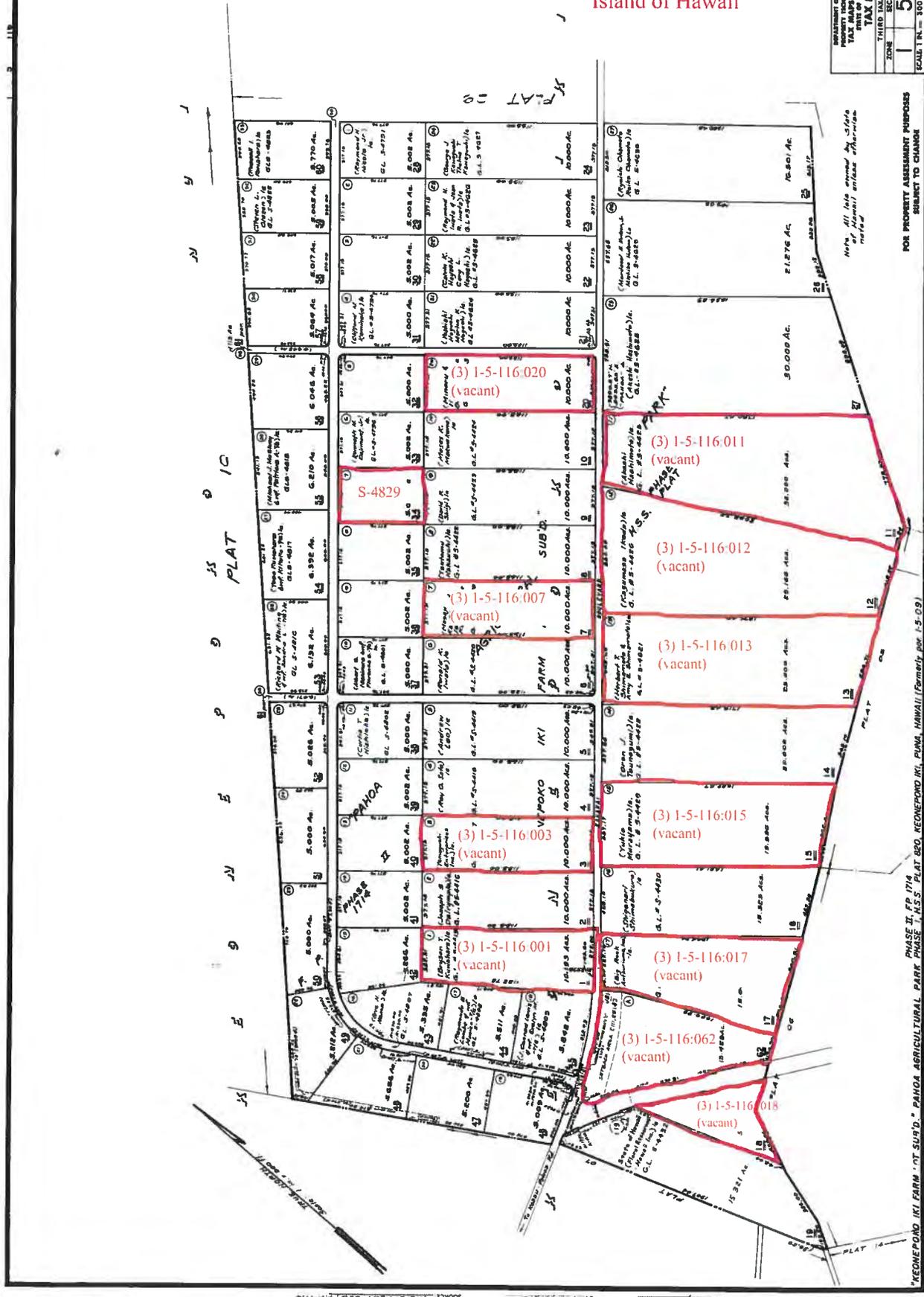
SCALE: 1" = 500.0 FT.
PRINTED:

B12

B13

Exhibit "A" Pahoa Agricultural Park Island of Hawaii

DEPARTMENT OF LAND AND NATURAL RESOURCES	
PROPERTY TECHNICAL SERVICE DIVISION	
STATE OF HAWAII	
TAX MAP	
THIRD EDITION DISTRICT MAP	15116
ZONE	EC
SCALE	1" = 300 FT.



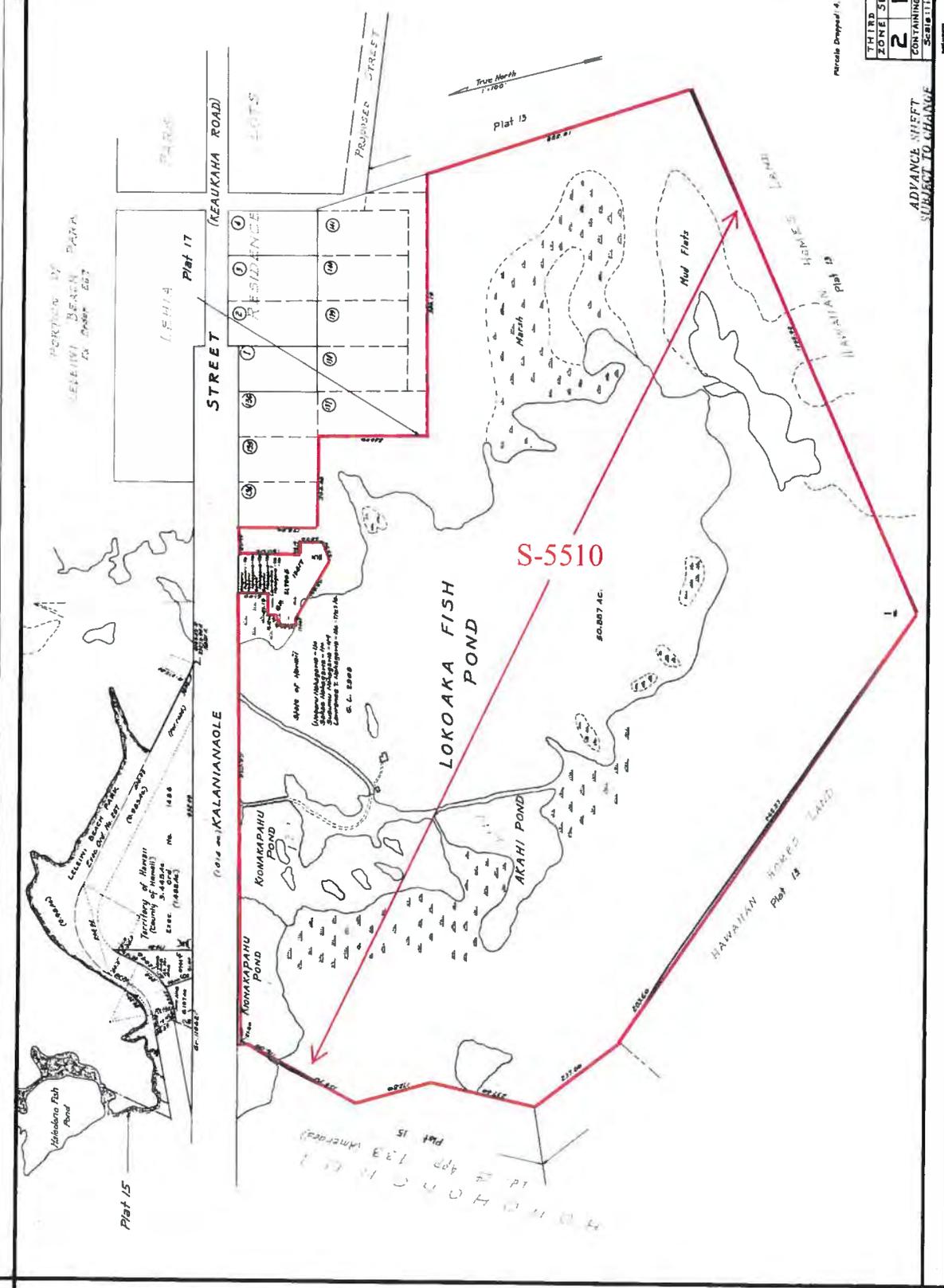
Note: All lots owned by State of Hawaii unless otherwise noted.

FOR PROPERTY ASSESSMENT PURPOSES
SUBJECT TO CHANGES

PHASE II, EP. 1714
PHASE I, ASS. PLAT 850, KEONEPOI RD., PUNA, HAWAII (Formerly Plat 1-5-09)

Exhibit "A"
Island of Hawaii

Z 1 16



Parcels Drapped 4.

THIRD DIVISION	2
ZONE SEC PLAT	1 16
CONTAINING PARCELS	
SCALE IN FEET	

ADVANCE SHEET
SUBJECT TO CHANGE

PRINTED

BY PLAN
6
13 1916
15
7
13
17

By J.A. KEC...
Source...
107 133 (Intersect)
Plat 15

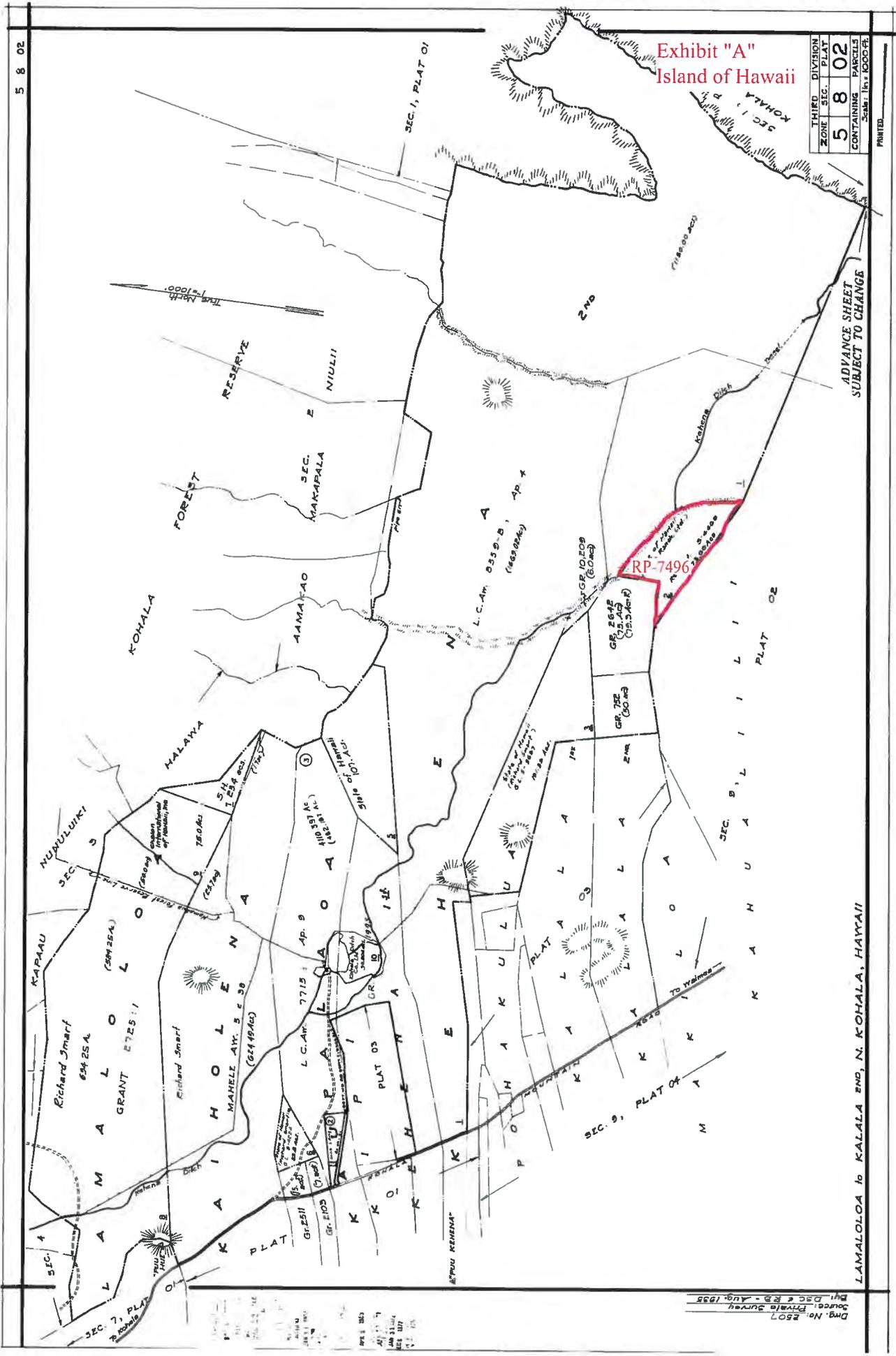
B14

5 8 02

Exhibit "A"
Island of Hawaii

THIRD DIVISION	PLAT
ZONE	SEC.
5	8
CONTAINING PARCELS	
Scale: 1 in. = 1000 ft.	

PRINTED



ADVANCE SHEET
SUBJECT TO CHANGE

LAMALOLOA to KALALA END, N. KOHALA, HAWAII

Dwg. No. 2507
Source: Private Survey
By: DSC & P. - Aug. 1935

BIB

Exhibit "A"
Island of Hawaii

ADVANCE SHEET
SUBJECT TO CHANGE

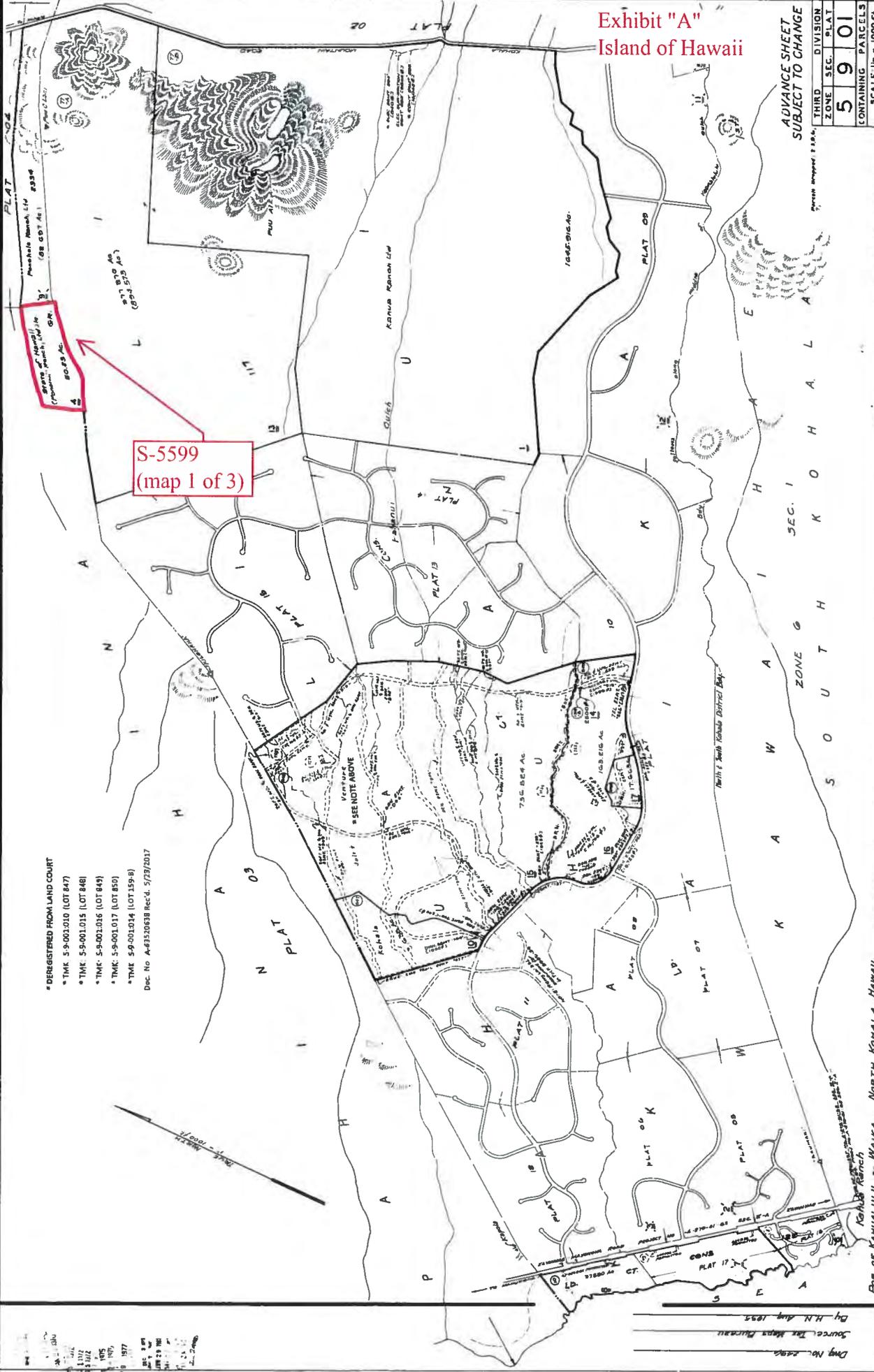
ZONE	DIVISION	THIRD
5	9	01
CONTAINING PARCELS		
SCALE 1 in = 1000 FT		

PRINTED

B17

- * REGISTERED FROM LAND COURT
- * T.M.K. 5-9-001010 (LOT 847)
- * T.M.K. 5-9-001015 (LOT 848)
- * T.M.K. 5-9-001016 (LOT 849)
- * T.M.K. 5-9-001017 (LOT 850)
- * T.M.K. 5-9-001014 (LOT 159-8)

Doc. No. A-43520638 Rec'd. 5/23/2017



FOR OF KAHUALULUI E. WAIKA, NORTH KONA, HAWAII.

Drawn No. 2296
Source: The Maps Bureau
By H.N. Aug. 1975

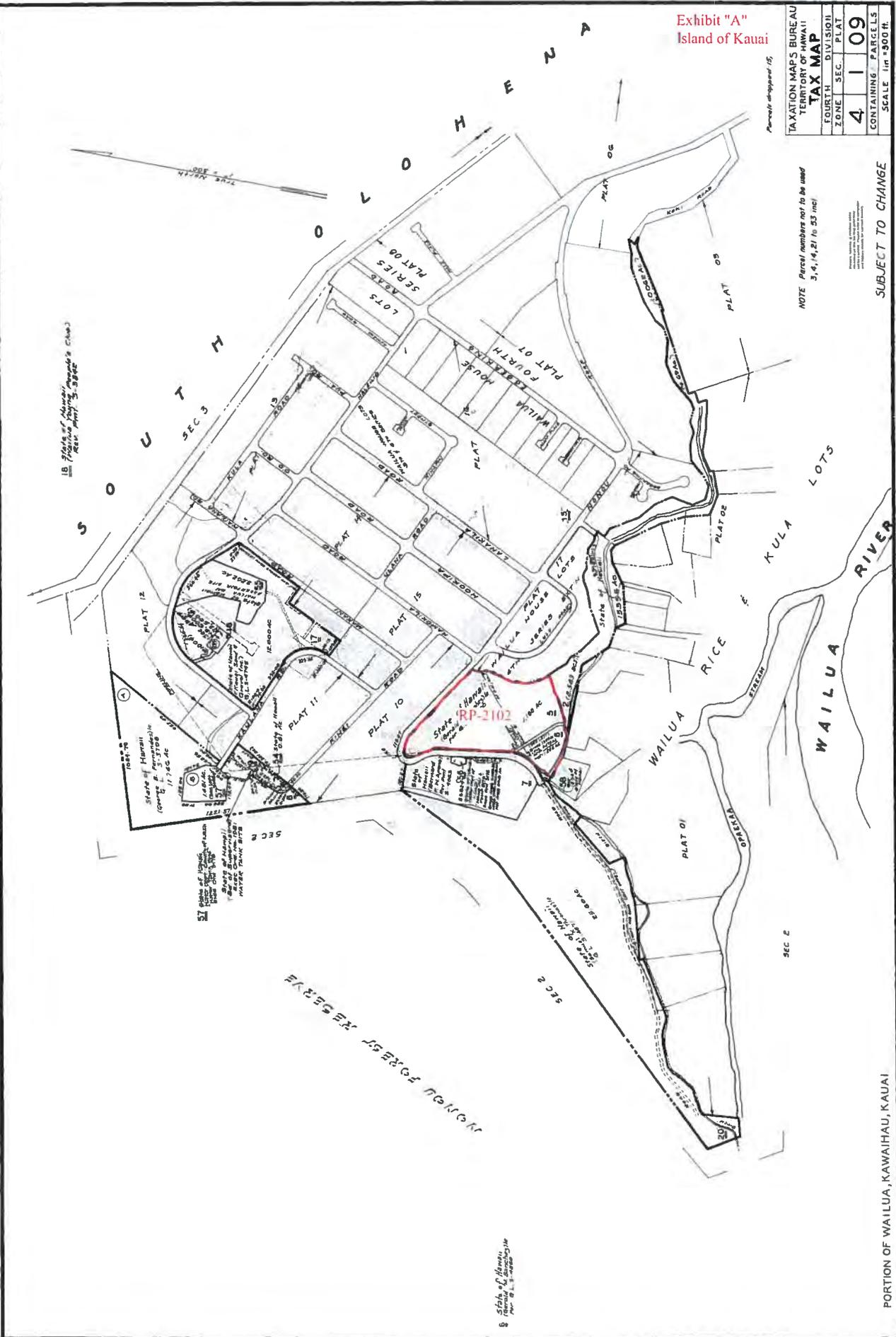


Exhibit "A"
Island of Kauai

Parcels depicted 1/5

TAXATION MAPS BUREAU			
TOWN OF KAWAII			
TAX MAP			
FOURTH	DIVISION	PLAT	
ZONE	SEC.	PLAT	
4	1	09	
CONTAINING PARCELS			SCALE 1" = 800 FT.

NOTE: Parcel numbers not to be used
3, 4, 14, 21 to 53 incl

SUBJECT TO CHANGE

10. Plans of Survey (revised) (Chas)
REV. APRIL 3, 1962

Source Tax Maps Bureau & Survey Dept.
By H.N.I. BY 11/1/11
DMS No 3550
11-1-11

B23

4 4 82 4TH DIST.

SEC. 5

RESERVE

FOREST

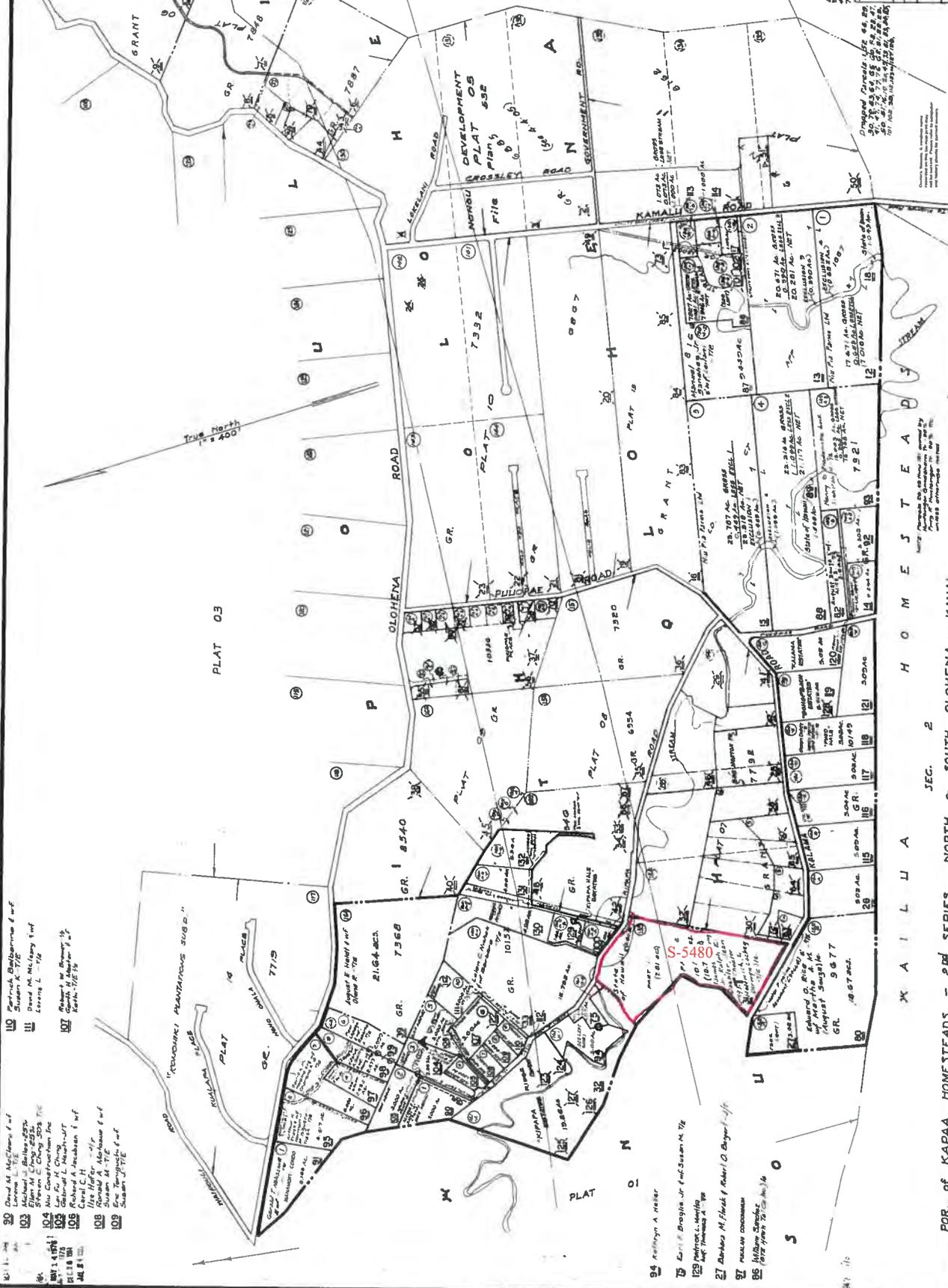
NON DU

Exhibit "A"
Island of Kauai

Dropped parcels 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100	
TAXATION MAPS BRANCH STATE OF HAWAII	
FOURTH	DISTRICT
ZONE	SEC.
4	4
02	02
CONTAINING PARCELS	
SCALE: 1 in = 400 FE.	

SUBJECT TO CHANGE

PRINTED



POR. of KAPAA HOMESTEADS - 2nd SERIES, NORTH & SOUTH OLOHEHA, KAUAI.

SEC. 2

X A I L U A

H O M E S T E A D S

PLAT

4 4 02

4 4 02

B24

- 90 David M. McClellan & w/f
- 91 Lorenz L. Tye
- 92 Elizabeth M. Bellows
- 93 Steven C. Cheng 50%
- 94 New Construction, Inc
- 95 Gabriel L. Neuhoff-JT
- 96 Richard A. Jacobson & w/f
- 97 Uwe H. H.
- 98 Ronald A. MacInnes & w/f
- 99 Susan M. Tye
- 100 Susan J. Tye & w/f

- 94 Kathryn A. Heiser
- 95 David P. Douglas, Jr. & Susan M. Tye
- 129 Patricia L. Hoville
- 130 W. H. Hoville & w/f
- 27 Barbara M. Field & Robert O. Boyer & w/f
- 85 William Conner

Dwg No: 2845
 Source: Tax Maps Bureau & Reg. Map 2456
 Date: July, 1956
 R.K.B. & S.L.C.

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR CONSENT TO ASSIGNMENT OF GENERAL LEASE NO. S-4925; LOUNARETH SOULATHA, LESSEE/ASSIGNOR; TO MAHIKU FARM LLC, ASSIGNEE; TMK: 1ST DIV/4-1-035:004, LOT 4, WAIMANALO AGRICULTURAL PARK, KOOLAUPOKO, WAIMANALO, ISLAND OF OAHU, HAWAII

Authority: Section 166-7 and 166-9, Hawaii Revised Statutes (HRS), and Section 4-153-33(a)(6)(D) and Section 4-153-3(b)(4), Hawaii Administrative Rules (HAR)

Lessee/Assignor: Lounareth Soulatha

Assignee: Mahiku Farm LLC

Land Area: 10.171 acres

Tax Map Key: 1ST DIV/4-1-035:004 (Exhibit "A")

Land Status: Encumbered by Governor's Executive Order No. 3464 to the Department of Agriculture for agricultural park purposes in 1990

Rental: \$7,325.00 per year, until July 31, 2021, lease expiration

Additional Rent: The amount by which 2% of the gross proceeds from the sale of commodities produced on the demised premises that exceeds the base rentals

Character of Use: Diversified Agriculture purposes

Lease Term: August 1, 1986 through July 31, 2021

Consideration: None

B25

B26

BACKGROUND:

General Lease No. S-4925 was awarded to Henry C. Y. Liu by the Board of Agriculture in 1986. In 1992 the lease was assigned to Lounareth Soulatha who has been successfully farming a variety of food crops including but not limited to basil, mint, taro, kafir leaves, mango, avocado, limes, lemons, bananas, etc. For estate planning purposes, Mr. Soulathata is requesting an assignment of General Lease No. S-4625 to corporate successor Mahiku Farm LLC. Lounareth Soulatha and his wife Prany Soulatha are named as member-managers of the Hawaii limited liability company.

Since 1999, Prany Soulatha has worked all facets of the farming operation with her husband, Lounareth Soulatha, including propagating and maintaining products, marketing and sales, overseeing general operations, bookkeeping/accounting, and more.

Prany Soulatha qualifies as a bona fide farmer with more than two years of full-time farming experience and meets application and eligibility of three years residency requirement commensurate with sections 4-153-1 and 13, HAR.

Mahiku Farm LLC qualifies as an agricultural limited liability company with more than 75 percent of its members qualifying as bona fide farmers.

There is no consideration to be paid for the assignment.

CONCLUSIONS:

1. The Assignor Lounareth Soulatha is a Lessee in good standing under General Lease No. S-4624 and requests an assignment of General Lease No. S-4925 to corporate successor Mahiku Farm LLC, which is a permitted basis for an assignment under the lease provisions and Section 4-153-33(a)(6)(D), HAR;
2. The Assignee, Mahiku Farm LLC qualifies as an agricultural limited liability company with more than 75 percent of its members qualifying as bona fide farmers.
3. Prany Soulatha, wife of Lounareth Soulatha, qualifies as a bona fide farmer with more than two years of full-time farming experience and meets application and eligibility of three years residency requirement commensurate with sections 4-153-1 and 13, HAR.

RECOMMENDATION:

That the Board of Agriculture consent to the assignment of General Lease No. S-4925 from Lounareth Soulatha, Lessee/Assignor, to Mahiku Farm LLC, Assignee, subject to the approval as to form of the assignment and consent documents by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer
Agricultural Resource Management Division

SEE ATTACHMENT – EXHIBIT “A”

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

B27



16
 Division Number, 1-1-79
 Section Number, 1-1-79
 Area, 1.0000
 Area, 1.0000

Note: All lots owned by State of Hawaii unless otherwise noted.

DROPPED PARCELS: 19, 17, 18

DEPARTMENT OF FINANCE			
PROPERTY ASSESSMENT DIVISION			
TAX MAP FOR THE YEAR 1981			
TAX MAP			
CITY & COUNTY OF HONOLULU	PLAT	35	
ZONE	SEC.	4-1-35	
SCALE: 1" = 300 FT.			

FOR PROPERTY ASSESSMENT PURPOSES
 SUBJECT TO CHANGE

WAIMANALO AGRICULTURAL PARK PHASE I, P. 1B50, WAIMANALO, KOOLAUPONO, OAHU, HAWAII (FORMERLY PARS. 4-1-08, 4-1-B B 4-1-25)

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100



STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR APPROVAL OF CONSENT TO ASSIGNMENT OF GENERAL LEASE NO. S-9014, THOMAS DECOURCY, LESSEE/ASSIGNOR; TO THOMAS DECOURCY AND BRADLEY TSUGIO SAKAMOTO, ASSIGNEE; TMK: 2ND DIV/ 5-2-001:022, LOT NO. 13, MOLOKAI AGRICULTURAL PARK, HOOLEHUA-APANA, ISLAND OF MOLOKAI, COUNTY OF MAUI, HAWAII

Authority: Section 166-7 and 9, Hawaii Revised Statutes (HRS), and Sections 4-153-3 (b)(4) and 4-153-33(a)(6)(C), Hawaii Administrative Rules (HAR)

Lessee/Assignor: Thomas DeCourcy

Assignee: Thomas DeCourcy and Bradley Tsugio Sakamoto

Land Area: 32.969 Acres

Lease Term: March 1, 1999 through February 28, 2024 (25 Years)

Tax Map Key: 2ND DIV/ 5-2-001:022 (Exhibit "A")

Land Status: Encumbered by Governor's Executive Order No. 3696 to the Department of Agriculture for agricultural park purposes in 1997

Annual Base Rental: \$2,160.00 Per Year

Character of Use: Diversified agriculture purposes

Consideration: None

B29

BACKGROUND:

General Lease No. S-9014 (the Lease) was awarded to Thomas DeCourcy in 1999 who originally established an orchard farm. For estate planning purposes, Mr. DeCourcy is requesting an assignment of General Lease No. S-9014 to Thomas DeCourcy and Bradley Tsugio Sakamoto, his son-in-law. Brad will be added to hold title to the lease, due to Tom DeCourcy's increasing physical disabilities and health issues.

Since 2008, Brad Sakamoto has farmed with father-in-law Tom DeCourcy. They produce various vegetable crops, banana, avocado and honey from their honeybee hives. Their products are only sold on Molokai at farmers markets, the local grocery store and directly to customers.

Pursuant to the terms of General Lease No. S-9014 and Section 4-153-33(a)(6)(A) and (B), HAR, an assignment of lease is permitted due to physical disability.

Brad Sakamoto qualifies as a bona fide farmer with more than two years of fulltime farming experience and meets residency eligibility requirements commensurate with 4-153-1 and 13, HAR.

RECOMMENDATION:

That the Board of Agriculture approve the consent to assignment of General Lease No. S-9014 from Thomas DeCourcy, Lessee/Assignor, to Thomas DeCourcy and Bradley Tsugio Sakamoto, Assignee. All assignment and consent documents shall be subject to review and approval by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer
Agricultural Resource Management Division

Attachment (Exhibit "A")

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR APPROVAL OF EXTENSION OF LEASE TERM, GENERAL LEASE NO. S-5480, TMK: (4) 4-4-002:031; LELAN C. NISHEK AND BARBARA M. NISHEK, LESSEE; KAPAA HOMESTEADS, 2ND SERIES, OLOHENA KAWAIHAU, ISLAND OF KAUAI, HAWAII

Authority: Section 166E-5, Hawaii Revised Statutes (“HRS”), and Section 4-158-9, Hawaii Administrative Rules (“HAR”)

Lessee: Lelan C. Nishek and Barbara M. Nishek

Lease Term: August 31, 1995 through August 30, 2020

Current Rent: \$928.00 per year

Tax Map Key: (4)4-4-002:031

Land Area: 19.15 gross acres; 18.55 net acres

Tax Maps: Exhibit “A”

Land Status: Encumbered by Governor’s Executive Order No. 4259, dated January 6, 2009, set aside for control and management by the Department of Agriculture for general agricultural purposes.

Character of Use: General Agriculture

832

BACKGROUND

The Board of Land and Natural Resources awarded General Lease No. S-5480 to Lelan C. Nishek and Barbara M. Nishek, commencing August 31, 1995 and expiring August 30, 2020.

Lelan Nishek and his wife Barbara Nishek have been in the nursery business on Kauai for over 35 years. They own and operate Kauai Nursery & Landscaping, Inc. which was founded in 1975. The character of use for the premises is general agricultural which includes the cultivation of flower and nursery crops and pasture use for livestock except for pigs. The land topography is fairly steep and currently is used primarily for the pasturing of several heads of cows and horses.

The Nishek's are requesting an extension of General Lease No. S-5480 for 35 years, not more than the allowed maximum length of time for a cumulative total of 65 years commensurate with 4-158-18(a)(1), HAR, from August 31, 2020 through April 30, 2055. The base annual rent shall be reopened at the 15th and 30th years on August 31, 2035 and August 31, 2050.

The Lessee qualifies and meets the requirements of Sections 4-158-9 and 4-158-10, HAR, stated, in pertinent sections, as follows:

- The tenant must hold a current lease for use of lands transferred to the department;
- The holder of an encumbrance shall be satisfactorily performing in full compliance with the terms and conditions of the existing lease, permit, or license;
- The holder of the encumbrance shall not be in arrears in the payment of taxes, rents, or other obligations owed to the State or any county; and
- The holder of an encumbrance's agricultural activity or farming operation shall be fully and economically viable as specified in section 4-158-11, HAR.
- All extensions shall require the determination of the base rent and additional rents. The rental value shall be based on the appraisal conducted by a disinterested appraiser or appraisers contracted by the administrator. In no case shall the base annual rent of the existing encumbrance be reduced from its current rate.

An appraisal was completed pursuant to Section 4-158-10(b), HAR, for the purpose of determining the fair market rentals and the percentage of additional rents set for the first fifteen years of the extension period at \$2,347.00 per year for the subject parcel.

RECOMMENDATION:

That the Board of Agriculture approve the request for an extension of the lease term of General Lease No. S-5480 from August 31, 2020 through August 30, 2055 with the appraised rent set for the first 15 years of the extension period. All documents shall be subject to review and approval as to form by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer
Agricultural Resource Management Division

Attachments – Exhibit “A”

APPROVED FOR SUBMISSION:

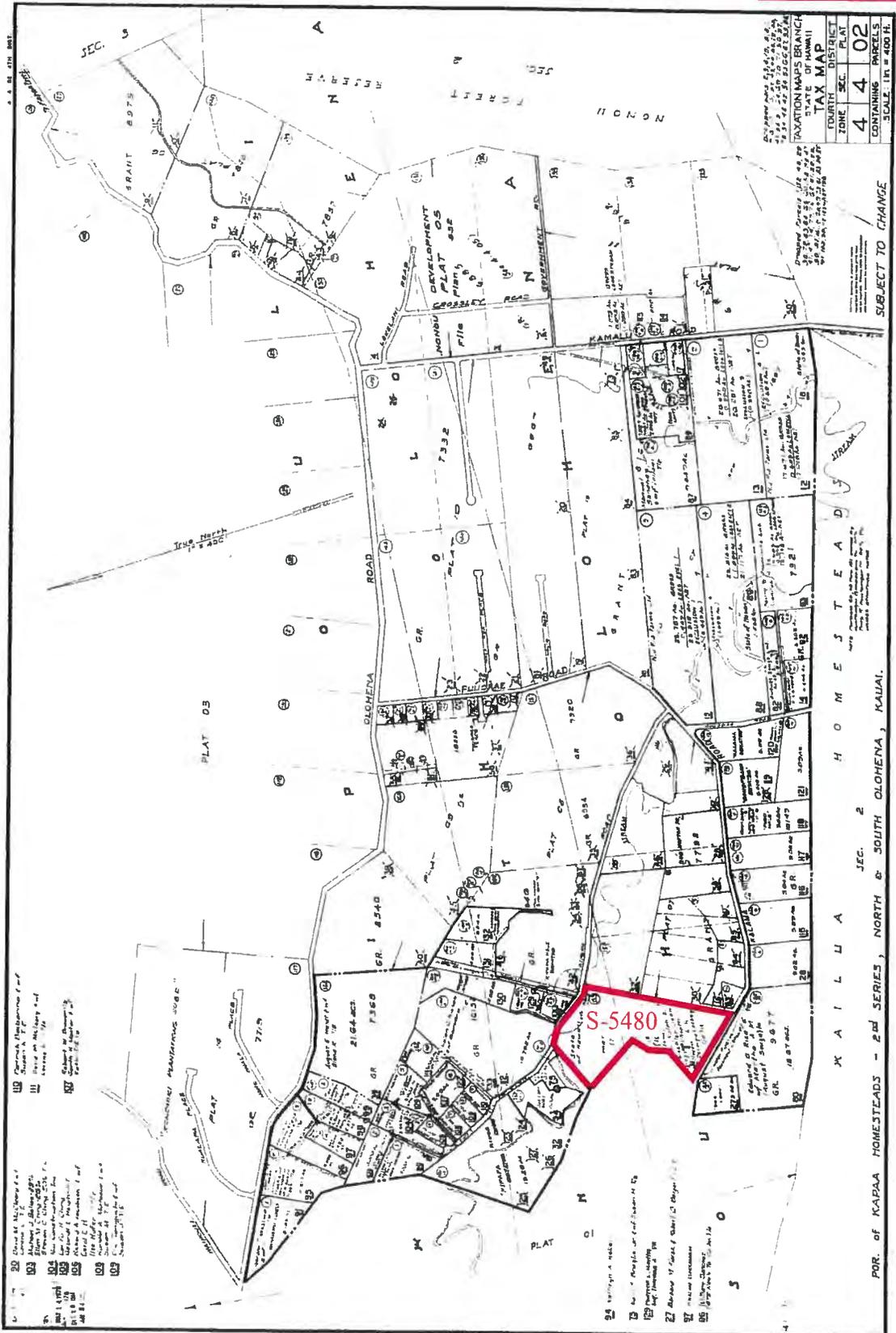


PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

B34

B35

EXHIBIT "A"



- 01. Containing a copy of the original survey map.
- 02. Containing a copy of the original survey map.
- 03. Containing a copy of the original survey map.
- 04. Containing a copy of the original survey map.
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PUR. OF KAPAA HOMESTEADS - 2ND SERIES, NORTH & SOUTH OLOHENA, KAULAI.

SUBJECT TO CHANGE

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR APPROVAL TO SUBLEASE BETWEEN THE
HAMAKUA AGRICULTURAL COOPERATIVE,
LESSEE/SUBLESSOR, AND STANLEY CYPRIANO,
SUBLESSEE; GENERAL LEASE NO. S-5551, TMK: (3) 4-6-
003:01,02,20(por), LOT NOS. 3,5,9,10,20,21,22,23, AND
GENERAL LEASE NO. S-5554, TMK: (3) 4-6-
001:007,008,018(por), LOT NO. 002, HONOKAIA MAKAI
TRACT, AND LAUKA-KULIHAI, HAMAKUA, ISLAND OF
HAWAII

Authority: Section 166E-6, Hawaii Revised Statutes, (HRS), and Section 4-
158-19(a)(6), Hawaii Administrative Rules (HAR),

Lessee/Sublessor: Hamakua Agricultural Cooperative

Sublessee: Stanley Cypriano

Land Area: 115.312 gross acres
General Lease No. S-5551: Lot No. 03 – 25.057 acres
Lot No. 05 – 11.371 acres
Lot No. 09 – 13.659 acres
Lot No. 10 – 12.232 acres
Lot No. 20 – 9.610 acres
Lot No. 21 – 8.298 acres
Lot No. 22 – 10.408 acres
Lot No. 23 – 9.677 acres
General Lease No. S-5554: Lot No. 02, 15.000 acres

Tax Map Key: General Lease No. S-5551: (3) 4-6-003:01,02,20 (por)
General Lease No. S-5554: (3) 4-6-001:007,008,018 (por)
Exhibit "A"

B36

B37

Land Status: The Hamakua lands were transferred to the Department of Agriculture by Governor's Executive Order No. 4250, dated October 22, 2008 pursuant to Act 90, SLH 2003.

Lease Term: June 30, 1998 through June 29, 2033

Sublessee Term: February 28, 2020 through June 29, 2033

Sublease Base Rental: \$12,663.33 per year

General Lease No. S-5551

\$2,770.00/year – Lot 03 until June 29, 2033 (Expiration Date)

\$1,260.00/year – Lot 05 “ “ “ “ “ “

\$1,507.00/year – Lot 09 “ “ “ “ “ “

\$1,355.00/year – Lot 10 “ “ “ “ “ “

\$1,065.00/year – Lot 20 “ “ “ “ “ “

\$ 919.33/year – Lot 21 “ “ “ “ “ “

\$1,053.00/year – Lot 22 “ “ “ “ “ “

\$1,072.00/year – Lot 23 “ “ “ “ “ “

General Lease No. S-5554

\$1,662.00/year – Lot 02 until June 29,2033 (Expiration Date)

Character of Use: General Agriculture and pasture purposes in accordance with a Plan of Utilization and Development approved by the Department

REMARKS:

Stanley Cypriano is an existing Hamakua Agricultural Cooperative member who holds several subleases with the Co-op. Mr. Cypriano has run the family cattle business since 2000 and wishes to expand his current operations which is located in the same general area. The additional land will allow him to expand his breeding program to further improve his stock, producing high-quality grass-finished cattle. He is sole proprietor of the business.

Stanley Cypriano qualifies as a bona fide farmer with more than two years of full-time farming experience and meets application and eligibility requirements in accordance with sections 4-158-1 and 27, HAR.

RECOMMENDATION:

That the Board of Agriculture approve the Subleases between the Hamakua Agricultural Cooperative, Lessee/Sublessor, and Stanley Cypriano, Sublessee, for Lot Nos. 03,05,09,10,20,21,22, and 23 under General Lease No. S-5551 and Lot No. 02 under General Lease No. S-5554 until the lease expiration date of June 29, 2033; and further, subject to the review and approval as to form of the Sublease document by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer
Agricultural Resource Management Division

Attachment – Exhibit “A” 2 pages

APPROVED FOR SUBMISSION:

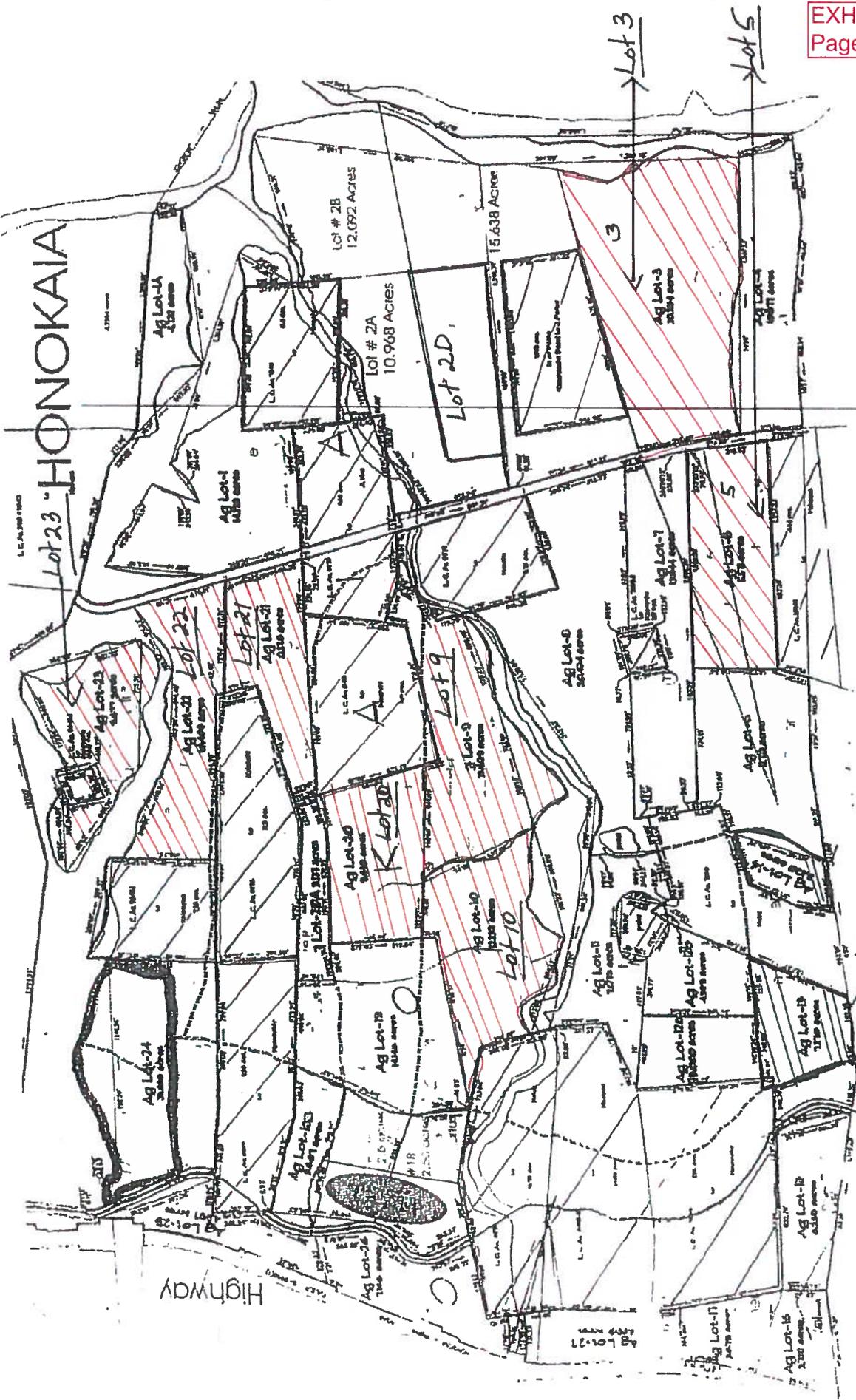


PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

B38

B39

TUK: 4-6-03: 01, 02, 920



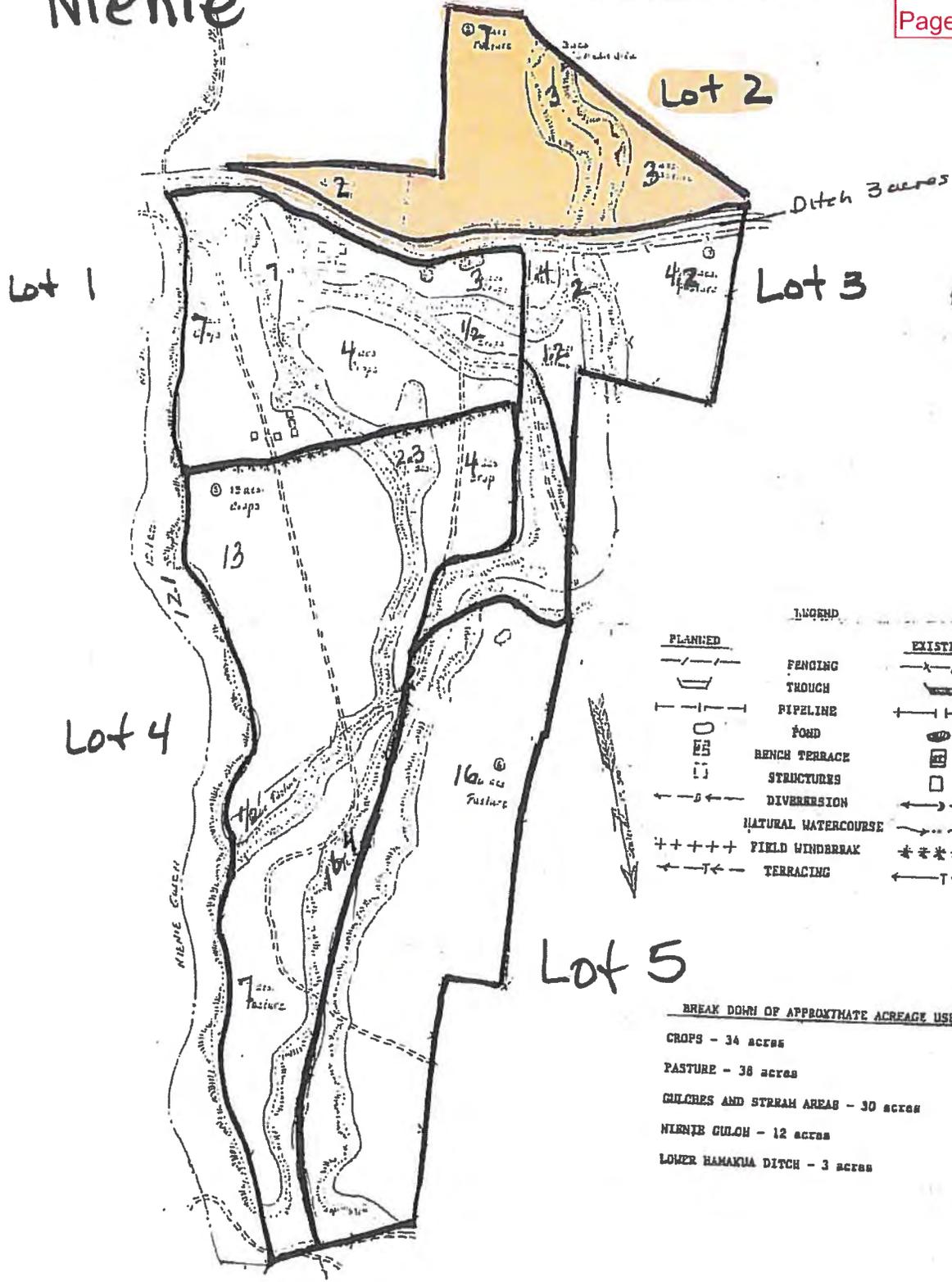
= Roads/Access

▨ = Bishop Estate Land

EXHIBIT "A"

Nienie

EXHIBIT "A"
 Page 2 of 2



LEGEND

PLANNED		EXISTING
	FENCING	
	TROUGH	
	PIPELINE	
	FORD	
	BENCH TERRACE	
	STRUCTURES	
	DIVERSION	
	NATURAL WATERCOURSE	
	FIELD WINDBREAK	
	TERRACING	

BREAK DOWN OF APPROXIMATE ACREAGE USE

- CROPS - 34 acres
- PASTURE - 38 acres
- GULCHES AND STREAM AREAS - 30 acres
- NINIIE GULCH - 12 acres
- LOWER HAMAKUA DITCH - 3 acres



B40

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR APPROVAL TO EXTEND SUBLEASE BETWEEN THE HAMAKUA AGRICULTURAL COOPERATIVE, LESSEE/SUBLESSOR, AND ROBERT M. BOWMAN, SUBLESSEE; GENERAL LEASE NO. S-5551, TMK: (3) 4-6-003:001,002,020(por), LOT NO. 18B, HONOKAIA MAKAI TRACT, HAMAKUA, ISLAND OF HAWAII

Authority: Section 166E-6, Hawaii Revised Statutes, (HRS), and Section 4-158-19(a)(6), Hawaii Administrative Rules (HAR)

Lessee/Sublessor: Hamakua Agricultural Cooperative

Sublessee: Robert M. Bowman

Land Area: Lot No. 18B – 6.000 acres - General Lease No. S-5551

Tax Map Key: (3) 4-6-003:001, 002, 020 (por) (Exhibit “A”)

Land Status: The Hamakua lands were transferred to the Department of Agriculture by Governor’s Executive Order No. 4250, dated October 22, 2008 pursuant to Act 90, SLH 2003.

Lease Term: June 30, 1998 through June 29, 2033

Sublessee Term: January 17, 2020 through June 29, 2033

Sublease Base Annual Rental: \$665.00/year – Lot 18B until June 29, 2033 (Expiration Date)

Character of Use: General Agriculture and pasture purposes in accordance with a Plan of Utilization and Development approved by the Department

B41

BAZ

REMARKS:

Robert M. Bowman held a probationary sublease with the Hamakua Agricultural Cooperative, General Lease No. S-5551, Lot No. 18B, since December 1, 2014 which was approved by the Board of Agriculture at its meeting held on November 17, 2014. The probationary sublease expired, and he has been a holdover subtenant. Mr. Bowman is requesting an extension of sublease from January 17, 2020 to June 29, 2033.

Robert has satisfactorily completed the development of Lot. No. 18B in accordance with his business plan as scheduled. Robert continues to produce taro on his 6-acre farm and is the sole proprietor of such.

Robert M. "Kai" Bowman qualifies as a bona fide farmer with more than two years of full-time farming experience and meets application and eligibility requirements in accordance with sections 4-158-1 and 27, HAR.

RECOMMENDATION:

That the Board of Agriculture approve the extension of Sublease between the Hamakua Agricultural Cooperative, Lessee/Sublessor, and Robert Kai Bowman, Sublessee, for Lot No. 18B in Honokaia, under General Lease No. S-5551, until the expiration date of June 29, 2033; and further subject to the review and approval as to form of the Sublease document by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interest of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer
Agricultural Resource Management Division

Attachment – Exhibit "A"

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

Exhibit "A"

TRK: 4-6-03 01.02.20

HONOKAIA



Roads/Access

= Bishop Estate Land

B43

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR CONSENT TO ASSIGNMENT OF GENERAL LEASE
NO. S-4790, SORIANO FARM, INC., LESSEE/ASSIGNOR, TO LESTER
GEBIN, ASSIGNEE, TMK: 3rd DIV/8-8-004:010, LOT 10, PAPA
HOMESTEADS, PAPA 1ST, SOUTH KONA, ISLAND OF HAWAII

Authority: Section 166E-3, Hawaii Revised Statutes (HRS), as amended,
and Section 4-158-19(a)(4)(A), Hawaii Administrative Rules
(HAR)

Lessee/Assignor: Soriano Farm, Inc.

Assignee: Lester Gebin

Land Area: Approximately 7.850 acres

Tax Map Key: 3rdDiv/8-8-004:010 (Exhibit "A")

Land Status: Encumbered by Governor's Executive Order No. 4430 to the
Department of Agriculture for non-agricultural park land
purposes

Lease Term: 50 years, March 23, 1982 through March 22, 2032

Annual Base Rent: \$3,200/year until rental re-opening – March 22, 2027

Character of Use: Diversified Agriculture purposes

Consideration: \$30,000.00

B44

BAS

BACKGROUND

The Department of Land and Natural Resources (DLNR) held a Public Auction on March 23, 1982, whereby, General Lease No. S-4790, a 35-year lease, was awarded to Fred Soriano. At its meeting held on March 14, 2017, the Board of Agriculture (BOA) approved an extension of lease for 15 years to expire March 22, 2032.

On June 20, 2017, the BOA consented to the assignment of the subject lease from Fred Soriano to Soriano Farm, Inc., an existing family business since 1999. Officers and operators of Soriano Farm, Inc. are Fred Soriano, Jose Soriano and Rueben Soriano. Soriano Farm, Inc. operates a successful coffee and macadamia nut farm.

Due to physical disability, Fred Soriano, Jose Soriano and Rueben Soriano, officers of Soriano Farm, Inc., are requesting the assignment of General Lease No. S-4790 to Lester Gebin. Pursuant to the terms of General Lease No. S-4790 and Section 4-158-19(a)(4)(A), HAR, an assignment of lease is permitted due to physical disability.

Lester Gebin has over 17 years of farming experience. He lived and worked on the Soriano's farm since 2003 where he learned all aspects of coffee and macadamia nut farming, from the planting, harvesting and processing of coffee beans and macadamia nuts to the delivering of the crops to their customers.

After the assignment of lease is approved and finalized, Soriano Farms, Inc. has agreed to provide support and guidance to Lester for a minimum of one year.

Lester qualifies as a bona fide farmer, with more than two years of full-time farming experience and satisfies the eligibility requirements pursuant to Sections 4-158-1 and 27, HAR.

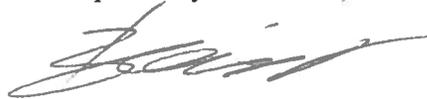
There is a consideration of \$30,000.00 for the assignment of the lease. Staff does not recommend an adjustment of the annual rental rate as the consideration amount appears to be consistent with fair market values.

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RECOMMENDATION:

That the Board of Agriculture approve the assignment of General Lease S-4790 from Soriano Farm, Inc., Lessee/Assignor, to Lester Gebin, Assignee, subject to the approval as to form of the assignment and consent documents by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer,
Agricultural Resource Management Division

Attachments - Exhibit "A"

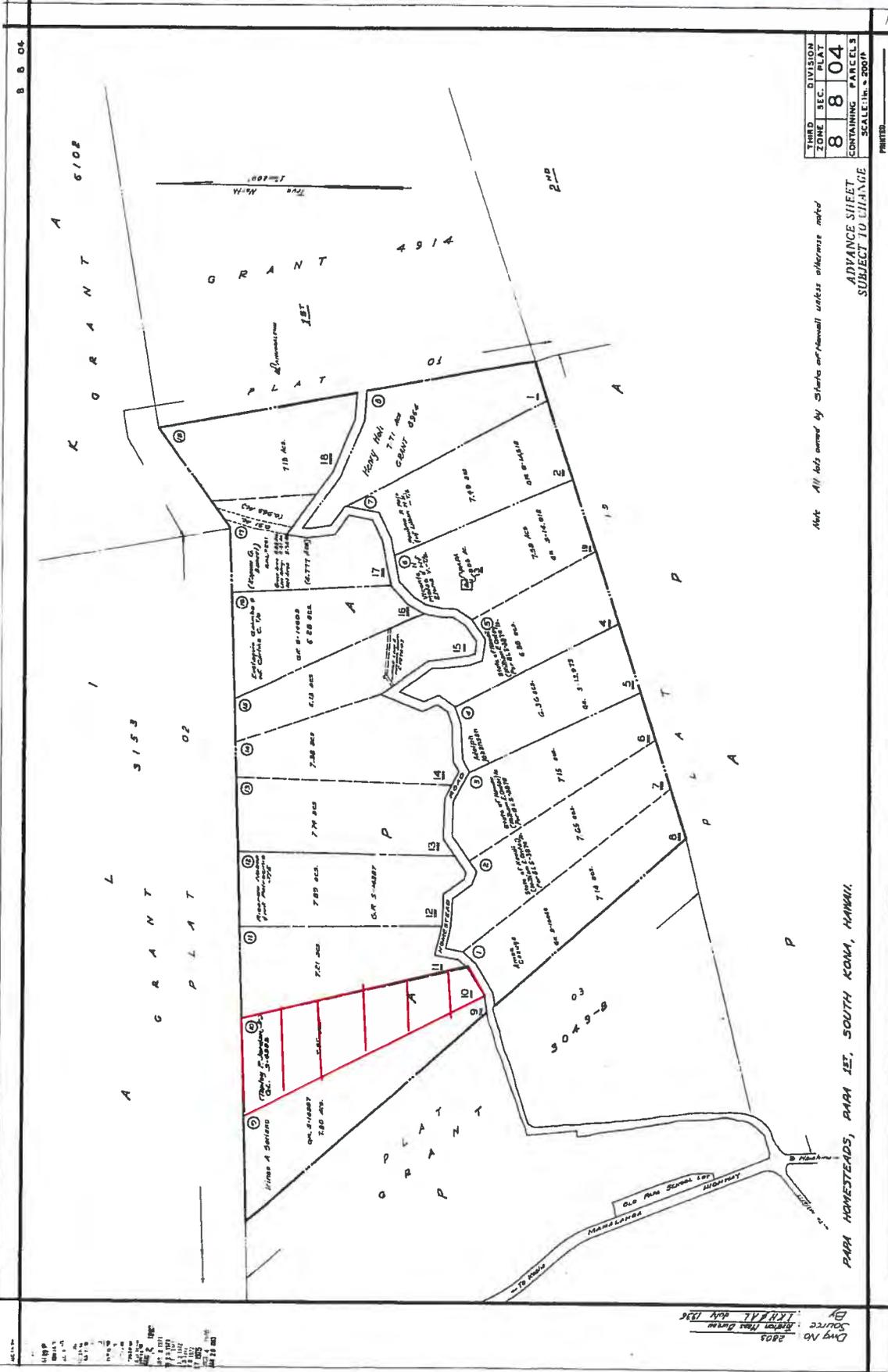
APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

BAG

B47



THIRD ZONE	DIVISION
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8	04
CONTAINING PARCELS	
SCALE 1/8" = 200'	

ADVANCE SHEET
SUBJECT TO CHANGE

PARA HOMESTEADS, PARA 1ST, SOUTH KONA, HAWAII.

Drawn by: KENAL
Source: KENAL

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Old Palm School Lot
Makalea Highway

PRINTED

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR CONSENT TO ASSIGNMENT OF GENERAL LEASE NO. S-4822, TED SCOTT PHILIPS, LESSEE/ASSIGNOR, TO SUSAN CHRISTINE PHILIPS, ASSIGNEE, TMK: 3rd DIV/1-5-116:059, LOT 32 PAHOA AGRICULTURAL PARK, PHASE II, KEONEPOKO IKI, PUNA, ISLAND OF HAWAII

Authority: Section 166-7 and 166-9, Hawaii Revised Statutes (HRS), as amended, and Section 4-153-33(a)(6)(B), Hawaii Administrative Rules (HAR)

Lessee/Assignor: Ted Scott Philips

Assignee: Susan Christine Philips

Land Area: Approximately 5.005 acres

Tax Map Key: 3rdDiv/1-5-116:059 (Exhibit "A")

Land Status: Encumbered by Governor's Executive Order No. 3380 to the Department of Agriculture for agricultural park land Purposes in 1988

Lease Term: 55 years, May 1, 1982 through April 30, 2037

Annual Base Rent: \$830/year until rental re-opening – April 30, 2022

Character of Use: Diversified Agriculture purposes

Consideration: None

BACKGROUND

The Board of Land and Natural Resources (BLNR) awarded General Lease No. S-4822, a 55- year lease, to Steven L. Oleson effective May 1, 1982. By mesne assignment, at its meeting held on October 26, 2004, the BOA consented to the assignment of said lease to Ted Scott Philips. Mr. Philips produces various fruit trees and dendrobium orchids on his farm.

B48

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Due to physical disability, Ted Philips is requesting the assignment of General Lease No. S-4822 to Susan Christine Philips. Pursuant to the terms of General Lease No. S-4822 and Section 4-153-33(a)(6)(B), HAR, an assignment of lease is permitted due to physical disability.

Susan Philips has owned and operated Tropical Colors since its inception in 1987 growing and selling tropical flowers including anthuriums, ginger, and heliconia at her farm in Leilani Estates, Pahoa. In 2018, the disastrous volcanic eruptions and Hurricane Lane caused extreme damage to the flowers and improvements on the property. Through hard work and determination, she has "almost made a complete recovery" to pre-disaster times. Ms. Phillip's intent is to further grow her business by assuming General Lease No. S-4822. She plans to expand the existing orchard of fruit trees which include lychee, lime, lemon, logan, tangerine, avocado, etc. and grow tropical flowers as well. She intends to sell these products at local farmers markets and resume exporting flowers to mainland destinations in the future.

Susan Christine Philips qualifies as a bona fide farmer, with more than two years of full-time farming experience, and satisfies the eligibility requirements pursuant to Sections 4-153-1 and 13, HAR.

There is no consideration for the assignment of the lease.

RECOMMENDATION:

That the Board of Agriculture approve the assignment of General Lease No. S-4822 from Ted Scott Philips, Lessee/Assignor, to Susan Christine Philips, Assignee, subject to the approval as to form of the assignment and consent documents by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer,
Agricultural Resource Management Division

Attachments - Exhibit "A"

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

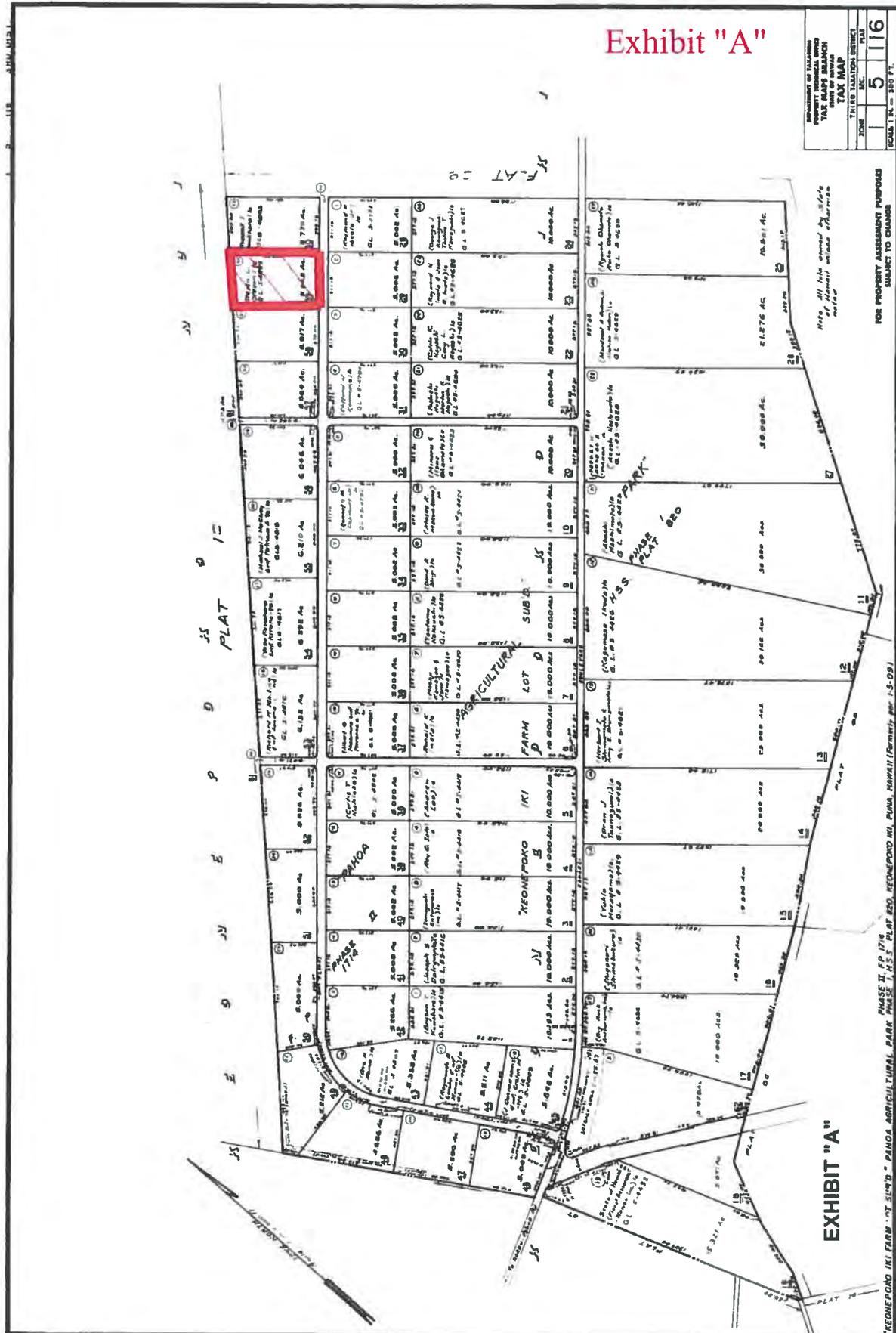


EXHIBIT "A"

REQUIREMENTS OF TARRANTS	
PROPERTY, TARRANTS, OWNER	
TARRANTS BRANCH	
TAX MAP	
THIRD TAXATION DISTRICT	15116
ZONE	5
PLAT	116
SCALE 1 IN. = 300 FT.	

Note: All lots owned by State of Hawaii unless otherwise noted.

FOR PROPERTY ASSESSMENT PURPOSES
SUBJECT TO CHANGE

PHASE II, PP 1714
"KEDUPONO IKI FARM" - LOT 5149 - PANOA AGRICULTURAL PARK PHASE I, N.S. PLAT 850, KEDUPONO KI, PUNA, HAWAII (FORMERLY PP 1-5-09)

EXHIBIT "A"

B50

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR CONSENT TO ASSIGNMENT OF GENERAL LEASE NO. S-4855, MOUNTAIN SHORE FARM LLC, LESSEE/ASSIGNOR, TO ZACHARIAH WEIMER, ASSIGNEE, TMK: 3rd DIV/7-3-049:030, LOT 34, KEAHOLE AGRICULTURAL PARK, KALAOA, NORTH KONA, ISLAND OF HAWAII

Authority: Section 166-7 and 166-9, Hawaii Revised Statutes (HRS), and Section 4-153-33(a)(6)(B), Hawaii Administrative Rules (HAR)

Lessee/Assignor: Mountain Shore Farm LLC

Assignee: Zachariah Weimer

Land Area: Approximately 5.027 acres

Tax Map Key: 3rdDiv/7-3-049:030 (Exhibit "A")

Land Status: Encumbered by Governor's Executive Order No. 3379 to the Department of Agriculture for agricultural park land purposes

Lease Term: 45 years, January 1, 1999 to December 31, 2043

Annual Base Rent: \$2,790/year until rental re-opening – January 1, 2024

Additional Rent: The amount by which 1.5% of the gross proceeds from the sale of commodities produced on the demised premises that exceeds the base rental.

Character of Use: Diversified Agriculture purposes

Consideration: \$415,000.00

BACKGROUND

The subject lease was originally awarded to Robert J. Albert by the Board of Agriculture at its meeting held on June 10, 1998. On February 27, 2007, the Board consented to the assignment of General Lease No. S-4855 from Robert Albert to himself and his wife, Genevieve Albert.

B51

BS2

On August 23, 2016, the Board consented to the assignment of the subject lease to Mountain Shore Farm LLC owned and operated by Hideaki Yamagishi and Mari Nakamichi. Mountain Shore Farm, LLC continued the farming of plumeria and Noni.

Due to physical disability, Mr. Yamagishi and Ms. Nakamichi, owners of Mountain Shore Farm LLC, are requesting the assignment of General Lease No. S-4855 to Zachariah Weimer. Pursuant to the terms of General Lease No. S-4855 and Section 4-153-33(a)(6)(B), HAR, an assignment of lease is permitted due to physical disability.

Zachariah has over 16 years of farming experience. He lived and worked on a coffee farm where he learned all aspects of coffee farming, from planting to harvesting and processing of the coffee beans.

Since 2012, Zachariah has been employed with Tropical Tree Care. Through his employment with Tropical Tree Care, Zachariah was trained in arboriculture. He was also trained in planting, fertilizing and herbicide application on a variety of trees and palms. He became the owner and operator of Tropical Tree Care in 2018.

Zachariah qualifies as a bona fide farmer, with more than two years of fulltime farming experience and satisfies the eligibility requirements for agricultural parks pursuant to Sections 4-153-1 and 4-153-13, HAR.

There is a consideration of \$415,000.00 for the assignment of lease, which includes two existing permitted farm dwellings. Staff does not recommend an adjustment of the annual rental rate as the consideration amount appears to be consistent with fair market values.

RECOMMENDATION:

That the Board of Agriculture approve the assignment of General Lease S-4855 from Mountain Shore Farm LLC, Lessee/Assignor, to Zachariah Weimer, Assignee, subject to the approval as to form of the assignment and consent documents by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interest of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer,
Agricultural Resource Management Division

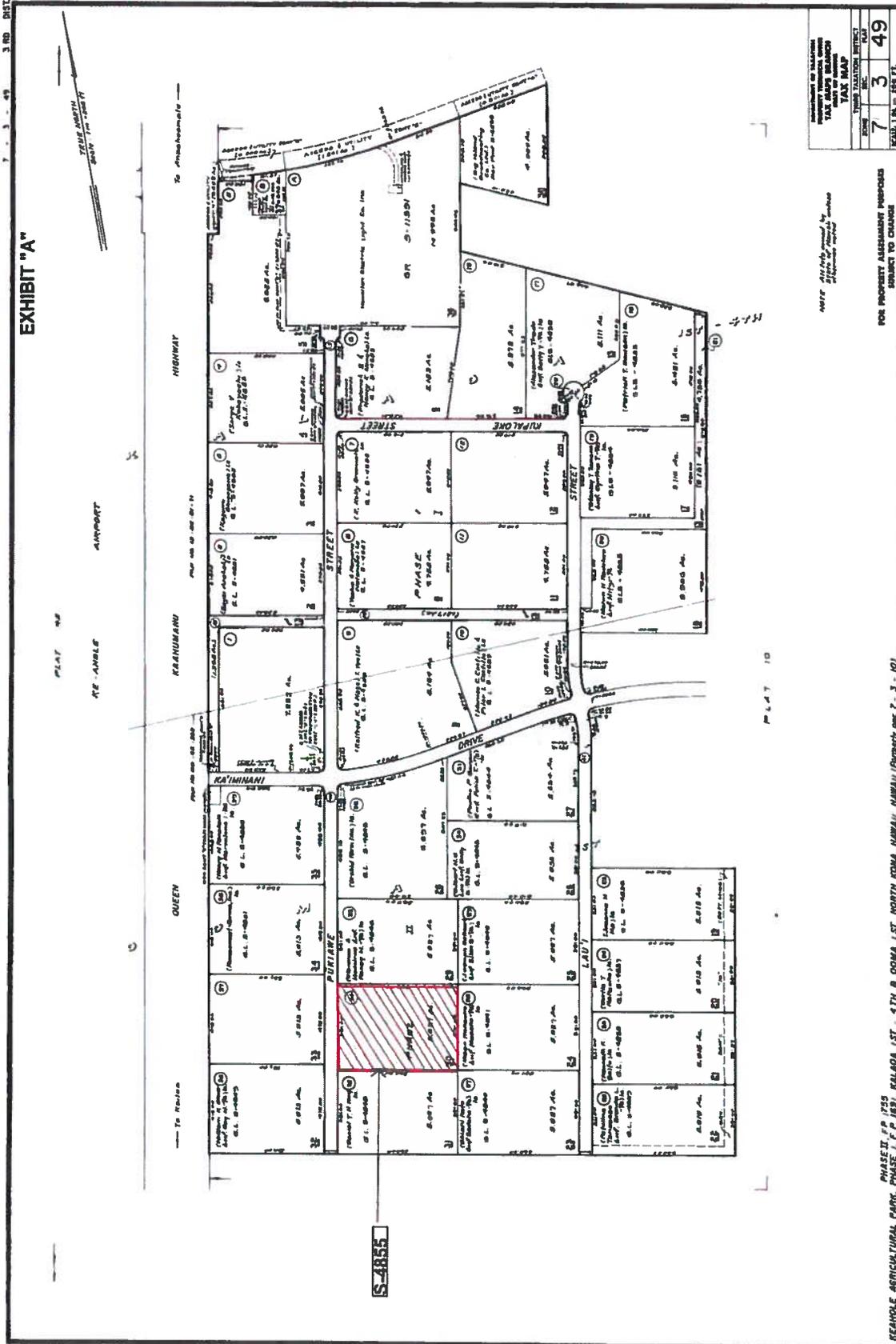
Attachments - Exhibit "A"

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

EXHIBIT "A"



PLAT NO. 7-3-49
 KE-AMBLE
 AIRPORT
 3 RD DIST

DATE FOR 1955
 BY M/R/MS
 PL 1955
 SOURCE

RECORDS OF SALES	7
TAX MAPS	3
PLAT	49
DATE	1955

NOT AGRICULTURAL PURPOSES
 FOR PROPERTY ASSESSMENT PURPOSES
 SUBJECT TO CHANGE

PHASE II, P. 1955
 KEANOLE AGRICULTURAL PARK, PHASE 2, P. 1955, KALANOA 1ST - 4TH & OOMA 1ST, NORTH OOMA, HAWAII (Remarks pgs. 7, 3-10)

B53

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR CONSENT TO ASSIGNMENT OF GENERAL LEASE NO. S-6024, BOTEILHO HAWAII ENTERPRISES, INC., LESSEE/ASSIGNOR; DUTCH-HAWAIIAN DAIRY FARMS, LLC, ASSIGNEE, TMK: 3RD DIV/5-5-003:004, 005 AND 006; 3RD DIV/5-5-005:001; 3RD DIV/5-5-006:002, 003, 004 AND 015, OPIHIPAU-HUKIAA, KOKOIKI, NORTH KOHALA, ISLAND OF HAWAII, HAWAII

Authority: Section 166E-3, Hawaii Revised Statutes, (HRS), Section 4-158-19(a), Hawaii Administrative Rules (HAR)

Lessee/Assignor: Boteilho Hawaii Enterprises, Inc.

Assignee: Dutch-Hawaiian Dairy Farms, LLC

Land Area: Approximately 907.892 gross acres, 879.549 net acres

Lease Term: 30 years, June 23, 2011 through June 22, 2041

Tax Map Key: 3rdDiv/5-5-003:004, 005 and 006 (Exhibit "A")
3rdDiv/5-5-005:001
3rdDiv/5-5-006:002, 003, 004 and 015

Land Status: Encumbered by Governor's Executive Order No. 4553 to the Department of Agriculture for non-agricultural park land purposes

Base Rent: \$15,000/year – until June 22, 2021 (Reopening date)

Character of Use: Dairying and allied purposes.

Consideration: \$700,000.00

BSA

BSS

BACKGROUND:

The Board of Land and Natural Resources (BLNR) awarded General Lease No. S-6024 to Boteilho Hawaii Enterprises, Inc. (BHEI), a 30-year direct lease commencing June 23, 2011.

On April 12, 2018, under Act 90, Executive Order 4553, General Lease No. S-6024 BHEI, was transferred from the Department of Land and Natural Resources (DLNR) to the Department of Agriculture (DOA) for management purposes.

Commensurate with Section 4-158-19(a)(4)(B), BHEI is requesting the assignment of General Lease S-6024, BHEI to Dutch-Hawaiian Dairy Farms, LLC (DHDFL) due to extreme economic hardship. In 2019, severe drought conditions caused a significant increase in BHEI's feed costs, which put them in poor financial condition. Since then, BHEI has not recovered from their losses and their financial condition remains poor and they are at risk of shutting down operations.

The assignment of lease will include improvements, trade fixtures, livestock, equipment and vehicles.

Kees Kea, his wife Malena Kea and their son Cornel Kea have been the owners and operators of DHDFL since December 16, 2019. Additionally, Kees and Malena Kea have been successful owners and operators of Mauna Kea Moo since 2008 located at O'okala, Hawaii, where they raise Holstein cows and grow grass feed. They also owned and operated Paramount Dairy in Tillamook, Oregon from 1989 until 2003.

Kees and Malena Kea have over 31 years of experience in the dairy industry. In addition, all three members of DHDFL were raised on family dairies and were directly involved in the day-to-day operations of the businesses.

DHDFL qualifies as an agricultural company with more than 75 percent of its members qualifying as bona fide farmers and meeting eligibility requirements pursuant to Sections 4-158-1 and 27, HAR.

There is a consideration of \$700,000.00 for the assignment of lease. In accordance with Exhibit "B" ASSIGNMENT OF LEASE EVALUATION POLICY of General Lease No. S-6024, any net proceeds are subject to a Premium Percentage charge benefiting the Lessor. In this case, calculations in accordance with this provision net \$0.00 to the Lessor (see attached Exhibit "B").

RECOMMENDATION:

That the Board of Agriculture approve the assignment of lease from Boteilho Hawaii Enterprises, Inc., Lessee/Assignor, to Dutch-Hawaiian Dairy Farms, LLC, Assignee.

Board of Agriculture
June 23, 2020
Page 3 of 3

All related documents are subject to the review and approval as to form by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer,
Agricultural Resource Management Division

Attachments - Exhibit "A", Exhibit "B"

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

B56

Exhibit "A"
(map 3 of 3)

BS9

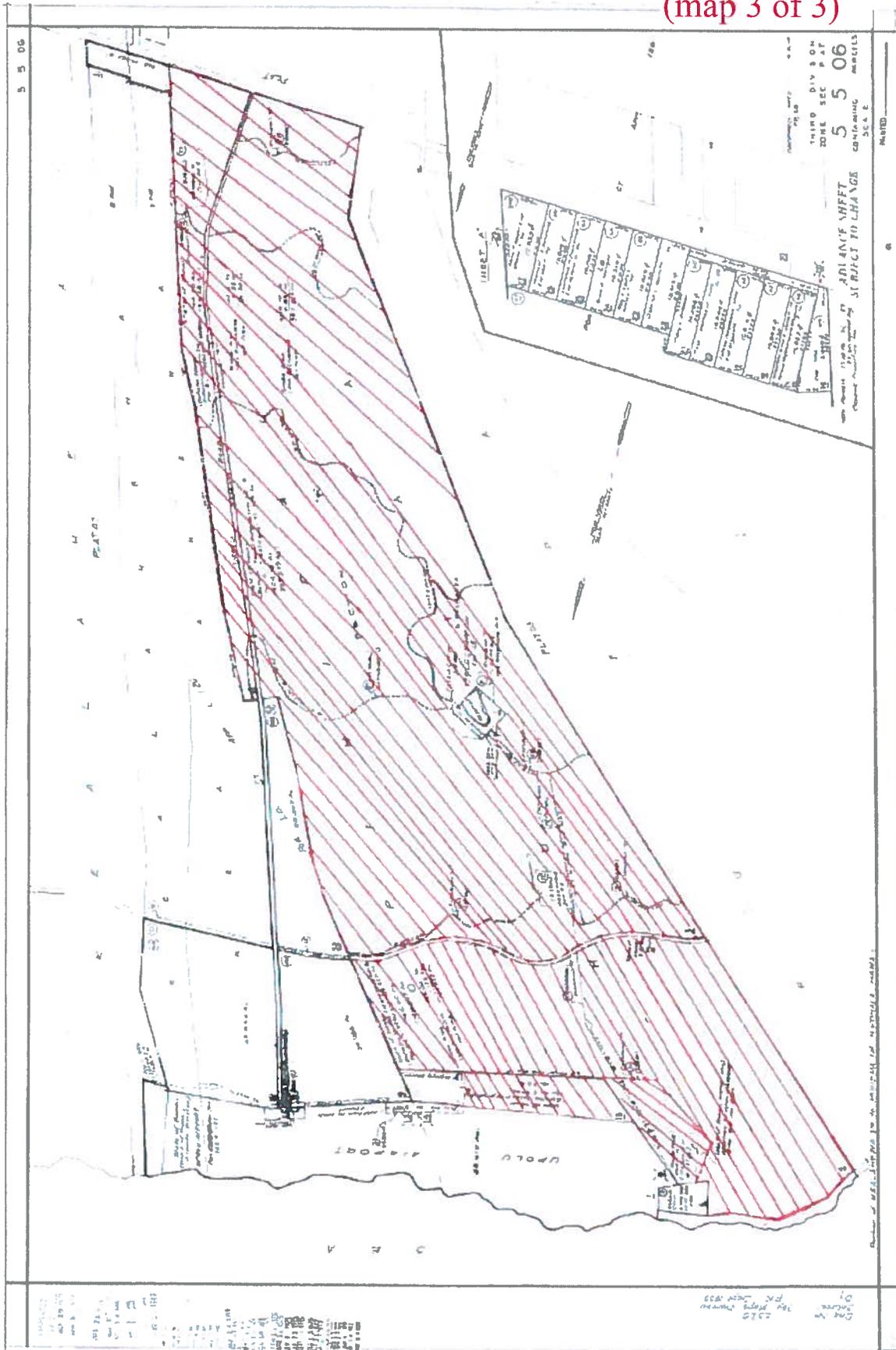


EXHIBIT "B"

**ASSIGNMENT OF LEASE CALCULATIONS FOR
GENERAL LEASE NO. S-6024**

Purchase Price	\$	700,000.00	
1. Cost of Cattle Conveyed			
	Total Cost of Cattle:	\$677,637.00	
2. Property Taxes Owing			
	TMK: 3-5-5-006-002	\$2,487.37	
	TMK: 3-5-5-006-003	\$4,655.34	
3. Foreclosure Amount			
	Paul Pozzi DBA Poz Trading (as of 1/15/2020)	411,000.00	
4. Net Profit/Loss		\$ (395,779.71)	

B60

STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: REQUEST FOR CONSENT TO ASSIGNMENT OF GENERAL LEASE NOS. S-7000, S-7014, S-7015 AND S-7016; HAWAII BEEF PRODUCERS, LLC, LESSEE/ASSIGNOR, TO HAWAII BEEF LEASE, LLC, ASSIGNEE; TMK: 3RD DIV/4-3-005:002; 3RD DIV/4-3-005-002-5002; 3RD DIV/4-3-005-002-5003 AND 3RD DIV/4-3-005-002-5004, HAMAKUA AGRICULTURAL PARK, POHAKUHAKU AND KEMAU 1ST, HAMAKUA DISTRICT, ISLAND OF HAWAII, HAWAII

Authority: Section 166-7 AND 166-9, Hawaii Revised Statutes, (HRS),
Section 4-153-33(a)(6)(B), Hawaii Administrative Rules
(HAR)

Lessee/Assignor: Hawaii Beef Producers, LLC

Assignee: Hawaii Beef Lease, LLC

Land Area: Approximately 152.385 gross acres, 120.791 net acres
General Lease No. S-7000: Lot No. 4a - 7.470 acres
General Lease No. S-7014: Lot No. 2 - 45.911 acres
General Lease No. S-7015: Lot No. 3 - 54.348 acres
General Lease No. S-7016: Lot No. 4 - 44.656 acres

Tax Map Key: 3rdDiv/4-3-005:002 (por) (Exhibit "A")
3rdDiv/4-3-005-002-5002
3rdDiv/4-3-005-002-5003
3rdDiv/4-3-005-002-5004 (por)

Lease Term: General Lease No. S-7000:
35 years, January 1, 1996 through December 31, 2030.
General Lease No. S-7014:
35 years, June 30, 1998 through June 29, 2033.
General Lease No. S-7015:
35 years, June 30, 1998 through June 29, 2033.
General Lease No. S-7015:
35 years, June 30, 1998 through June 29, 2033.

B61

B62

- Land Status: Hamakua Agricultural Park lands were acquired in fee by the Department of Agriculture under foreclosure and Bankruptcy Settlement Agreement with Hamakua Sugar Company, Inc.
- Base Rent: General Lease S-7000:
\$2,906.08/year – until December 31, 2021 (Reopening biennial)
General Lease S-7014:
\$4,030.00/year – until June 30, 2028 (Reopening date)
General Lease S-7015
\$670.00/year – until June 30, 2028 (Reopening date)
General Lease S-7016
\$450.00/year – until June 30, 2028 (Reopening date)
- Character of Use: General Lease S-7000:
Livestock slaughtering and processing purposes
General Lease S-7014:
Diversified Agriculture or Pastoral and related purposes
General Lease S-7015:
Pastoral related purposes
General Lease S-7016:
Pastoral related purposes

BACKGROUND:

On January 1, 1996, the Board of Agriculture (BOA) awarded General Lease No. S-7000, a 35 direct-year lease to Hawaii Beef Producers, LLC. On June 30, 1998, the BOA awarded 35 direct-year leases to Hawaii Beef Producers, LLC (HBPL), under General Lease Nos. S-7014, S-7015 and S-7016.

Due to physical disability, Jill Andrade, General Manager of HBP, is requesting the assignment of General Lease No.'s S-7000, S-7014, S-7015 and S-7016, to Hawaii Beef Lease, LLC (HBL). Pursuant to the terms of the subject General Leases and Section 4-153-33(a)(6)(B), HAR, an assignment of lease is permitted due to physical disability.

Barney "Zanga" Schutte, general members of HBLL, has a lifetime of involvement within the cultivating and farming industry. He was raised on a ranch and later became the manager Hale Kea Farms for 26 years. Since 2006, Barney has been the successful owner and operator of Z Bar Ranch, LLC, located in Kamuela, which further compliments his knowledge in the cattle industry. His experience encompasses grazing practices, raising of cattle and sales and shipping of cattle for slaughter. Barney Schutte holds 75 percent of the ownership interest of the company and qualifies as a bona fide farmer with more than two years of fulltime farming experience and satisfies the eligibility requirements pursuant to Sections 4-153-1 and 13, HAR.

The Frank Vandersloot Trust is a general member of HBLL, however, does not qualify as a bona fide farmer or meet eligibility requirements.

HBLL qualifies as an agricultural company whose members with more than 75 percent ownership interest in the company qualify as bona fide farmers and meet eligibility requirements pursuant to Sections 4-153-1 and 13, HAR.

HBPL will continue to manage the operations of the slaughterhouse business and pasture properties.

There is no consideration for the lease assignments.

RECOMMENDATION:

That the Board of Agriculture approve the assignment of lease from Hawaii Beef Producers, LLC, Lessee/Assignor, to Hawaii Beef Lease, LLC, Assignee. All related documents are subject to the review and approval as to form by the Department of the Attorney General, and such other terms and conditions as may be prescribed by the Chairperson to best serve the interests of the State.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator and Chief Engineer,
Agricultural Resource Management Division

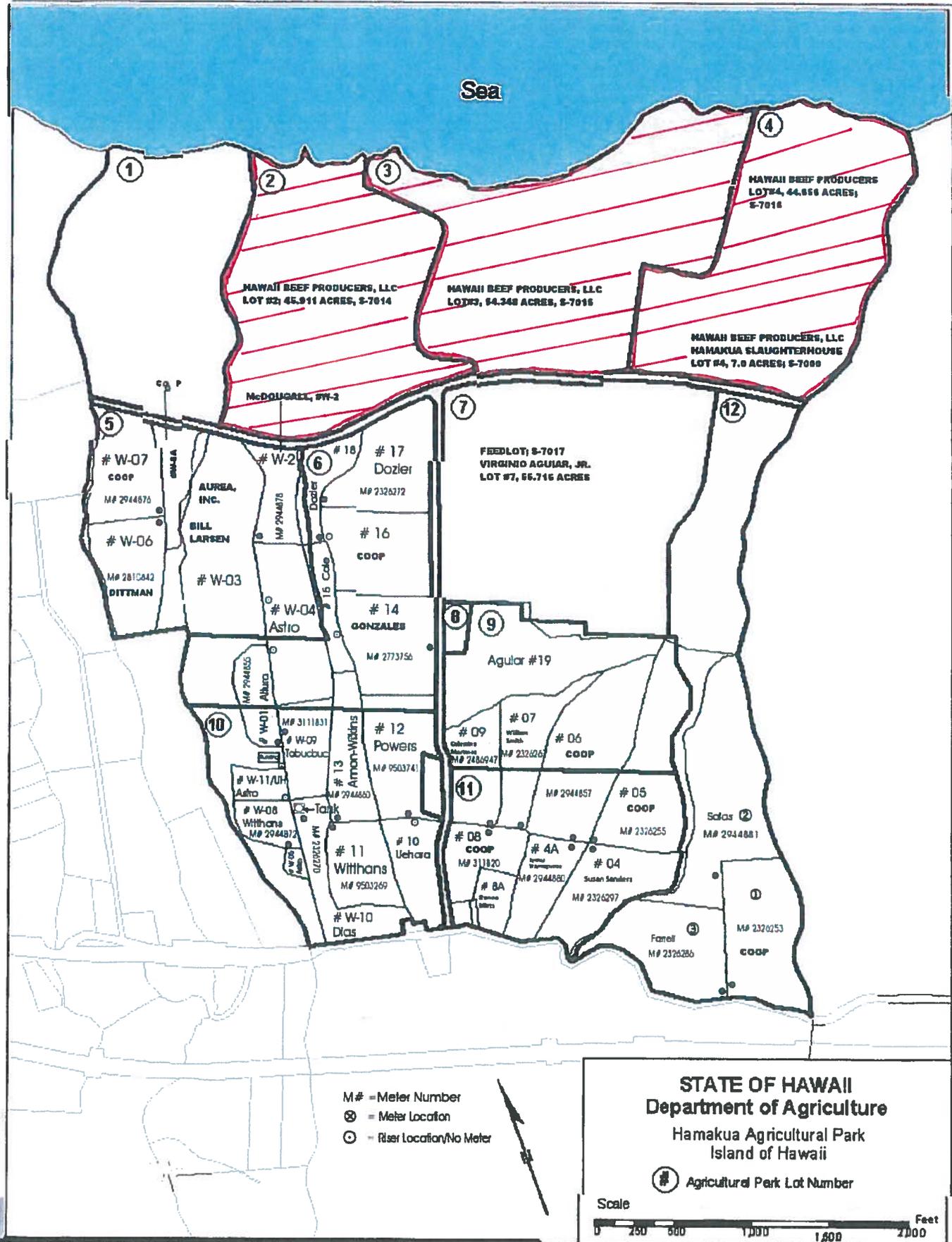
Attachments - Exhibit "A"

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

B64



STATE OF HAWAII
DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESOURCE MANAGEMENT DIVISION
HONOLULU, HAWAII

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

Subject: CERTIFICATION OF ACREAGE ASSESSMENTS FOR
THE HONOKAA-PAAUILO, KAHUKU, MOLOKAI,
WAIMANALO, AND WAIMEA IRRIGATION SYSTEMS,
2021 FISCAL YEAR

BACKGROUND:

Section 167-19(a), Hawaii Revised Statutes, states, “The board shall determine and certify on or before June 30 of each year the amount of acreage assessments necessary in that fiscal year for the acquisition, construction, operation, and maintenance of irrigation facilities for each project, and the acreage of agricultural and pasture land of each land occupier within the project.” For the 2021 fiscal year, the Agricultural Resource Management Division has determined that acreage assessments for the following irrigation systems are:

Irrigation System	Acreage Assessment
Honokaa-Paauilo	\$90,537.00
Kahuku	\$27,258.00
Molokai	\$90,537.00
Waimanalo	\$90,537.00
Waimea	\$90,537.00

The acreage of agricultural and livestock lands of each land occupier within the Irrigation Systems are as follows:

Irrigation System	Agricultural Acreage	Livestock Acreage	Land Occupier Exhibit
Honokaa-Paauilo	757	5,806	A
Kahuku	168	None	B
Molokai	3,360	None	C
Waimanalo	1,011	None	D
Waimea	746	None	E

B65

Bldo

Board of Agriculture
June 23, 2020
Page 2

RECOMMENDATION:

1. That the Board determine and certify that the amount of acreage assessments necessary for annual maintenance of the listed five (5) irrigation systems for fiscal year 2021 are as listed;
2. That the Board determine and certify that the acreage of agricultural and livestock lands of each land occupier within the listed irrigation system is as set forth in attachments A through E;
3. That the Board determine and certify that agricultural lands shall bear 100% of the annual acreage assessments, for the Kahuku, Molokai, Waimanalo, and Waimea Irrigation Systems; and
4. That the Board determine and certify that agricultural and pastoral lands shall bear 70% and 30%, respectively, of the annual acreage assessments for the Honokaa-Paauilo Irrigation System.

Respectfully submitted,



BRIAN KAU, P.E.
Administrator
Agricultural Resource Management
Division

Attachments

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

Exhibit A – Honokaa-Paauilo System, Acreage by Account FY2020

<u>Agricultural Acreage</u>					
<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>
6801	7	6876	5	6997	5
6803	10	6880	3	6998	14
6804	7	6892	5	6999	5
6810	2	6894	12	68011	13
6812	2	6897	10	68060	13
6813	5	6901	5	68091	5
6819	9	6904	4	68250	3
6822	11	6905	14	68260	4
6823	20	6907	9	68341	5
6824	5	6908	5	68381	6
6830	14	6910	6	68402	6
6832	6	6911	22	68430	4
6833	5	6914	39	68461	12
6835	3	6921	17	68600	5
6837	4	6935	1	68680	4
6841	3	6940	4	68690	5
6845	7	6953	11	68790	3
6851	5	6954	13	68910	15
6853	5	6955	16	68930	16
6855	5	6956	8	68981	6
6857	5	6960	12	68990	3
6859	5	6962	21	69090	9
6861	2	6967	8	69311	3
6862	4	6969	7	69331	10
6863	5	6970	4	69341	5
6864	5	6971	4	69360	4
6865	5	6972	3	69371	7
6867	5	6975	12	69380	2
6868	3	6987	2	69410	2
6870	5	6990	5	69581	11
6871	4	6991	4	69640	13
6873	5	6993	6	69650	8
6874	5	6995	6	69661	10

B67

B68

Board of Agriculture
June 23, 2020
Page 4

ACCT	ACRES
6875	5

ACCT	ACRES
6996	2

ACCT	ACRES
69760	10
69830	8
Total	757

Livestock Acreage

ACCT	ACRES
6821	14
7000	15
7005	60
7006	21
7007	4
7008	8
7009	10
7010	192
7011	9
7012	3
7013	34
7016	57
7017	27
7018	260
7020	163
7036	677

ACCT	ACRES
7037	125
7038	3
7040	3
7042	311
7043	351
7044	32
7045	716
7047	682
7048	47
7049	32
7050	13
7051	2
7052	4
7053	10
7054	142
7055	140

ACCT	ACRES
7056	4
7057	6
7058	594
7059	15
7060	29
7061	1
7062	2
7063	446
7064	17
7066	163
7069	68
7073	100
7074	68
7077	26
7080	100
Total	5,806

Exhibit B – Kahuku, Acreage by Account FY2020

ACCT	ACRES
3501	15
3502	7
3503	7
3504	11
3505	4
3506	4
3507	9
3508	7
3509	9
3510	4
3511	4
3512	4
3513	6
3514	5
3515	2
3516	6
3517	8
3518	7
3519	8
3520	9
3521	6
3522	8
3523	8
3524	10
Total	168

B69

ACCT	ACRES	ACCT	ACRES	ACCT	ACRES
5036	2	5130	2	5227	3
5038	10	5131	150	5228	2
5039	2	5132	2	5229	2
5040	5	5133	3	5230	2
5041	15	5134	2	5231	2
5043	3	5135	2	5232	2
5044	30	5138	3	5233	2
5045	11	5139	2	5234	2
5046	2	5140	2	5235	2
5047	2	5141	12	5236	2
5048	3	5142	2	5239	2
5049	95	5143	2	5240	2
5050	22	5148	16	5241	2
5051	30	5150	2	5242	2
5052	2	5151	3	5243	2
5053	2	5152	25	5244	2
5055	3	5153	30	5246	2
5056	2	5155	2	5247	2
5057	23	5156	2	5248	2
5058	2	5157	2	5249	2
5059	29	5159	2	5250	2
5060	39	5161	5	5251	2
5061	30	5162	2	5252	2
5062	30	5163	2	5253	12
5063	2	5164	4	5254	2
5064	5	5165	28	5255	2
5065	2	5166	3	5256	2
5066	3	5167	2	5257	2
5067	2	5168	2	5258	2
5068	3	5169	35	5259	2
5069	22	5170	10	5260	2
5070	26	5171	27	5261	2
5072	3	5172	3	5262	2
5073	2	5174	45	5267	2
5074	2	5175	2	5271	2

B71

B72

Board of Agriculture
June 23, 2020
Page 8

<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>
5075	3	5177	3	5272	2
5076	2	5178	148	5273	20
5077	2	5179	2	5274	5
5078	2	5180	4	5276	5
5079	2	5181	5	5280	5
5080	2	5182	2	5281	272
5081	3	5183	3	8282	27
5082	2	5184	2	5283	16
5083	30	5185	2	5284	9
5084	2	5186	8	5285	25
5085	2	5187	7	5286	5
5086	5	5188	30	51360	2
5087	8	5189	50	52240	30
5088	2	5190	90	Total	3,360

Exhibit D – Waimanalo, Acreage by Account FY2020

ACCT	ACRES	ACCT	ACRES	ACCT	ACRES
2000	10	2068	9	2127	11
2001	3	2069	8	2128	9
2002	9	2070	4	2129	10
2003	8	2072	2	2131	8
2004	9	2073	3	2132	6
2005	3	2074	8	2133	2
2006	11	2075	9	2134	2
2007	9	2076	8	2137	3
2008	6	2079	9	2138	2
2010	9	2081	5	2142	4
2012	2	2082	14	2143	3
2015	9	2083	4	2147	0
2016	6	2084	4	2148	0
2018	9	2085	11	2157	8
2021	8	2088	6	2158	8
2022	10	2089	7	2159	2
2023	6	2090	8	2160	2
2024	2	2091	9	2161	2
2026	11	2092	9	2162	2
2028	3	2093	5	2163	3
2029	4	2094	2	2164	5
2030	9	2095	4	2165	3
2032	2	2096	3	2167	2
2033	6	2097	5	2172	2
2034	10	2098	10	2173	3
2036	10	2102	5	2180	9
2037	9	2104	2	2182	8
2039	2	2105	4	2183	9
2040	10	2106	8	2184	4
2041	11	2107	128	2186	6
2042	7	2109	5	2187	2
2043	10	2110	9	2189	7
2044	2	2111	5	2190	10
2046	7	2112	48	2192	3

B73

B74

Board of Agriculture
June 23, 2020
Page 10

<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>
2047	5	2114	3	2193	2
2049	10	2115	10	2195	14
2050	9	2116	5	2196	2
2053	6	2117	8	2198	2
2054	9	2118	3	2199	2
2055	4	2119	3	2200	10
2057	3	2120	11	2201	2
2058	6	2121	12	2203	2
2060	5	2122	7	2204	3
2061	2	2123	11	2205	5
2062	2	2124	11	2207	2
2064	9	2125	11	2208	3
2065	5	2126	10	Total	1,011

B76

Board of Agriculture
June 23, 2020
Page 12

<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>	<u>ACCT</u>	<u>ACRES</u>
1040	6	1100	2	1156	5
1041	12	1101	2	1157	3
1043	6	1102	2	1158	5
1045	7	1104	2	1159	5
1048	6	1105	2	1160	2
1049	5	1106	2	1161	9
1050	5	1107	2	1162	5
1052	2	1108	2	1163	5
1053	3	1109	2	1166	4
1054	6	1111	2	10140	0
1056	4	1112	2	10250	7
1057	2	1113	2	10460	7
1058	2	1114	2	10470	6
1059	2	1115	5	Total	746
1060	2	1116	4		

State of Hawaii
Department of Agriculture
Plant Industry Division
Plant Quarantine Branch
Honolulu, Hawaii

June 23, 2020

Board of Agriculture
Honolulu, Hawaii

- SUBJECT: Request to: (1) Allow the Importation of the Coronaviruses: Alphacoronavirus Strains NL63 and 229E, and Non-Select Agent Betacoronavirus Strains OC43 and HKU1, Viruses on the List of Restricted Microorganisms (Part A), for Laboratory Research by the University of Hawaii, by Emergency Permit;
- (2) Establish Permit Conditions for Importation of the Coronaviruses: Alphacoronavirus Strains NL63 and 229E, and Non-Select Agent Betacoronavirus Strains OC43 and HKU1, Viruses on the List of Restricted Microorganisms (Part A) for Laboratory Research by the University of Hawaii;
- (3) Allow the Importation of the Coronaviruses: SARS-CoV-2 Betacoronavirus Isolates USA-WA1/2020, Germany/BavPat1/2020, and USA CA3/2020, Viruses on the List of Restricted Microorganisms (Part A), for Laboratory Research by the University of Hawaii, by Emergency Permit; and
- (4) Establish Permit Conditions for Importation of the Coronaviruses: SARS-CoV-2 Betacoronavirus Isolates USA-WA1/2020, Germany/BavPat1/2020, and USA CA3/2020, Viruses on the List of Restricted Microorganisms (Part A) for Laboratory Research by the University of Hawaii.

I. Summary Description of the Request

PQB NOTES: *The Plant Quarantine Branch (PQB) submittal for requests for import or possession permits, as revised, distinguishes information provided by the applicant from procedural information presented by PQB. With the exception of PQB notes, hereafter "PQB NOTES," the text shown below in section II from page 4 through page 28 of the*



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Coronavirus
Dr. Vivek Nerurkar

submittal was taken directly from Dr. Vivek R. Nerurkar's application and subsequent written communications provided by the applicant, Dr. Nerurkar. For instance, the statements on page 27 regarding the potential effects on the environment, are the applicant's statements in response to standard PQB questions and are not PQB's statements. This approach for PQB submittals aims for greater applicant participation in presenting import and possession requests in order to move these requests to the Board of Agriculture (Board) more quickly, while distinguishing applicant-provided information from PQB information. The portion of the submittal prepared by PQB including the Environmental Assessment, advisory review, and proposed permit conditions, are identified as section III, IV, and V of the submittal, which start at pages 29, 31, and 49 respectively.

We have a request to review the following:

COMMODITY: Multiple Shipments of Various Coronaviruses in the table below.

The applicant is interested in coronaviruses which infect humans and mammals. These coronaviruses have been divided into alphacoronaviruses and betacoronaviruses, based on genome sequence homology.

Common Name	Scientific Name Genus	Number of Shipments	Quantity	Biocontainment Level
Coronaviruses	<i>Alphacoronavirus</i> strains: NL63 and 229E	2-4	1 mL each in 1-2 vials (each shipment)	BSL-2
Coronaviruses	Non-select Agent <i>Betacoronavirus</i> strains: OC43 and HKU1	2-4	1 mL each in 1-2 vials (each shipment)	BSL-2
SARS-CoV-2	<i>Betacoronavirus</i> isolates: USA-WA1/2020, Germany/BavPat1/2020, and USA CA3/2020	2-4	1 mL each in 1-2 vials (each shipment)	BSL-3

SHIPPERS: Shipments from multiple sources are requested. These include, but are not restricted to:

American Type Culture Collection (ATCC)
10801 University Blvd
Manassas, Virginia 20110 USA

BEI Resources
10801 University Blvd
Manassas, Virginia 20110 USA

Coronavirus
Dr. Vivek Nerurkar

National Institutes of Health
National Institute of Aids and Infectious Disease
5601 Fishers Lane, MSC 9806
Bethesda, Maryland 20892-9806

Colorado State University
585 Salida Way
Aurora, Colorado 80018

University of Texas Medical Branch
301 University Boulevard
Galveston, Texas 77555

Washington University in St Louis
One Brookings Drive
St. Louis, Missouri 63130

Other universities on the continental U.S.

IMPORTER: Vivek R. Nerurkar, D.M.L.T., M.Sc., Ph.D., Professor and Chair
Department of Tropical Medicine, Medical Microbiology and
Pharmacology Director, John A. Burns School of Medicine (JABSOM)
Biocontainment Facility, JABSOM, University of Hawaii at Manoa, 651
Ilalo Street, Biosciences Research Building (BSB) 320G, Honolulu, HI
96813. (see attachment 2 for Dr. Nerurkar's CV)

CATEGORY: The Coronavirus group is listed on the List of Restricted
Microorganisms (Part A). Pursuant to Chapter 4-71A, Hawaii
Administrative Rules (HAR) the coronavirus group may be imported and
possessed by permit approved by the Board.

Additionally, pursuant to Chapter 4-71A-12, HAR, the department may
issue an emergency permit on a case-by-case basis to a state or
federal agency or state university to allow importation and possession
of a microorganism on the List of Restricted Microorganisms or an
unlisted microorganism for the purpose of remediating any emergency
or disaster affecting agriculture, horticulture, the environment, or animal
or public health, provided that:

1. The Board, without advisory committee review, first obtains
advice from qualified persons with relevant expertise;

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Coronavirus
Dr. Vivek Nerurkar

2. The Board determines that import in less time than is required for issuance of a special permit under subsections (b)* and (c)* (see PQB NOTES) as applicable, is necessary to remediate the emergency or disaster; and
3. The importer is able to meet conditions established by the Board.

II. Information Provided by the Applicant in Support of the Application

PQB NOTES: *This request was submitted for review by the Advisory Subcommittee on Viruses (Subcommittee) between June 5 - June 12, 2020. Some crucial comments and questions from the Subcommittee were provided before the deadline and were emailed to the applicant, Dr. Nerurkar on June 11, 2020 to provide him with an opportunity to address them. Dr. Nerurkar subsequently revised his request by identifying specific coronavirus for importation, eliminating animal inoculation (including respective SOPs in attachments 6 & 7) and revising the SOPs for BSL-2 and BSL-3 (see attachment 8). The most recent information for review is provided below. See attachments 6, 7, and 9 for Dr. Nerurkar's original SOPs and submission.*

PROJECT: A novel coronavirus was isolated in late 2019, early 2020 which caused severe pneumonia. Today that pneumonia is called COVID-19 (Coronavirus disease 2019). Its etiological agent is known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11, 2020, The World Health Organization (WHO) declared COVID-19 a pandemic. Within three months of its discovery, this infection has spread to more than 114 countries, adversely affecting nearly every social, economic, and health care system worldwide.

There is an urgent need to understand the biology of SARS-CoV-2 and the pathogenesis of COVID-19. Our principal objective for requesting laboratory strains of SARS-CoV-2 and other human coronaviruses is to conduct *in vitro* cell culture-based research in the following high-priority areas:

1. Understand protective antibody responses to SARS-CoV-2 and develop virus neutralization assays.
2. Understand the target cells of SARS-CoV-2 and pathogenesis of COVID-19 by infecting human cells (such as lung epithelial cells, cardiac fibroblasts, myocytes and Sertoli cells)

3. Evaluate the efficacy of different antiviral drugs in preventing virus infection and tissue damage, using *in vitro* cell and organoid culture models.

Researchers in the Department of Tropical Medicine, Medical Microbiology, & Pharmacology have unique expertise in delineating basic pathogenesis mechanisms of viruses; developing vaccine candidates; and understanding protective antibody responses to virus infection that also makes them attractive collaborators in several multi-PI collaborative studies nationally and internationally. The Department at Kaka'ako, thus, has the human capital and infrastructure to address gaps in knowledge about SARS-CoV-2 and COVID-19. The proposed research can only be conducted if the researchers have access to the current NIH- and CDC-authenticated strains of SARS-CoV-2. Therefore, we request to import SARS-CoV-2 and other human coronaviruses (229E and OC43) to conduct research on vaccines, therapeutics, pathogenesis, and the development of novel sensitive and specific tests for prevention of COVID-19. We plan to compare the cellular immune responses to SARS-CoV-2 and other human coronaviruses, such as 229E and OC43, to better understand why SARS-CoV-2 causes serious complications.

OBJECTIVE: Our objective is to join the global effort to combat COVID-19 disease. We propose to conduct experiments to:

1. Antibody response to SARS-CoV-2 infection
 - Develop a safe and efficacious vaccine
 - Develop virus neutralization assays
 - Develop and/or improve point-of-care assays
2. Basic pathogenic mechanism
 - Understand the cellular target of this virus
 - Understand the pathogenesis mechanisms including how it causes damage in multiple organs
 - Understand the mechanism of the cytokine storm
3. Anti-viral drugs
 - Evaluate the efficacy of FDA approved drugs on virus replication in vitro
 - Evaluate the efficacy of FDA approved drugs on virus replication in organoid culture models

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Coronavirus
Dr. Vivek Nerurkar

JUSTIFICATION FOR IMPORTATION OF CORONAVIRUSES

Common Name	Scientific Name	Justification
SARS-CoV-2	SARS related Coronavirus 2 - Isolate USA-WA1/2020, Isolate Germany/BavPat1/2020, Isolate USA CA3/2020	These strain will be most widely used in the proposed projects including infection of cells and virus neutralization assays in the BSL-3 lab
Coronavirus 229E	Alpha Coronavirus 229E	This strain will be used in few experiments to compare select host responses with SARS-CoV-2 to understand why SARS-CoV-2 cause serious complications, and used in neutralization assay in the BSL-2 lab
Coronavirus OC43	Beta Coronavirus OC43	This strain will be used in few experiments to compare select host responses with SARS-CoV-2 and used in neutralization assay in the BSL-2 lab
Coronavirus NL63	Alpha Coronavirus NL63	This strain will be used in neutralization assays to understand antibody response at BSL-2 lab
Coronavirus HKU1	Beta Coronavirus HKU1	This strain will be used in neutralization assays to understand antibody response in the BSL-2 lab

POTENTIAL RISKS AND BENEFITS

Risks: The potential risks associated with manipulating SARS-CoV-2 in a research laboratory setting are similar to those encountered in handling infectious clinical specimens in a diagnostic microbiology laboratory. Note that community wide spread of SARS-CoV-2 is documented in the State of Hawaii. In the event of an accidental exposure of laboratory personnel to SARS-CoV-2, the individual will self quarantine at home for 14 days, as per CDC guidelines. (Interim

Guidance for Implementing Home Care of People Not Requiring Hospitalization for Coronavirus Disease 2019, Feb 12, 2020, (<https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>). We will not wait for symptoms to develop to prevent potential transmission to family members and to the community during the asymptomatic or presymptomatic phase.

Advantages: The realistic advantage of virus importation will be significant advances in our knowledge about SARS-CoV-2. The data will not only unravel the broader landscape of COVID-19 pathogenesis but will also contribute to the further development of promising SARS-CoV-2 vaccine candidates. It further has the potential to contribute to improved understanding on how to improve vaccine efficacy. In addition, further understanding of human immunity to SARS-CoV-2 will help with the development of novel tools for research, including the development of improved point-of-care diagnostic tests and the discovery of effective therapeutic drugs. Being able to work with the SARS-CoV-2 virus at UH will allow successful competition for COVID-19 funding on a national level (refer to the attached funding table, which lists the grants submitted and to be submitted by the department faculty). Collectively, these advantages will counterbalance the potential risks associated with virus handling in the BSL-3 containment facility.

PROCEDURE:

a. Virus measurement using plaque assay: Plaque assay using VeroE6 cells is a widely used method to measure infectious virus in the supernatant. Vero cells grown in 6-well plates will be incubated with the supernatant from infected cells at different time points and overlaid with 1% agarose as described in previous studies. The colonies will be counted after 3-4 days. Completion of this experiment takes total 5-6 days (3).

b. Virus Neutralization Assay: Virus neutralization assay, is considered the gold standard to determine protection from infection. Either whole virus or pseudovirus will be incubated with various dilutions of serum and the dilution which yields a 50% reduction of plaques determined.

c. Virus infection of different human cell types: Different human cells will be cultured in 24-, or 12-well plates and grown to 80% confluency. The cells will then be infected with lower dose of different coronaviruses (MOI 0.01 to 1) for 1 h at 37°C. Following the infection, wells will be washed with PBS and replenished with fresh media. Supernatant will be collected every day up to day 5 of infection and cells will be washed with PBS and used to extract RNA and proteins for measuring different host responses as described below. These infection experiments will take between 2-5 days for sample collection before the plates are discarded. RNA and proteins samples will only contain inactive virus particles and will be safe to handle.

d. Cell viability assays: Death of cells caused by the virus at different days after infection will be measured using widely used cell viability kit as described in our previous studies. This experiment takes total 2-4 hrs.

e. Host response studies using inactive virus particles: Infected cells will be washed and RNA will be extracted using commercially available kit and cDNA will be used to run RT-PCR assays to profile host immune and inflammatory genes as described in our previous studies. Virus copy number will be also measured using commercially available coronavirus primers. After RNA extraction, these samples do not remain infectious and RNA can be stored in -80°C for months to run RT-PCRs.

f. Efficacy of anti-viral drugs: Tissue culture cells and organoids will be incubated with multiple concentrations of FDA approved drugs and virus replication evaluated (see above). Additionally, host immune and inflammatory responses will be investigated (see above).

BSL-2 Biosafety Practices: Coronaviruses **EXCLUDING** SARS-CoV-2 will be used and stored at the JABSOM, Biosciences Building 3rd Floor, 651 Ilalo Street, Honolulu, Hawaii 96813. BSL-2 laboratories will be used to propagate the virus and subsequent experimentation using cell cultures.

Biosafety level-2 (BSL-2) facilities at JABSOM Kakaako

1. General Background

Although the microorganisms studied by Researchers at the JABSOM Kaka'ako in the Department of Tropical Medicine, Medical Microbiology, and Pharmacology are known human pathogens, they can be studied safely in a properly equipped, limited-access laboratory setting in which certain standard procedures are practiced. All manipulations of the live, infectious, pathogens are performed under Biosafety Level 2 (BSL-2) conditions using BSL-2 plus practices. Access to the designated pathogen laboratory is restricted to only trained, authorized laboratory personnel. All persons entering the laboratory are advised of the potential hazards and meet specific entry/exit requirements.

The T3MP Department Chair, the Principal Investigators (PI), and the Laboratory Supervisors must enforce the institutional policies that control access to the laboratory and must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions are encouraged to self-identify to the institutions healthcare provider for appropriate counseling and guidance.

Before initiating work with viruses in our laboratories, individuals read the full Standard Operating Procedures (SOPs), receive a tour and orientation of the laboratory and all safety equipment, and attend all trainings required by the Kaka'ako Environmental Health and Safety Office (EHSO) and Institutional Biosafety Committee's (IBC) Biosafety Compliance Program. Any questions about the contents of these documents and trainings should be directed to the Principal Investigator(s) of the research project(s). Individuals must certify that all documents have been read and fully understood before initiating work on these pathogens.

Individuals will have understanding of and/or demonstrated proficiency in each of the following:

- Aseptic technique

- Concept and definition of biosafety levels
- Disinfection/decontamination and sterilization procedures
- Safe use of work place equipment, including: biological safety cabinets (BSC), autoclaves, centrifuges, and incubators
- Handling of specific pathogenic agents
- Infectivity, pathogenicity, mode(s) of transmission and surveillance requirements of the pathogen

All virus work is performed in the designated pathogen laboratories at the UHM JABSOM campus. BSL-2 practices, containment equipment, and facilities must be used when working with the live infectious virus, or potentially infectious culture fluids, and specimen materials.

2. Individual Responsibility

Each employee/student is responsible for knowing and understanding the hazards associated with the work he/she is performing or that exist within the work area. If an employee/student is uncertain about the hazards and proper handling procedures for the biological materials that are being used, the employee/student must consult their supervisor.

Each employee/student must comply with spill prevention and response procedures.

3. Facilities and Equipment, Biosafety Level 2

The laboratory is designed so that it can be easily cleaned:

- Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
- Laboratory furniture is sturdy, and spaces between benches, cabinets, and equipment are accessible for cleaning.
- A sink is available for hand washing.
- An autoclave is available for decontamination of infectious wastes.
- An eyewash station is available within the laboratory.

A. Class IIA Biological Safety Cabinet(s)

A Class IIA Biological Safety Cabinet (BSC) is one in which typically 70% of the air is recirculated within the cabinet and the exhaust

passes through a HEPA filter before discharge. The exhaust may be exhausted into the room and positive-pressure contaminated ducts and plenums within the cabinet are allowed. Type A cabinets shall have a minimum calculated face velocity of 75 fpm.

These cabinets are for working with low- to moderate-risk biological samples and for protection of personnel against biological material while providing a sterile atmosphere in which to handle the material.

Materials that are TOXIC or VOLATILE must not be used in these cabinets. Chemical fume hoods, which exhaust outside of the building, are used for the handling of toxic or volatile materials.

A1. Use of Class IIA Biological Safety Cabinets

The Class IIA Biological Safety Cabinet must never be used unless the fan is running and the air-flow indicator (Magnehelic gauge) indicates that the cabinet air flow is functioning correctly (i.e., the air flow indicator is in the "safe" position) according to the values established by the most recent BSC certification. The Class IIA BSC adjustable glass viewing panel must not be raised above the certified air flow level when the cabinet is in use. The amount of apparatus and materials present in the cabinet during operation must be kept to a minimum.

All work must be performed in the middle and to the rear of the cabinet and be visible through the glass window. All users must understand that the cabinet will protect neither the hands nor the worker from gross spillage, breakage, or poor technique. The cabinet fan must be running for at least 30 minutes prior to starting work, and for at least 30 minutes after completing work in the cabinet.

A2. Certification

All Class IIA BSCs are tested and certified in-situ at the time of installation, at any time when a cabinet is moved, and once a year by a trained and authorized individual. The annual certification is currently done by a contracted third party vendor.

4. Apparel

A full-length, long-sleeved, fully fastened laboratory coat is worn. Laboratory coats are removed before leaving the laboratory area.

Coronavirus
Dr. Vivek Nerurkar

Long pants and skirts are worn in the laboratory area. Shorts, kilts, and mini-skirts are not considered appropriate attire for working in the laboratories and they do not protect the legs against splashing or spill hazards.

Closed-toe shoes are worn; no open-toe shoes, sandals or slippers are permitted in the work area.

Disposable gloves are used. Gloves are discarded into a labeled biohazard container, placed within the pathogen laboratory to ensure doorknobs and other surfaces are not inadvertently contaminated.

Eye protection, such as safety glasses or face shields, are available in the laboratory for any procedures where splashing is a hazard (e.g., retrieving cells from the liquid nitrogen cryo-storage tanks).

5. Standard Microbiological Practices

There is no eating, drinking, chewing of gum or tobacco, application of cosmetics, handling of contact lenses or storage of food in areas within the pathogen laboratory. Personnel wash their hands immediately following any procedure employing a pathogen and when they leave the laboratory.

Good housekeeping is maintained, and work areas are free of clutter. Work areas are free of tripping hazards, with adequate access to exits, emergency equipment, etc. Specific work areas, such as the BSC, are cleaned and disinfected immediately following each use and at the end of the day.

Water baths must contain disinfectants.

When laboratory vacuum is used, a secondary reservoir containing disinfectant and a HEPA filter is employed, and changed annually.

Cleaning of the laboratory is the responsibility of the authorized personnel who use it.

General Working Procedure

All working sites, containers, and equipment which might come in direct contact with the etiologic agents are clearly marked with a biohazard label.

All solutions, reagents and chemicals are labeled with chemical name/composition, PI Name, Preparer's name, and Date of preparation.

Etiologic agents are kept in closed containers when not in use. Cultures, solutions, or dried etiologic agents in vessels transported within the pathogen laboratory are handled in non-breakable, leak-proof pans, trays, pails, carboys, or other secondary containers large enough to contain all the material, in case of leakage or breakage of the vessel. Etiologic agents removed from the pathogen laboratory for transport to another approved area within the same building are placed in a closed, unbreakable secondary container containing absorbent materials before removal from the laboratory. The secondary container is labeled on the exterior with a biohazard symbol and identification of the contents, including the required biosafety level, the scientific name, the concentration (if applicable), and the responsible individual. The secondary container is wiped with suitable disinfectant before removal from the laboratory.

Working stocks of etiologic agents are stored in double containers. The primary containers will provide a positive seal and the secondary container are unbreakable.

All procedures will minimize the creation of aerosols. Grinding, blending, shaking, mixing, sonicating, and lysing infectious materials must be done within the BSC, preferentially with a buddy, and extra PPE may be required such as a respirator and safety glasses and/or face shield.

Flammable solutions are not stored in non-explosion proof refrigerators.

Pipetting

Oral pipetting is prohibited. Mechanical pipet aids are used for all pipetting procedures.

Pipetting of infectious materials is done within the BSC. Infectious materials are delivered to receiving vessels using the minimal speed/force necessary, and then the pipettes are decontaminated. Serological Pipettes used with infectious or toxic materials are plugged with cotton. Pipette tips with aerosol filters are used with infectious or toxic materials.

Coronavirus
Dr. Vivek Nerurkar

Infectious mixtures in an open vessel CANNOT be prepared by bubbling air through a liquid.

Sharps

The use or handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be minimized and eliminated whenever possible. The use of sharps such as needles and scalpels must be approved of by the Principal Investigator and/or the Department Chair and a detailed, written SOP must be developed, submitted, and approved of by the IBC prior to commencement of procedures involving the use of sharps.

Studies involving human donors must have protocol approval from the Committee on Human Studies (CHS) and a signed consent form.

Syringes with needles are NEVER used to make dilutions of etiologic agents.

Hypodermic needles and syringes are used only for:

- parenteral injection and/or aspiration of fluids from laboratory animals and diaphragm bottles
- removal of blood from human donors via venipuncture by trained technicians

When removing a syringe and needle from a rubber-stoppered bottle containing viable etiologic agents, an alcohol-soaked pledget is used to decontaminate the stopper. Excess fluid and bubbles should ideally be expelled from syringes before removal from the stoppered vials, or vertically discarded into a pledget soaked with disinfectant, or into a small bottle containing disinfectant-soaked cotton.

Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of infectious fluids.

Extreme caution is used when handling needles and syringes to avoid auto-inoculation and the generation of aerosols during use and disposal. Needles must not be bent, sheared, recapped, replaced in the sheath or guard or removed from the syringe following use. The needle and syringe are promptly placed in a puncture-resistant container and decontaminated by autoclaving.

Metal sharps waste that has been autoclaved is transferred to EHSO for disposal.

Non-disposable sharps such as pipette tips must be placed in a hard walled container for transport to the autoclave for decontamination.

Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.

Centrifuges

Before centrifuging, tubes, rotors, seals and gaskets are checked for cleanliness and integrity. In low-speed clinical-type centrifuges, a germicidal solution may be added between the tube and truggen cup to disinfect the outer surfaces of both and to provide cushion against shocks that might otherwise break the tube. Metal or plastic tubes (other than nitro-cellulose) are used.

Decanting from centrifuge tubes is minimized. If decanting is necessary, the outer rim is wiped with a disinfectant after decanting to prevent accidental spread of infectious materials. Centrifuge tubes will not be filled beyond the level recommended by the manufacturer.

High concentrations or large volumes of infectious agents may be centrifuged in the open laboratory, but only within a sealed rotor or aerosol tight containers. These safety devices should be opened within the BSC. Extra precautions, such as respirators and safety glasses and/or face shields may be required.

Test tubes

Tubes containing viable etiologic agents are manipulated with extreme care. Studies have shown that simple procedures, such as removing a tube cap or transferring an inoculum, can create a potentially hazardous aerosol.

Manipulation of biohazardous test tubes are conducted in BSCs. Tubes and racks of tubes containing biohazardous materials should be clearly marked. It is the responsibility of the individual employee/student to insure that tubes containing biohazardous material are properly sterilized prior to disposal or glassware washing. Safety test tube trays should be used in place of

conventional test tube racks to minimize spillage that might arise from broken tubes. When safety test tube trays are not used, the conventional test tube racks are placed in a tray large enough to contain any potential spill. A safety tube tray is one having a solid bottom and sides deep enough to hold all liquids, should a test tube break.

Refrigerators and deep freezers are checked, cleaned out, and/or defrosted semiannually, as necessary, to remove any ampoules, tubes, etc., containing etiologic agents that may have broken during storage.

6. Decontamination

All materials or equipment that are potentially contaminated with etiologic agents are rendered nonhazardous before disposal (i.e., autoclaved or chemically inactivated). In general, all infectious materials and all contaminated equipment or apparatus are sterilized before being washed and stored, or discarded.

Infectious materials are only manipulated within the BSC and liquid waste as well as solid waste coming into direct contact with infectious materials (e.g., serological pipettes, pipette tips, flasks, conical tubes) will not leave the BSC without being chemically neutralized with 10% bleach solution with detergent (made fresh daily), or equivalent disinfectant.

All infectious or potentially infectious material generated in the designated pathogen laboratory are placed in non-soluble plastic autoclave bags and sterilized by autoclaving, before removal from the designated pathogen laboratory.

After the autoclave bag is placed in the autoclave, the operator will ensure that the mouth of each autoclave bag is sufficiently open to allow complete and effective penetration of steam throughout its contents. Autoclaved ("treated") infectious waste are removed from the designated pathogen laboratory and disposed of as trash, only after infectious waste have been certified decontaminated. The primary means of verifying routine sterilization are through the use of chemical indicators --- autoclave tape and labels --- placed on the waste bags. A Biological Indicator, such as a commercial spore test are run in the autoclave and verified as effective by Kaka'ako EHSO on a monthly basis.

Autoclave Certification

Each autoclave run is recorded, and a permanent record of time and temperature of the operation taken.

The performance of the autoclaves in the designated pathogen laboratories are checked by commercial spore test monthly. Autoclave bags containing autoclaved ("treated") infectious waste are held in the pathogen laboratory until the results of the performance tests on that particular run are known.

Commercial Biological Indicators are ampoules containing suspensions of *Bacillus stearothermophilus* spores in culture medium. These ampoules are placed within normal load, in a position that is difficult for steam to penetrate. After autoclaving, the test ampoule is incubated according to the manufacturer's directions. If the color of medium in the autoclaved ampoule remains purple, sterilization was effective. If color of the medium turns yellow, sterilization was NOT EFFECTIVE and should be repeated.

Liquid Disinfectants

Sodium hypochlorite is a universal disinfectant that is active against all microorganisms, and is commercially available as Clorox™. It is a strong oxidizing agent and extremely corrosive to metals such as stainless steel containers and sinks. Dilute hypochlorite solutions gradually lose strength, necessitating frequent preparation of fresh solutions. A general all-purpose laboratory disinfectant solution should have a concentration of 1 g/liter (1000 ppm) as available chlorine. A stronger solution containing 10 g/liter (10,000 ppm) of available chlorine is recommended for disinfection involving blood spillage and the presence of gross organic matter. Typically, a 5-10% liquid solution is made fresh daily, with a few drops of liquid detergent to assure proper wetting.

The characteristics of chlorine and iodine are similar. Iodophor compounds with 1,600 ppm free available iodine provide a relatively rapid inactivation of all microorganisms, including some bacterial spores. A commonly available iodophor is Wescodyne. The manufacturer of Wescodyne recommends a range of dilution from 1-3 ounces per 5 gallons of water, giving a solution containing from 25-75 ppm of free iodine. At these concentrations, available iodine may be rapidly taken up by any extraneous protein present and will

Coronavirus
Dr. Vivek Nerurkar

not be an effective sporicide. A solution providing 1,600 ppm iodine is recommended for hand washing or for use as a sporicide.

7. Disposal

No infectious waste is disposed of until verified safe. Inactivation is the first step in the disposal of etiologic agents or materials that the potentially contaminated. All contaminated or potentially contaminated material must be effectively disinfected or sterilized by an approved procedure.

Solid waste is placed in cans, sturdy bags or boxes. Rigid, puncture-resistant, sealable containers are used for packaging "sharps." When wet materials are packaged for disposal, the materials are placed in a leak-proof container. Heavy waste is placed in rigid containers ensuring that the burst strength of the container is not exceeded.

8. Emergencies

Please see JABSOM Kaka'ako Department of Tropical Medicine, Medical Microbiology and Pharmacology Biosafety Level 2 Emergency and Incident Response Plan for more information.

9. Regarding Imported and Permitted Microorganisms

Typically in the State of Hawaii, research using infectious agents often involves the use of imported microorganisms which fall under the categories of Restricted A, Restricted B, Non Restricted, or Unlisted Microorganisms according to the Hawaii Administrative Rules (HAR). It is the responsibility of the Principal Investigator to obtain information, guidance, and permits if necessary for research involving microorganisms. Furthermore, it is the responsibility of the PI to understand and follow all rules for the use, handling, storage, and disposal of the microorganism.

All incidents involving the theft, accidental release, exposure, or disease outbreak involving imported microorganisms must be reported to the Hawaii Department of Agriculture, Plant Quarantine Branch Chief.

For matters relating to inspection of imported microorganisms as the port-of-entry, the PI must contact the airport supervisor at (808) 837-8413. For matters relating to the permit itself or the imported

microorganism, the Microorganism Specialist at PBQ must be contacted at (808) 832-0566.

Shipment of permitted organisms must be approved by the Biosafety Office by submitting a BSP-2 form. Shippers and receivers of biological agents must be appropriately trained, and all packaging materials must meet International Air Transport Association (IATA) standards.

Viral stocks in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, are under the supervision of Dr. Vivek R. Nerurkar. The virus is only grown in closed lid cell culture vessels in CO₂ incubators, in secured labs that are only accessible by trained laboratory personnel authorized by Dr. Nerurkar. Culture vessels are only opened inside the Class II Biosafety Cabinet (BSC), using aseptic techniques. Viral stocks are transported in triple packaging, and typically no more than 3 mL of diluted virus is transported at a time for viral manipulations. All procedural manipulations of cell culture testing will be done inside a BSC. All manipulation will be done by skilled and trained researchers.

The Department of Tropical Medicine, Medical Microbiology and Pharmacology personnel are required to wear a laboratory coat and gloves. Researchers never conduct work with exposed skin surfaces on hands and arms and are discouraged from working with any deep wounds or cuts, not matter how well bandaged. Proper personal protection equipment practically eliminates any potential lab infection, except when handling sharps and needles. Activities involving the use of sharps are limited whenever possible. In the laboratory, virus is presumed to be present in all blood or clinical specimens contaminated with blood, in any unfixed tissue or organ (other than intact skin) from clinical samples, regardless of latent or convalescent coronavirus infection, in all materials derived from coronavirus culture, and in/on all equipment and devices coming into direct contact with any of these materials. Laboratory personnel take great care in decontaminating all of the above items when not involved in active manipulations.

Coronavirus infection from stock vial to human is not likely. Since all active manipulations are done in a BSC, and procedures minimize the likelihood of aerosol generation, the only plausible cause of infection in the laboratory setting is if a technician during active manipulation of the virus, self-innoculates himself deep into the skin

Coronavirus
Dr. Vivek Nerurkar

with a contaminated needle or sharp object, providing direct access of the virus to the bloodstream. Sharps, as defined as needles, have been eliminated from all in vitro cell culture work. Furthermore, strict adherence to the aforementioned PPE, will further lower the risk of a laboratory acquired infection.

With proper precautions in place, training of personnel, and strict adherence to SOP, not only is the risk of laboratory infection extremely unlikely, but accidental release is nearly impossible. Experiments and procedures are designed to limit the amount and concentration of virus. Stocks are aliquoted in small amounts and the virus is contained at all time points except for during direct manipulation. Typical viral manipulations, such as inoculations, only involve approximately 0.5 mL of virus to be used at one time. If an accidental spill were to occur in the lab, research technicians are trained to respond to isolate the spill immediately and chemically neutralize the spill, virtually eliminating all possibility of adverse environmental and health effects. As mentioned above in the lab we handle limited quantity and concentration of the virus at any given time, therefore it is relatively easy to contain the virus spill. Furthermore all active manipulations of virus are done in a BSC. Additionally, all infected culture plates are placed in trays meant to contain any spills.

Specific receptors are required for the virus to bind and enter the cells, thus, skin provides an excellent primary barrier. Coronavirus and other similar viruses are transmitted by aerosols or need to be injected into the body to infect an individual.

BSL-3 Biosafety Practices: SARS-CoV-2 will be manipulated and stored in the JABSOM, Biosciences Building, JABSOM Biocontainment Facility (JBF), 651 Ilalo Street, Honolulu, Hawaii 96813. BSL-3 laboratories will be used to propagate the virus and subsequent experimentation using cell cultures.

SARS-CoV-2 viral stocks in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, are under the supervision of Dr. Vivek R. Nerurkar. SARS-CoV-2 will be only grown in closed lid cell culture vessels in CO₂ incubators, in secured labs that are only accessible by trained laboratory personnel authorized by Dr. Nerurkar. Culture vessels will be only opened inside the Class II Biosafety Cabinet (BSC), using aseptic techniques. Viral stocks will

be transported within the laboratory in triple packaging, and typically no more than 0.5 mL of stock virus is transported at a time for viral manipulations. All procedural manipulations of cell culture and clinical sample testing will be done inside a BSC. All manipulations will be done by skilled and trained researchers. Once inside the BSL-3 SARS-CoV-2 will not leave the BSL-3. Virus will be chemically treated followed by autoclaving using SOP.

Personnel will undergo rigorous training and testing prior to entry into the BSL3 facility, and will be required to continue to train and keep abreast of training requirements, and new techniques. SARS-CoV-2 will only be manipulated in a Class II certified Biosafety Cabinet. The Department of Tropical Medicine, Medical Microbiology and Pharmacology personnel working in the BSL3 laboratories with SARS CoV-2 will be required to wear following PPE-

- a long, wrap around gown that close in the back
- a double layer of gloves
- manipulation sleeves over gown and booties
- hair bonnet and safety glasses/goggles
- N95 respirator is required for all SARS-CoV-2 related activities
- Face shield

Researchers never conduct work with exposed skin surfaces on hands and arms, and are discouraged from working with any deep wounds or cuts, not matter how well bandaged. Proper personal protection equipment practically eliminates any potential lab infection. Activities involving the use of sharps are avoided whenever possible. In the laboratory, virus will be presumed to be present in all blood or other clinical specimens like urine or saliva, in any unfixed tissue from clinical samples, in all materials derived from SARS-CoV-2 culture, and in/on all equipment and devices coming into direct contact with any of these materials. Laboratory personnel will take great care in decontaminating all of the above items when not involved in active manipulations.

The most common routes of laboratory acquired infection (LAI) are inhalation (particularly by aerosols), percutaneous inoculation (needlestick injuries, broken glass injury, and/or animal bites or scratches), direct contact between contaminated surfaces (gloves, hands), and mucous membranes as well as through ingestion – for example by smoking, eating, or accidental aspiration through a

Coronavirus
Dr. Vivek Nerurkar

pipette. SARS-CoV-2 requires specific receptors to bind and enter the cells that are not present on the skin. Thus, skin provides an excellent primary barrier. Infection is via inhaled respiratory droplets from a cough leading to infection of nasal or upper respiratory cells directly (1). The risk of an LAI are minimal in cell culture experiments where the use of sharps are very limited. In the cell culture setting, the only risk of infection is the generation of aerosols during sonication of infected tissue. Thus, we have designed our protocols and procedures to avoid any sonication procedures and limit, and nullify if possible, the need for sharps. However, strict SOPs and use of N95 masks and face shields during handling of any type of virus cultures will be in place to protect against any potential exposure. All wastes will be treated with chemical neutralizing agents such as sodium hypochlorite solution or quaternary ammonium compound solution.

With proper precautions in place, training of personnel, and strict adherence to SOP, not only is the risk of laboratory infection extremely unlikely, but accidental release is nearly impossible. Experiments and procedures are designed to limit the amount and concentration of virus. Stocks are aliquoted in small amounts and the virus is contained at all time points except for during direct manipulation. If an accidental spill were to occur in the lab, due to the limited quantity and concentration, the risk of virus spread would be minimum. Moreover, research technicians are trained to respond to isolate the spill immediately and chemically neutralize the spill, virtually eliminating all possibility of adverse environmental and health effects.

Equipment use for research: Equipment commonly used for live virus culture are described below. Only inactive virus samples containing virus RNA is used for PCRs and other assays.

Basic equipment for live virus culture and for inactivated virus

- Class II biosafety cabinet
- Incubator (humid CO₂ incubator)
- Water bath
- Centrifuge with "O" ring buckets
- Refrigerator and freezer (-20°C and -80°C)
- Cell counter (Countess® Automated Cell Counter or hemacytometer)
- Inverted microscope

Coronavirus
Dr. Vivek Nerurkar

- plate reader for ELISA and cell viability assays
- autoclave to decontaminate waste

Supplies: Cell culture vessels (e.g., virus storage vials, flasks, Petri dishes, roller bottles, multi-well plates), pipettes and pipettors, waste containers, media, sera, and reagents.

DISCUSSION:

- 1. Person Responsible:** Vivek R. Nerurkar, D.M.L.T., M.Sc., Ph.D., Professor and Chair, Department of Tropical Medicine, Medical Microbiology and Pharmacology Director, JABSOM Biocontainment Facility, John A. Burns School of Medicine, UH at Manoa, 651 Ilalo Street, BSB 320G Honolulu, Hawaii 96813.

Dr. Nerurkar, a Virologist by training, conducts research on the pathogenesis of WNV-associated meningoencephalitis, dengue hemorrhagic fever, Zika virus disease and pathogenesis of the fatal demyelinating disease, progressive multifocal leukoencephalopathy. He has extensive experience in classical and molecular microbiological techniques, as documented in publications appearing in nearly 135 peer-reviewed journals and in successful grant applications from local and national agencies. He has been the Director of the JABSOM BioContainment Facility, a state-of-the art BSL3 and ABSL3 facility, for the past 15 years.

- 2. Safeguard Facility and Practices:** Non-select agent SARS-CoV-2 will be used and stored in the JABSOM BioContainment facilities (JBF; BSL-3) located in the Biosciences Building First Floor, 651 Ilalo Street, Honolulu, Hawaii 96813. BSL-3 laboratory will be used to propagate the virus and subsequent experimentation using cell cultures as described below.

Coronavirus assigned BSL-2 status by the HDOA will be stored in the BSL-2 laboratories located in the Biosciences Building Third Floor, 651 Ilalo Street, Honolulu, Hawaii 96813.

Specifically:

BSL-2 storage – BSB rm 331 or 334

BSL-2 manipulation – BSB rm 303, 336

BSL-2+ manipulation – BSB rm 332, 333, 324B

JBF storage – BSL-3 preproom freezer

JBF manipulation – BSL-3 manipulation rooms

Coronavirus
Dr. Vivek Nerurkar

JBF room numbers will be provided only to the HDOA inspectors in a separate document

- JBF**
- a. Directions to the facility: Driving from H-1 West Take Exit 23 to Merge onto Lunalilo Street Turn Left on Ward Avenue Continue onto Ilalo Street Driving from H-1 East Take Exit 21A Turn Left onto Aala Street Turn Left onto N Beretania Street then Turn Right onto River Street Turn Right onto HI-92 W then make a Sharp Left onto HI-92 E Turn Right on Coral Street then Left on Ilalo Street.
 - b. Pictures of the facility: See attachment
 - c. Containers in which the virus will be stored: See attachment

- 3. Biosecurity:** The JABSOM BioContainment Facility (JBF) relies on multiple levels of physical security and extensive training of all researchers to protect both researchers and the public from escape, theft, or release of the organism or associated disease and/or pests.

a. Physical Security:

- The JABSOM Bioscience Building, housing the JBF, is a secure building. Access is restricted to only those individuals who have an activated access card. Access cards are limited to only those that have completed JABSOM specific training and approval by the JBF Director, Dr. Vivek R. Nerurkar, Chair Department of Tropical Medicine, Medical Microbiology, and Pharmacology, and the JABSOM Environmental Health and Safety Office
- Access to the corridor to the JBF requires an activated access card
- Entry into the JBF itself requires use of a biometric reader
- Security guards are posted at the entrance of the BSB to monitor and observe all access to the building from the front lobby
- The exterior of the building, vivarium, and all JBF doors are monitored by closed circuit TV
- Security software is used to manage access to the JBF

b. Extensive Training requirements

- All JBF researchers must complete on-line training, hands-on training, and demonstrate proficiency before they are allowed to work in the JBF.
- All JBF researchers must understand and comply with all regulations put forth in the JBF manual.

- All JBF researchers must understand and adhere to all agent specific SOPs.
- c. **Practices to minimize theft:** Only personnel approved by the BSL3 Director will be authorized to enter BSL3 laboratories. There are already protocols in place to monitor entry and exit of personnel in the BSL3 laboratories. In addition, proper inventories will be kept and closely monitored by the Director and just as with other permits granted to Dr. Nerurkar, all annual inventories will be submitted yearly to the Hawaii Department of Agriculture.
4. **Method of Disposition:** The most accepted method to inactivate waste generated while conducting coronavirus studies is by autoclaving of solid waste and treatment with 10% sodium hypochlorite for liquid waste. All liquid waste such as excess viral stock in volumes of less than 1 mL, dilute, working virus inoculum and infected virus cultures will be chemically neutralized with 10% sodium hypochlorite solution for a minimum of 15 minutes, then diluted to a suitable neutral pH and disposed of down the drain. Solid wastes like plastic ware associated with the viral agent will be chemically neutralized with 10% sodium hypochlorite solution for a minimum duration of 15 minutes, sodium hypochlorite solution will be decanted and plastic wares rinse with tap water. The neutralized plastic ware will be placed in red bags, and then autoclaved. These methods will completely destroy the virus (4).
5. **Abstract of Organism: Severe Acute Respiratory Syndrome-Coronavirus-2 (SARS-CoV-2)** is a member of the *Coronaviridae* family, genus *Betacoronavirus*. The virus has a lipid envelope and has a single stranded, positive-sense RNA genome. SARS-CoV-2 is the cause of coronavirus disease, named as COVID-19. SARS-CoV-2 infection symptoms include fever, cough, shortness of breath or difficulty breathing, chills, muscle pain, headache, sore throat, loss of taste or smell and GI discomfort. These symptoms may appear 2-14 days after exposure to the virus. **Older adults and people who have severe underlying medical conditions** like heart or lung disease or diabetes seem to be at higher risk for developing more serious complications from COVID-19 illness. Most people infected with SARS-CoV-2 do not develop any symptoms. Incubation period is 2-14 days, with symptom onset lasting from 7-14 days on average (1, 5, 6).

Morbidity: low (<20 % of affected people developed symptoms)

Mortality: low (<1.8-2.5%)

Inactivation: SARS-CoV-2 has a lipid envelope and most lipid enveloped viruses are sensitive to 70% (v/v) ethanol, sodium hypochlorite, formaldehyde,

Coronavirus
Dr. Vivek Nerurkar

glutaraldehyde, phenolics, iodophors, and quaternary ammonium compounds. Contact time should be minimum 5 min.

Transmission: SARS-CoV-2 mode of transmission in nature is not well understood. SARS-CoV-2 is transmitted from person-to-person through close contact such as caring for, living with, or having direct contact with respiratory secretions or body fluids of a suspect or probable case. SARS is thought to be spread primarily through droplets, aerosols and possibly fomites (1, 5, and CDC Website on COVID-19).

Host range and habitat: The natural reservoir for SARS CoV-2 is unclear. It is believed that before humans, this virus was harbored in bats and ferrets. Currently, human-to-human spread is the main cause of disease spread in humans. There is no evidence that animals can transmit this virus to people. In some rare situations, people have spread this virus to certain types of animals. Virus is shown to infect in cats although such studies are still in the initial stages of investigation and cats to human transmission has not been shown. SARS-CoV-2 is detected in human respiratory, blood, or stool specimens. The exact mode of transmission of SARS-CoV laboratory-acquired infection has not been established, but in clinical settings the primary mode of transmission appears through direct or indirect contact of mucous membranes with infectious respiratory droplets. The virus has not been shown to live in ocean water. Although virus can survive in drinking water for 1-2 days it cannot replicate in water or any plants or wet forest trees. So far, SARS-CoV-2 has not been detected in live stock, fishes or birds and routine testing of animals or fishes for SARS-CoV-2 is not recommended by the CDC at this point (7).

SARS-CoV-2 in Hawaii: Cases of COVID-19 have been reported in Hawaii since mid-February 2020. The index case might have been a Japanese visitor who traveled to Maui and Oahu, and tested positive for the virus when he returned to Japan in early February. Initial cases were all travel associated (imported), however later community spread of the virus was established. By early April, after two weeks of lock-down, the majority of cases were community acquired. As of April 29, 2020, there were 613 cases of COVID-19 and 16 deaths reported in Hawaii, and virus has been detected in patients on Oahu, Hawaii, Kauai, Maui and Lanai. Therefore, this virus is currently circulating in Hawaii. Many different protocols including social distancing and shelter-in-place have been instituted to effectively reduced the spread in Hawaii (8).

Impact of import in Hawaii: COVID-19 has been detected in various communities in the State of Hawaii. There will be no potential impact of virus importation in Hawaii. All in vitro, cell culture based research with the virus will be conducted in a Class II BSC in BSL-3 facility. These labs are highly secured, and also located in a highly secured building. All viral stocks are highly guarded, monitored, and

accounted for. There are strict procedures and SOP's in place that all personnel are trained for and demonstrate proficiency before working in the Level 3 facilities; not only in techniques, but response to biological spills, acts of nature and facility failures. Due to all of these precautions there is minimal to zero risk of impact on Hawaii from coronavirus research at JABSOM facilities.

6. Effects on the Environment: There will be no additional impact of the import of this virus and research at JABSOM facility on the environment. With proper precautions in place, training of personnel, and strict adherence to SOP, not only is the risk of laboratory infection extremely unlikely, but accidental release is nearly impossible. Experiments and procedures will be designed to limit the amount and concentration of virus. Stocks will be aliquoted in small amounts and the virus will be contained at all time points except for during direct manipulation. Typical viral manipulations, such as infection, only involve approximately 0.3 – 0.5 mL of virus to be used at one time. If an accidental spill were to occur in the lab, due to the limiting of quantity and concentration, taking care of the spill over will not be a problem. A spill kit is always available for use in case of any spill of small quantity of virus as per CDC and WHO guide of taking care of spills (4). The research technicians are trained to respond to isolate the spill immediately and chemically neutralize the spill, virtually eliminating all possibility of adverse environmental and health effects. Based on the fact that there is no evidence of this virus affecting any plants, there will be no effect of this virus on native plants. Similarly, there is no evidence so far that SARS-CoV-2 outbreak in Hawaii has affected any native or endemic bird species or ocean animals. A recent study from China showed that domestic poultry were unlikely to have been the reservoir, or associated with dissemination, of SARS coronavirus in the animal markets of southern China (9). Based on these reports we speculate that this virus will not infect native Hawaiian birds. Further, although there have been few reports of virus RNA present in sewage and wastewater but no study have shown the presence of infectious virus in wastewater or ocean water as yet. Therefore, there will be minimum or no additional economic or environmental impact on natural resources and human and animal safety because of import of SARS-CoV-2 and research at JABSOM.

7. Alternatives: COVID-19 is a disease cause by a new coronavirus that has spread throughout the world. There is very little known about the many aspects of the SARS-CoV-2 that is the causative agent of this disease. Clinical data is still being gathered and many questions regarding, what is the best diagnostic method, how to track if the protective antibodies are produced in humans and how this virus causes severe disease symptoms in high-risk group are not known. Similarly, to develop a robust antibody, we need to understand more about the immune response associated with this virus. Therefore, new studies using clinical samples, in vitro cell/virus cultures and in vivo animal models are needed to improve our knowledge

Coronavirus
Dr. Vivek Nerurkar

about COVID-19 and only by using live virus we can gain this objective. There are no alternatives to live virus use. There are some virus proteins available commercially, but they do not provide complete knowledge of the pathogenesis of the SARS-CoV-2.

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III. Environmental Assessment (EA):

Pursuant to a May 2008 Hawaii Intermediate Court of Appeals decision (*Ohana Pale Ke Ao v. Board of Agriculture*, 118 Haw. 247 (Haw. App. 2008)), the Department of Agriculture's (Department's) import permit process is subject to the requirements of the Hawaii Environmental Protection Act, chapter 343, Hawaii Revised Statutes (HRS). Under this decision, the requirement for an EA as a condition of the import permit or related authorization applies in those circumstances where the underlying permit activity for the importation initiates a "program or project" and where the use of state or county funds or state or county lands is involved. When those circumstances are present, as they appear to be when a new organism is used at University of Hawaii (state lands), an EA is required to determine whether the proposed project or program is likely to have a significant impact on the environment. However, certain activities may be eligible for "exemption" from an EA under provisions established through the Environmental Council, State Office of Environmental Quality Control (OEQC), provided that the project or program is determined to have little or no impact on the environment.

Exemption from EA: In September 2008, the Department obtained the concurrence of OEQC's Environmental Council for exemption from EA for those Plant Quarantine Branch import permits and related authorizations that satisfy certain criteria, including conditions to minimize risk to agriculture, horticulture, the environment, or animal or public health. The exemption from EA for microorganisms applies to the import of microorganisms for various purposes according to their placement on lists maintained by the Board of Agriculture (Board) and subject to permit conditions appropriate to eliminate or minimize risks associated with the microorganisms and their use. (See Exemption Class #10., item 3.a of the Department's exemptions, under the links for exemption lists for state agencies at: <http://hawaii.gov/health/environmental/oeqc/index.html/>). Permit conditions address matters such as health requirements, special precautions, and safeguarding from escape, theft or release. Under the exemption, purposes for importation of microorganisms include, but are not limited to, food and beverage processing; clinical laboratory diagnostics or quality control testing; medical or scientific research by qualified entities and universities in standard research settings; classroom instruction at universities or high schools; microbial products; algae research or algae cultivation and production for food, feed, or export for processing for uses such as cosmetics, food supplements, and pharmaceuticals. The exemptions from EA are only applicable when a project or program will probably have minimal or no significant effect on the environment. Under OEQC's rules and the Department's exemption list, exemptions are inapplicable when the cumulative impact of planned successive actions in the same

Coronavirus
Dr. Vivek Nerurkar

place, over time, is significant, or when an action that is normally insignificant in its impact on the environment may be significant in a particularly sensitive environment.

PQB Process for Exemption from EA: When seeking an exemption from EA for an import request that requires the full Board review process, the Department must obtain the advice of other outside agencies or individuals having jurisdiction or expertise as to the propriety of the exemption. (Section 11-200-8(a), HAR.) The Board review process already includes recommendations and comments from the technical consultants (Advisory Subcommittee members). The representation of outside agencies such as the University of Hawaii and Hawaii Department of Health on the Advisory Subcommittee on Viruses provide opportunity for these agencies input on the public health and environmental aspects of the import and appears to meet the consultation requirement of OEQC's rule. In addition, the input received from the Department's technical consultants on the Advisory Subcommittees, as individuals with expertise on the subject matter and the presence of individuals from the Hawaii Department of Health and University of Hawaii, appears to meet the consultation requirement. Where the recommendations from the technical consultants support exemption from an EA, the Department may prepare a declaration of exemption, which includes a description of the import request, lists of consultants, consultants' recommendation and comments, and the basis for the Department's determination of "probably minimal or no significant effect on the environment." The declaration of exemption from EA is submitted to the Board together with the import request. Where the recommendations from the technical consultants and Advisory Committee support an EA, the Department may require an EA as a prerequisite for Board review.

Analysis of Application re EA: Under the above-cited court decision, the EA requirement is triggered under certain circumstances, including when an applicant proposes an action on state lands that requires agency approval and is not specifically exempted under chapter 343, HRS. That is the case here. The applicant's request in this instance involves importation of specific strains of the Coronavirus group that are listed on the List of Restricted Microorganisms, Part A and are considered high-risk. High risk microorganisms for which importation and possession requires a permit approved by the Board, for purposes approved by the Board, and subject to permit conditions approved by the Board (§150A-6.3(c), HRS, Section§ 4-71A-25, HAR). This would also include Microorganisms imported under an Emergency Permit (see pages 3-4 of this submittal.) So, agency approval is required for the applicant's proposed action/activity on state lands. As PQB understands the court's analysis in the Ohana Pale decision, the activity proposed under this permit application would initiate a project that uses state lands, triggering the EA requirement. As this request moves through the review process to the Board, a determination will be made as to whether or not the applicant's proposed project qualifies for exemption from EA under the Department's

Coronavirus
Dr. Vivek Nerurkar

Plant Industry Division Exemption List filed with OEQC. The Plant Industry Division Administrator is authorized to make this determination.

IV. Advisory Subcommittee Review

This request was submitted to the Advisory Subcommittee on Viruses for their review and recommendations. Their recommendations and comments are as follows:

PQB NOTES: *Due to the nature of the Subcommittee's responses regarding this request, their responses were sent to Dr. Nerurkar to be addressed. Dr. Nerurkar's responses are listed after the respective Subcommittee responses.*

*Due to Dr. Nerurkar's changes, PQB revised the review questions to coincide with the specific coronavirus strains. The Subcommittee members subsequently reviewed Dr. Nerurkar's revised request and their recommendations and comments to PQB's revised questions are listed at the end of each of the initial review questions. Each new question will be noted in **bold** with ***REVISED SUBCOMMITTEE RECOMMENDATION*** prior to the question and associated Subcommittee responses.*

1. I recommend approval ___ / ___ disapproval to allow the importation of the coronaviruses: Alphacoronavirus, Non-Select Agent Betacoronavirus, and Gammacoronavirus, viruses on the List of Restricted Microorganisms (Part A), for laboratory research by the University of Hawaii at Manoa, through **emergency permit.**

Dr. David Clements: Recused.

PQB NOTES: *Dr. Clements notified PQB after receiving the submittal that he has collaborated with UH JABSOM in the past and could be a potential future collaborator with Dr. Nerurkar. To avoid a potential or perceived conflict of interest, Dr. Clements recused himself from commenting on this submittal. He will be listed under each question as "Recused."*

Dr. Raquel Wong: Recommends approval.

Dr. Edward Desmond: Recommends disapproval.

Comments: "There are a number of weaknesses to this application. There are potential risks to permitting importation of coronaviruses. The project description does not appear to demonstrate realistic advantages to counterbalance potential

Coronavirus
Dr. Vivek Nerurkar

risks. For project component a (basic epidemiology), there is not a convincing argument why SAR-CoV-2 strains already present in Oahu would be inferior to imported viral strains for this purpose. The same reservation applies to component b, basic pathogenic mechanism. Strains already present in Oahu should suffice for this purpose. For component c, vaccine development, the University of Hawaii would not appear to be timely or competitive for such a project. Please refer to: <https://www.cnn.com/2020/06/03/health/fauci-coronavirus-vaccine-2021/index.html>."

Dr. Nerurkar's response to Dr. Desmond's comments:

Comment 1.6: *The project description does not appear to demonstrate realistic advantages to counterbalance potential risks.*

Response:

Risks: The potential risks associated with manipulating SARS-CoV-2 in a research laboratory setting are similar to those encountered in handling infectious clinical specimens in a diagnostic microbiology laboratory. In the event of an accidental exposure of laboratory personnel to SARS-CoV-2, the individual will self quarantine at home for 14 days, as per CDC guidelines. (Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for Coronavirus Disease 2019, Feb 12, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html>). We will not wait for symptoms to develop to prevent potential transmission to family members and to the community during the asymptomatic or presymptomatic phase.

Advantages: The realistic advantage of virus importation will be significant advances in our knowledge about SARS-CoV-2. The data will not only unravel the broader landscape of COVID-19 pathogenesis but will also contribute to the further development of promising SARS-CoV-2 vaccine candidates. It further has the potential to contribute to improved understanding on how to improve vaccine efficacy. In addition, further understanding of human immunity to SARS-CoV-2 will help with the development of novel tools for research, including the development of improved point-of-care diagnostic tests and the discovery of effective therapeutic drugs. Being able to work with the SARS-CoV-2 virus at UH will allow successful competition for COVID-19 funding on a national level

(refer to the attached funding table, which lists the grants submitted by the department faculty). Collectively, these advantages will counterbalance the potential risks associated with virus handling in the BSL-3 containment facility.

Comment 1.7: *For project component a (basic epidemiology), there is not a convincing argument why SARS-CoV-2 strains already present in Oahu would be inferior to imported viral strains for this purpose. The same reservation applies to component b, basic pathogenic mechanism. Strains already present in Oahu should suffice for this purpose.*

Response: *We currently do not have access to locally circulating strains of SARS-CoV-2. More importantly, however, our proposed research requires access to nationally and internationally accepted SARS-CoV-2 reference strains, such as USA-WA1/2020, Germany/BavPat1/2020, to compare our research findings with the vast published literature on SARS-CoV-2. This is the fundamental basis for obtaining scientifically rigorous and reproducible data to develop research tools, and test efficacy of vaccines and therapeutics.*

Comment 1.8: *For component c, vaccine development, the University of Hawaii would not appear to be timely or competitive for such a project. Please refer to: [http://www.enn.com/2020/06/03/health/fauci-coronavirus-vaccine-> 2021/index.html](http://www.enn.com/2020/06/03/health/fauci-coronavirus-vaccine-2021/index.html) .*

Response: *While several vaccine candidates are being produced by multiple big pharma companies, none of the vaccine constructs of the so-called "Big Five" deemed as frontrunners in the race are based on conventional technology. This significantly increases the risk that one or more of these platforms will fail to produce significant durable immunity, or most concerningly, actual protection. In addition, RNA-based vaccine candidates (such as that of Moderna) or virally vectored platforms (as used by Johnson & Johnson, Astra-Zeneca and Merck) require their products to be stored and distributed using complex cold-chain logistics. The vaccine candidate currently under development at UH is based on a recombinant subunit protein platform with an excellent safety profile that has shown the potential to be lyophilized. While offering potent*

Coronavirus
Dr. Vivek Nerurkar

immunogenicity (which has already been demonstrated for a SARS-CoV-2 prototype), this would also reduce the logistical burden significantly, an important factor for being able to control the global pandemic.

<https://www.staradvertiser.com/2020/03/23/hawaii-news/university-of-hawaii-researcher-and-team-pursue-potential-coronavirus-vaccine-ready-later-this-year/>

<https://www.khon2.com/coronavirus/hawaiistrong-uh-researchers-join-global-fight-to-find-covid-19-vaccine/>

<https://www.bizjournals.com/pacific/news/2020/03/23/uh-researcher-team-aid-in-development-of-covid-19.html>

<https://www.kitv.com/story/41930070/uh-scientist-working-to-develop-covid19-vaccine>

Dr. A. Christian Whelen: Recommends disapproval.

Comments: "Unclear what the purpose and necessity for importation. The SOPs don't describe methods that would meet project goals. What part of animal inoculation protocol constitutes an emergency or a response to the COVID-19 pandemic as the requestors claim? Appears to be a blanket request with no justification. Appears the ABSL2 SOP is for arboviral methods that has been re-flagged coronavirus. ABSL3 is titled experimental, uses arboviral methods, and then indicates it is for diagnostics (which in the current environment would require FDA Emergency Use Authorization (EUA) for a Lab Developed Test (LDT). The bold print at the bottom of page 2 acknowledges the dangerous nature of what they are proposing, and that they are not equipped to handle it when they get surprised. Proposed animal model methods are not consistent with SARS animal models in the literature.

Project Objective is already performed by DOH and the community clinical labs.

Bottom of page 8 the requestor incorrectly states that workers cannot get infected, and goes on to describe blood borne transmission rather than respiratory: "**Coronavirus infection from stock vial to human is not possible. The only plausible cause of infection in the laboratory setting is if a technician during active manipulation of the virus, accidentally pokes himself deep into the skin with a contaminated needle or sharp object,**

providing direct access of the virus to the bloodstream”

Dr. Nerurkar's response to Dr. Whelen's comments:

Comment 1.1: Unclear what the purpose and necessity for importation?

Response: We further expand on the purpose and necessity for importation below.

There is an urgent need to understand the biology of SARS-CoV-2 and the pathogenesis of COVID-19. Our principal objective for requesting laboratory strains of SARS-CoV-2 and other human coronaviruses is to conduct *in vitro* cell culture-based research in the following high-priority areas:

1. Understand protective antibody responses to SARS-CoV-2 and develop virus neutralization assays.
2. Understand the target cells of SARS-CoV-2 and pathogenesis of COVID-19 by infecting human cells (such as lung epithelial cells, cardiac fibroblasts, myocytes and Sertoli cells)
3. Evaluate the efficacy of different antiviral drugs in preventing virus infection and tissue damage, using *in vitro* cell and organoid culture models.

Researchers in the Department of Tropical Medicine, Medical Microbiology, & Pharmacology have unique expertise in delineating basic pathogenesis mechanisms of viruses; developing vaccine candidates; and understanding protective antibody responses to virus infection that also makes them attractive collaborators in several multi-PI collaborative studies nationally and internationally. The Department at Kaka'ako, thus, has the human capital and infrastructure to address gaps in knowledge about SARS-CoV-2 and COVID-19. The proposed research can only be conducted if the researchers have access to the current NIH- and CDC- authenticated strains of SARS-CoV-2. Therefore, we request to import SARS-CoV-2 and other human coronaviruses (229E and OC43) to conduct research on vaccines, therapeutics, pathogenesis, and the development of novel sensitive and specific tests for prevention of COVID-19. We plan to compare the cellular immune responses to SARS-CoV-2

Coronavirus
Dr. Vivek Nerurkar

and other human coronaviruses, such as 229E and OC43, to better understand why SARS-CoV-2 causes serious complications.

Comment 1.2: *The SOPs don't describe methods that would meet project goals.*

Response: *Please note that all animal work-related SOPs for ABSL-2 and ABSL-3 are now removed from the application as the immediate goals of our research focuses on only in vitro cell culture systems. The modified SOPs are reflective of the project goals and are described below. These are meant to replace the SOPs in the original application. The new SOPs included in the application are:*

- *SARS-CoV-2-specific SOPs for virus infection and cell harvesting; plaque assay and cell viability assays in BSL-3 containment*
- *Other coronavirus-specific SOPs for infection and plaque assays in BSL-2 containment.*

Comment 1.3: *What part of an animal inoculation protocol constitutes an emergency or a response to the COVID-19 pandemic as the requestors claim? Appears to be a blanket request with no justification. Appears the ABSL-2 SOP is for arboviral methods that has been re-flagged coronavirus. ABSL-3 is titled experimental, uses arboviral methods, and then indicates it is for diagnostics (which in the current environment would require FDA Emergency Use Authorization (EUA) for a Lab Developed Test (LDT). The bold print at the bottom of page 2 acknowledges the dangerous nature of what they are proposing, and that they are not equipped to handle it when they get surprised. Proposed animal model methods are not consistent with SARS animal models in the literature.*

Response: *We agree that to address our immediate project goals, in vitro cell culture experiments under BSL-3 containment will be more relevant. Animal experiments may follow later to validate results of cell culture experiments or to test in vivo drug efficacy and develop small animal challenge models for vaccine-efficacy testing. When we decide to conduct animal experiments, we will submit an amendment to this protocol. In this proposal we will only request research to be conducted on imported*

SARS-CoV-2 in the BSL-3 facility. Based on these modifications, we have revised the application and removed all SOPs for animal experiments.

Comment 1.4: Project Objective is already performed by DOH and community clinical labs.

Response: We would like to emphasize that the main objective of our research is to help understand the biology of SARS-CoV-2 and the pathogenesis of COVID-19, using different human cell types in tissue culture under BSL-3 containment. In addition, we plan to use the requested coronaviruses to develop virus neutralization assays that can be used ultimately to evaluate vaccine responses. While some of this research involves developing or improving assays that can be used for point-of-care diagnostic testing, none of these objectives are covered by currently available assays at the Hawaii DOH State Lab or private clinical laboratory facilities in Hawaii.

Comment 1.5: Bottom of page 8 the requestor incorrectly states that workers cannot get infected, and goes on to describe blood borne transmission rather than respiratory: "Coronavirus infection from stock vial to human is not possible. The only plausible cause of infection in the laboratory setting is if a technician during active manipulation of the virus, accidentally pokes himself deep into the skin with a contaminated needle or sharp object, providing direct access of the virus to the bloodstream"

Response: We have clarified that UH personnel working with SARS-CoV-2 will wear personal protective equipment, including N-95 mask, face shield, double gloves, gown, sleeves etc (as described in the SOPs) and all virus handling will be performed in biosafety cabinets (BSC). All precautions and safety guidelines recommended by the CDC (Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019, updated June 5, 2020, <https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html#guidance>) will be taken to prevent airborne exposure of personnel to SARS-CoV-2. Further, our proposed experiments, including virus infection of cell cultures and plaque assays, do not generate aerosols. These precautionary measures will minimize the risk of airborne

Coronavirus
Dr. Vivek Nerurkar

infection of SARS-CoV-2. Additionally, as per our revised application, we do not plan to conduct any animal experiments with SARS-CoV-2, which will further minimize the risk of infection via needlestick injury in the laboratory setting.

Dr. Hongwei Li: Recommends approval.

Comments: "During COVID-19 pandemic, it is very important to have a local laboratory to conduct research on the causative agent SARS-CoV-2 and other related viruses. Such efforts could greatly expand the capability, capacity and potential in the disease management in Hawaii, such as diagnostics, surveillance, case tracing, epidemiology, investigation of therapeutic drugs, vaccine development, etc. The research team led by DR. Nerurkar has the knowledge, training and experience in dealing with a variety of BSL-2 and BSL-3 microorganisms, especially viruses; and the state-of-art facilities (BSL-2 and BSL-3) in JABSOM will provide assurance in biosafety and biosecurity for proposed research activities."

REVISED SUBCOMMITTEE RECOMMENDATION, Question #1

1. I Recommend Approval ____ / Disapproval ____ to Allow the Importation of the Coronaviruses: Alphacoronavirus Strains NL63 and 229E, and Non-Select Agent Betacoronavirus Strains OC43 and HKU1, Viruses on the List of Restricted Microorganisms (Part A), for Laboratory Research by the University of Hawaii, by Emergency Permit.

Dr. Edward Desmond: Recommends Approval.

Comments: "OK for these common seasonal coronaviruses which cause common colds."

Dr. A. Christian Whelen: Recommends Approval.

Comments: "These are common cold viruses."

2. I recommend approval ___/___ disapproval to establish permit conditions for the importation of the coronaviruses: Alphacoronavirus, Non-Select Agent Betacoronavirus, and Gammacoronavirus, viruses on the List of Restricted Microorganisms (Part A), for laboratory research by the University of Hawaii at Manoa.

Coronavirus
Dr. Vivek Nerurkar

Dr. David Clements: Recused.
Dr. Raquel Wong: Recommends approval.
Dr. Edward Desmond: Recommends disapproval.

Comments: "The SARS coronavirus which caused the 2003 pandemic has now been classified as a Select Agent. It is likely that SARS-CoV-2 will also eventually be classified as a Select Agent. Even before that happens, it would be desirable for the JABSOM laboratory to be able to demonstrate the ability to work safely at that level. A risk analysis would be appropriate, to include the qualifications of staff, facility factors, and history of incidents/accidents if any at JABSOM. The attachment 7 SOP would appear to have some deficits related to safety. It appears to be directly adapted from an arbovirus SOP and does not appear to reflect the distinguishable risks associated with a virus well known to be spread by the respiratory route. For example, the protocol for spill cleanup calls for immediate cleanup. For a virus notorious for spread by respiratory route, consideration must be given to instructing staff to immediately evacuate and to preform cleanup after ventilation has had time to clear aerosol from the room."

Dr. Nerurkar's response to Dr. Desmond's comments:

Comment 2.2: *The SARS coronavirus which caused the 2003 pandemic has now been classified as a Select Agent. It is likely that SARS-CoV-2 will also eventually be classified as a Select Agent. Even before that happens, it would be desirable for the JABSOM laboratory to be able to demonstrate the ability to work safely at that level. A risk analysis would be appropriate, to include the qualifications of staff, facility factors, and history of incidents/accidents if any at JABSOM. The attachment 7 SOP would appear to have some deficits related to safety. It appears to be directly adapted from an arbovirus SOP and does not appear to reflect the distinguishable risks associated with a virus well known to be spread by the respiratory route. For example, the protocol for spill cleanup calls for immediate cleanup. For a virus notorious for spread by the respiratory route, consideration must be given to instructing staff to immediately evacuate and to perform cleanup after ventilation has had time to clear aerosol from the room.*

Coronavirus
Dr. Vivek Nerurkar

Response: *While we agree that there is a remote possibility that SARS-CoV-2 may at some point in time be added to the Select Agents Program, there is also sufficient evidence that it will not, based on the epidemiology of SARS-CoV-2 which more closely resembles that of distantly related seasonal influenza viruses to which some in the population may have no pre-existing immunity. In contrast to SARS-CoV-1 (which is a Select Agent, causing rapidly progressive respiratory disease of high mortality), SARS-CoV-2 infection is frequently asymptomatic and the case-fatality rate is substantially lower. This would argue against SARS-CoV-2 being considered a Select Agent in the future and as such we believe it is prudent to allow UH to work with SARS-CoV-2 under BSL-3 containment, as approved and recommended by the CDC. The UH BSL-3 facility is in safe working condition and only appropriately trained individuals work within the laboratory. In its 15 years of operations, there have been no workplace-related injuries or infections in the BSL-3/ABSL-3 facilities. In reference to the concern about the spill cleanup procedures, there is a misunderstanding. The SOP clearly states that in the event of any spill that is likely to cause aerosols, operators present in the space are to immediately vacate the place so the air handling system can first remove particulates from the air prior to a safe re-entry to conduct the spill cleanup. In contrast, minor spills inside the BSC can be handled immediately as per the SOP.*

Dr. A. Christian Whelen: Recommends disapproval.

Comments: "The UH JABSOM labs have a long history of troubled facilities and operations that attracted national headlines: <https://www.usatoday.com/story/news/2015/05/28/biolabs-pathogens-location-incidents/26587505/>. I believe these labs eventually withdrew from the Select Agent program. Although the request specifies non-select agent coronaviruses, SAR-COV-2 will likely be classified as a select agent like the 2003 SARS-COV-1. This appropriate classification will likely take years (as it did with SARS-COV-1). Furthermore, in 2017 communications with the DOH Director (in which I and Dr. Sarah Park were asked to participate), Dean Hedges indicated that UH could not sustain BSL3 operations, and without DOH or legislative funding intervention, they would shut down July 2018. DOH was unable to provide funding; unclear if legislature did. I am quite surprised at the claim that BSL3/ABSL3 are still in operation. The submission did not contain evidence of annual certification. I and/or my staff have participated in many reviews (Import Permit, IBC, etc.), and

Coronavirus
Dr. Vivek Nerurkar

I have repeatedly found these labs lacked a culture of safety. When at DOH, I know of at least one laboratory-acquired dengue infection in a graduate student working alone on a weekend as a result of a needle stick that wasn't reported until the student fell ill (dengue is reportable to DOH), and they did not have an exposure control plan. Unless a lot has changed, I think that they will have significant deviations when they get their first CLIA inspection."

Dr. Nerurkar's response to Dr. Whelen's comments:

Comment 2.1: *The UH JABSOM labs have a long history of troubled facilities and operations that attracted national headlines: <https://www.usatoday.com/story/news/2015/05/28/biolabs-pathogens-location><<http://www.usatoday.com/%20story/%20news/%202015/%2005/%2028/%20biolabs-pathogens-location>> incidents/26587505/. I believe these labs eventually withdrew from the Select Agent program. Although the request specifies non-select agent coronaviruses, SARS-CoV-2 will likely be classified as a select agent like the 2003 SARS-CoV-1. This appropriate classification will likely take years (as it did with SARS-CoV-1).*

Response: *Concerns about public safety have been raised in articles about multiple BSL-3 facilities in the past, including those at premier institutions, such as the Centers for Disease Control and Prevention (CDC) in Atlanta and the US Army Medical Research Institute of Infectious Diseases (USAMRIID) in Frederick. We do not agree that the UH lab has had a "long history of troubled facilities and operations".*

Comment 2.1.1: *Furthermore, in 2017 communications with the DOH Director (in which I and Dr. Sarah Park were asked to participate), Dean Hedges indicated that UH could not sustain BSL-3 operations, and without DOH or legislative funding intervention, they would shut down July 2018. DOH was unable to provide funding; unclear if legislature did. I am quite surprised at the claim that BSL-3/ABSL-3 are still in operation. The submission did not contain evidence of annual certification. I and/or my staff have participated in many reviews (Import Permit, IBC, etc.), and I have repeatedly found these labs lacked a culture of safety.*

Coronavirus
Dr. Vivek Nerurkar

Response: While it is true that the continued operations of the BSL-3 facility at UH was being considered for closure in 2017, Dean Jerris Hedges, of the John A. Burns School of Medicine (JABSOM), recognizing the vital need of this unique infrastructure, has provided funds to systematically renovate and upgrade the facility. In just 2019 alone, the JABSOM Biocontainment Facility (JBF) renovation and certification was accomplished at a cost of approximately \$250,000, through funds provided by Dean Hedges. As such, the JBF at UH is now fully certified and functional and operational. The following documents have been provided to the HDoA inspector, Mr. Wil Leon Guerrero. Attached is a single pdf file containing the following documents.

- BSL-3 compliant certificate from World BioHaztec
- ABSL-3 compliant certificate from World BioHaztec
- UH IBC Approval
- HDoH/HDoA approval
- Gantt chart showing the 2019 timeline for JBF renovation and certification

Please note that some of these docs are sensitive and must be handled accordingly.

Comment 2.1.2: When at the DOH, I know of at least one laboratory-acquired dengue infection in a graduate student working alone on a weekend as a result of a needle stick that wasn't reported until the student fell ill (dengue is reportable to DOH), and they did not have an exposure control plan.

Response: For the past 15 years, since the JBF was established in 2005, there have been **no incidents** of laboratory-acquired infection among personnel working in the BSL-3/ABSL-3 biocontainment facility at Kaka'ako. It is true that 10 years ago, in 2010, there was a dengue virus incident in the BSL-2 laboratory in a student under another PI's supervision (not Dr. Nerurkar). That incident was resolved immediately and the person was in quarantine with appropriate measures. As per Dr. Nerurkar's records this incident was conveyed to Dr. Sarah Park. If needed, a paper trail of this confidential information can be provided to appropriate authorities at HDoA by UH. Exposure control plan is part of any BSL-3 facility. Exposure control plan is listed in the JBF manual,

Coronavirus
Dr. Vivek Nerurkar

which is reviewed and revised annually and approved by the UH Biosafety Officer.

Comment 2.1.3: *Unless a lot has changed, I think an unannounced audit would find substandard training material, records, risk assessments, etc. I suspect that they will have significant deviations when they get their first CLIA inspection.*

Response: *Thank you for your comment. Please refer to the above responses 2.1 and 2.1.1.*

Dr. Hongwei Li: Recommends approval.

Comments: "Same as #1."

REVISED SUBCOMMITTEE RECOMMENDATION, Question #2

2. I Recommend Approval ___ / Disapproval _____ to Establish Permit Conditions for Importation of the Coronaviruses: Alphacoronavirus Strains NL63 and 229E, and Non-Select Agent Betacoronavirus Strains OC43 and HKU1, Viruses on the List of Restricted Microorganisms (Part A) for Laboratory Research by the University of Hawaii.

Dr. Edward Desmond: Recommends Approval.

Comments: "OK for these common seasonal coronaviruses which cause common colds."

Dr. A. Christian Whelen: Recommends Approval.

Comments: "Virus lab operating at BSL2 should suffice."

3. I recommend approval ___ / ___ disapproval to allow the importation of the coronaviruses: SARS-CoV-2 Betacoronavirus and Reported SARS-CoV-2 Betacoronavirus, viruses on the List of Restricted Microorganisms (Part A), for laboratory research by the University of Hawaii at Manoa, through emergency permit.

Dr. David Clements: Recused.

Coronavirus
Dr. Vivek Nerurkar

Dr. Raquel Wong: Recommends approval.

Dr. Edward Desmond: Recommends disapproval.

Comments: "A request to be permitted to import "viruses on the List of Restricted Microorganisms" appears to be unduly broad. To approve such permission should require an item analysis and justification for each virus."

Dr. Nerurkar's response to Dr. Desmond's comments:

Comment 3: *A request to be permitted to import "viruses on the List of Restricted Microorganisms" appears to be unduly broad. To approve such permission should require an item by item analysis and justification for each virus*

Response: *List of specific coronavirus strains and justification is described below.*

Common Name	Scientific Name	Justification
SARS-CoV-2	SARS related Coronavirus 2, Isolate USA-WA1/2020	This strain will be most widely used in the proposed projects including infection of cells and virus neutralization assays in the BSL-3 lab
Coronavirus 229E	Alpha Coronavirus 229E	This strain will be used in few experiments to compare select host responses with SARS-CoV-2 to understand why SARS-CoV-2 cause serious complications, and used in neutralization assay in the BSL-2 lab
Coronavirus OC43	Beta Coronavirus OC43	This strain will be used in few experiments to compare select host responses with SARS-CoV-2 and used in neutralization assay in the BSL-2 lab
Coronavirus NL63	Alpha Coronavirus NL63	This strain will be used in neutralization assays to understand antibody response at BSL-2 lab
Coronavirus HKU1	Beta Coronavirus HKU1	This strain will be used in neutralization assays to understand antibody response in the BSL-2 lab

Coronavirus
Dr. Vivek Nerurkar

Dr. A. Christian Whelen: Recommends disapproval.

Comments: "See above."

Dr. Hongwei Li: Recommends approval.

Comments: "Same as #1."

REVISED SUBCOMMITTEE RECOMMENDATION, Question #3

3. I Recommend Approval _____ / Disapproval _____ to Allow the Importation of the Coronaviruses: SARS-CoV-2 Betacoronavirus Isolates USA-WA1/2020, Germany/BavPat1/2020, and USA CA3/2020, Viruses on the List of Restricted Microorganisms (Part A), for Laboratory Research by the University of Hawaii, by Emergency Permit.

Dr. Edward Desmond: Recommends Disapproval.

Comments: "Manual of Clinical Microbiology, 12th ed., Chapter 92 on coronaviruses says "virus isolation in culture should not be attempted unless laboratories have the relevant expertise ... ". It also says: "To reduce the risk of laboratory -acquired infection in a novel CoV scenario, nucleic acid-based detection is recommended because it does not require virus propagation ... " JABSOM has not demonstrated the expertise to work safely with cell culture propagation in this novel CoV scenario."

Dr. A. Christian Whelen: Recommends Disapproval.

Comments: "Rebuttal is insufficient to gain this reviewer's confidence. UH should not attempt cultivation of SARS-COV-2. It's too dangerous. According to CDC/NIH Biosafety in Microbiological and Biomedical Laboratories, 5th edition, laboratory acquired infections of SARS-COV-1 in Taiwan, Singapore, and China occurred in research labs. It took 9 years to finally classify SARS-COV-1 as a Select Agent, and SARS-COV-2 is behaving much worse."

4. I recommend approval ___ / ___ disapproval to establish permit conditions for the importation of the coronaviruses: SARS-CoV-2 Betacoronavirus and Reported SARS-CoV-2 Betacoronavirus, viruses on the List of Restricted Microorganisms (Part A), for laboratory research by the University of Hawaii at Manoa.

Coronavirus
Dr. Vivek Nerurkar

Dr. David Clements: Recused.
Dr. Raquel Wong: Recommends approval.
Dr. Edward Desmond: Recommends disapproval.

Comments: "See previous comments."

Dr. Nerurkar's response to Dr. Desmond's comments:

Response: Refer to above responses

Dr. A. Christian Whelen: Recommends disapproval.

Comments: "See above."

Dr. Nerurkar's response to Dr. Whelen's comments:

Response: Refer to above responses

Dr. Hongwei Li: Recommends approval.

Comments: "Same as #1"

REVISED SUBCOMMITTEE RECOMMENDATION, Question #4

4. I Recommend Approval _____ / Disapproval _____ to Establish Permit Conditions for Importation of the Coronaviruses: SARS-CoV-2 Betacoronavirus Isolates USAWA1/2020, Germany/BavPat1/2020, and USA CA3/2020, Viruses on the List of Restricted Microorganisms (Part A) for Laboratory Research by the University of Hawaii.

Dr. Edward Desmond: Recommends Disapproval.

Comments: "Manual of Clinical Microbiology, 12th ed., Chapter 92 on coronaviruses says "virus isolation in culture should not be attempted unless laboratories have the relevant expertise ... ". It also says: "To reduce the risk of laboratory -acquired infection in a novel CoV scenario, nucleic acid-based detection is recommended because it does not require virus propagation ... " JABSOM has not demonstrated the

expertise to work safely with cell culture propagation in this novel CoV scenario.”

Dr. A. Christian Whelen: **Recommends Disapproval.**

5. Are the proposed permit conditions sufficient to assure that the requested microorganisms: Alphacoronavirus, Non-Select Agent Betacoronavirus, SARS-CoV-2 Betacoronavirus, Reported SARS-CoV-2 Betacoronavirus, and Gammacoronavirus, viruses on the List of Restricted Microorganisms (Part A), requested for import presents probably minimal or no significant effects on the environment?

Yes

No (If “No,” please explain and suggest appropriate conditions.)

Dr. David Clements: Recused.

Dr. Raquel Wong: Yes

Dr. Edward Desmond: No

Comments: “Please see previous comments.”

Dr. Nerurkar’s response to Dr. Desmond’s comments:

Response: Please refer to the above responses.

Dr. A. Christian Whelen: N/A

Dr. Nerurkar’s response to Dr. Whelen’s comments:

Response: Please refer to the above responses.

Dr. Hongwei Li: Yes

Comments: “Same as #1”

6. If the requested microorganisms: Alphacoronavirus, Non-Select Agent Betacoronavirus, SARS-CoV-2 Betacoronavirus, Reported SARS-CoV-2 Betacoronavirus, and Gammacoronavirus, viruses, on the List of Restricted Microorganisms (Part A), are accidentally released, what is the probable impact on the environment?

Coronavirus
Dr. Vivek Nerurkar

___ probably minimal or no significant effects on the environment.
___ other (If "other," please explain.)

Dr. David Clements: Recused.

Dr. Raquel Wong: Probably minimal or no significant effects on the environment.

Comments: "The virus is currently circulating world-wide in the human population. Animal infections (cats and dogs) have been associated with close contact with infected humans and there is no evidence that animal with the SARS-CoV-2 can transmit to humans. Animals exhibit mild signs and recover quickly."

Dr. Edward Desmond: Other

Comments: "The impact is unknown. As we have seen, release of viruses of the coronavirus family may have serious effects."

Dr. A. Christian Whelen: Other

Comments: "Biggest risk is laboratory acquired infection and secondary spread to family members and contacts while asymptomatic or pre-symptomatic."

Dr. Nerurkar's response to both Dr. Desmond's & Dr. Whelen's comments:

Response: All research with the SARS-CoV-2 and other coronaviruses will be conducted in a Class II BSC in the BSL-3 and BSL-2 facilities, respectively. These laboratories are highly secured, and also located in a highly secured building. There are strict procedures and SOPs in place to protect all personnel working in the BSL-3 containment facility. These SOPs include response to biological spills, acts of nature and facility failures. Due to all of these precautions we will minimize the risk of exposure to laboratory personnel. However, in case of any potential exposure of the personnel to the virus, we have procedures in place to quarantine the personnel under medical supervision immediately after exposure as per CDCs guidelines for home quarantine (Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for Coronavirus Disease 2019, Feb 12, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home->

Coronavirus
Dr. Vivek Nerurkar

[care.html](#)). We will not wait for symptoms to develop to prevent potential transmission to the family and community during the asymptomatic or presymptomatic phase. We have two physicians on call and SOPs for incident response.

Dr. Hongwei Li: probably minimal or no significant effects on the environment.

Comments: "Same as #1. SARS-CoV-2 is already in Hawaii, and no concerns about other BSL-2 coronaviruses."

V. **Proposed Permit Conditions:**

Because the applicant is requesting multiple strains of coronaviruses with differing BSL requirements, two separate sets of conditions, one for BSL-2 appropriate coronaviruses and another for BSL-3 appropriate coronaviruses, are proposed to address associated risks.

BSL-2 coronaviruses

1. The restricted article(s), alphacoronavirus strains NL63 and 229E, and non-select agent betacoronavirus strains OC43 and HKU1, shall be used for laboratory research, a purpose approved by the Board of Agriculture (Board), and shall not be sold, given, or transferred in Hawaii, unless approved by the Board in writing. Release of the restricted articles into the environment is prohibited.
2. The permittee, Vivek R. Nerurkar, Ph.D., University of Hawaii (UH), Department of Tropical Medicine and Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), 651 Ilalo Street, Biosciences Building (BSB) 320, Honolulu, Hawaii 96813, shall be responsible and accountable for all restricted article(s) imported, from the time of their arrival to their final disposition.
3. The restricted article(s) are subject to the pre-entry requirements of section 4-71A-8, Hawaii Administrative Rules (HAR), and the inspection requirements of section 4-71A-9, HAR.
4. The restricted article(s), alphacoronavirus strains NL63 and 229E, and non-select agent betacoronavirus strains OC43 and HKU1, shall be safeguarded in BSB rooms 303, 324B, 331, 332, 333, 334, and 336, at UH, JABSOM, 651 Ilalo Street, Honolulu, Hawaii, 96813, sites and rooms inspected and approved by the Plant Quarantine Branch (PQB) prior to importation. Removal of the restricted

Coronavirus
Dr. Vivek Nerurkar

article(s) to another site or room shall require site inspection and prior approval by the PQB chief.

5. The restricted article(s) shall be maintained by Vivek R. Nerurkar, Ph.D., UH, Department of Tropical Medicine and Medical Microbiology and Pharmacology, JABSOM, 651 Ilalo Street, BSB 320, Honolulu, Hawaii 96813, as the responsible person or by trained or certified personnel designated by the responsible person.
6. The permittee shall adhere to the use, facility, equipment, procedures, and safeguards proposed and described in the permit application, as approved.
7. The approved site(s), restricted article(s), and records pertaining to the restricted article(s) under permit shall be subject to post-entry inspections pursuant to section 4-71A-16, HAR.
8. The permittee shall immediately notify the PQB chief in writing in the following circumstances:
 - a. Any theft, accidental or other release or exposure, involving the restricted article(s).
 - b. Any known or suspected disease outbreaks involving the restricted article(s).
 - c. Any changes to the approved sites, facilities, procedures, or equipment used to contain the restricted article(s). Any such changes must be in compliance with permit conditions.
 - d. When the permittee will no longer import or keep the restricted article(s) authorized under this permit. In that event, the permit will be cancelled.
 - e. Any changes to laboratory protocols for handling of the restricted article(s) as the result of updated Center for Disease Control or other State or Federal guidelines.
 - f. If any of the restricted article(s) are included on the Federal Select Agent Program's Select Agents and Toxins List by the U.S. Department of Health (HHS) and Human Services or the United States Department of Agriculture (USDA).
9. The permittee shall immediately notify the Hawaii Department of Health if a laboratory acquired infection occurs or is suspected or in the event of any known

or suspected release, exposure, or disease outbreak involving the restricted article(s).

10. In the event any of the restricted article(s) are included on the Federal Select Agent Program's Select Agents and Toxins List by the HHS or the USDA, this permit shall be canceled and the affected restricted article(s) shall be immediately destroyed or sent out of state at the discretion of the PQB chief.
11. Upon completion or termination of the use of the restricted article(s), the restricted article(s) shall be destroyed by autoclaving. In the event autoclaving is not possible, the permittee shall obtain written authorization from the PQB chief for an appropriate alternate method of destruction.
12. The permittee shall submit an annual report of all the restricted article(s) imported for the calendar year by January 31st of the following year. The report shall include the permit number, scientific name, and quantity of each microorganism species imported, and status of use of the restricted article(s).
13. The permittee shall submit a final report on the method of destruction of the restricted article(s) to the PQB chief within 30 days of completion or termination of the use of the restricted article(s).
14. The permittee shall have available a procedural or safety manual at the time of inspection which identifies the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks of exposure or contamination.
15. It is the responsibility of the permittee to comply with any applicable requirements of municipal, state, or federal law pertaining to the restricted article(s). The permittee shall also comply with UH Institutional Biosafety Committee instructions and the John A. Burns School of Medicine Biocontainment Facility Guidance Policies.
16. The permittee shall submit to the PQB chief a copy of all valid licenses, permits, certificates or their equivalent required for the operation of the facility where the microorganisms are safeguarded. The permit issued by the PQB chief may be cancelled upon revocation, suspension, or termination of any of the aforementioned documents required for operation of the facility.
17. Any violation of the permit conditions may result in citation or in cancellation of the permit, or both.

Coronavirus
Dr. Vivek Nerurkar

18. A cancelled permit is invalid and upon written notification from the PQB chief, all restricted article(s) listed on the permit shall not be imported. In the event of permit cancellation, any restricted article(s) imported may be moved, seized, treated, quarantined, destroyed, or sent out of state at the discretion of the PQB chief. Any expense or loss in connection therewith shall be borne by the permittee.
19. The permit conditions are subject to cancellation or amendment at any time due to changes in statute or administrative rules restricting or disallowing import of the microorganisms or due to Board action disallowing a previously permitted use of the restricted article(s).
20. The permittee shall comply with the Centers for Disease Control and Prevention and National Institutes of Health Biosafety Level 2 guidelines for laboratory facility and Biosafety Level 3 guidelines for safety equipment, standard microbiological practices and special practices as found in the current edition of the *Biosafety in Microbiological and Biomedical Laboratories*.
21. The permittee shall agree in advance to defend and indemnify the State of Hawaii, its officers, agents, and employees for any and all claims against the State of Hawaii, its officers, agents, or employees that may arise from or be attributable to any of the restricted article(s) that are introduced under this permit. This permit condition shall not apply to a permittee that is a federal or State of Hawaii entity or employee, provided that the federal or state employee is a permittee in the employee's official capacity.

BSL-3 coronaviruses

1. The restricted article(s), SARS-CoV-2 betacoronavirus isolates USA-WA1/2020, Germany/BavPat1/2020, and USA CA3/2020, shall be used for laboratory research, a purpose approved by the Board of Agriculture (Board), and shall not be sold, given, or transferred in Hawaii, unless approved by the Board in writing. Release of the restricted articles into the environment is prohibited.
2. The permittee, Vivek R. Nerurkar, Ph.D., University of Hawaii (UH), Department of Tropical Medicine and Medical Microbiology and Pharmacology, John A. Burns School of Medicine (JABSOM), 651 Ilalo Street, Biosciences Building (BSB) 320, Honolulu, Hawaii 96813, shall be responsible and accountable for all restricted article(s) imported, from the time of their arrival to their final disposition.

Coronavirus
Dr. Vivek Nerurkar

3. The restricted article(s) are subject to the pre-entry requirements of section 4-71A-8, Hawaii Administrative Rules (HAR), and the inspection requirements of section 4-71A-9, HAR.
4. The restricted article(s), SARS-CoV-2 betacoronavirus isolates USA-WA1/2020, Germany/BavPat1/2020, and USA CA3/2020, shall be safeguarded in the JABSOM Biocontainment Facility, UH, JABSOM, 651 Ilalo Street, Honolulu, Hawaii, 96813, sites and rooms inspected and approved by the Plant Quarantine Branch (PQB) prior to importation. Removal of the restricted article(s) to another site or room shall require site inspection and prior approval by the PQB chief.
5. The restricted article(s) shall be maintained by Vivek R. Nerurkar, Ph.D., UH, Department of Tropical Medicine and Medical Microbiology and Pharmacology, JABSOM, 651 Ilalo Street, BSB 320, Honolulu, Hawaii 96813, as the responsible person or by trained or certified personnel designated by the responsible person.
6. The permittee shall adhere to the use, facility, equipment, procedures, and safeguards proposed and described in the permit application, as approved.
7. The approved site(s), restricted article(s), and records pertaining to the restricted article(s) under permit shall be subject to post-entry inspections pursuant to section 4-71A-16, HAR.
8. The permittee shall immediately notify the PQB chief in writing in the following circumstances:
 - a. Any theft, accidental or other release or exposure, involving the restricted article(s).
 - b. Any known or suspected disease outbreaks involving the restricted article(s).
 - c. Any changes to the approved sites, facilities, procedures, or equipment used to contain the restricted article(s). Any such changes must be in compliance with permit conditions.
 - d. When the permittee will no longer import or keep the restricted article(s) authorized under this permit. In that event, the permit will be cancelled.
 - e. Any changes to laboratory protocols for handling of the restricted article(s) as the result of updated Center for Disease Control or other State or Federal guidelines.

Coronavirus
Dr. Vivek Nerurkar

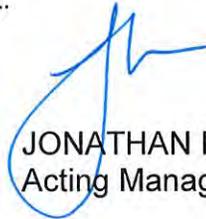
- f. If any of the restricted article(s) are included on the Federal Select Agent Program's Select Agents and Toxins List by the U.S. Department of Health (HHS) and Human Services or the United States Department of Agriculture (USDA).
9. The permittee shall immediately notify the Hawaii Department of Health if a laboratory acquired infection occurs or is suspected or in the event of any known or suspected release, exposure, or disease outbreak involving the restricted article(s).
10. In the event any of the restricted article(s) are included on the Federal Select Agent Program's Select Agents and Toxins List by the HHS or the USDA, this permit shall be canceled and the affected restricted article(s) shall be immediately destroyed or sent out of state at the discretion of the PQB chief.
11. Upon completion or termination of the use of the restricted article(s), the restricted article(s) shall be destroyed by autoclaving. In the event autoclaving is not possible, the permittee shall obtain written authorization from the PQB chief for an appropriate alternate method of destruction.
12. The permittee shall submit an annual report of all the restricted article(s) imported for the calendar year by January 31st of the following year. The report shall include the permit number, scientific name, and quantity of each microorganism species imported, and status of use of the restricted article(s).
13. The permittee shall submit a final report on the method of destruction of the restricted article(s) to the PQB chief within 30 days of completion or termination of the use of the restricted article(s).
14. The permittee shall have available a procedural or safety manual at the time of inspection which identifies the hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks of exposure or contamination.
15. It is the responsibility of the permittee to comply with any applicable requirements of municipal, state, or federal law pertaining to the restricted article(s). The permittee shall also comply with UH Institutional Biosafety Committee instructions and the John A. Burns School of Medicine Biocontainment Facility Guidance Policies.

16. The permittee shall submit to the PQB chief a copy of all valid licenses, permits, certificates or their equivalent required for the operation of the facility where the microorganisms are safeguarded. The permit issued by the PQB chief may be cancelled upon revocation, suspension, or termination of any of the aforementioned documents required for operation of the facility.
17. Any violation of the permit conditions may result in citation or in cancellation of the permit, or both.
18. A cancelled permit is invalid and upon written notification from the PQB chief, all restricted article(s) listed on the permit shall not be imported. In the event of permit cancellation, any restricted article(s) imported may be moved, seized, treated, quarantined, destroyed, or sent out of state at the discretion of the PQB chief. Any expense or loss in connection therewith shall be borne by the permittee.
19. The permit conditions are subject to cancellation or amendment at any time due to changes in statute or administrative rules restricting or disallowing import of the microorganisms or due to Board action disallowing a previously permitted use of the restricted article(s).
20. The permittee shall comply with the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) Biosafety Level 3 guidelines for laboratory facility and Biosafety Level 3 guidelines for safety equipment, standard microbiological practices and special practices as found in the current edition of the *Biosafety in Microbiological and Biomedical Laboratories*.
21. The permittee shall agree in advance to defend and indemnify the State of Hawaii, its officers, agents, and employees for any and all claims against the State of Hawaii, its officers, agents, or employees that may arise from or be attributable to any of the restricted article(s) that are introduced under this permit. This permit condition shall not apply to a permittee that is a federal or State of Hawaii entity or employee, provided that the federal or state employee is a permittee in the employee's official capacity.

STAFF RECOMMENDATION: Based upon prior site approvals; internal review; the recommendations and comments of the Advisory Subcommittee on Viruses; subsequent changes made by the applicant in response to Subcommittee comments and further Subcommittee review and recommendation, the PQB recommends approval of parts one and two of this request with proposed BSL-2 permit conditions.

Coronavirus
Dr. Vivek Nerurkar

Based upon recommendations and comments of the initial and revised request for SARS-COV-2 coronaviruses, the PQB recommends disapproval of parts three and four of this request for an emergency permit.



JONATHAN K. HO
Acting Manager, Plant Quarantine Branch

CONCURRED:



KEVIN. M. HOFFMAN, Ph.D.
Administrator, Plant Industry Division

APPROVED FOR SUBMISSION:



PHYLLIS SHIMABUKURO-GEISER
Chairperson, Board of Agriculture

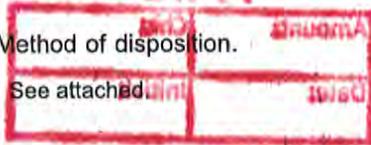
PLEASE COMPLETE THE FOLLOWING INFORMATION (attach extra sheet if necessary)

1. State in detail the reasons for introduction (include use or purpose).
See attached.

2. Person responsible for the organism (include name, address and phone number).
Vivek R. Nerurkar, D.M.L.T., M.Sc., Ph.D. Professor and Chair
Department of Tropical Medicine, Medical Microbiology, & Pharmacology, BSB 320G
University of Hawaii, John A. Burns School of Medicine (JABSOM)
651 Ilalo Street
Honolulu, HI 96813
Telephone - 808-692-16628(office); 808-692-1980 (fax)
email - nerurkar@hawaii.edu

3. Location(s) where the organism will be kept and used (include address, contact and phone number).
See attached.

4. Method of disposition.



See attached.

5. Give an abstract of the organism with particular reference to potential impact on the environment of Hawaii (include impact to plants, animals and humans).
See attached.

I request permission to import the articles as listed on the permit application and further, request that the articles be examined by an authorized agent of the Department of Agriculture upon arrival in Hawaii.

I agree that I, as the importer, will be responsible for all costs, charges or expenses incident to the inspection or treatment of the imported articles.

I further agree that damages or losses incident to the inspection or the fumigation, disinfection, quarantine, or destruction of the articles, by an authorized agent of the Department of Agriculture, shall not be the basis of a claim against the department or the inspectors for the damage or loss incurred.

Signature _____

(Applicant)

Date _____

04.06.2020

April 05, 2020
June 13, 2020 (Revised)

State of Hawaii Department of Agriculture
Import Permit Application of Coronavirus
Department of Tropical Medicine, Medical Microbiology, & Pharmacology
University of Hawaii, JABSOM

Requested Information

1. State in detail the reasons for introduction (including use of purpose).

Coronavirus disease 2019 (COVID-19) is currently a global pandemic affecting nearly every social, economic, and health care system worldwide. The etiological agent for COVID-19 is the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that belongs to the coronavirus family. World Health Organization (WHO) declared the SARS-CoV-2 pandemic on March 11, 2020.

Currently there are no antivirals or vaccines to combat the spread of this virus. Since SARS-CoV-2 is a newly identified virus there are several unknowns that hamper our ability to control virus spread and develop novel testing tools, therapeutics and vaccines. There is an urgent need to understand both, basic biology of SARS-CoV-2 and pathogenesis mechanisms. Our objective is to join the global effort to combat COVID-19 disease. We propose to conduct experiments to:

- Understand protective antibody responses to SARS-CoV-2 and develop virus neutralization assays for testing vaccine efficacy.
- Understand the target cells of SARS-CoV-2 and pathogenesis of COVID-19 by infecting human cells (such as lung epithelial cells, cardiac fibroblasts, myocytes and Sertoli cells)
- Evaluate the efficacy of different antiviral drugs in preventing virus infection and tissue damage, using *in vitro* cell and organoid culture models.

2. Locations(s) where the organism will be kept and used (include address, contact and phone number).

- Biosafety Level 2 Laboratories: BSB room – 303, 331, 334, 336; 651 Ilalo Street, Honolulu, HI 96813 -- inspected by UH Biosafety 18 October 2019
- BioSafety Level 2+ Laboratories: BSB room – 332, 333, 324B; 651 Ilalo Street, Honolulu, HI 96813 – inspected by UH Biosafety 18 October 2019
- Animal Biosafety Level 2 Vivarium: BSB room 156; 651 Ilalo Street, Honolulu, HI 96813
- BioSafety Level 3 Laboratories: JABSOM Biocontainment Facility (JBF); 651 Ilalo Street, Honolulu HI 96813 – inspected by UH BioSafety 3 January 2020 and HDoA/HDoH 27 August 2019.
- Laboratory contact information: Vivek R. Nerurkar, Ph.D.; 808-692-1668; 808-753-6961
- Animal Biosafety Level 3 Vivarium: JBF – ABSL3 preproom freezer & Suite AL2; 651 Ilalo Street, Honolulu, HI 96813
- Vivarium contact information: Sylvia Kondo, DVM; 808-956-4444
- Vivarium has been inspected by UH IACUC, IBC, JABSOM-EHSO, and UH Biosafety

Various biosafety level laboratories (BSL-2, BSL-2+, BSL-3; and ABSL-3- will be used as surge capacity for conducting BSL3 work -no animals) will be used to store and work on coronavirus based on their pathogenicity as per CDC BMBL guidelines.

3. Method of disposition.

BSL-2/2+/3 containment: All solid wastes and materials associated with the viral agent will be autoclaved at 250° F for 60 minutes at >15 psi, or chemically disinfected with 10% bleach for a minimum duration of 15 minutes. All equipment or solid surfaces will be decontaminated with 70% ethanol or Cavicide. Liquid waste will be chemically neutralized with 10% sodium hypochlorite solution for a minimum of 15 minutes, then diluted to a suitable neutral pH and disposed of down the drain.

4. Give an abstract of the organism with particular reference to potential impact on the environment of Hawaii (include impact to plants, animals and humans).

Coronaviruses are a group of related viruses that cause diseases in mammals and birds. They are enveloped viruses with a positive-sense single-stranded RNA genome and a nucleocapsid of helical symmetry. The genome size of coronaviruses ranges from approximately 27- to 34-kilobases, the largest among known RNA viruses. They mostly cause enteric or respiratory disease, which can sometimes be severe and life threatening depending on the type of coronavirus.

Human coronaviruses (hCoVs) can be divided into low pathogenic and highly pathogenic coronaviruses. The low pathogenic CoVs infect the upper respiratory tract and cause mild, cold-like respiratory illness (229E, NL63, OC43, HKU1). In contrast, highly pathogenic hCoVs predominantly infect lower airways and cause fatal pneumonia (MERS-CoV, SARS-CoV, SARS-CoV-2). Case fatality rates range from MERS-CoV at 35%, to SARS-CoV at 14-15%, to the newly emerged human coronavirus SARS-CoV-2 at 2-3%.

Economically significant coronaviruses of farm animals include chicken coronavirus (infectious bronchitis virus, IBV), targeting the respiratory tract and the urogenital tract, and porcine coronavirus (transmissible gastroenteritis coronavirus, TGE) and bovine coronavirus, which both result in diarrhea in young animals. Additionally, viruses have been identified which infect felines, ferrets, canines, mice and rats.

Transmission of coronaviruses are thought to mainly occur through respiratory droplets of infected individuals via aerosols and fomites or a fecal/oral. Direct contact transmission in some farm animals have been suggested. With regards to SARS-CoV-2, as per US CDC, there is no evidence to suggest that any animals, including pets, livestock, or wildlife, might be a source of CoV-2 infection at this time.

Importation of coronavirus will have no foreseeable impact on the environment due to the fact that all research with this virus will be confined to the aforementioned laboratories, which are high security locations and have been certified as appropriate biological containment facilities. All personnel undergo rigorous training prior to entering the laboratories, and wearing of appropriate PPE is enforced. Furthermore, all manipulations will be done in a Biosafety Cabinet, providing even more protection and security that no virus will leave the confines of the facilities and impact the environment. All standard operating procedures are strictly enforced, there are spill management plans, and emergency procedures in place.

Grants submitted or in process of submission by the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM related to COVID-19

PI Name	Project Title	Agency	Collaborators	Submission Deadline	Estimated Funds (DC+IDC)	Comments
Kaufusi, Pakieli H. & Nerurkar, Vivek R.	Elucidation of Potential Transmission and Rapid Diagnostics of SARS-CoV-2 in Animal Production and Processing Operations in the Hawaiian Islands	NEFA, USDA	CTAHR Faculty (Daniel Jenkins, Mohammad Arif, Jenee Odani)	Submitted June 04, 2020	\$1,000,000 (Total cost)	Rapid Response to Novel Coronavirus (SARS-CoV-2) Impacts Across Food and Agricultural Systems.
Lehrer, Axel T.	Preclinical Development of a Thermostable Recombinant Subunit Vaccine against SARS-CoV-2	NIAID	Soligenix, BIOQUAL, Hawaii Biotech	Submitted May 12, 2020	\$2,379,328 (Total cost)	Rapid Preclinical Development of a subunit vaccine in Partnership with Soligenix and Hawaii Biotech
Lehrer, Axel T.	Inhalable angiotensin receptor blocker nanocrystal for treating COVID-19	NHLBI	Johns Hopkins University (Dr. Jung Soo Suk) and BIOQUAL	Submitted May 12, 2020	\$250,000 (DC) Total estimated cost - \$412,500	Project is focused on establishing feasibility in mouse and non-human primate models. (Follow-on study may be submitted shortly as R21)
Verma, Saguna	Modeling SARS-CoV-2 cardiac complications using human 3D multicellular heart organoids and hACE2 mouse model	NIH	Michelle Talaquist, UHM	Submitted - May 15, 2020	\$311,000	
Verma, Saguna	Modeling SARS-CoV-2 infection in human 3D testicular organoid system to understand	NIH		Submitted May 29, 2020	\$275K DC Total estimated cost - \$425,000	Two year grant

	male susceptibility to severe COVID-19					
Verma, Saguna	Engineered multicellular 3D human airway organoids: An in vitro system to model SARS-CoV-2 infection	NIH	Sean Murphy, Wake Forest Univ.	Submitted - May 15, 2020	\$197,000	
Lehrer, Axel T.	Inhalable Angiotensin Receptor Blocker as Treatment of severe Lung Pathology associated with COVID-19	BARDA	Soligenix, Inc.	Techwatch Meeting occurred on 5/7/2020	No limit	Techwatch resulted in some additional data points requested that would make a Whitepaper (next step) more successful
Lehrer, Axel T.	Clinical Development of a thermostable recombinant subunit vaccine for COVID-19	BARDA	Soligenix, Hawaii Biotech	Rolling Expected Whitepaper submission in next two weeks	No limits	This is based on a Techwatch meeting in January 2020. Next step is submission of a whitepaper.
Lehrer, Axel T. & Fujimoto, Brent	Effect of type II diabetes on the immunogenicity and efficacy of COVID-19 vaccines	NIAID	Mariana Gerschenson/ BIOQUAL	Target: June 2020	\$275K DC Total estimated cost - \$425,000	As severe pathology in SARS and MERS animal models has been observed with inactivated vaccines adjuvanted with Alum, increased risk may exist diabetic patients.
Wang, Wei-Kung	SARS-CoV2 detection and serological tests	NIH	Dr. Jih-Jin Tsai, Taiwan or Dr. Carlos Brites, Brazil	Rolling Deadline	\$275K DC Total estimated cost - \$425,000	Two year grant
Total grants related to COVID-19 submitted by the Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM is estimated at \$4,724,828. These grants depend on importation of SARS-CoV-2 in the State of Hawaii for conducting research in the BSL-3 facility at JABSOM, UHM						

UNIVERSITY OF HAWAII AT MANOA

John A. Burns School of Medicine

Department of Tropical Medicine, Medical Microbiology and Pharmacology

April 5, 2020

Inspector
State of Hawaii, Department of Agriculture
Plant Quarantine Branch
1849 Auiki Street
Honolulu, Hawaii

RE: Import Permit for non-Select Agent Coronaviruses – request for expedited review

Dear Inspector:

As of today, 371 COVID-19 cases have been detected and four COVID-19- associated death have been reported in Hawaii. In response to the current COVID-19 pandemic, the Department of Tropical Medicine, Medical Microbiology, and Pharmacology, John A. Burns School of Medicine, University of Hawaii has initiated wide variety of research projects to combat the disease, and to further basic knowledge. As part of this response, we request the importation of non-select agent coronaviruses. It is imperative that we study not only the current SARS-CoV-2, but compare its pathogenesis with other coronaviruses within the family.

We are requesting an expedited review of our application per Emergency Importation Rules. Importation of the authentic virus of known sequences is imperative to conduct this research.

Please contact me if you need additional information.

I appreciate your assistance.

Aloha,



Vivek R. Nerurkar, D.M.L.T., M.Sc., Ph.D.
Professor and Chair
Department of Tropical Medicine, Medical Microbiology and Pharmacology
Director Biocontainment Facility
Cell - 808-753-6961

Attachment – PQ7 form.

cc: Hubert Olipares, BSO UH; Dr. Eileen Nakano, Supervisor, JBF, JABSOM, UHM

651 Ilalo Street, BSB 320G
Honolulu, Hawaii 96813
Telephone: (808) 692-1668 • Facsimile: (808) 692-1980/ (808) 692-1984
E-mail: nerurkar@hawaii.edu • Websites: <http://t3mp.jabsom.hawaii.edu/>; <http://pceidr.jabsom.hawaii.edu/>

Curriculum Vitae**Vivek R. Nerurkar, D.M.L.T., M.Sc., Ph.D.****Work Address**

Department of Tropical Medicine, Medical Microbiology and Pharmacology,
 John A. Burns School of Medicine, University of Hawaii at Manoa, 651 Ilalo Street
 BSB 320G, Honolulu, Hawaii 96813.
 Telephone (808) 692-1668, Cell (808) 753-6961, Fax (808) 692-1980/1984,
 E-mail: nerurkar@hawaii.edu,
 Web Sites: <http://manoa.hawaii.edu/tropicalmedicine/>
<http://pceidr.jabsom.hawaii.edu/>

Home Address

3216 Oahu Avenue, Honolulu, Hawaii 96822. Telephone (808) 988-2797

Education

- | | | |
|------|----------|---|
| 1980 | B.Sc. | Biology, Chemistry, Physics; First Class; University of Bombay, Bombay, India |
| 1981 | D.M.L.T. | Diploma in Medical Laboratory Technology; University of Bombay, Bombay, India |
| 1983 | M.Sc. | Zoology (Animal Physiology); First Class; University of Bombay, Bombay, India |
| 1987 | Ph.D. | Applied Biology (Cell and Molecular Biology). Comparative Oncology Unit, Cancer Research Institute, University of Bombay, Bombay, India |

Professional History

- | | |
|-----------|---|
| 1981 | Technical Assistant, Department of Pathology and Clinical Biochemistry, Lokmanaya Tilak Medical College and Hospital, Bombay, India |
| 1981-1983 | Technical Assistant, Indian Red Cross, Bombay, India |
| 1987 | Research Associate, Department of Cell and Developmental Pathology, Cancer Research Institute, Bombay, India |
| 1987-1989 | Research Associate, Cancer Center, University of Rochester, Rochester, New York |
| 1989 | Postdoctoral Fellow, Department of Biological Sciences, State University of New York at Buffalo, Buffalo, New York |
| 1989-1992 | Visiting Fellow, Fogarty International Center (FIC), Laboratory of Central Nervous System Studies (LCNSS), National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health (NIH), Bethesda, Maryland |
| 1992-1993 | Visiting Associate, FIC, LCNSS, NINDS, NIH, Bethesda, Maryland |
| 1993-1994 | Guest Researcher, FIC, LCNSS, NINDS, NIH, Bethesda, Maryland |
| 1994-1996 | Assistant Researcher (Virology), Retrovirology Research Laboratory (RRL), Pacific Biomedical Research Center (PBRC), University of Hawaii at Manoa (UHM), Honolulu, Hawaii |
| 1995-2003 | Acting Director, RRL, PBRC, UHM, Honolulu, Hawaii |
| 1996-2003 | Associate Researcher (Virology), RRL, PBRC, UHM, Honolulu, Hawaii |

1996-2000	Associate Professor, Interdisciplinary Biomedical Sciences Graduate Program, UHM, Honolulu, Hawaii
1998-1999	Associate Professor, Department of Epidemiology, School of Public Health, UHM, Honolulu, Hawaii
1999-2003	Associate Professor, Department of Public Health Sciences and Epidemiology, John A. Burns School of Medicine (JABSOM), UHM, Honolulu, Hawaii
2000-2003	Associate Professor, Cell and Molecular Biology (CMB) Graduate Program, and Tropical Medicine and Medical Microbiology (TMMM) Graduate Program, JABSOM, UHM, Honolulu, Hawaii
2001-2003	Associate Professor, Microbiology Department Graduate Program, College of Natural Sciences, UHM, Honolulu, Hawaii
2001-2006	Activity Leader, Pathobiology of HIV-Associated Disorders, NIH-NCRR Research Centers in Minority Institutions (RCMI) Program, JABSOM, UHM, Honolulu, Hawaii
2002-2003	Associate Professor, Molecular Biosciences and Biosystems Engineering (MBBE) Graduate Program, College of Tropical Agriculture and Human Resources UHM, Honolulu, Hawaii
2002-2004 (Sept.)	Member, PBRC Executive Committee, PBRC, UHM, Honolulu, Hawaii
2002-2003	Director, RRL, PBRC/JABSOM, UHM, Honolulu, Hawaii
2003 (July)	Researcher (Virology), RRL, PBRC, UHM, Honolulu, Hawaii
2003 (September)-	Professor, Department of Tropical Medicine and Medical Microbiology, JABSOM, UHM, Honolulu, Hawaii
2003-	Professor, Microbiology, CMB, MBBE, TMMM, and Epidemiology Graduate Programs, UHM, Honolulu, Hawaii
2003-2008	Director Technical Core, Pacific Center for Emerging Infectious Diseases Research, Center of Biomedical Research Excellence NIH-NCRR, JABSOM, UHM, Honolulu, Hawaii
2005 (July)-	Professor (Tenured), Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM, Honolulu, Hawaii
2006-2008	Associate Activity Leader, Tropical Infectious Diseases Detection and Prevention Core (TDDPC) activity, NIH-NCRR RCMI, JABSOM, UHM, Honolulu, Hawaii
2008-present	Core Director, BSL-3/ABSL-3, COBRE, PCEIDR, NIH/NIGMS, JABSOM UHM, Honolulu, Hawaii
2008 (August)- 2011	Activity Leader, TDDPC activity, NIH-NCRR RCMI Program, JABSOM, UHM, Honolulu, Hawaii
2008 (November)-2010	Interim Chair, Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM, Honolulu, Hawaii

- 2009-2010 President-Elect, American Society for Microbiology Hawaii Chapter, Honolulu, Hawaii
- 2009 (February)- Director, Biocontainment Facility, JABSOM, UHM, Honolulu, Hawaii
- 2010 (January)- Chair, Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM, Honolulu, Hawaii
- 2010 - 2011 President, American Society for Microbiology Hawaii Chapter, Honolulu, Hawaii

Training Courses

- 1983 "Techniques in immunohaematology and blood bank serology", conducted by the Institute of Immunohaematology, Indian Council of Medical Research, Bombay, India
- 1984 "Safety aspects in the research applications of ionizing radiations", conducted by the Bhabha Atomic Research Center, Bombay, India
- 1985 Molecular biology techniques: To isolate and characterize canine mammary tumour virus. Supervisor: Dr. M.R. Das, Assistant Director, Center for Cellular and Molecular Biology (CCMB), Hyderabad, India
- 1986 Molecular biology techniques: To isolate and characterize retrovirus from mammary tumours and normal milk from canines. Supervisor: Dr. M.R. Das, Assistant Director, Center for Cellular and Molecular Biology, Hyderabad, India
- 1990 "Basic cell and tissue culture training course", conducted by The Foundation for Advanced Education in the Sciences, Inc., NIH, Bethesda, Maryland
- 1992 "Future technologies for DNA analysis", conducted by the Armed Forces Institute of Pathology, Washington D.C.
- 1992 "Introduction to DOS and WordPerfect for Windows", conducted by the Computer Training Center, NIH, Bethesda, Maryland
- 1993 "Advanced Recombinant DNA Technology Workshop", conducted by the American Type Culture Collection, Rockville, Maryland
- 1993 Molecular Cytogenetics Workshop: Introduction to chromosome *in situ* analysis; Oncor, Inc., Gaithersburg, Maryland
- 1996 "AMPLICOR™ PCR HIV Monitor (RNA Quantitation)" conducted by Roche Diagnostics Systems, Somerville, New Jersey
- "The Complete Guide to The Clinical Mycobacteriology Laboratory" conducted by National Laboratory Training Network, Berkeley, California, U.S.A.
- 2000 "Survival Skills and Ethics Program" conducted by University of Pittsburgh and the NINDS, NIH, Vail, Colorado, U.S.A.
- 2002, 2005 "Grantsmanship Training Workshop" conducted by Federation of American Societies for Experimental Biology (FASEB), University of Hawaii at Manoa, Honolulu, Hawaii, U.S.A.

- 2003 Attended the Career Development Technical Assistance Workshop sponsored by the National Institute of Neurological Disorders and Stroke, NIH from March 31–April 1, 2003, Washington, DC.
- 2004 “Neuroinformatics Workshop” conducted by US-Japan Brain Research Cooperative Program, Hawaii, Hawaii, U.S.A.
- 2005 “Design and Construction of BSL3 and BSL-3 Seminar Series” conducted by the Eagleson Institute, Atlanta, Georgia, U.S.A. February 7-11, 2005.
- 2008 I. Biosecurity/Crisis & High Stakes Communication; II. Biosafety with Risk Assessment Communication. Six-hours workshop conducted at UHM-JABSOM by Dr. Louise Barden, CDC, Atlanta, GA. May 12 and 14, 2008.
- 2009 BSL-3 Training. Two-hours seminar conducted at UHM-JABSOM by Dr. Robert Ellis, American Biological Safety Association President and Colorado State University Biosafety Program Director. February 26, 2009.
- 2009 NCRR Core Facilities Workshop conducted by NCRR at the Natcher Auditorium, NIH, Bethesda. July 14-16, 2009.
- 2009 Six-hour BSL-3/ABSL-3 training workshop conducted by UHM-Biosafety Office. November 30, 2009.
- 2010 Preventing and Treating Biological Exposures Colloquium Conducted by Eagleson Institute, June 14-15, 2010, Cambridge, Massachusetts.
- 2012 Invitation to attend NIH Rocky Mountain Regional Center of Excellence (RMRCE) for Biodefense and Emerging Infectious Diseases Research sponsored “Viral Encephalitis Workshop” at Utah State University in Logan, Utah on April 23-24, 2012
- 2014 Advanced BSL3 Work Practices and Procedures at North Carolina State Laboratory of Public Health. Conducted by Eagleson Institute, April 30 - May 1, 2014, Raleigh, North Carolina.

Honors and Awards

- 1980 Ruia Prize for First Class at B.Sc.
- 1980-83 Government open merit scholarship for three consecutive years
- 1983-86 Junior Research Fellowship; Cancer Research Institute, Bombay, India
- 1986-87 Senior Research Fellowship; Lady Tata Memorial Trust, Bombay, India
- 1987 Travel fellowship to pursue higher education in U.S.A., from The Lady Tata Memorial Trust and Sir Dorabji Tata Memorial Trust, Bombay, India
- 1992 Travel award from the Esai Co. Ltd., Tokyo, Japan, to attend the 5th International Conference on Human Retrovirology: HTLV in Kumamoto, Japan
- 1992 Travel award from the Medical Virology Club of the American Society for Virology to attend the annual meeting in Ithaca, New York

- 1994 Travel award from the Medical Virology Club of the American Society for Virology to attend the annual meeting in Madison, Wisconsin
- 1996 Travel award from the University Research Council, University of Hawaii at Manoa to attend the American Society for Virology Annual Meeting in London, Ontario, Canada
- 1997 Travel award from the University Research Council, University of Hawaii at Manoa to attend the 4th International Congress on AIDS in Asia and the Pacific in Manila, Philippines
- 1998 Elected as a Fellow of the Infectious Diseases Society of America
- 2007 Dean's Award for Best Poster in the Faculty Category, Biomedical Sciences Symposium, John A. Burns School of Medicine, University of Hawaii at Manoa, March 13, 2007.

Other Professional Activities

Grant Reviews

- 1997-2000 Grant Review Committee: American Cancer Society Institutional Grant, Cancer Research Center of Hawaii, Honolulu, Hawaii
- 2002 - present Member of the Scientific Advisory Board, Clinical Research Center, Kapiolani Medical Center for Women and Children and University of Hawaii. Meets quarterly to review grant applications.
- 2002 Reviewed 145 HIV/AIDS related abstracts for the Eighth RCMI International Symposium on Health Disparities, held in Honolulu, Hawaii.
- 2005 Grants Review Committee, Veterans Affairs Merit Review Subcommittee for Infectious Diseases A, June 10, 2005, Washington, D.C.
- 2004 Grant review member for U.S. Civilian Research And Development Foundation Science Centers Program, Washington D.C.
- 2009 Grant review member for U.S. Civilian Research And Development Foundation Science Centers Program, Washington D.C.
- 2010 Grant review member for U.S. Civilian Research And Development Foundation Science Centers Program, Washington D.C.
- 2010-14 Grant review COBRE EID pilot projects
- 2011 Grant review - The Wellcome Trust/Department of Biotechnology, India.
- 2012-2014 Grant review RTRN, UHM
- 2013-current Grant review member for Hawaii Community Foundation
- 2015 Grant review – RMATRIX, JABSOM, UHM
- 2016 Grant review –ZAI1-UKS-M-S1 –Special Emphasis Panel Special Emphasis Panel for NIAID Rapid Assessment of Zika Virus (ZIKV) complications (R21) NIH/NIAID Study Section

- 2016 Grant review – Florida Department of Health Zika Research Review
Special Emphasis Panel, NIH/NIAID – Rapid Assessment of Zika virus Complications (R21)
- 2018 Special Emphasis Panel, NIH/Fogarty HIV Research Training Programs in Low- and Middle-Income Country Institutions
NIH/NIAID peer review panel for global health applications
- 2019 Special Emphasis Panel, NIH/Fogarty HIV Research Training Programs in Low- and Middle-Income Country Institutions

Dissertation Committees

- 1997 Member of the Ph.D. dissertation committee for Angel Yanagihara, Bekesy Laboratory of Neurobiology – Dissertation title: “A Novel Approach to the Study of Structure-Function Relationships in the Sodium Ion Channel”, Graduated August 1997
- 1998 External Examiner (Ph.D. dissertation): Postgraduate Section, Faculty of Medicine, University of Sydney, NSW 2006, Australia
- 1999 Member of the Ph.D. dissertation committee for Ryuichi Komatsu, Department of Epidemiology, School of Public Health, UHM – Dissertation title: “HIV/AIDS Prevention and Control in Vietnam”, Graduated - Summer 2004. Currently employed by the Ministry of Health, Japan as an epidemiologist.
- 1999 External Examiner: Department of Microbiology, College of Natural Sciences, University of Hawaii at Manoa, Honolulu, Hawaii
- 2003 External Examiner (Ph.D. dissertation): Postgraduate Section, Faculty of Medicine, University of Sydney, NSW 2006, Australia
- 2007 External Examiner (Ph.D. dissertation): Postgraduate Section, Faculty of Medicine, University of Sydney, NSW 2006, Australia
- 2008 Chair of the Ph.D. dissertation committee for Jason Barnhill, Department of Cell and Molecular Biology, JABSOM, UHM.
- 2009 Member of the M.S. dissertation committee for Kelsey Roe, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “ Characterization of the markers of blood-brain barrier disruption in West Nile virus infected mice”, Graduated May 2011
- 2011 Member of the Ph.D. dissertation committee for Kelsey Roe, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “ A role of triggering receptor expressed on myeloid cells (TREM) in the innate immune defense against flavivirus infection”, Graduated in May 2016
- 2012 Chair of the Ph.D. dissertation committee for Kenji Obadia Mfuh, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “Infectious etiologies of febrile illnesses in Cameroon”, Graduated in May 2017
- 2012 Member of the Ph.D. dissertation committee for Pavlos Anastasiadis, Department of Molecular Biosciences and Bioengineering – Dissertation title: “ FLNa complex

- regulates vascular permeability under flow-induced shear stress”, Graduated in May 2015
- 2013 Member of the M.S. dissertation committee for Jacob Nelson, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “Novel antiviral and histone deacetylase inhibitors increase survival of WNV-infected mice”, Graduated in May 2015
- 2014 Member of the Ph.D. dissertation committee for Alanna Tseng, Department of Molecular Biosciences and Bioengineering – Dissertation title: “A novel role for West Nile virus non-structural protein 1 in the biogenesis of vesicle packets for viral RNA synthesis”, Anticipated graduation in Spring 2020
- 2014 Chair of the M.S. (Plan B) dissertation committee for Priscilla Seabourn, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “Epigenetic regulation of archetype and rearranged human polyomavirus JCV”, Graduated in December 2016
- 2015 Member of the M.S. dissertation committee for David Siemann, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “Zika virus infects human sertoli cells and trespasses the blod-testis barrier to gain entry into the seminiferous epithelium. Graduated in August 2017
- 2016 Member of the Ph.D. dissertation committee for Sourish Gosh, National Brain Research Center (Deemed University), Dept of Biotechnology, Ministry of Science and Technology, Government of India, Manesar, Haryana, India – Dissertation title: “Deciphering mechanism of neuronal death in Chandipura virus (CHPV) infection: From molecule to network”, Graduated in June 2016
- 2016 Member of the M.S. dissertation committee for Danielle Clements, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “A novel role for West Nile virus non-structural protein 1 in the biogenesis of vesicle packets for viral RNA synthesis”, Graduated in December 2016
- 2016 Chair of the Ph.D. dissertation committee for Lauren Ching, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “Immunopathogenesis of Kawasaki disease”, Anticipated graduation in Fall 2020
- 2016 Chair of the M.S. dissertation committee for Michelle Fisher, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “*Histone deacetylase inhibitors modulates human polyomavirus JC replication.*” Graduated: Spring 2019.
- 2018 Member of the Ph.D. dissertation committee for Daniel Strange, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “In vitro and in vivo investigation of Zika virus persistence in the human testes”, Anticipated graduation in May 2020
- 2019 Member of the Ph.D. dissertation committee for Thomas Premeaux, Department of Tropical Medicine, Medical Microbiology and Pharmacology – Dissertation title: “Defining the role of galectin-9 in HIV and aging in the era of ART.” Anticipated graduation in May 2020

Manuscript Reviews

Manuscript review: *AIDS Research and Human Retroviruses* (1998, 1999); *American Journal of Tropical Medicine and Hygiene* (1998-2002), *Antiviral Research* (2008), *Heart and Vessels* (2007); *International Journal of Infectious Diseases* (1999, 2000); *Clinical Infectious Diseases* (2002, 2004), *Neurology* (2002); *Emerging Infectious Diseases* (2003, 2005, 2006), *Journal of Molecular Evolution* (2003); *European Journal of Immunogenetics* (2004); *Cancer Therapy* (2004), *Clinical Biochemistry* (2002, 2004); *Journal of General Virology* (2008); *Journal of Virological Methods* (2007, 2008), *Journal of Medical Virology* (2005, 2006, 2008), *Journal of NeuroVirology* (2009). Due to other time commitments, since 2010, I have reviewed maximum three manuscripts per year. For invited manuscript reviews I have requested the editors to send them to our departments junior faculty.

Invited Seminars and Membership of Working Groups

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| 1998 | Member of the Hepatitis Working Group of the Virology PSG, Adult Clinical Trials Group, National Institute of Allergy and Infectious Diseases, NIH, Bethesda, Maryland |
| 1999 | Invited Speaker: National Institute of Virology, Pune, India, January 6, 1999. Title: Molecular Epidemiology of HIV and HCV Infection in Asia Pacific |
| 1999 | Grand Rounds Invited Speaker at the 12 th Annual Kapiolani Health Research Symposium, Kapiolani Medical Center for Women and Children, Honolulu, Hawaii, June 7-18, 1999. Title: GB Virus C/Hepatitis G Virus and TT Virus: Molecular Epidemiology of Two Recently Described Orphan Viruses. |
| 1999 | Invited Speaker: Department of Microbiology, College of Natural Sciences, University of Hawaii at Manoa, Honolulu, Hawaii, September, 1999. Title: GB Virus C/Hepatitis G Virus and TT Virus: Molecular Epidemiology of Two Recently Described Orphan Viruses |
| 1999-2001 | Member of the Hawaii Advisory Committee for Elimination of Tuberculosis, Subcommittee on Tuberculosis Diagnostic Laboratory Issues, Hawaii Department of Health, Honolulu, Hawaii |
| 2000 | Invited to participate as a member of the U.S. AIDS Panel of the US-Japan Cooperative Medical Sciences Program (Regional Emerging Infectious Disease Workshop, January 7-9, 2000) in Chennai, India, and Indo-US Bilateral HIV/AIDS Workshop (January 11-12, 2000) in Chennai. |
| 2000 | Invited to participate as a U.S. panel member and present my research in the U.S.–Japan Cooperative Medical Science Program, 12 th Joint Scientific Meeting of the AIDS Panel, March 22-24, 2000, Santa Fe, New Mexico. |
| 2000 | Grand Rounds Invited Speaker at the 13 th Annual Kapiolani Health Research Symposium, Kapiolani Medical Center for Women and Children, Honolulu, Hawaii, June 15, 2000. Title: Role of JC Virus (JCV) in the Pathogenesis of Progressive Multifocal Leukoencephalopathy (PML) |
| 2000 | Invited Speaker: Cell and Molecular Biology Program in Biomedical Sciences, Graduate Division, University of Hawaii at Manoa, Honolulu, Hawaii, February 15, 2000. Title: “Search for the Etiology of Orphan Diseases and Orphan Microbes” |
| 2000 | Invited Speaker: Hawaii Biotechnology Group, Inc., Aiea, Hawaii, February 16, 2000 Title: Molecular Epidemiology of HIV-1 Infection: Vignettes from Asia and the Pacific |
| 2001 | Jointly organized the First Neurovirology Symposium at UHM, January 18, 2001 |

- 2002 Chair, HIV/AIDS session, Eighth RCM International Symposium on Health Disparities, Honolulu, Hawaii.
- 2003 Invited to participate as a member and co-chair of the U.S. AIDS Panel of the US-Japan Cooperative Medical Sciences Program's 8th International Conference on Emerging Infections in the Pacific Rim, December 11-13, 2003 in Dhaka, Bangladesh.
- 2004 Invited to participate as a U.S. panel member and present my research in the Joint Meeting of the U.S.-Japan Cooperative Medical Science Program, 14th Joint Scientific Meeting of the AIDS Panel, March 8-10, 2004, Nashville, Tennessee.
- 2004 Chair of the Epidemiology of Polyomaviruses Session, 2nd International Conference: Polyomaviruses and Human Diseases: Basic and Clinical Perspectives, June 11-13, 2004, Sapporo, Japan.
- 2004 Convenor for the Papilloma, Polyoma and Circoviruses Session at the 23rd Annual American Society for Virology Meeting, July 10-15, 2004, Montreal, Canada.
- 2004 Judge for the Hawaii Chapter of the American Society for Microbiology Spring 2004.
- 2004 Served on three UHM Academic Grievance Committees in 2003-2004.
- 2006-2009 Member, Dean's Appointment, Promotion and Tenure Review Committee, JABSOM, UHM.
- 2006 Chair, Department Tenure and Promotion Committee, Department of Tropical Medicine, Medical Microbiology and Pharmacology, JABSOM, UHM, Appointment, Promotion and Tenure Review Committee.
- 2006 Member, Tenure and Promotion Review Committee, UHM.
- 2007 Chair, Tenure-track Pharmacologist Selection Committee, JABSOM, UHM.
- 2007 Symposium - Interactions Among Infectious Agents, Environmental Carcinogenesis, and Genetics in Human Cancer Development arranged by JABSOM and CRCH, UHM. Chairpersons Michele Carbone and Vivek R. Nerurkar, JABSOM Kakaako Auditorium, February 16, 2007.
- 2008 Chair, Tenure-track Virologist Selection Committee, JABSOM, UHM.
- 2008 Chair, HIV/AIDS session, 11th RCM International Symposium on Health Disparities, Honolulu, Hawaii.
- 2009 Chair, Post-Tenure Review Committee, JABSOM, UHM.
- 2009-2011 Chair, Dean's Appointment, Promotion and Tenure Review Committee, JABSOM, UHM.
- 2011-2012 Co-Chair, Dean's Appointment, Promotion and Tenure Review Committee, JABSOM, UHM.
- 2009 Invited to participate in the Translational Cancer Care Symposium, Preventive and Therapeutic Opportunities In Gene-Environment Interaction and Immunotherapy arranged by JABSOM and CRCH, UHM. Invited Speaker *Dr. Harald zur Hausen, 2008 Nobel Laureate in Physiology and Medicine*. The Queen's Conference Center,

	February 17 & 18, 2009. Title - Suppression of Polyomavirus JC Replication by Soluble Factors From Activated T-cells: Implications for Progressive Multifocal Leukoencephalopathy Therapy
2010-11	Member, UH Tenure and Promotion Review Committee
2010	Member, JABSOM Research Director selection committee.
2011-13	UH Compliance Office, Member Permit Review Committee. Chair Dr. Sylvia Yuen.
2012	Ad hoc DPC Member, Department of Obstetrics and Gynecology, JABSOM, UHM.
2012	Convenor for the Flavivirus session at the 31 st Annual American Society for Virology Meeting, July 21-25, 2012, University of Wisconsin-Madison, Madison, WI.
2012	UHM Member of the Faculty Advisory Committee on Academic Freedom. July-August 2012
2013	Convenor for the Flavivirus session at the 32 nd Annual American Society for Virology Meeting, July 20-24, 2013, Pennsylvania State University, PA.
2013	Chair, Post-Tenure Review Committee, JABSOM, UHM.
2013-2014	Ad hoc DPC Member, Department of Pathology, JABSOM, UHM.
2014	Ad hoc DPC Member, Department of Anatomy and Physiology, JABSOM, UHM.
2014	Chair, Post-Tenure Review Committee, JABSOM, UHM.
2014	Member, JABSOM Research Director selection committee.
2014-15	Member, UH Promotion Review Panel
2016-2018	Member, JABSOM Admissions Committee
2018 -	Member Internal Advisory Committee. PBRC/UHM – Centers of Biomedical Research Excellence (COBRE) - Integrative Center for Environmental Microbiomes and Human Health
2019	Member University of Hawaii Advisory Committee - Society for Advancement of Chicanos/Hispanics and Native Americans (SACNAS) Conference. October 31 to November 2, 2019, Honolulu, Hawaii
2019 -	Member UH System Global Health and Social Justice Working Group. Meets four times a year.

Instructional Activities

Spring 2001-present	TRMD605 Infectious Disease Micro II (3 credits), Lecturer, Spring semester, one class Title: Retroviruses II; HTLV-I, -II, JC virus and BK virus. Since 2009 I teach this class along with Dr. Wang and other faculty. In 2010, when I was appointed Department Chair, I completely revamped this class and other tropical medicine classes. Focus was to move away from didactic teaching to PBL-based teaching. This class is now taught by other faculty in the department.
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- Fall 2003- present TRMD 607 Advances in Neurovirology (1 Credit) - Designed and conducted the first Neurovirology seminar course at the UHM. Since 2007 this course has focused on NeuroAIDS in collaboration with Johns Hopkins University R25 grant. Since 2014 the course was offered for 2 credits.
- Fall 2003 - 2014 PHS792T Current issues in Public Health, Infectious Diseases of Public Health Importance (1 credit), Lecturer, Fall semester, I gave a 90-min lecture.
- Spring 2004, 2005 PHS792T Current issues in Public Health Infectious Diseases of Public Health Importance (1 credit), Lecturer, Spring semester, I gave a one-hour lecture.
- Fall 2004, Spring 2005
Spring 2006 and 2008 TRMD690/PHS755 Seminars in Tropical Medicine (1 Credit) – Designed and conducted the seminar course.
- Spring 2006 PHS696 Continuing Education in Public Health: Overview of current topics relating to environmental risks to public health (1 credit), one-hour lecture.
- Fall 2007 - present TRMD 672 Advances in Virology (2 credits). I reformatted this course with assistance from other faculty and team-taught with Dr. Arwind Diwan and Mr. Joe Elm. In 2010, when I was appointed Department Chair, I completely revamped this course and other tropical medicine courses. Focus was to move away from didactic teaching to PBL-based teaching. Since 2010, I co-teach this class with Dr. Wang and other department faculty.
- Fall 2007, 2008 Participated in Problem Based Learning course (TRMD 705) along with Dr. Sandra Chang. Two hours per week for three weeks.
- Summer 2010, 2011,
2012, 2013 Lecturer, MEDT 591 (Medical Technology), Clinical Training Didactic Sessions
- Spring 2011 – present Lecturer PHS666 (Public Health), Seminar in Infectious Disease Control – Dengue virus
- Spring, Summer
2014 –present Instructor for Minority Health International Research Training (MHIRT) Program (TRMD 440, 441, 442; total 10 credits). Between September and January advertise, interview and accept undergraduates and graduate students in the MHIRT program. From January to May meet and work with students for 2 hrs a week (5:30 to 7:30 PM) to implement the MHIRT curriculum. In May conduct a 5 days, 8 hours a day, pre-travel workshop. Monitor and work with students remotely for 8 to 10-weeks (May to July) when they conduct research at their international destinations. In August conduct a 5 days, 8 hours a day, post-travel workshop to analyze and finalize data, prepare final report, posters and seminars for presentation during the faculty, peers, family and friends get together. For past 6 years we have trained 60 undergraduate and graduate students who are ethnic minorities underrepresented in science or have socioeconomically disadvantaged background.
- Fall 2011, 2012, 2013,
2014 Lecturer, MD6 (Infections of the Nervous System). I started teaching this course in 2011. For past 2 years the course is co-taught along with department faculty.
- Spring and Fall
2007 - present Member, Tropical Medicine Qualifying Examinations.

2006 - present	Member, Tropical Medicine Graduate Students Admission committee, TMMMP, JABSOM, UHM
2007- present	Member, Tropical Medicine Curriculum Development Committee, TMMMP, JABSOM, UHM
2007- present	Member, Tropical Medicine Awards Committee, TMMMP, JABSOM, UHM
Spring 2019	TRMD690/PHS755 Seminars in Tropical Medicine (1 Credit). Taught with assistance from Dr. Chang.

Apart from participating in teaching activities, I interact with Tropical Medicine Graduate Program Chair and faculty routinely to go over the courses and address any faculty or students related issues. In 2016 we successfully completed the 5-year Tropical Medicine Graduate Program review.

Membership in Professional and Scientific Societies

1991	American Society of Tropical Medicine and Hygiene
1992	American Society for Virology
1992	Indian Association for Cancer Research
1995	American Society for Microbiology
1995	American Society for Microbiology (Hawaii Chapter)
1998	Infectious Diseases Society of America

Workshops and Field Research

1996	Visited Christian Medical College, Vellore, Tamil Nadu, India for collection and processing of specimen from HTLV-I and HIV-infected patients.
1998	Training Program in Public Health and Prevention Research for HIV Control in Vietnam, National Institute of Hygiene and Epidemiology, Hanoi Vietnam, May 25 to June 15, 1998: Conducted a one-week HIV/AIDS Polymerase Chain Reaction workshop. Collected and processed specimens from HIV-infected individuals from northern provinces of Vietnam.
1999	Visited An Giang Province and Hanoi, Vietnam. Collected and processed specimens from HIV-infected individuals from Vietnam.
2014	Visited Mahidol University, Bangkok, Thailand and University of Malaya, Kuala Lumpur, Malaysia to initiate collaborative HIV and flavivirus related research activities.
2015	Organized the Northern Pacific Global Health (NPGH) Program sponsored HIV: Qualitative Research Methods – Social and Behavioral Sciences Workshop from January 12-13, 2015 at the Thai Red Cross AIDS Research Center (TRCARC) in Bangkok, Thailand. Organized along with NPGH PI and Chief of TRCARC.
2015	Visited Dean, Faculty of Tropical Medicine, Mahidol University, Bangkok, Thailand to initiate collaborative flavivirus related training and research activities, and grant submission.

2016

Visited University of Ponce and University of Puerto Rico, Puerto Rico, Faculty and PIs of various NIH grants from November 18-21, 2016 to establish Zika virus research collaboration between Puerto Rico and Hawaii.

Research Interests

Virology, Neurovirology, Neurooncology, Neurotoxicology, Immunopathogenesis of retroviral diseases, Etiology of infectious diseases, Molecular epidemiology and evolution

Patent

U.S. Patent application filed on February 28, 1991; application serial no. 7/662,368 entitled "Solomon Islands Variants of Human T Lymphotropic Virus Type I". Cell line, SI-5 (CRL 10683), deposited with the American Type Culture Collection on February 8, 1991. U.S. Patent application serial no. 8/095,043 entitled "Solomon Islands Variants of Human T Lymphotropic Virus Type I": Allowance denied on September 19, 1994.

Yanagihara R, Nerurkar VR, Jenkins CL, Miller MA and Garruto RM. Human T-cell line persistently infected with a Papua New Guinean variant of human T-lymphotropic virus type I. United States Patent and Trademark Office, Patent number 5,397,696; March 14, 1995.

Funding Record

ONGOING RESEARCH SUPPORT

1U01GH002256-01 (Lehrer) NIH/NIMHD <i>Epidemiology and immunity to Ebola virus and other emerging viral infections in Liberia</i> Goal is to establish a serological baseline for a future surveillance platform, allowing the study of underlying etiologies, characteristics, and response to emerging infections. Role: Co-investigator	09/30/19-09/29/24	1.2 CM
AHA 18TPA34230081 (Bratincsak) American Heart Association <i>Doxycycline treatment to prevent coronary artery lesions in Kawasaki disease</i> The aim of this study is to complete a randomized placebo-controlled double-blinded clinical trial on assessing the efficacy of doxycycline to prevent coronary artery dilation and aneurysm in Kawasaki disease. Role: Collaborator	07/01/18-06/30/21	0.6 CM
5R21DE027235-02S3 (Campos Maribel, UPR) NIH/NIMHD <i>Dental and craniofacial effects of intrauterine Zika virus infection</i> The goal of this proposal is to characterize the outcome of maternal Zika virus infection on craniofacial skeletal and dental phenotype in infants with or without microcephaly at birth. Role: UHM Consultant	09/01/17-08/31/20 \$250,000	0.3 CM
1R21 AI11072-01-A1 (Dennis Grab, USUHS) NIH/NIAID <i>LAMPoles for dengue diagnosis</i> The goal of this proposal is to link three (3) powerful technologies - LAMP, 'tadpoles' and Nanobodies (Nbs) - to create a dynamic protein-DNA chimera-based diagnostic for detection of dengue with high specificity and sensitivity compared with existing technologies. Role: Consultant	06/01/15-05/31/20 \$248,111 (direct cost)	Consultant
5P30GM114737-04 (Yanagihara) NIH/NIGMS <i>Pacific Center for Emerging Infectious Diseases Research</i> The goal of this COBRE proposal is to augment and strengthen the infectious diseases-related research capacity at the UHM and to expand and develop biomedical faculty research capability and enhance research infrastructure through support of a multi-disciplinary infectious disease program. Role: Director Biocontainment Core and Mentor since 2003	07/01/15-06/30/20	1.2 CM
5R25MH080661-09 (McArthur, Johns Hopkins) NIH/NIMH <i>Translational Research in Neuro-AIDS and Mental Health (TR-NAMH): An innovative mentoring program to diversify workforce</i> The goal of this multi-institutional project is to improve the capacity of high quality research by developing mentoring programs for doctoral and post doctoral candidates and junior faculty from racial and ethnic minorities and non-minority individuals at the same levels, whose research focusses on Neuro-AIDS disparity issues. Role: Mentor University of Hawaii site since 2007	02/01/07-01/31/20 \$243,761	0.3 CM
1D71TW010434-01 (Nerurkar and Weeks – MPI) NIH/FIC <i>Sustainable Research Training and Capacity Building in Liberia for Emerging Viral Epidemics</i>	09/01/17-08/31/20 \$50,000	1.2 CM

The goal of this project is to partner with faculty at the Univ of Liberia (UL) to establish a creative training program with the goal of garnering interest and improving teaching and student learning experience in biomedical sciences at UL, and providing training in the conduct of research on emerging viral epidemics.

Role: MPI (Contact) and Mentor University of Hawaii Site

5D43TW009345-07 (Prasad, Kolaras, Nerurkar, Zunt - MPI) 04/04/12-06/30/22 1.2 CM
NIH/FIC

Northern/Pacific Universities Global Health Research Training Consortium

The goal of this project is to provide outstanding mentored research training to post-doctorate trainees and doctoral students at six international partner institutions with robust clinical research programs and exceptional histories of training Fogarty International Clinical Research Scholars and Fellows and strengthen global health research programs to help globalize the research portfolios of all of the sponsoring NIH ICs, and develop sustainable multidisciplinary partnerships between the four Consortium institutions and institutions in the six international partnering countries.

Role: MPI and Mentor University of Hawaii Site

5P20GM125508-02 (Mc Fall-Ngai & Ruby) 08/15/18-07/31/23 non-measurable effort
NIH/NIGMS

Integrative Center for Environmental Microbiomes and Human Health

The proposed projects aim to address two critical and intertwined health problems: the deteriorating environment, and the current spread of insect-vector borne diseases.

Role: IAC Member

5K12HL143960-02 (Shikuma, Seto, Ndhlovu) 08/01/18-06/30/23 non-measurable effort
NIH/NIMHD

Hawaii interdisciplinary mentored career development in HIV Co-morbidities

The long-term objective of this K12 program is to establish a cadre of research competitive junior investigators in HIV heart, lung, blood and sleep research.

Role: Mentor

5T37MD008636-06 (Nerurkar and Kaholokula- MPI) 12/01/13-11/30/23 1.2 CM
NIH/NIMHD

Transdisciplinary Health Disparities Research Training for Native Hawaiians and Pacific Students

The goal is to increase the number of Native Hawaiians and Pacific Students who are trained in research incorporating a diversity of ideas, culture, and talents while tailoring their research to be community and culturally sensitive.

Role: MPI (Contact) and Mentor

5R25DK078386-13 (Hui) 06/01/07-02/28/22 0.3 Calendar
NIH/NIDDK

High School Students STEP-UP to Biomedical Research

The goal of this project is to provide research exposure and training for high school students of ethnic minority or the socio-economically disadvantaged. The purpose is to extend the pipeline of opportunities to the high school students in order to provide a continuum of support and fostering for these under-represented individuals.

Role: Mentor for University of Hawaii Site

PENDING

1R21AI154042-01 (Melendez, Univ. of Puerto Rico) 06/01/20-05/31/22 0.3 CM
NIH/NIAID

Role of placenta cystatin B in mother-to-child transmission of Zika virus

Using clinical data, placenta pathology, virology, and proteomic approaches we propose to elucidate the role of *cystatin B* (CTS_B) in ZIKV vertical transmission. We will determine if CST_B is deregulated in ZIKV infection of placental cells and if CST_B expression affects ZIKV replication and interferon type 1 (*IFN-1*) responses.

Role: Collaborator and PI for University of Hawaii Site

Vivek R. Nerurkar, Ph.D.
Curriculum Vitae, Page 15
April 2020

R61HL144892-01A1 (Bratincsak, Melish, Nerurkar, Shohet) 04/01/20-03/31/24 0.6 CM
 NIH/NHLBI Score 31
DEAL Study (Doxycycline Efficacy in Preventing Coronary Artery Lesions in Children with Kawasaki Disease)
 Our goal is to test a 3-week course of oral doxycycline during the acute phase of KD, which will prevent the progression of *coronary artery lesions*, and prevent elastin degradation by inhibiting matrix metalloproteinases (MMP) activity by decreasing level of circulating soluble elastin fragments and MMPs.
 Role: MPI

AHA Predoctoral Application for Ms. Lauren Ching 04/01/20-03/31/22 0.3 CM
 American Heart Association
Pentraxin 3 as a modulator of the vascular dysfunction in Kawasaki Disease
 Our goal is to define the function of entraxin-3-associated vascular dysfunction in formation of coronary artery lesions (CAL) and understand the mechanism by which doxycycline ameliorates KD-associated CAL.
 Role: Mentor

DoD PRMIIRA CDMRP (Grab Dennis, USUHS) 04/01/20-03/31/23 0.3 CM
 NIH/NIAID
Camelid nanobodies as anti-dengue virus therapeutics
 Overall objective is to develop nanobodies based therapeutics than can protect military and civilian personnel at-risk of DENV exposure and reduce burden of transmission of virus by non-symptomatic carriers.
 Role: Collaborator and PI for University of Hawaii Site

IU01 (Kanki Phyllis, Harvard) 04/01/20-03/31/24 0.6 CM
 NIH/NIAID
West Africa-Research on Emerging Infectious Disease Initiative" (West Africa-REIDI)
 This project focuses on seroepidemiology, virus detection and virus isolation in various West African countries with a common goal to build and connect regional research laboratories.
 Role: Collaborator

1R21AI137889-01A1 (Kaufusi, Nerurkar) 04/01/20-03/31/22 1.2 CM
 NIH/NIAID
Identifying novel flaviviral targets for antiviral drug discovery
 Goal is to characterize the viral and host proteins that promote the movement of NS3 and NS5 and reduce the effectiveness of inhibitors currently being tested.
 Role: MPI

GRANT APPLICATIONS SUBMITTED BUT NOT FUNDED

R01AI151154-01 (Sharma Anuj, USUHS) 04/01/20-03/31/24 1.2 CM
 NIH/NIAID \$1,000,000
Gamma-irradiated Zika virus vaccine for protection against in-utero transmission of the virus
 The goal of this proposal is to develop an inactivated-ZIKV vaccine where inactivation is performed by very high doses of gamma-radiations generating reliably inactivated virus.
 Role: Co-investigator (UH PI)

1D43TW011280-01A1 (Lehrer) 03/01/20-06/30/25 1.2 CM
 NIH/FIC
Sustainable Research Training and Capacity Building in Liberia for Emerging Viral Epidemics
 The goal of this project is to partner with faculty at the Univ of Liberia (UL) to establish a creative training program with the goal of garnering interest and improving teaching and student learning experience in biomedical sciences at UL, and providing training in the conduct of research on emerging viral epidemics.
 Role: Co-investigator

GRANT12712305 for PR181571– CDMRP/DoD (Nerurkar) 08/01/19-07/31/22 1.2 CM

Gamma-radiation Inactivated Zika Virus Vaccine: Novel approach for Improved Safety and Immunogenicity
The goal of the proposed study is to demonstrate the feasibility of proposed inactivation approach on generating a safe and highly immunogenic ZIKV vaccine candidate.

Role: PI

Hawaii Community Foundation (Nerurkar) 06/01/19-12/31/20 0.6 CM

Pentraxin 3 as a modulator of the vascular dysfunction in Kawasaki Disease

Our goal is to define the function of entraxin-3-associated vascular dysfunction in formation of coronary artery lesions (CAL) and understand the mechanism by which doxycycline ameliorates KD-associated CAL.

Role: PI

1T32AI145814-01 (Nerurkar) 07/01/19-06/30/24 1.2 CM

Basic and Applied Research Training in Tropical Medicine and Emerging Infectious Diseases.

The goal of the proposed training program is to provide research training for University of Hawaii PhD students in tropical medicine and emerging infectious diseases.

Role: PI

1T32 NIGMS (Ramos) 07/01/19-06/30/24 non-measurable effort

Predocutorial Interdisciplinary Biomedical Education Program

The goal of the proposed training program is to provide research training for University of Hawaii PhD students in transdisciplinary research.

Role: Mentor

1D43TW011280-01 (Lehrer) 03/01/19-06/30/24 1.2 CM

NIH/FIC

Sustainable Research Training and Capacity Building in Liberia for Emerging Viral Epidemics

The goal of this project is to partner with faculty at the Univ of Liberia (UL) to establish a creative training program with the goal of garnering interest and improving teaching and student learning experience in biomedical sciences at UL, and providing training in the conduct of research on emerging viral epidemics.

Role: Co-investigator

R21AI137922-01A1 (Sharma Anuj, USUHS) 10/01/18-09/30/20 1.2 CM

NIH/NIAID

\$275,000

Development of a Novel Gamma-irradiated Zika virus vaccine

The goal of this proposal is to develop an inactivated-ZIKV vaccine where inactivation is performed by very high doses of gamma-radiations generating reliably inactivated virus.

Role: Co-investigator (UH PI)

1D43TW010938-01 (Wong, Shikuma, Nerurkar) 04/01/18-03/31/23 1.2 CM

NIH/FIC

T.R.A.I.N. Vietnam (Training Researchers for AIDS Investment Networks)

The long-term goal of this proposal is to increase the number of in-country researchers by establishing the *Training Researchers for AIDS Investment Networks*

Role: Mentor

DEB-1716940 (Novotny) 06/01/17 – 05/31/20 0.60 CM

NSF/Ecology and Evolution of Infectious Diseases (EEID) \$2,500,000

Tropical Island Ecosystems (TIE): modeling of ecological, social, and vector dynamics and outcomes in the context of dengue and Zika virus infections

The goal is to model the ecological and sociological factors influencing mosquito-borne viral infections by collecting information about the entire human population inhabiting a tropical island, Kosrae, in the Pacific Ocean.

Role: Co-PI

1R21AI129193-01 (Lehrer) 06/01/17 – 05/31/19 0.6 CM

Vivek R. Nerurkar, Ph.D.

Curriculum Vitae, Page 17

April 2020

NIH/NIAID	\$412,000	
<i>Development of a Recombinant Subunit Zika Virus Vaccine</i>		
The goal is to develop one formulation of a <i>recombinant</i> subunit ZIKV vaccine allowing rapid vaccination of at-risk populations.		
Role: Collaborator		
1R03AI128564-01 (Kaufusi)	09/01/17 – 08/31/19	0.5 CM
NIH/NIAID	\$100,000	
Project Location – Honolulu, HI		
<i>Identifying Novel Flaviviral Targets for Antiviral Drug Discovery</i>		
The goal is to identify and characterize the West Nile virus proteins that promote the movement of NS3 and NS5 between replication organelle compartments, which may modulate their structures and functions.		
Role: Collaborator		
RTRN- RCMI Pilot Project (Nerurkar)	07/01/16-06/31/17	0.6 CM
NIH/NIMHD	\$50,000	
<i>Zika virus associated microcephaly</i>		
The goal of this proposal is to study the natural history of ZIKV infection and to characterize the immune response in pregnant women and their babies. The principal objective is to define the association of ZIKV infection with microcephaly and to characterize the breadth and depth of the T-cell response to ZIKV infection in pregnantwomen and their babies.		
Role: PI		
R21AI117766-01 (Lehrer and Nerurkar, MPI)	01/01/16-12/31/17	1.2 CM
NIH/NIAID	\$412,000	
<i>Multiplex diagnostic platform for clinical research targeting filovirus Infections.</i>		
The goal of this proposal is to develop a sample-sparing, rapid, multiplex immunoassay, capable of detecting major filovirus antigens and host immune responses, to significantly improve the identification of suspected filovirus cases in an outbreak and establish prior immunity in community contacts.		
Role: MPI		
American Diabetes Association (Nerurkar)	04/06/16-4/15/19	2.11 CM
	\$344,987 (Total cost)	
<i>Pathogenesis of West Nile encephalitis in a mouse model of diabetes mellitus</i>		
The aim of this study is to use a mouse model to establish a link between the expression of CAM, adhesion and migration of CD8 ⁺ T cells across the BBB and cytotoxicity of these cells in the brains of WNV-infected mice to address a significantly important mechanistic question about efficient clearance of WNV from brains of diabetics.		
Role: PI		
NSF (Saksena)	06/01/16 – 05/31/19	0.60 CM
NSF/Ecology and Evolution of Infectious Diseases (EEID)	\$2,500,000	
<i>The Role of Integrated Agriculture-Aquaculture in the Environmental Dissemination of Avian Influenza</i>		
This proposal seeks funding for developing spatial epidemiological models, conducting field sampling, laboratory experiments, organizing community college summer workshops, and graduate student scholarships related to the highly pathogenic avian influenza (HPAI).		
Role: Collaborator		
SBIR/NIH/ (Andrew Wang, Ocean Nano Tech LLC)	04/01/15-03/31/17	
Development of Sensitive dengue diagnostic test		
The goal of this proposal is to develop a quantum dot based Lateral Flow Immunochromatographic assay with better than ELISA sensitivity for detection of dengue infection at early stage.		
Role: Consultant		
R01NS085365 (Nerurkar)	04/01/15-03/31/19	2.5 CM
NIH/NINDS	\$375,000	
Vivek R. Nerurkar, Ph.D.		
Curriculum Vitae, Page 18		
April 2020		

Neuropathogenesis of West Nile virus encephalitis in diabetes

The goal of this proposal is to elucidate the effect of diabetes on adhesion and transmigration of CD8+ cells across the blood-brain barrier and activation and cytotoxicity of CD8+ T cells.

Role: PI

Hawaii Community Foundation (Nerurkar) 07/01/15-06/30/16
\$50,000 (Total cost) 1.2 CM

Neuropathogenesis of West Nile virus encephalitis in diabetics.

The principal objective of the proposed research is to elucidate the effect of diabetes on adhesion and transmigration of human CD8+ T cells across the BBB.

Role: PI

1R03 HD0842463-01 (Andras Bartincsak) 01/01/15-12/31/18 0.3 CM
NIH/NHLBI \$142,232

MMP9 as a response identification biomarker for doxycycline in Kawasaki disease.

The goal is to evaluate the use of MMP-9 as a response identification biomarker to doxycycline treatment in children during the acute phase of KD when coronary artery dilation and aneurysm formation can occur.

Role: Collaborator

Hawaii Community Foundation (Kaufusi) 06/01/14-12/31/15
\$50,000

West Nile virus NS1 protein a potential target for antiviral drug discovery.

The goal is to elucidate the regulatory mechanisms controlling the formation of WNV-induced membrane structures as a prerequisite to the development of a therapeutic approach that can be used to attenuate the disease process

Role: Collaborator

1 T32 AI112548-01 (Nerurkar and Hoang) 07/01/14-06/30/19 0.6 CM
\$109,928 (Direct Cost)

Training in immunology and pathogenesis of tropical and emerging infectious diseases

This 5-year program will provide the infrastructure and support for 4 PhD students per year at the UHM. The field- and laboratory-based training program will focus on epidemic infectious diseases of global importance, including dengue, malaria and HIV/AIDS, as well as emerging infectious diseases caused by NIAID Category A, B and C Priority Pathogens.

Role: Lead MPI

1 R21 NS070709-01 (Nerurkar) 04/01/10-03/31/12
\$275,000 (Direct Cost) 1.2 CM

HIV-Infected Humanized Mouse Model for Progressive Multifocal Leukoencephalopathy

The objective of the proposed R21 exploratory research grant is to employ an established humanized mouse model, RAG2^{-/-} γ c^{-/-} (RAG-hu), to better understand the molecular pathogenesis of JCV infection.

Role: PI

1 R21 AI088435-01 (Verma) 04/01/10-03/31/12
NIH/NIAID \$250,000 (Direct Cost) 0.6 CM

NLRP3 inflammasome in WNV-induced neuroinflammation

The studies proposed in this application are designed to identify and better characterize the pathophysiological consequences of activation of nucleotide-binding domain (NOD) leucine rich repeat 3 (NLRP3) inflammasome, a multi-protein molecular platform, which plays key role in initiating innate immune responses and release of IL-1 β in WNV neuropathogenesis.

Role: Co-Investigator

1 R01 NS067302-01 (Verma) 09/01/09-08/30/13
NIH/NIAID \$750,000 (Direct Cost) 1.2 CM

Cyclooxygenase 2 and glial cells – Role in WNVE-associated neuroinflammation

Vivek R. Nerurkar, Ph.D.

Curriculum Vitae, Page 19

April 2020

The primary objective of the proposed research is to characterize the pathophysiological consequences of COX-2 over-expression in WNV neuropathogenesis.

Role: Co-Investigator

1 R21NS065427-A1 (Verma) 09/01/09-08/30/11
NIH/NIAID (Re-submission March 13, 2009)
\$250,000 (Direct Cost) 1.2 CM

BBB tight junctions and MMP in cell-associated WNV-CNS trafficking

This proposal employs both, *in vitro* and *in vivo* model systems to define the potential routes of WNV entry into the CNS, and will address the mechanisms involved in the BBB breakdown and its relation to disease progression.

Role: Co-Investigator

1 R01 AT005437-01 (Nerurkar PV) 09/01/09-08/30/14
NIH/NCCAM \$1,000,000 (Direct Cost) 1.2 CM

Alternative medicine and Sirt: Role in obesity-associated neuroinflammation

Our long-term goal is to understand how Ayurvedic medicine, *Momordica charantia*, (bitter melon, BM), can ameliorate the adverse effects of obesity and type 2 diabetes on cellular and molecular functions of the brain. The objective of the proposed research is to investigate the molecular targets of BM-associated hypothalamic Sirt1 activation to ameliorate neuroinflammation.

Role: Co-Investigator

COMPLETED (after 2015)

5R21OD024896-02 (Kumar) 09/01/17-08/31/19 0.60 calendar
NIH/NIAID

Guinea Pig Model of Zika Virus Disease

The goal is to characterize and utilize the guinea pig model to study *in utero* ZIKV infection, sexual transmission and ZIKV neurological disease.

Role: Collaborator

1R21AI117766-01 (Verma) 09/01/2016-08/31/19 0.60 calendar
NIH/NIAID \$275,000

Under Attack: Modulation of the Blood-Testes Barrier by Zika Virus

The goal of this proposal is to develop blood-testes model to determine mechanisms of Zika virus entry into the testes.

Role: Collaborator

1R21NS099838-01 (Kumar) 09/01/16-08/14/19 1.2 calendar
NIH/NINDS \$275,000

Defining the function of Schlafen4 in the pathogenesis of flavivirus encephalitis

The goal is to define the function of SLFN4 in West Nile virus and Japanese encephalitis virus replication and pathogenesis, using novel mice models.

Role: Collaborator

1R03HD0842463-01A (Bartincsak) 09/01/16 - 08/30/18 1.2 calendar
NIH/NICHD \$100,000

MMP9 as a response identification biomarker for doxycycline in Kawasaki disease

The goal is to evaluate the use of MMP-9 as a response identification biomarker to doxycycline treatment in children during the acute phase of KD when coronary artery dilation and aneurysm formation can occur.

Role: Collaborator

U54GM104944-04 (Kumar Parvesh – PI; Melish Subproject) 07/15/16 - 06/30/17 0.3 calendar
NIH/NIGMS \$71,500

Effect of Doxycycline Treatment on Developing Coronary Aneurysms in Kawasaki Disease

We will test if 3-week course of doxycycline during the critical period of vascular damage in KD patients will decrease the levels of biomarkers and prevent the progression of coronary artery aneurysms

Role: Mentor

5P20GM103516 (Yanagihara) 07/01/15-06/30/20 1.2 Calendar
NIH/NIGMS \$1,125,000

Center of Biomedical Research Excellence (COBRE)

Pacific Center for Emerging Infectious Diseases Research

The goal of this COBRE proposal is to augment and strengthen the infectious diseases-related research capacity at the UHM and to expand and develop biomedical faculty research capability and enhance research infrastructure through support of a multi-disciplinary infectious disease program.

Role: Director Biocontainment Facility and Mentor

5T37MD008636-04 (Nerurkar and Taylor - MPI) 12/01/13-11/30/18 1.2 Calendar
NIH/NIMHD \$242,883

International Biomedical Research Training for Hawaiian & Pacific Island Students

The goal is to train minority students to conduct summer research in Cameroon and Thailand.

Role: MPI and Mentor

5R25TW009345-05 (Prasad, Kolars, Nerurkar, Zunt – MPI) 04/04/12-02/28/17 0.6 Calendar
NIH/FIC \$1,011,000

Northern/Pacific Universities Global Health Research Training Consortium

The goal of this project is to provide outstanding mentored research training to post-doctorate trainees and doctoral students at six international partner institutions with robust clinical research programs and exceptional histories of training Fogarty International Clinical Research Scholars and Fellows and strengthen global health research programs to help globalize the research portfolios of all of the sponsoring NIH ICs, and develop sustainable multidisciplinary partnerships between the four Consortium institutions and institutions in the six international partnering countries.

Role: MPI and Mentor University of Hawaii Site

5D43TW009074-06 (Taylor) 08/01/11-07/31/18 0.3 Calendar
NIH/FIC \$186,857

Training of Cameroonian Scientist in Research on Malaria

The goal of this project is to provide state-of-the-art training and education for scientist from Cameroon to conduct research on infectious diseases, primarily focused on malaria.

Role: Mentor for University of Hawaii Site; PI in the last year of the grant

50154 Hawaii Community Foundation (Andras Bartincsak) 03/29/13-11/30/16
\$48,000

Doxycycline treatment to prevent progressive coronary artery dilation in children with Kawasaki disease.

The goal is to assess the usefulness of doxycycline in preventing the progressive enlargement of coronary arteries in children with KD.

Role: Consultant (\$27,000 for MCI Core- George Hui)

13ADVC-60318 - Hawaii Community Foundation (Nerurkar) 03/29/13-06/30/15 0.12 Calendar
(\$47,619 Direct cost)

The role of Aedes albopictus in DENV-1 transmission in Hawaii.

The goal is to investigate the competency of *Ae. albopictus* in transmitting the DENV-1 that was isolated in Hawaii and to examine the physiological effects of the virus on the mosquito.

Role: PI

120712 (Frisque) 12/01/12-06/30/15 0.3 Calendar
PML Consortium LLC (\$52,500 Direct cost)

Mechanisms of PML Pathogenesis: Contributions of JC Virus Genomic Variation

In the proposed project, Dr. Nerurkar will transfect HBMVE cells with several archetype constructs generated by the PI, determine replication using qPCR, passage the infected cell lysates followed by screening for mutations in the NCCR using sequencing. He will train the PI in conducting the aforementioned experiments and will assist with technology transfer.

Role: Collaborator

COMPLETED (before 2015)

5P20GM103516-10 (Yanagihara) 07/01/10-06/30/15 2.4 Calendar
NIH/NIGMS (\$2,025,561)

Center of Biomedical Research Excellence (COBRE)

Pacific Center for Emerging Infectious Diseases Research

The goal of this COBRE proposal is to augment and strengthen the infectious diseases-related research capacity at the UHM and to expand and develop biomedical faculty research capability and enhance research infrastructure through support of a multi-disciplinary infectious disease program.

Role: Director BSL-3/ABSL-3 Core Facility and Mentor

5U54MD008149-07 (Bazargan and Rice - MPI) 07/15/12-06/30/17
NIH/NIMHD

RCMI Translational Research Network

The overall goal of RTRN is to reduce health disparities among diverse minority populations through a translational research network.

Role: Assistant Director of Research Coordinating Center (09/30/13-02/28/14)

1R03-NS060647-01 (Nerurkar) 5/15/08-4/30/11 25%
Migration of polyomavirus JC across the blood-brain barrier (\$100,000, Direct cost)

The goal of this project is to identify cellular and molecular mechanisms underlying migration of JCV across the BBB.

Role: PI

115054959 (Nerurkar) 09/1/07-2/15/11 2.5%
Myra W. and Jean Kent Angus Foundation (\$159,266) (Direct cost)

Luminex technology based serodiagnostic assay for the rapid detection of avian influenza virus and arboviruses. The goal of this project is to develop rapid diagnostic tests for detection and surveillance of dengue virus, Chikungunya virus, Zika virus, and avian influenza virus infections.

Role: PI

4305 (Nerurkar) 11/05/08-02/15/11 2.5%
Hawaii Community Foundation \$47,619 (Direct cost)

WNV NS4B as a novel target for generating a live attenuated WNV vaccine

The major goal of this project is to introduce a novel second-site mutation into the 3'SL mutant infectious DNA clone, on the premise that this strategy will enhance WNV attenuation phenotypes in mice and hamster.

Role: Principal Investigator

U01 AI075385-01 (Felgner, University of California at Irvine) 07/1/08-07/31/13
RFA AI-06-029 \$318,548 (Direct cost) 5%

Multiplex serodiagnostic protein microarray

The goal of this project is to fabricate a protein microarray chip containing 678 antigens from emerging infectious diseases and biodefense agents, such as arboviruses, hantaviruses, influenza, HPV, HIV, and to probe serum obtained from different regions of the world where these diseases are endemic to determine the true prevalence on infection. This chip will be useful for assessing the spread of exposure in a population following a bioterrorism attack. It will also be useful for determining whether military personnel or civilians entering a region where these agents are endemic are exposed to any of them.

Role: UHM PI (Virologist)

1R01AI075057-01A1 (Yanagihara) 08/08/08-07/31/12 2.5%
 NIH/NIAID
 Intraspecies transmission and infectivity of insectivore-borne hantaviruses.
 The major goal of this multi-institutional collaborative project is to determine the intraspecies transmission of a newly recognized hantaviruses and to ascertain its importance to human health and disease.
 Role: Collaborator

5G12RR003061-23 (Ostrander/Yanagihara) 08/01/06-07/31/11 25%
 NIH/NCRR \$14,188,906 (Direct cost)
 Research Centers in Minority Institutions Program \$2,201,543 (Activity 3 Total Direct cost)
 Research Outcomes Accelerating Discoveries for Medical Applications and Practice
 Activity 3 – Tropical Infectious Diseases Detection and Prevention Core activity
 The Tropical Infectious Diseases Detection and Prevention Core activity consisting of the *Pathogen Reference and Reagent Core Facility*, *Molecular Pathology Core Facility* and the *Microarray Core Facility* responds to an urgent local, regional and national need to position UHM in a leadership role to detect exotic infectious diseases that may be introduced to Hawaii and the continental United States from Asia. Our expectations are that at the end of the grant period, UHM will be one of the premier institutions for tropical infectious diseases research and training in Asia and the Pacific.
 Role: Activity Leader Activity 3

5P20RR018727-05 (Yanagihara) 10/01/2003-06/30/10 10%
 NIH/NCRR \$7,196,080 (Direct cost)
 \$1,485,552 (Total direct cost)
 Center of Biomedical Research Excellence (COBRE)
 Pacific Center for Emerging Infectious Diseases Research
 The goal of this COBRE proposal is to augment and strengthen the infectious diseases-related research capacity at the UHM and to expand and develop biomedical faculty research capability and enhance research infrastructure through support of a multi-disciplinary infectious disease program. Four young investigators will be conducting hypothesis-driven research projects on infectious diseases such as the dengue hemorrhagic fever, group A streptococcus associated acute rheumatic fever, human papillomavirus associated malignancies in men and tuberculosis.
 Role: Mentor and Leader of the COBRE core facility

Hawaii Community Foundation (Verma) 01/1/08-04/30/09
 NIH/NIAID \$47,619 (Direct cost) 5%
 Role of human brain microvascular endothelial cells in West Nile virus- central nervous system (CNS) invasion.
 The major goals of this project are to determine and delineate the mechanism(s) of infection and injury induced by West Nile virus to human brain microvascular endothelial cells, disruption of the blood-brain barrier and the trafficking of WNV into the CNS.
 Role: Collaborator

2 U54 NS039406 (Spiess) 09/01/04-08/31/09
 NIH/NINDS \$10,107,025 (Total cost)
 Specialized Neurosciences Research Programs at Minority Research Institutes, National Institute of Neurological Disorders and Stroke
 The major goal is the advancement of neuroscience research at the University of Hawaii.
 Role: Collaborator

COMPLETED (before 2009)

5R25MH080661-08 (McArthur, Johns Hopkins) 04/16/07-04/30/15 0.3 Calendar
 NIH/NIMH \$231,254
Translational Research in Neuro-AIDS and Mental Health (TR-NAMH): An innovative mentoring program to diversify workforce
 The goal of this multi-institutional project is to improve the capacity of high quality research by developing
 Vivek R. Nerurkar, Ph.D.
 Curriculum Vitae, Page 23
 April 2020

mentoring programs for doctoral and post doctoral candidates and junior faculty from racial and ethnic minorities and non-minority individuals at the same levels, whose research focusses on Neuro-AIDS disparity issues.

Role: Mentor for University of Hawaii Site

Hawaii Community Foundation (*Verma*)

7/1/05-4/30/08

\$47,619 (Direct cost)

Oxidative stress and its implications in the pathogenesis of West Nile virus infection

The goal of this project is to delineate the pathophysiological mechanisms underlying oxidative stress-induced disease pathogenesis.

Role: Collaborator

R44NS052139 (*Lieberman*)

10/1/04-4/30/08

\$125,865 (Direct cost)

SBIR, NIH/NIAID

Development of a Recombinant Subunit Vaccine for the Prevention of West Nile Virus Infection in Humans

The goal of this project is to produce a safe and effective vaccine for WNV infection in humans. We will be conducting the viremia and plaque reduction neutralization test.

Role: Principal Investigator, UHM

Hawaii Biotech (*Weeks-Levy*)

06/1/05-05/31/07

\$26,795 (Total cost)

Protective efficacy of a vaccine to West Nile virus (WN80E) in domestic geese (*Anser anser*).

The long-term goal of this project is to vaccinate Hawaiian endangered bird "Nene" for WNV infection.

Role: PI

Hawaii Community Foundation (*Melish*)

07/1/05-06/30/07

\$50,000

Kawasaki Disease diagnosis project

The goal of this project is to define biochemical and molecular markers of KD using state-of-the-art technologies.

Role: Collaborator

S11 NS041833 (*Nerurkar*)

09/01/00 to 08/31/06

NIH/NINDS

\$1,559,856 (Total cost)

Collaborative Neurological Sciences

Genetic Determinants of JC Virus Replication and Pathogenicity

The goal of this project is to study the mechanisms underlying pathogenesis of progressive multifocal leukoencephalopathy.

Role: PI

NS-03-024 (*Nerurkar*)

01/01/04 to 08/31/06

NIH/NINDS

\$7,633 (Total cost)

US-Japan Brain Research Collaborative Program (BRCP) – The US Component

Pathogenesis of Progressive Multifocal Leukoencephalopathy: Mechanisms Underlying Interaction of Host and JC Virus Proteins

The major goal is to study the interaction between host and JC virus proteins.

Role: PI

5 G12 RR003061-16 (*Shomaker/Yanagihara*)

09/01/01 to 08/31/06

NIH/NCRR

\$3,092,705 (Activity 4

Research Centers in Minority Institutions Program

total cost)

Selective Research Excellence in Biomedicine and Health. Activity 4 – Pathobiology of HIV-Associated Disorders

The goals of this RCMI-funded activity are to establish a committed and competent mentoring group, with multidisciplinary expertise, to assist junior faculty succeed as independent biomedical researchers, more fully develop the HIV/AIDS research infrastructure to become a center of clinical and biomedical research excellence

Vivek R. Nerurkar, Ph.D.

Curriculum Vitae, Page 24

April 2020

in the pathobiology of HIV-associated disorders, mentor and support a cadre of promising clinical and basic science investigators to develop and implement hypothesis-driven research proposals on HAART-associated lipodystrophy and metabolic disorders and HIV-associated malignancies for future independent funding. This infrastructure development will foster a multidisciplinary approach to selective research excellence and focus on critical health-related issues of the ethnic minority population in Hawaii and the greater Pacific.

Role: Leader Activity 4

P20 RR018727 (Yanagihara) 07/01/04-06/30/05
Pacific Center for Emerging Infectious Disease Research \$50,000 (Total Cost)
Effects of Selenium Deficiency on Genomic Mutations of RNA viruses. (PI: Verma)

The primary goal of this project is to investigate how RNA viruses may be affected by selenium deficiency within the cells in which they replicate. The objective is to develop an in vitro system to grow cells in selenium deficient conditions and then check the susceptibility of these cells to cause specific mutations in RNA viruses.

Role: Co-Investigator

Clinical Research Center of Hawaii (*Verma*) 01/01/04-12/31/04
Diagnosis of Kawasaki Disease \$10,000 (Total Cost)

The major role of this project is to develop new molecular-based technologies for the diagnosis of KD.

Role: Co-Investigator

U54 NS039406 (Rayner) 09/01/99 to 08/31/04
NIH/NINDS \$5,490,732
\$1,471,867
(Total cost Project 3)

Specialized Neurosciences Research Programs at Minority Research Institutes,
National Institute of Neurological Disorders and Stroke
Project 3: Infectious etiology of Viliuisk encephalomyelitis (*Nerurkar*)

The major goal of this study is to study the neuropathogenesis of Viliuisk encephalomyelitis.

[This project received a high priority score from the reviewers but was denied implementation by the NINDS scientific administration because of the geo-political situation between the United States and Russia in 1999. Nevertheless, the money was awarded by the NINDS and has been judiciously utilized by the SNRP director to further the SNRP activities at UHM.

American Heart Association (Melish) 07/01/01 to 06/30/03
Kawasaki Syndrome: The Diagnosis Project \$132,000 (Total cost)

The goal of this project is to employ gene array technology to quantitate the differences in Kawasaki Syndrome (KS) compared to febrile controls. cDNA microarrays will be utilized to profile the expression of host factors in early KS.

Role: Co-PI.

0000 (Nerurkar) 07/01/99 to 09/01/03
Hawaii Community Foundation \$59,275 (One year total cost)

Molecular analysis of hepatitis C virus in injection drug users and in individuals co-infected with human immunodeficiency virus in Hawaii

The goal of this project is to analyze hepatitis C virus in injection drug users and in individuals co-infected with human immunodeficiency virus in Hawaii at the molecular level.

East-West Center (Aumakhan) 07/01/02 to 10/31/02
\$5,000 (Total cost for four months)

Vivek R. Nerurkar, Ph.D.
Curriculum Vitae, Page 25
April 2020

Molecular- and Sero-epidemiology of Emerging Infectious Diseases in High-Risk Mongolian Population

The goal of this project is to contribute to the evaluation of the epidemiologic situation of STDs and certain blood borne infections in Mongolia and provide the necessary basis and data for further investigations in this important health issue. I am a mentor and co-investigator on this project.

S11 NS41833-02S1 (Nerurkar) 09/01/01 to 08/31/02
NIH/NINDS \$50,000
Collaborative Neurological Sciences (Total cost one year)
Genetic Determinants of JC Virus Replication and Pathogenicity

Supplement award to purchase flow cytometer. In collaboration with Dr. Martin Rayner, we purchased a flow cytometer (\$100,000) to conduct my projects as well as projects within the SNRP and RCMI programs. This flow cytometer was the first on campus available to all biomedical investigators.

5 G12 RR/AI03061 (Mortimer) 09/30/96 to 08/31/01
NIH/NCRR \$4,915,898
Research Centers in Minority Institutions Program (Five year direct cost)
Selective Excellence in Health-Related Research. Activity 3 - Human Retroviruses and Other Emerging Pathogens –
Leader: Richard Yanagihara, Associate Leader: Cecilia M. Shikuma

The goals of this RCMI-funded activity are to further integrate the clinical and basic science infrastructure of the Hawaii AIDS Research Program; to further expand and implement a multidisciplinary research agenda on human retroviruses and AIDS-related disorders, as well as new, emerging and re-emerging infectious diseases affecting Asians and Pacific Islanders and other ethnic minority groups; to mentor and support a cadre of clinical and basic science investigators to develop hypothesis-driven research proposals on human retroviruses and other emerging pathogens for independent funding; and to facilitate professional development and training of ethnic minority investigators, as well as under-represented students, from Asia and the Pacific. I was a senior investigator on this five-year proposal and assisted in planning and implementation of the proposal.

RCRII Pilot Project Grant (Nerurkar) 02/01/99 to 08/31/00
NIH/NCRR \$10,000 (One year direct cost)
Prevalence of early natural history of a recently described post-transfusion hepatitis-associated DNA virus (TTV) in multiply transfused infants and children

The goal of this project is to determine the prevalence of TT virus infection among multiply transfused pediatric patients.

WAF RFA 1999 (Yanagihara) 09/01/99 to 08/31/01
World AIDS Foundation \$110,000 (Two year direct cost)
Maximizing the Benefits of HIV/STD Prevention Efforts among High-Risk Women and their Partners in Southern Vietnam

The principal goal of this multi-institutional collaborative project is to conduct a community intervention trial comparing two HIV/STD prevention approaches: one focusing exclusively on sex workers and the other simultaneously reaching out to both sex workers and their clients or partners; in addition, this project aims to expand Vietnam's capacity at both national and provincial levels to evaluate the efficacy and cost-effectiveness of prevention efforts, thereby strengthening its overall capability to effectively respond to the epidemic spread of HIV. I was a co-investigator on this project.

0000 (Mocz) 06/01/00 to 08/31/01
DOD HBCU/MI \$200,000
Infrastructure Support Program
A Nucleic Acid Microarray System for the Biotechnology/Molecular Biology Instrumentation and Training Facility at the University of Hawaii

The major goal of this proposal is to become fully equipped with DNA microarray instrumentation to support education, research and training in biological and biomedical programs at the University of Hawaii. I submitted four abstracts to the granting agency in support of this project.

R03 TW00866 subcontract (Detels) 07/01/97 to 06/30/00
NIH/FIC \$60,000 (Total cost for three years)
HIV-1 Subtype E in Vietnamese IVDU - Dual or Recombinant Infection?

The goal of this project is to determine the relative frequencies of multiclade infection and genetic recombination in HIV-1-infected injection drug users in Vietnam. I was a co-investigator on this project and executed this project in Hawaii.

0000 (Zheng) 01/01/99 to 12/31/99
Queen's Medical Center \$17,500 (Total cost for one year)
Leahi Fund
Molecular diagnosis of leptospirosis infection in Hawaii

The goal of this project is to develop a rapid PCR-based assay for the diagnosis of leptospirosis infection. I was a co-investigator on this project.

0000 (Nerurkar) 01/01/98 to 10/30/99
Hawaii Community Foundation \$50,000 (Total cost for one year)
HIV-1-infected long-term survivors in Hawaii: synergistic effect of mutated HIV-1 co-receptor CCR5 and defective HIV-1 accessory protein Nef

The goal of this project is to analyze the CCR5 genotype in relation to *nef* gene deletions and the rate of clinical progression to AIDS in HIV-1-infected individuals in Hawaii.

WAF 124 (Yanagihara) 08/01/97 to 12/31/99
World AIDS Foundation \$80,000 (Total cost for two years)
Training program in public health and prevention research for HIV control in Vietnam

The goals of this project are to identify and train a carefully selected group of epidemiologists, behaviorists and virologists in public health and prevention approaches in order to characterize epidemic HIV-1 infection in Vietnam, to identify targets for intervention, and to multiply training capacity. I was a co-investigator on this project.

0000 (Nerurkar) 01/01/97 to 06/30/99
Leahi Fund \$25,000 (Total cost for two years)
Molecular diagnosis of tuberculosis and multidrug-resistant *Mycobacterium tuberculosis*
The goal of this project is to develop a rapid PCR-based assay for the diagnosis of tuberculosis and multidrug-resistant *Mycobacterium tuberculosis*.

Seed Money Grant (Nerurkar) 10/01/96 to 09/30/97
University Research Council \$14,000 (Total cost for one year)
HIV-1 Replication Kinetics and T-Cell Receptor V β Gene Expression to HIV-1 Subtypes B and E in Tuberculin Skin-Test Reactive and Nonreactive Individuals
The goal of this project is to ascertain if T-cell receptor V β genes are selectively expressed in tuberculin skin test reactive or *bacille Calmette-Guérin*-exposed individuals.

I P20 RR/AI-11091 (Kenneth P. Mortimer) 10/01/96 to 08/31/98
National Center for Research Resources, NIH \$14,000 (Total cost for two years)
RCRII Pilot Project Grant (Nerurkar)
In vitro Susceptibility of Peripheral Blood Mononuclear Cells from Asians and Pacific Islanders to HIV-1 Infection and Their T-Cell Receptor V β Gene Responses to HIV-1 Subtypes B and E.

Vivek R. Nerurkar, Ph.D.
Curriculum Vitae, Page 27
April 2020

R03 TW00866 subcontract (Detels) 10/01/95 to 09/20/98
NIH/FIC \$50,000 (Total cost for three years)
The Changing HIV-1 Epidemic in Vietnam
The goal of this project is to determine the relative frequencies of HIV-1 subtypes among various high-risk groups from Vietnam. I was a co-investigator on this project.

Grant-in-Aid, Public Health Fund (Nerurkar) 05/26/95 to 05/25/97
The Chamber of Commerce of Hawaii \$13,500 (Total cost for two years)
Molecular Characterization and Genetic Analysis of a Putative Hantavirus (Manoa Virus) Isolated from Rat Populations in Hawaii

This pilot project aims at characterizing a presumptive hantavirus (Manoa virus) isolated from rats in Hawaii to determine its phylogenetic and genetic relationship to other well-characterized disease-causing hantaviruses.

Project Grant (Morens) 12/01/95 to 09/30/97
UH-EWC Collaborative Research Committee \$20,000 (Total cost for two years)
HIV Transmission in Commercial Sex Workers (CSW) in Vietnam: A Behavioral and Molecular Epidemiologic Study of Risk Factors for Infection

The goals of this project are to determine risk factors for HIV-1 infection among CSW in An Giang Province and to analyze the molecular epidemiology of HIV-1 in this high-risk behavior group. I was a co-investigator on this project.

Project Grant (Nerurkar) 01/01/95 to 12/31/95
American Cancer Society Institutional Research \$15,000 (Total cost for one year)
Grant from Cancer Center of Hawaii
Genotyping of HIV-1 from patients with HIV-1-associated malignancies in Hawaii

This pilot project is designed to determine the genetic diversity of HIV-1 from patients with HIV-1-associated malignancies (HAM) in Hawaii. Viral sequences of HIV-1 amplified from lymph node, peripheral blood mononuclear cells and tumor tissues of the same patient will be compared, as will HIV-1 sequences from infected individuals without HAM.

5 U01 CA-66529 subcontract (Nerurkar) 09/30/94 to 07/31/98
National Cancer Institute, NIH \$144,000
(Direct cost for four years)
Hawaii HIV-Associated Malignancies, Biological Fluids and Tissue Banks Program

The major goal of this project is to collect biological fluids and tissues from patients with HIV-1-infected malignancies to conduct future national pathogenesis-related studies. This is the first grant I wrote within two months after joining the UHM. This grant led to additional funding from ACSIG, CRCH, followed by excellent review and approval of the five-year RCMI award in 1996. After Dr. Bruce Shiramizu joined UHM in 1997, I did not reapply for this grant. Dr. Shiramizu is currently continuing this area of research.

Student Assistants, Research Associates and Graduate Assistants trained and supervised

Graduate Students Trained and Supervised

1. Rebecca Melland Graduate Assistant, NIH June 1991 - December 1992
M.S. Dissertation Title: *Amino acid sequence conservation of three immunodominant gag and env epitopes of human T-cell lymphotropic virus type 1 variants from Melanesian families.* Graduated: Fall 1992 (Thesis Co-advisor and Dissertation Committee Member).
2. Peter Hoffmann Graduate Assistant, UHM February 1995 - August 1997
M.S. Dissertation Title: *Descriptive and molecular epidemiology of HIV-1 infection in women in Hawaii.* Graduated: Summer 1997 (Dissertation Committee Chairperson). Graduated summer 1997. Graduated (Ph.D.) from the National Jewish Center, September 2002. Currently Assistant Professor, Department of Cell and Molecular Biology, UHM.
3. Chaoquan Yin Graduate Assistant, UHM July 1995 - August 1997
Ph.D. Dissertation Title: *Effect of Bacille Calmette-Guerin vaccination and Mycobacterium tuberculosis infection on the expression of T-cell receptor V β and of chemokines and their receptors.* Graduated: Summer 1997 (Dissertation Committee Chairperson). Currently at the Hawaii Department of Health.
4. Pong Chua Graduate Assistant, UHM August 1996 – August 2001
Ph.D. Dissertation Title: *Kawasaki Syndrome: Search for the etiological agent, diagnostic markers and insights into pathogenesis.* Graduated: Summer 2001 (Dissertation Committee Chairperson). Postdoctoral fellow University of Texas Medical Campus in Galveston (2001-2005). Currently research scientist at Merck Laboratories.
5. Fumiya Isami Volunteer, Grad. Res. Asst., UHM June 1999 – December 2003
M.S. Dissertation Title: *Bioinformatic Approach for Tracking HIV-1 Evolution in Vietnam and Neighboring Southeast Asian Countries.* Graduated: Fall 2002 (Dissertation Committee Chairperson). Currently working for a Biotech company in Japan.
6. Sunite Ganju Graduate Assistant, UHM January 2002 – January 2004
M.P.H. Thesis Title: *Role of B-lymphocytes in the pathogenesis of progressive multifocal leukoencephalopathy.* Graduated: Spring 2004. (Dissertation Committee Chairperson). Currently working as Associate Professor of Medicine in Shimla, India.
7. Bulbul Aumakhan, M.D. Graduate Assistant, UHM July 2002 – August 2003
M.P.H. Thesis Title: *HIV Subtype A in Mongolia.* Graduated: Fall 2003. Recipient of the East-West Center research award to conduct HIV research in Mongolia. Currently enrolled in the Ph.D. program at the Johns Hopkins University, Baltimore, MD.
8. Praveen Ananthula Graduate Student, UHM September 2002 – August 2005
M.S. Dissertation Title: *Replication of JC virus in U87MG cells, a glioblastoma cell line.* Graduated: Summer 2005. Currently working as a pharmacologist in a Biopharma company in Florida.
9. Joseph Mariano Graduate Student, UHM January 2003 – Summer 2004
M.S. Thesis Title: *Molecular characterization of JC virus from HIV-infected patients with progressive multifocal leukoencephalopathy in India.* Graduated: Summer 2004. Recipient of the travel award to attend the American Society for Virology Meeting in Montreal, Canada in July 2004. Currently working in a Biotech Company in Seattle, WA.
10. Pakieli Kaufusi Graduate Student, UHM January 2003 – December 2005
Conducted research on characterization of WNV NS4B protein.
11. Juliene Co Graduate Student, UHM Fall 2004 – Fall 2006
M.S. Dissertation Title: *IFN- α and - β restrict JC virus replication in primary human fetal glial cells: Implications for progressive multifocal leukoencephalopathy therapy.* Graduated: Fall 2006. Awarded Ph.D. from Johns Hopkins University. Currently PDF in Singapore.
12. Yeung Lo Graduate Student, UHM August 2005 – March 2008
M.S. Dissertation Title: *In vitro characterization of human breast microvascular endothelial cells infected with West Nile virus.* Graduated: Spring 2008. Awarded Ph.D. from University of Hawaii.
13. Moti Chapagain Graduate Student, UHM August 2005 – May 2009

Ph.D. Dissertation Title: *Polyomavirus JC infection of human brain microvascular endothelial (HBMVE) cells and B-lymphocytes: Mechanisms of JCV transmigration across the blood-brain barrier.*

14. Ushii Gurjav Graduate Student, UHM January 2006 – May 2009
M.S. Dissertation Title: *Production of double-stranded RNA by human polyomavirus JC.*
15. James Kelley Graduate Student, UHM January 2006 – July 2011
East-West Center Scholar
Ph.D. Dissertation Title: *Maturation of dengue virus nonstructural protein 4B in monocytes induces dengue hemorrhagic fever-associated immunomediators that modulate microvascular endothelial cell adhesion molecules and permeability.*
16. Mukesh Kumar Graduate Student, UHM Spring 2008 – Spring 2010
M.S. Dissertation Title: *Role of pro-inflammatory cytokines released from West Nile virus-infected neurons in mediating neuroinflammation and neuronal death.*
17. *Nelson Lazaga Graduate Student, UHM Fall 2008 – Fall 2011
M.S. Dissertation Title: *Propagation and characterization of urine-derived archetype human polyomavirus JC.*
18. Esther Volper Graduate Student, UHM Fall 2008 – Spring 2011
Ph.D. Dissertation Title: *Early detection and rapid diagnosis of dengue virus infection: Development of Luminex platform-based microsphere bead assays.*
19. Madhuri Namekar Graduate Student, UHM Spring 2010 – Spring 2013
M.S. Dissertation Title: *Development, optimization and validation of microsphere-based Luminex assays for identification of West Nile virus and dengue virus infections.*
20. Mukesh Kumar Graduate Student, UHM Fall 2010 – Spring 2013
Ph.D. Dissertation Title: *Diabetes as a risk factor for West Nile virus associated encephalitis.*
21. *Nelson Lazaga Graduate Student, UHM Spring 2012 – Spring 2017
Ph.D. Dissertation Title: *Propagation and characterization of urine-derived archetype human polyomavirus JC.* Anticipated graduation: Fall 2015.
22. *Kenji Obadia Graduate Student, UHM Fall 2012 – Spring 2016
Ph.D. Dissertation Project Title: *Infectious etiologies of febrile illnesses in Cameroon.* Anticipated graduation: Spring 2017.
23. *Priscilla Seabourn Graduate Student, UHM Fall 2014 – Fall 2016
M.S. Project Title: *Epigenetic regulation of archetype and rearranged human polyomavirus JCV.* Graduated: Fall 2016.
24. *Michellei Fisher Graduate Student, UHM Fall 2016 – Spring 2019
M.S. Project Title: *Histone deacetylase inhibitors modulates human polyomavirus JC replication.* Graduated: Spring 2019.
25. Lauren Ching Graduate Student, UHM Spring 2016 – present
Ph.D. Project Title: *Immunopathogenesis of Kawasaki disease.* Anticipated graduation: Fall 2020

Postdoctoral Fellows, Visiting Fellows and Faculty Trained, Mentored and Supervised

1. Shekar Chakrabarti, Ph.D. Visiting Professor August/September 1997
Visiting Indian professor from the National Institute of Cholera & Enteric Diseases, Indian Council of Medical Research, Calcutta, India to learn molecular techniques to study HIV infection in India.
2. Yoshihiro Nishiura, M.D. Postdoctoral Fellow June 1997 – May 1998
Japanese postdoctoral fellow was invited to the RRL for one year to learn molecular techniques to study HIV infection in Japan.
3. Pham H. Thang, M.D. Postdoctoral Fellow May 2000 – June 2001
Vietnamese PDF was invited by me for one year to acquire advanced molecular biology techniques to study HIV infection in Vietnam. Since returning to Vietnam he has further developed the HIV molecular laboratory established by me in Vietnam in summer of 1998.
4. Pham K. Chi Visiting Fellow April – May 2001
Collaborator from Vietnam visited for studying techniques in molecular epidemiology and phylogeny.
5. Peter Hoffmann, Ph.D. Postdoctoral Fellow Nov. 2002 – Jan. 2004
Conducted research on bioterrorism related agents and West Nile virus.

6. Haiyan Luo Postdoctoral Fellow, UHM Jan. 2006 – June 2009
Conducts research on pathogenesis of WNV infection.
7. Moti L. Chapagain Assistant Research Professor May 2009 – May 2012
Conducted research on pathogenesis of WNV and JCV infection.
8. Saguna Verma, Ph.D. Postdoctoral Fellow Feb. 2003 – Nov. 2005
Assistant Research Professor Dec. 2005 – Sept. 2010
Assistant Professor Sept. 2010 – Aug 2014
Associate Professor August 2014 – present
Conducted research on pathogenesis of Kawasaki disease and progressive multifocal leukoencephalopathy.
Conducts research on pathogenesis of flaviviruses.
9. Frederic Mercier, Ph.D. Assistant Research Professor Nov. 2005 – present
Conducts research on pathogenesis of viral encephalitis and fractones
10. Pakieli Kaufusi, Ph.D. Junior Researcher, UHM Jan. 2006 – July 2013
Assistant Researcher, UHM July 2013 – present
Conducts research on characterization of WNV NS4B protein.
11. *James Kelley, Ph.D. Junior Researcher Aug. 2011 – Oct. 2013
NPGH Postdoctoral Fellow Nov. 2013 - present
Instructor May 2013 – present
12. Mukesh Kumar, PhD Instructor
Conducts research on pathogenesis of WNV and JCV infection.
13. Axel Lehrer, PhD Assistant Professor Jan. 2013 – present
Conducts research on pathogenesis of filovirus vaccine and diagnostics.
14. Qiyi Tang, Ph.D Assistant Professor, Ponce School of Med. Aug. 2013- July 2014
Conducts research on Cytomegalovirus early gene regulation in HIV infection
15. Charlene Tomas, Ph.D. NPGH Postdoctoral Fellow Nov. 2014 – Jan. 2016
Conducts research on HIV/AIDS among transgender women.
16. Jupimai Thidarat, M.Sc. Docotoral candidate Univ of Amsterdam. Deputy Head Clinical Research Associate Department, SEARCH, Bangkok, Thailand
NPGH Scholarship applicant Dec. 2014 – Nov. 2015
Conducts research on HIV/AIDS clinical trials deciphering socio-behavioral effects of HIV and clinical outcomes of HIV therapy.
17. Ahmar Hashimi NPGH Scholarship applicant Nov. 2014 – Feb. 2015
Conducts research on malnutrition and infectious diseases among refugees on the Thai-Myanmar border.
18. Charlene Tomas, Ph.D. Adjunct Assistant Prof Jan. 2016 – Dec. 2018
Conducts research on HIV/AIDS among transgender women.
19. Esemu Livo Forgu, Ph.D. Doctoral Candidate, Univ of Yaounde 1, Cameroon. Awarded UK HIV Research Trust Scholarship for 6-months to conduct research in the Deapartment of Tropical Medicine, Medical Microbiology and Pharmacology Aug. 2016 – Feb. 2017
20. Ray Ashwini NPGH Scholarship applicant Aug 2018 – Sept 2018
Conducts research on development of *C. elegans* tool for cardio metabolic disorder, which will be easy and cost effective than other animal model system.
21. Besong Ebangha NPGH Scholarship applicant Aug 2018 – Sept 2018
Conducts research on CMV infection in HIV exposed but uninfected infants and its association to poorer health outcomes.
22. Pinder Norma Visiting Scholar from Mahidol University, Bangkok, Thailand April 2019 – June 2019
Conducts research on development of assays to detect Flavivirus and Hepacivirus infections among Thai and Vietnamese patients infected with HIV and HCV.

Research Associates Trained and Supervised

1. Tammy Rowe Research Associate, NIH May 1990 - December 1991
2. Tracy DeLozier Research Associate, NIH January 1992 - May 1993
3. Anne Book Research Associate, NIH June 1993 - April 1994
4. Mohaiza Dashwood Research Associate, UHM April 1994 - August 1998

- Currently working as a Laboratory Manager, Oregon State University.
5. Ted Conrado Research Associate, UHM February 1995 – May 2003
Currently working as a High School Teacher, DOE, Hawaii
 6. David Kellogg Research Associate, UHM January 1996 - April 1997
 7. Cora Woodward Research Associate, UHM May 1996 – June 1999
Enrolled in the Ph.D. program UCLA in Fall 1998.
 8. Alexandra Zalles-Ganley Research Associate, UHM June 1998 – August 1999
 9. Jay Fajardo Research Associate, UHM June 1999 – August 2000
 10. Minh Nguyen Research Associate, UHM February 2000 – March 2001
 11. Michelle Tulang Research Associate, UHM September 2000 – June 2002
Admitted to the M.D. program, JABSOM, UHM in Fall of 2002
 12. Thomas Bui Research Associate, UHM February 2001 – Fall 2008
 13. Precy Calimlim Research Associate, UHM October 2002 – November 2003
Currently working for the Bioterrorism Program in Hawaii State DOH
 14. Fukun Hoffmann Research Associate, UHM November 2002 – October 2003
Currently working for the CMB department, JABSOM, UHM
 15. Minh Nguyen Research Associate, UHM April 2004 – February 2006
Rehired after obtaining research experience at the Pendelton Institute, LA (refer #10 above)
 16. Miyoko Bellinger Research Associate, UHM February 2004 – October 2004
Currently working for the CMB department, JABSOM, UHM
 17. Moti Chapagain Research Associate, UHM August 2004 – July 2005
 18. Yanira Molina Research Associate, UHM May 2004 – October 2005
Currently working for a Biotech company in San Francisco
 19. Esther Volper Research Associate, UHM March 2006 – Fall 2008
 20. Alexandra Gurary Research Associate, UHM March 2003 – Fall 2010
 21. *Stephanie Lum Research Associate, UHM November 2007 – July 2009
Research Associate, UHM July 2010 – August 2011
 22. Rachel Behrend Research Support, UHM 2013-2014
 23. Janet Meeks Research Support, UHM Sept. 2008 – Dec. 2013
 24. Maile O'Connell Research Support, UHM September 2010 – Dec. 2015
 25. *Beverly Orillo Research Support, UHM January 2011 – May 2016
 26. *Laarni Sumibcay Research Associate, UHM February 2006 – May 2012
Research Support, UHM April 2014 – August 2018
 27. Madhuri Namekar Microbiologist, UHM July 2013 – August 2018
 28. Eileen Nakano Research Associate, UHM July 2016 – present
 29. Keeton Krause Microbiologist, UHM January 2019 – October 2019

Student Assistants and Volunteers Trained and Supervised

1. Bruce Temura Student Assistant, UHM May 1994 - August 1995
Graduated (M.D.) from JABSOM, UHM
2. Harlan Nakanishi Student Assistant, UHM October 1994 - January 1996
3. Rampal Singh Student Assistant, UHM October 1994 – Dec. 1994
Currently working as a High School Teacher, DOE, Hawaii
4. Maury Manliguis Volunteer January 1995 - April 1995
5. Veena Jayaraman Student Assistant, UHM May 1995 - May 1996
6. Uthappa Mukatira Student Assistant, UHM May 1995 - August 1995
7. Frank Raymond Student Assistant, UHM May 1995 - August 1995
8. Ted Hatch Student Assistant, UHM June 1995 - September 1995
9. James Moulds MARC Student, UHM June 1995 - May 1996
10. Karen Warthman Student Assistant, UHM September 1995 – Dec. 1995
11. Xiaowei Cui Student Assistant, UHM January 1996 - June 1996
Currently at the Department of Health, Honolulu, HI.
12. Helen Kim Student Assistant, UHM February 1996 - August 1997
13. Ye Xia Student Assistant, UHM April 1996- August 1996
14. Bliss Kaneshiro Student Assistant, UHM May 1996 - August 1996

- Graduated (M.D.) from JABSOM, UHM.
15. Katherine Ajdukiewicz Volunteer May 1996 - July 1996
 16. Mao Zhang Student Assistant, UHM June 1996 - December 1998
 17. Ly Nguyen Student Assistant, UHM June 1996 - August 1996
Graduated (M.D.) from JABSOM, UHM.
 18. Luukia Padilla MARC Student, UHM June 1996 - May 1997
 19. Brian Curll Volunteer June 1996 - May 1997
 20. Caroline Li Volunteer July 1996 - September 1996
 21. Steven Lum Volunteer August 1996 - August 1997
Admitted to the JABSOM in Fall of 1999.
 22. M-C Jeong Student Assistant, UHM August 1996 - May 1998
Currently at the Department of Health, Honolulu, HI.
 23. Sherimay Ablan MARC Student, UHM January 1997 - August 1999
Currently at the National Institutes of Health, Bethesda, MD.
 24. Allen Que Student Assistant, UHM January 1997 - Dec. 1997
 25. Lance Tashima Student Assistant, UHM January 1997 - August 1999
 26. Tran Phung Research Assistant, UHM Sept. 1997 - August 1998
Accepted in the M.D. program at the University of South Florida, Tampa, Florida.
 27. Alex Vine Student Assistant, UHM January 1998 - May 1998
Graduated from CMB, UHM. Currently PDF CRCH, UHM, HI.
 28. Jason Tongson Student Assistant, UHM April 1998 - August 2001
Graduated from UHM in Biology and Master's of Business Management. Worked in RRL as Administrative and Fiscal Support Specialist. Currently works for Merck Co.
 29. Christopher M. Trujillo Student Assistant, UHM May 1998 - August 1998
 30. Anand Pathak Student Assistant, UHM July 1998 - September 1998
Admitted to the University of Cincinnati College of Medicine, Cincinnati, OH. Fall 2000
 31. Chi-Ling Lin Student Assistant, UHM January 1999 - March 2001
Currently at the Touro University, in Vallejo, California, Doctor of Osteopathy Program.
 32. *Joshua Hvidding MARC Student, UHM June 1999 - May 2001
Admitted to the M.D. program in JABSOM, UHM, HI. Fall 2006
 33. Claudia Lupp Student Assistant, UHM August 1999 - Dec. 1999
 34. Markus Jeude Visiting German Res. Assistant Sept. 1999 - February 2000
 35. Iris Scheirich Visiting German Res. Assistant March 2000 - August 2000
 36. Travis Lau Summer Student Summer 2000, 2001
Admitted to the Tufts University School of Medicine, Boston, MA. Fall 2002
 37. Sandy Liang Volunteer Student Summer 2000, 2002;
Winter 2000
Graduated from Sacred Heart Academy, Honolulu, HI in Spring 2000. Currently Senior at Stanford University. She conducted research with me as a high school and undergraduate student.
 38. Annette Kempkes Visiting German Res. Assistant September 2000 - Feb. 2001
 39. Nadine Sold Visiting German Res. Assistant March 2001 - August 2001
 40. *Ryan Susa MARC Student May 2001 - December 2001
 41. Currun Singh High School Senior Summer 2002, Summer Student
Charles Drew & NIH/NIDDK Fellowship. Recipient of the best award for research presentation at the NIH in August 2002. Admitted to Harvard University, Fall 2003.
 42. Dhiraj Girme Summer Student, HPU, HNL, HI Summer 2002
 43. Kuon Chun Summer Student, UHM Summer 2002
 44. *Maria L. Hansen Graduate Student Ass. (Rotation) September 2002 - Dec. 2002
 45. Katja Zeigler Visiting German Res. Assistant October 2002 - May 2005
Admitted to Ph.D. program in Fall 2005 in France.
 46. *Austin Nakatsuka Kamehameha High School Junior Summer 2003, 2005
Charles Drew & NIH/NIDDK Fellowship, summer 2005. Recipient of the best award for research presentation at the NIH in August 2005. Admitted to UCLA, Fall 2006.
 47. Katie Yeung Student Assistant August 2003 - May 2005

48. Cheynie Nakano Student Assistant June 2004 – May 2006
Admitted to the M.D. program in JABSOM, UHM, HI. Fall 2006
49. *Aileen Duran Farrington High School Senior Summer 2004,
Summer Student, Freshman UHM
Charles Drew & NIH/NIDDK Fellowship. Recipient of the best award for research presentation at the NIH in August 2004. Admitted to UHM, Fall 2004. Conducting research in Dr. Nerurkar's laboratory since Fall 2004. Assisted with research projects on JCV, dengue and hantavirus.
50. *Nathan Nakatsuka Kamehameha High School Freshman, Junior
Summer 2003, 2005
51. Mayee Wong Graduate Student Ass. (Rotation) Fall 2004
52. Dorene Marumoto Student Assistant September 2003 – present
53. *Dane Bishop Student Assistant September 2004 – January 2006
54. *Angelica Rockquemore High School Summer Student Summer 2006
Charles Drew & NIH Fellowship. Recipient of the best award for oral presentation at the NIH in August 2006. Admitted to Oregon State University, Fall 2006.
55. *Alexander Kayatani Graduate Student Ass. (Rotation) Fall 2006
Supported by U.S. Army.
56. *Austin Nakatsuka Undergraduate Summer Student Summer 2007
UCLA. NIH/NIDDK STEP up Program summer fellowship.
57. *Scott Serano Undergraduate Summer Student Summer 2007
UHM. NIH/NIDDK/UHM PRIDE Program summer fellowship.
58. *Fredalyn Alcaide High School Summer Student Summer 2008
Charles Drew & NIH Fellowship.
59. Chi Hui-Yuan Undergraduate Summer Student Summer 2008, 2009
UCLA. NIH/NIDDK STEP up Program summer fellowship.
60. * Gabrielle Faaiuasoo High School Summer Student Summer 2009
NIH/NIDDK STEP up Program summer fellowship
61. *Arielle Flores High School Summer Student Summer 2010
NIH/NIDDK STEP up Program summer fellowship.
62. Diana Lu Undergraduate Summer Student Summer 2010
NIH/NIDDK STEP up Program summer fellowship.
63. Mary Langley Volunteer Student University of British Columbia, Canada Student
Summer 2012
64. *Daniel Gomez Undergraduate Student 2013
65. *Michelle Fisher Undergraduate INBRE /Volunteer/UROP/MHIRT student
February 2013 to present
Received first place for oral presentation at the Fall 2014 UROP Symposium
66. *Samantha Esperanza Undergraduate MHIRT Student Summer 2015
Received first place for oral presentation at the Fall 2014 UROP Symposium.
67. *Tiana Elisara Undergraduate MHIRT Student Spring, Summer, Fall 2016
Received INBRE award.
68. Cindy Vuong Undergraduate MHIRT Student Spring, Summer, Fall 2017
Received INBRE award and was honors thesis student mentored by me.
69. *Jasmine Padamada Undergraduate MHIRT Student Spring, Summer 2018
70. *Awaphui Lee Undergraduate MHIRT Student Spring, Summer 2019
71. *Madison Shine Undergraduate MHIRT Student Spring, Summer 2019
72. I have unofficially mentored 60 MHIRT students over the past six years.

*Minority and/or underrepresented in science students and staff.

Since 2010, I have assigned junior faculty in the department to mentor several undergraduate and graduate students.

In addition, I have trained and supervised several senior investigators in technically demanding laboratory procedures who are co-authors on several of the peer-reviewed publications listed in the bibliography.

I have partly overseen the administrative activities performed by Mr. Leroy Lee, Administrative Officer, RRL, PBRC, from 1997-2002. I am responsible to oversee the administrative activities performed by Ms. Becky Nakama (since January 2003), Ms. Sheila Kawamoto (Retired) (since November 2008), Ms. Karen Amii (Retired) (November 2008-December 2010), Ms. Cori Watanabe (April 2003-June 2005 and since November 2008), Justin Forsthye (Resigned) (since 2011) and Cassidy Tabata since September 2019. Moreover, I routinely interact with several administrative staff of UHM, JABSOM and PBRC, who are responsible for managing grants and other personnel matters.

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Abstracts

Over the past 35 years, I have presented over 350 abstracts as oral or poster presentations at various local, national and international conferences and meetings. If required, I will be happy to provide a list of all abstracts.



Name: Vivek R. Nerurkar

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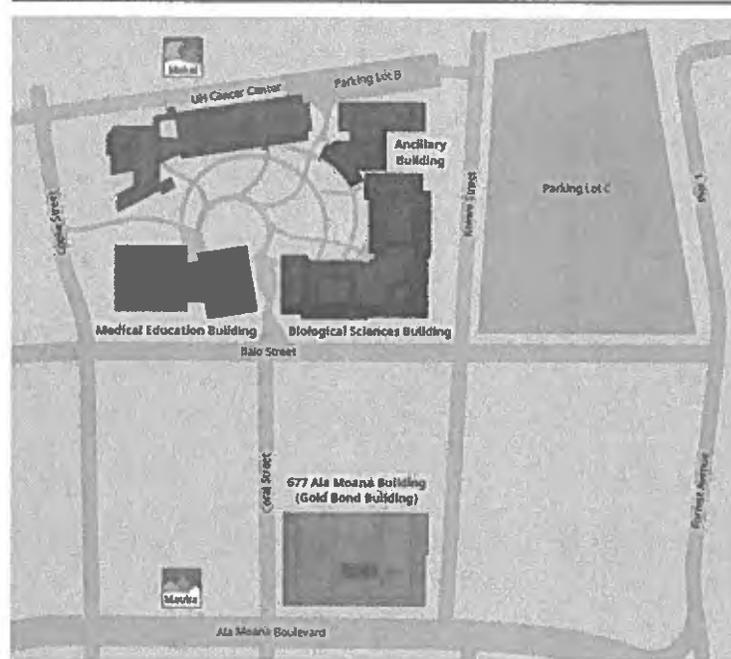
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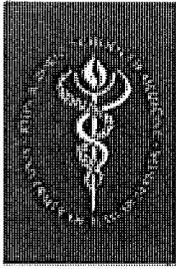
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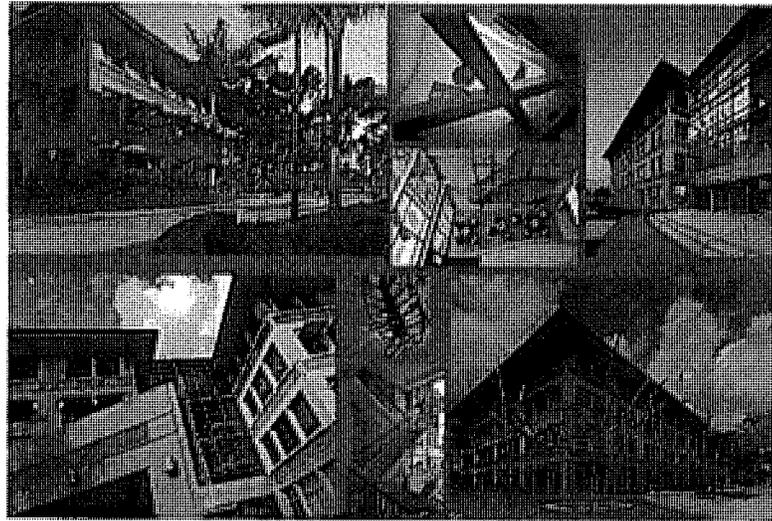
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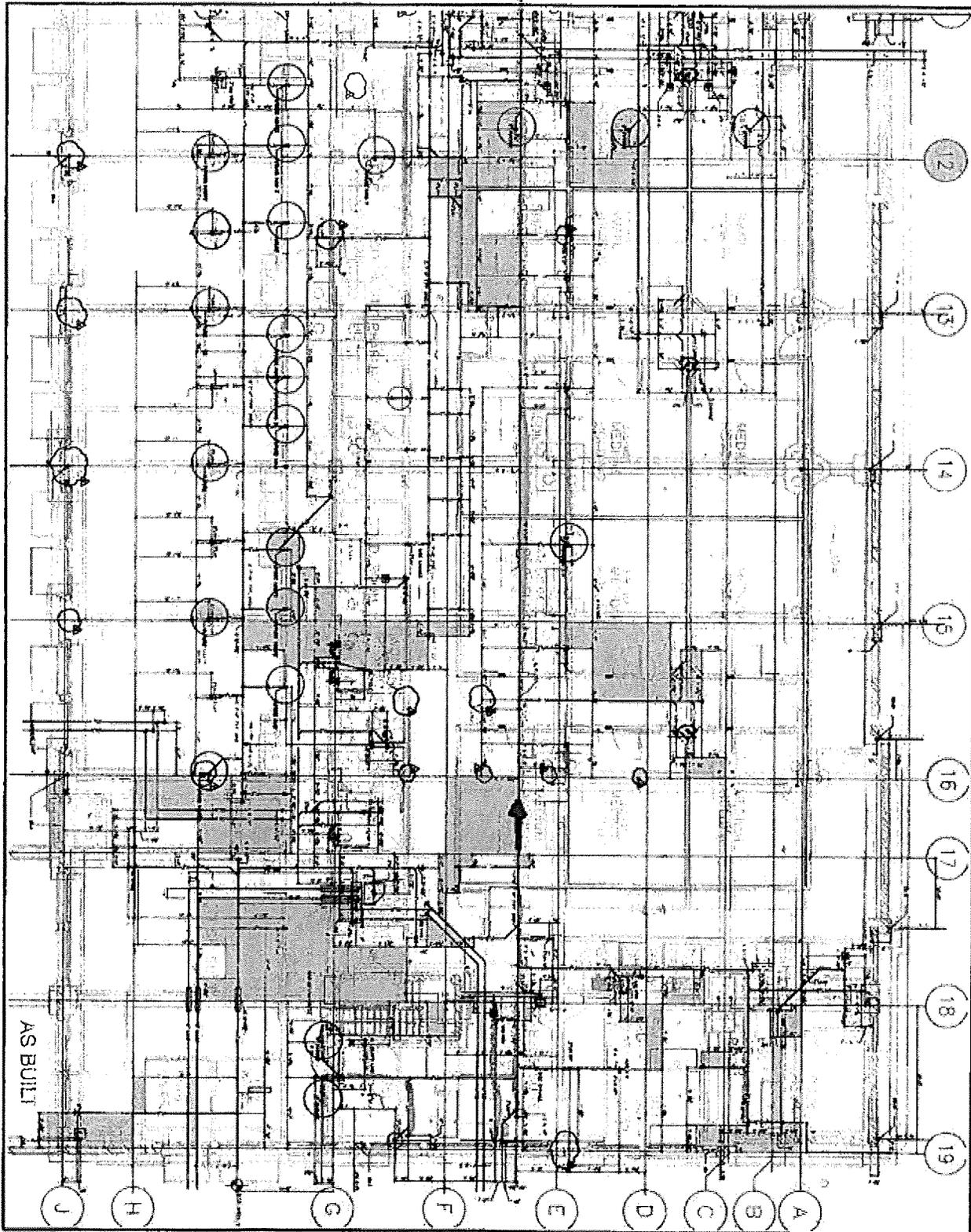
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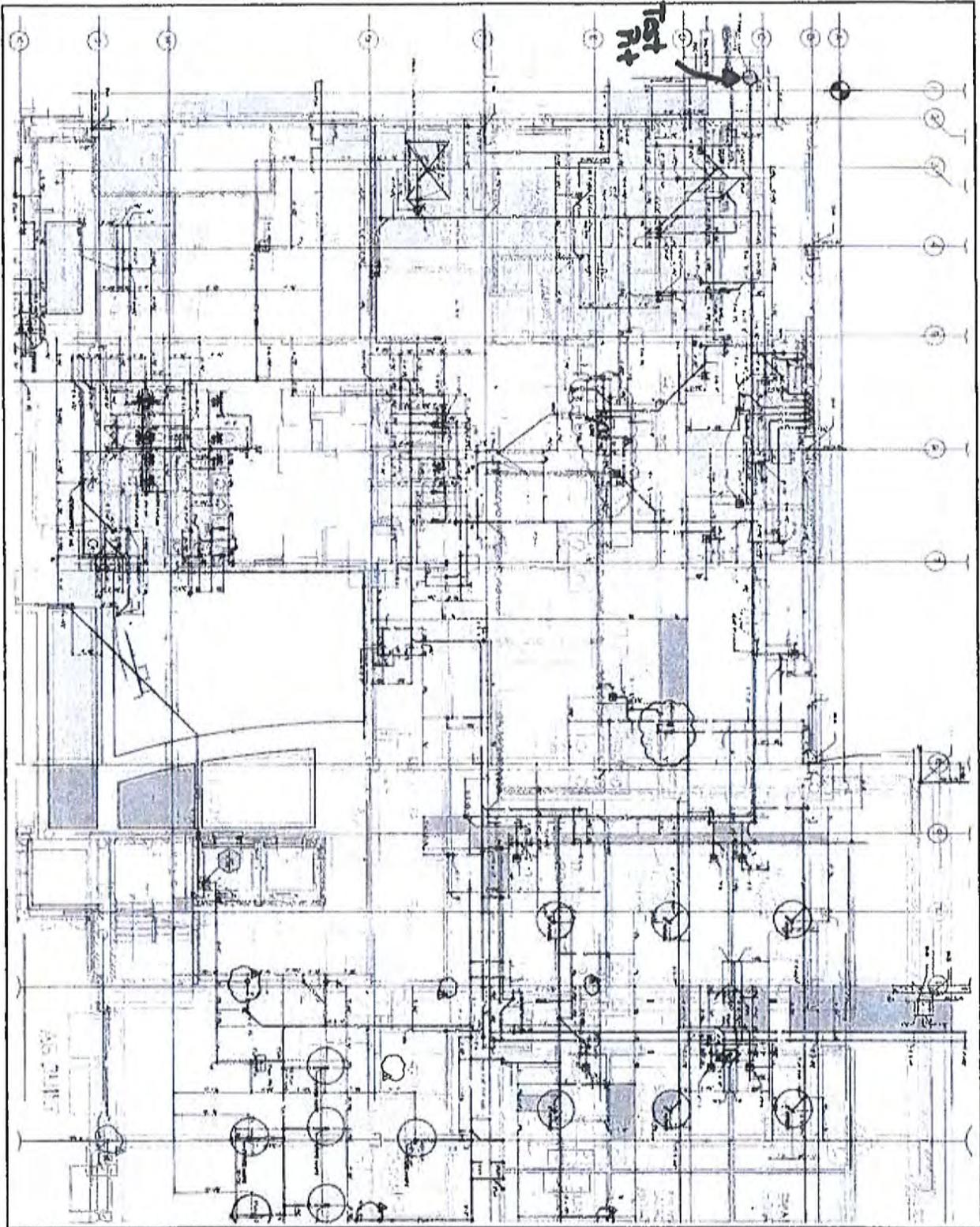
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1. Either World Courier or FedEx will send Coronavirus to Hawaii. The sender and the carrier will follow all standard safety measures. The sender will provide us with a tracking number so that we can track the location of the package containing the agent at any given time.
2. The agent will be packed in an air sea Biopack. This container 4G/class 6.2 is suitable for all infectious substance under I.C.A.O class 6.2, US DOT and IATA. This container will be placed in another container and labeled with an infectious substance, universal biohazard symbol and UN dry ice label and accompanied by documented paperwork.
3. The specific information about the arrival of the agent at Honolulu can be found electronically using the given tracking number. The airport quarantine office of Hawaii Department of Agriculture will call us as the package is cleared by inspection.
4. Steps for #5
 - a) The package will be delivered to Kaka'ako on working days between 8 AM to 5 PM by the courier. Dr. Vivek R. Nerurkar at 692-1668 or 753-6961 or his authorized designee of the Department of Tropical Medicine, Medical Microbiology & Pharmacology will receive and handle the package. We will not receive the package without HDOA stamp.
 - b) Alternatively, the package can be picked up at the airport by persons listed above or their authorized designee along with an authorized BSP 2 form. The package can be picked up at the airport regardless of the time or holiday.
5. The package now will be handled by the following method regardless of the route of its arrival at the Kaka'ako Bioscience Building:
 - a) After personnel have donned appropriate PPE, the package will be placed into a biosafety cabinet (BSC). The technician working in the BSC will remove the outer wrap and package materials. The inner small package (4G/6.2) will be disinfected chemically by spraying the surface with 10% bleach solution.
6. The 4G/6.2 packages will be placed in the locked freezer until the time experimental procedures can be conducted. The outer package material left in the BSC will be decontaminated with 70% Ethanol prior to removal from the BSC.

SOP #2 Receiving Pregnant Female Mice from Animal and Veterinary Services (AVS)

1. Rodents will be procured from approved commercial vendors of known specific pathogen free (SPF) status.
2. All shipments received by AVS will be assigned a unique AVS number on the corresponding Historical Data Sheet (HDS) that will be provided by the AVS Office. The AVS # will be noted on the **Chain of Custody Form**.
3. Animals will be tracked internally by AVS through Granite Cage Cards.
4. The mice used for experiments will be timed-pregnant animals, and will be acclimated 1-3 days in the Vivarium after arrival for the purposes of physiological, psychological, and nutritional stabilization before their use.
5. AVS will have Isocages™ and bedding ready before the shipment of pregnant female mice arrives.
6. AVS will receive the mice in the shipping container and will disinfect the box at the Vivarium airlock.
7. Mice will be transferred into clean Isocages™ and docked on the Isocage™ rack system. **The Isocage™ microisolator tops should not be placed tightly on the cage bodies until the cages are docked to their racks. Otherwise, because of the tight seal created by the microisolator top and the cage body, the mice will suffocate within 15 minutes if the microisolator top is secured while not docked to its air supply from the motor on the rack.**
8. Prior to transport of pregnant female mice to the dedicated ABSL-2 lab, check with the AVS staff regarding the following:
 - a) Number of cages
 - b) Live animal label on the cage
 - c) Granite cage cards present and accurate
 - d) Integrity of cages (proper filters tops, holes, deformation, wetness)
 - e) Record of Condition/Behavior of pregnant female mice
9. Personnel will secure the microisolator tops to the Isocage™ bodies and immediately dock it to its rack, ensuring that the motor is on and providing air supply to the cages. The cages containing the mice will remain until the completion of the experiment.
10. Pregnant female mice are then transported to the ABSL-2. It is very important to note that any mice that have been accepted and transported to the ABSL-2 lab will not, for any reason, be returned back to the AVS holding area. Once mice enter the ABSL-2 lab and inoculated with a BSL-2 agent, they do not leave the ABSL-2 laboratory or Vivarium alive.
11. Once the pregnant female mice have given birth, the number of suckling mice will be recorded on the Granite cage card and on the husbandry log sheet. A Suckling Mouse Log will also be maintained by investigators and kept on record (please see following log)

SOP#3 Daily Husbandry and Observations Prior to Inoculation

1. Daily husbandry and observations of animals must be recorded in the husbandry log sheet.
2. Check mice for vitality (healthy dieting, smooth coat, absence of injury, etc.) and note any abnormalities.
3. Ensure mice have eaten food daily and replenish feeders as they become low (3/4 empty). Feeders will not be near feces and urine and will be washed and sanitized bimonthly. Feed will be placed in a sterile container located at the housing site (See Feed Storage SOP #4).
4. Check water bottles (sipper tubes) daily and replenish with fresh water as they become low (1/2 empty). Water should be clear and will not be placed near feces and urine. To avoid microbial cross-contamination, water bottles will be replaced or refilled with potable, uncontaminated water and returned to the same cage from which they were removed. Water bottles will be washed and sanitized bimonthly.
5. The cages will be checked daily and will be changed after two weeks, depending on animal numbers, cage size, urinary and fecal output, and experimental conditions.
6. Cages will be decontaminated every two weeks.
7. Monitor temperature and humidity levels daily via the Edstrom Watchdog System. Record room temperature and room humidity on the housing site daily log and the electronic version of the Daily Husbandry Record. Room temperature should be 18-26°C and room humidity should be 40 to 70%. If temperature or humidity ranges are compromised, report to AVS immediately so a veterinarian can evaluate the impact on the animal's health and well-being.
8. Check that proper ventilation is maintained in the room via the Edstrom Watchdog System. At a minimum, the room should be receiving 10-15 fresh-air changes per hour. Record ventilation check on housing site log. Contact the AVS veterinarian and Facilities Management if ventilation is poor.
9. Inspect all lighting fixtures to ensure working condition. Lighting should be adequate for vision and for neuron-endocrine regulation of diurnal and circadian cycles. If lighting is poor, gently move cages and mice to areas of better lighting and contact the AVS veterinarian and Facilities Management.
10. Listen for any unnecessary noise that might startle the mice and appropriately take action to minimize it.
11. Any problems with maintaining the conditions specified in this SOP will be brought to the immediate attention of the Principal Investigator and the Attending Veterinarian.

SOP #4 Feed Storage

1. A 2-gallon sterile food container will be used to store a maximum of 20 lbs. of feed obtained from AVS.
2. Obtain rodent chow, such as Lab Rodent Diet 5050, irradiated from AVS and place into the sterile container and note the date received and expiration date on the Feed Storage Log.
3. Report to AVS and the attending Veterinarian if feed appears to be discolored, contaminated, or unusual.
4. Stock chow will be stored in a covered, labeled container including the milling date for the food, and kept in the animal suites. Rodent food must be discarded if it is older than six months past the milling date. AVS will keep it filled as needed.
5. The rodent chow will be fed ad libitum, in quantities sufficient to last two days (at 5 gm chow per day per adult mouse).
6. Sterilize the 2-gallon food container every month, removing or discarding any unused feed, and then cleaning with hypochlorite disinfection (Clorox, made fresh daily) or Quaternary Ammonium Compound (refer to Maintenance of Cleanliness and Safety SOP) followed by sending the container to AVS for final washing by the cage washer. Use new trash bags when new feeds are added to the sterilized food container.

SOP #5 Inoculation

All inoculations and tissue harvesting of suckling mice will be conducted in an approved, certified biosafety cabinet. The inoculation of a BSL-2 agent will be conducted only in a certified Class II BSC. Appropriate personal protective equipment (PPE) will be used when entering the laboratory space.

1. Inoculate the pups with a given volume (10-20 μ L) of specimen by intracranial (IC) route using a 0.5 mL retractable sleeve syringe permanently attached to a 26-gauge 3/8" needle. Immediately after use and WITHOUT further manipulation the syringe will be discarded directly into a puncture resistant sharps container inside the BSC. The Sharps container will be autoclaved and kept separate of regular trash.
2. The injection site is diagrammed below:



Note: Diagram shows injection site approximately 1 cm away from optical nerve (as indicated by the + sign). Although not depicted above, appropriate PPE will be worn at all times in the laboratory.

3. Return pups to the mother.

SOP #6 Post Inoculation Observations and Husbandry

1. Observe for any signs or symptoms of illness post inoculation at least twice daily.
2. Record any change in the appearance, activity, and size of the suckling mice on the daily record sheet (see Post Inoculation Daily Site Log).
3. Any pups showing signs of illness such as hunched, hyperactivity, hind limb paralysis, ataxia, and failure to thrive will be euthanized by cervical dislocation. If there are 3 or more pups showing the above symptoms, we will euthanize the entire litter to prevent unnecessary pain and suffering.
4. Euthanized pups will be frozen in an ultra low temperature -80°C freezer for future brain extraction. All pups that are frozen will be logged into the experimental notebook.

SOP #7 Carcass and Waste Disposal

1. On the completion of the experiment, all cages along with the bedding will be taken directly to the autoclave in red autoclave bags and autoclaved at 121°C and 18 psi for 1 hour. After the autoclave the cages will be placed in the general Vivarium cage waste stream.
2. All remaining infectious wastes generated from the ABSL-2 (unused feed and other disposables) will be transported in a leak proof container and directly placed into the autoclave for immediate sterilization. All other non-consumables (forceps, surgical scissors, etc.) will be disinfected in 10% bleach after use, collected in a separate box and autoclaved for sterilization. Sharps such as needle etc will also be autoclaved in separate sharps designated box.
3. Nozzles from the feeder bottles will be removed and the water from the water bottles will be discarded into the dirty cages. The bottles will then be placed in a separate red biohazard bag to be autoclaved along the Isocages™.
4. After the brain dissection the carcass and animal tissues will be wrapped in biodegradable absorbent paper and collected in a separate red bag, and stored at -80° C. The bag containing carcasses will be properly labeled with the following information before being autoclaved:
 - a) Room number
 - b) Date
 - c) Principal Investigator (PI)
 - d) Type of animal Waste
 - e) Number of animals
 - f) Name of BSL-2 agentArrangements and coordination must be made with the AVS staff 24 hours prior to disposal of carcass waste in tissue digester.
5. The carcass waste will be fed into the AVS tissue digester. No plastic or non-biodegradable items will be placed in the tissue digester.

SOP #8 Maintenance of Cleanliness and Safety

The ABSL-2 laboratory will undergo weekly sanitary and safety maintenance that will be conducted and logged as follows:

1. Disinfect bench tops and equipment with 10% hypochlorite solution (Clorox, made fresh daily) or Quaternary Ammonium Compound. This will be immediately followed by 70% Ethanol disinfection (stocks of these disinfectants kept under sink within Suite).
2. Disinfect floors by mopping.
3. Inspect safety devices such as eyewashes and emergency showers for operability and document on log sheet.
4. Tidy and reorganize areas that appear cluttered and/or disorganized.
5. Hazardous biological, chemical, or physical agents WILL NOT BE STORED WHERE ANIMALS ARE HOUSED. Remove any of these agents if they are found.
6. Log activities and observations regarding cleanliness and safety (See Cleanliness and Safety Log)
7. Half-yearly disinfection of feed storage containers will be conducted as described above for bench tops and equipment.
8. See Spill Clean-up SOP regarding spills.
9. In the event of an emergency, quickly secure animals and experimentation and evacuate (See Emergency Procedure SOP).

SOP #9 SPILL CLEAN UP

All mouse related dry and wet spills (feed, water, bedding, feces, and urine) in the ABSL-2 laboratory will be presumed contaminated and will be cleaned immediately as followed:

1. Disinfect the spill with sodium hypochlorite solution or Quaternary Ammonium Compound and allow the disinfectant to soak with the spill for a minimum of 10 minutes.
2. Clean up the spill area with paper towels and dispose of the waste in an appropriate biohazardous waste bin.
3. Follow the spill area with fresh 10% hypochlorite solution (Clorox) or disinfectant solution and wipe immediately for disposal into a biohazardous waste bin.
4. Use 70% Ethanol in the spill area and wipe up with paper towels to complete disinfection.
5. For larger spills greater than 10 mL use the designated spill kits located in the ABSL-3 Preparation Room.

SOP #10 LIQUID WASTE MANAGEMENT

All liquid waste generated during manipulation within the Biosafety Cabinet is chemically neutralized with no less than 10% sodium hypochlorite solution, made fresh daily. Contact time with the chemical neutralizer is to be no less than 20 minutes. Once the effective neutralization period elapses, the solution is diluted with water to an appropriate neutral pH level as indicated by the use of pH strips located in the sink area, and disposed of down the drain in the Manipulation suite.

SOP #11: ABSL-2 ENTRY PROCEDURES

Entrance into the ABSL-2 Suite

1. Pass keycard over reader at Vivarium hallway door and touch finger on biometric sensor.
2. Enter and pass through the Vivarium locker room.
3. Don the Vivarium PPE: White Tyvek gown and booties over your clothes immediately after exiting the locker room and entering the Vivarium PPE corridor.
4. Enter your PIN to have access to the Vivarium, and proceed down the clean corridor to the ABSL-2 area.
5. Proceed to the ABSL-2 animal holding suite.
6. Check for any special PPE requirements posted at the door of your assigned Animal Suite.
7. Monitor the animal suite by pressing the down arrow of the EDSTROM panel to monitor temp (should be between 70-74 degrees F), humidity (should be between 40-60%), and airflow (measured in CPM, changes per hour, which should be between 10 and 20; measured in CFM, cubic feet per minute which should be between 700 and 1500).
8. Open metal plate on door and view interior of the suite to be entered to make certain that entry into the Manipulation Suite is safe and not interfering with any active manipulations being conducted.
9. Post Active Manipulation sign and No Entry sign on Suite Door.
10. Enter PIN to gain access to the ABSL-2 suite. NO PIGGYBACK POLICY ENFORCED. Each person must use their own keycard to enter the ABSL-2 lab and all personnel must be IACUC and IBC approved protocol associates.
11. Enter the ABSL-2 suite. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.
12. Don primary layer of gloves (black gloves).
13. Don a second pair of booties.
14. Don a blue wrap-around gown.
15. Don sleeves.
16. Don Surgical Mask.
17. Survey the room for any irregularities and lab cleanliness.
18. Work within the Manipulation Suite can begin adhering to the guidelines and agent specific protocols that have received IACUC approval.

SOP #12 ABSL-2 EXIT PROCEDURES

Exit Procedures for the ABSL-2 Animal Suite

1. When finished with any active manipulations, be sure to remove the manipulation sleeves and the secondary glove and disposing of directly in the Biohazardous Waste container nearest the BSC.
2. Clean BSC with 10% bleach (made fresh daily) or 5% quaternary ammonium compound, dry and wipe down with 70% alcohol, allowing for the appropriate contact time specific for each cleaning agent—10 MINUTES.
3. DO NOT UV the Baker Sterilguard Hood. This model hood needs to be left on so that the suite exhausts properly.
4. Make certain that all waste generated for the day is contained within the Waste Container and that the lid is closed. Spray the Waste Container down with 70% Ethanol.
5. Note time finished in the BSC on the Logsheet.
6. Survey the area for any spilled bedding or irregularities in cleanliness. If something is detected, please treat as a Biological Spill and decontaminate as dictated in the Biological Spill SOP.
7. Survey and log the Isocage™ unit is functioning properly, reading at -100 Pascals, all cages are docked properly (noting that all yellow tabs are not visible—yellow flag means docking is improper and must be addressed before exit), and mice are behaving normally.
8. Doff outer layer of booties before removing outer gloves.
9. Doff blue gown and either store for future use or place in Waste Container.
10. Remove outer gloves and place in Waste Container.
11. Disinfect inner glove with 70% Ethanol.
12. Disinfect inner booties with 70% Ethanol spray just prior to exit.
13. Press release bar on the wall next to the door in order to open the door.
14. Walk to the Vivarium exit, following the soiled corridor and reach the exit door, which leads back to the Locker Rooms.
15. Press release bar and enter the PPE corridor.
16. Remove and gown and booties. Dispose of in the properly labeled containers.
17. Enter the Locker Room.
18. Wash hands inside Locker Room, and then exit.

19. Exit the Vivarium

SOP #13 Kaka'ako BSL-2 and ABSL-2 Sharps Management

1. Hypodermic syringes and needles will be issued only to authorized personnel, and must only be used for research purposes.
2. Stocks of hypodermic syringes and needles will be secured in a secure place (e.g., locked drawer, cabinet, or room) with controlled access. Hypodermic syringes and needles not in reserve, not in main stocks, and not in use must also be stored under suitable locked conditions.
3. All work will be conducted with only one uncapped hypodermic needle at a time. Keep uncapped needles and other sharps in view.
 - a) DO NOT place a needle cap in your mouth in order to remove the cap.
 - b) DO NOT leave sharps unattended.
4. Place a biohazard sharps container within an arm's reach of the area where sharps are used. Position the biohazard sharps container low enough in the work area so that you can readily visualize the opening. Biohazard sharps containers are available for purchase from laboratory supply companies (e.g., Fisher, VWR, etc.).
5. Immediately dispose of a used hypodermic syringe and needle, as a unit, directly into a sharps container, **without any further manipulation**. Avoid bending, breaking, shearing, or removing needles from syringes. Likewise, dispose of any broken glassware contaminated with biohazardous materials directly into a biohazard sharps container. Store reusable sharps in a puncture resistant container, to prevent accidental or unintentional contact. If contaminated with biohazardous materials, reusable sharps should be stored in disinfectant solution until processed.
 - a) Sharps MUST NOT be disposed in the regular trash.
 - b) If vacutainers are to be reused, secure the hub of the needle in a sharps container and unscrew it directly into the container.
6. DO NOT recap needles. Recapping of needles causes more injuries than it prevents. However, if it is absolutely necessary to recap needles, for example, as part of a protocol, you must use either:
 - a) A mechanical device such as forceps to replace the cap on the needle,
Or
 - b) Transport any recapped needles in secondary containers to prevent accidental inoculation.
7. Avoid handling any broken, contaminated glassware directly by hand, even if wearing gloves. Use a device such as tongs, forceps, brush and dustpan, or even two pieces of cardboard.
8. Biohazard sharps containers will be disposed when they are 3/4 full. Secure the containers to prevent leakage, punctures, and spillage during transport. Sharps containers must be disposed through the UH-EHSO program.
 - a) Sharps containers must not enter the regular solid waste stream.
 - b) DO NOT overfill biohazard sharps containers.
9. DO NOT force a sharps item into a container, or retrieve a discarded item.

SOP #14 EMERGENCY RESPONSES TO HVAC AND POWER FAILURE

Should a power outage or an HVAC failure occur at the University of Hawai'i-John A. Burns School of Medicine at Kaka'ako, these procedures will be followed:

POWER FAILURE

If a power outage does occur while you are working in the ABSL-2 labs, these labs are designed to run on back-up emergency power so you should not be affected. The back-up power should maintain the air pressure in the suites as well as in the Isocage™ system. Additionally, the Isocage™ system is an independent unit, which has its own back-up power—the UPS (Uninterrupted Power Supply) has the ability to supply power to the Isocage™ system for 3 to 6 hours, independent of the building systems, which will allow the Isocage™ to maintain negative pressure in the cages. If building power is not restored within the 3 to 6 hour timeframe, the exhaust fans of the Isocage™ will no longer function and the negative pressure of the Isocage™ will continue to draw in environmental air until the pressure is equalized (becomes static, NOT POSITIVE), at which point, the mice will have approximately 15 minutes of Oxygen, and will then suffocate and perish. Note that no air is being exhausted from the cage in this scenario and the DOUBLE HEPA filtration is still in place and functional.

HVAC FAILURE

The HVAC system is a redundant system consisting of two exhaust fans. When one fan becomes inoperable, the backup fan should engage and become operational in just moments. If both fans are not operating, the situation will be immediately noticeable, as the suites will no longer hold proper pressure and air exchanges. However, it will not have any effect on the BSC cabinet in ABSL-2, as it is not hard-ducted. The HVAC system failure will have NO effect on the Isocage™ itself. The Isocage™ system has complete containment and filtration independent of the building HVAC. The building HVAC serves as to help control the odors from the Isocages™ only, and is not necessary for Isocage™ biocontainment. In fact, there is a special "thimble" connection between the Isocage™ exhaust and the building HVAC specifically designed not to be airtight to prevent the interference of the building HVAC with the Isocage™ function. Again, it is important NOT to have an airtight connection between building exhaust and Isocage™ exhaust in order to prevent interference with the Isocage™ airflow rates and pressure balance.

RESPONSE

1. However, regardless of the nature of the failure, you should immediately stop working and start to secure any biological agents, animals, and/or chemicals. Depending upon the ongoing procedures following steps should be taken:

NOTE: While conducting following procedures, it is mandatory to wear a N95 mask.

- (a) Inoculation:** While inoculation, coronavirus inoculum is prepared in a 0.5 mL syringe. In case of power failure immediately flush the syringe with 10% bleach. Place the animals back in the Isocage™ and seal them immediately with the lid. Spray and wipe it clean with 70% ethanol and immediately place the Isocages™ in the Isocage™ rack. Discard the syringe in the sharps container. Close the BSC sash immediately and leave the suite.
- (b) Euthanasia:** During this investigation mice are sacrificed followed perfusion and tissue. If the power failure occurs before animal sacrifice, then immediately place the animals back in the cage. Seal the lid; wipe the cage with 70% ethanol from outside and then place the cage in the Isocage™ rack. If the power failure occurs during

sacrifice, then immediately spray mice with 10% bleach, cover with paper towel and place it in a red biocontainment bag. Dip surgical instruments in the bleach. In case the power failure occurs during tissue processing, discard any tissue harvested in the beaker with 10% bleach. Dip the surgical instruments used to process tissues in the bleach solution. Close the BSC sash and leave the suite. The virus is contained and decontaminated at this time point.

2. Remember to close all Biological Safety Cabinet sashes.
3. Notify Security (692-0911 or 692-1911).
4. Disconnect all equipment that could be damaged by a power surge when electricity is restored.
5. Turn off all appliances and other energy users to reduce the power requirements for restoration.
6. If animals are currently housed within the Isocage™ system DO NOT UNPLUG the unit, it has its own UPS and should not be unplugged.
7. Do not evacuate the building unless instructed to do so by emergency services (HPD, HFD, and JABSOM Security). If you are instructed to evacuate the building, use the emergency EXITS and go to a designated Evacuation Gathering Area to await further instructions from emergency services. (See Diagram for Designated Evacuation Gathering Area below).
8. If instructed to evacuate, follow SOP to exit the lab.

Appendix 1 – Pest Management Plan Specific for Kaka’ako BSL-2 and ABSL-2

The Kaka’ako, JABSOM, BSL-2 and ABSL-2 facilities infrastructure meets the standards defined in the 5th edition of the BMBL. Similarly, all BSL-2 and ABSL-2 experimental practices, and containment practices will be adhered to as prescribed in the 5th edition of the BMBL. The standard operation procedure (SOP) for conducting Coronavirus research is described in detail in the previously described SOPs.

General Level-2 Pest Management Plan

The following describes the JABSOM Kaka’ako Plan for minimizing the risk of insect and rodent vector transmission of hazardous agents from the Level 2 Facilities. Many pests can mechanically transmit disease pathogens and compromise the research environment. As such, integrated pest management (IPM) is an important part of managing a Research Facility. The Plan relies heavily on the education and assistance of JABSOM Facilities Staff who care for JABSOM buildings and grounds. Consequently, it is the policy of the JABSOM Facilities to reduce or eliminate the potential for pest breeding, harborage and entrance to the research facility. Proper sanitation, good housekeeping, and good building maintenance are key factors to keeping insects and rodents from entering the buildings.

Insects

1. Users of ABSL-2 and BSL-2 will routinely inspect the labs for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.
2. Facilities will contact a Licensed Pesticide Contractor on an as-needed basis to inspect, verify and take proper treatment to eradicate insects in the ABSL-2 and BSL-2 areas that are affected as well as other areas of the campus. The Contractor shall meet with EHSO to discuss the Pesticide to be used and application to ensure all EPA FIFRA requirements and guidelines are followed and to ensure the safety of the JABSOM Kaka’ako occupants. Pesticides may only be applied when the lab is closed down for maintenance, i.e. there are no active research being conducted.

Safety:

Every effort must be made to insure that pesticide application/exposure is held to a minimum to insure the safety and welfare of JABSOM Kaka’ako Occupants and Research Projects.

Preventive applications of pesticides are not encouraged in any Research Facility. As such, pesticide application(s) are restricted to areas where pest populations cannot be controlled by other means.

3. Facilities shall monitor the Pesticide Contractor to insure treatment was administered effectively.

Rodents

1. If there are signs of rodent infestations in the Level 2 Labs, the Users shall inspect the areas and capture any rodents. Traps shall be placed throughout the lab. The rodent shall

be contained in the Level 2 Lab until an investigation conducted by EHSO is concluded and decisions are made regarding testing the rodent for infection, destruction of the rodent, surveying the facility for ports of entry for rodents, decontamination of the facility, SOP evaluation and revisions as necessary.

2. Careful records of all animals shall be maintained and any unaccounted for rodents shall be reported to the Laboratory Director and Supervisor, LAS, and EHSO immediately.

Mosquitoes

1. JABSOM Facilities shall maintain the buildings and grounds according to the general JABSOM Kaka'ako Pest Management Plan to prevent, identify, monitor, and eliminate mosquito-breeding sites and to prevent wild mosquitoes from entering the research building. Refer to the General Plan. If wild mosquitoes are able to enter the building, there are several safeguards that prevent the wild mosquitoes from contacting infected animals or inoculated cultures; refer to the specific protocol SOPs.
2. ABSL-2 and BSL-2 protocols involving mosquitoes will include specific plans for monitoring mosquitoes. In addition to the engineering and work place controls, researchers may use blue light zappers, sticky tapes, baits, etc.; refer to specific protocol SOPs.

SPECIFIC PROTOCOL IPM

Specific IPM shall be protocol driven.

Arboviruses

1. Users of ABSL-3 and BSL-3 will routinely inspect the labs for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.
2. Hanging the sticky mosquitoes' trap is required
3. Users will keep the ABSL-3 and BSL-3 lab clean and make sure there is no standing water container in order to disrupt the reproductive cycle of the mosquitoes.
4. Animal inoculation will only be done in the BSC.

There are three potential Flaviviruses mosquito vectors in the Hawaiian Islands, *Culex quinquefasciatus*, *Aedes albopictus* and *Aedes (Ochlerotatus) japonicus*. The first two are ubiquitous and occur on all islands, including Oahu. *Ae japonicus* has recently been introduced to the Big Island, where its distribution is still relatively limited.

Moreover, JABSOM Facilities provide building, campus wide monitoring, and protection. The following is the Facilities Management Plan.

Many pests can mechanically transmit disease pathogens and compromise the research environment. As such, integrated pest management (IPM) is an important part of managing a Research Facility. Consequently, it is the policy of the JABSOM Facilities to reduce or eliminate the potential for pest breeding, harborage and entrance to the research facility

RECORD KEEPING AND PROGRAM EVALUATION

1. Visual sightings or other evidence of any pests shall be reported to the Lab Manager/Supervisors and EHSO immediately and shall be documented.
2. Reports communicated verbally and in writing concerning pest activity will be recorded and kept on file by Lab Manager/Supervisors, Facilities, and EHSO.
3. The Laboratory Director, JABSOM Facilities, and EHSO shall also maintain inspection results for review.

Quality assurance and program review must be performed to provide an objective, ongoing evaluation of pest management activities. EHSO is responsible for evaluating the effectiveness of all pest control procedures implemented and approving or redirecting efforts to control pests found.

JABSOM KAKA'AKO CAMPUS BUILDINGS AND GROUNDS

1. Building occupants should routinely inspect their work areas for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.
2. JABSOM Facilities will contact a Licensed Pesticide Contractor on an as-needed basis to inspect, verify and take proper treatment to eradicate insects in areas that are affected as well as other areas of the campus. The Contractor shall meet with JABSOM EHSO to discuss the pesticide to be used and application to ensure all EPA FIFRA requirements and guidelines are followed and to ensure the safety of the JABSOM Kaka'ako occupants.

Safety: Every effort must be made to insure that pesticide application/exposure is held to a minimum to insure the safety and welfare of JABSOM Kaka'ako Occupants and Research Projects.

Preventive applications of pesticides are not encouraged in any University Facility. As such, pesticide application(s) are restricted to areas where pest populations cannot be controlled by other means.

3. JABSOM Facilities shall monitor the Pesticide Contractor to insure treatment was administered safely and effectively.
4. If there are signs of rodent infestations in the buildings or on the grounds, contact Facilities and complete a Work Order Request.

All unaccounted for lab rodents shall be reported to EHSO, Security, and Facilities immediately.

REDUCING THE NUMBER OF MOSQUITOES ON THE JABSOM KAKA'AKO GROUNDS, NEAR BUILDING ENTRANCES, AND IN THE BUILDINGS

Proper sanitation, good housekeeping, and good building maintenance are key to keeping insects and rodents from entering the buildings.

Draining sources of standing water reduces possible breeding areas. In addition, larvicides (to control breeding areas) and other pesticides may be used to reduce mosquito populations.

- JABSOM Facilities shall respond to any standing water problems in the landscape on campus.
- JABSOM Facilities shall schedule preventive maintenance on gutters and downspouts and the fountain in front of the Medical Education Building.
- Potential mosquito breeding areas (wetter areas of landscaping, etc.) shall be inspected periodically and treated with pesticides when mosquito presence is reported. These “trouble” areas shall be monitored periodically to ensure there are no breeding mosquitoes.
- Trash, recyclables, and discarded equipment and materials must be contained in the trash compactor or promptly removed from all collection areas. Any spilled trash outside of the trash compactor shall be reported to JABSOM Facilities and Custodial staff shall promptly remove the trash.
- The checklist below is provided to JABSOM Facilities to identify and eliminate breeding sites such as empty containers, puddles on construction sites and areas of poor drainage.

RECORD KEEPING AND PROGRAM EVALUATION

Visual sightings or other evidence of any pests reported to the Facilities shall be documented. Reports communicated verbally and in writing concerning pest activity will be recorded and kept on file by Facilities.

Quality assurance and program review must be performed to provide an objective, ongoing evaluation of pest management activities. Facilities is responsible for evaluating the effectiveness of all pest control procedures implemented and approving or redirecting efforts to control pest found.

JABSOM FACILITIES CHECKLIST

Grounds - Lawn & Soil

- Are there low spots or potholes that hold water after a heavy rain?
- Are ditches and storm water drainage areas free of trash and debris?
- Are there any areas where standing (stagnant) water can be found regularly?

Grounds - Other

- Does water collect in the bottom of trashcans or the trash compactor?
- Does water collect in plant containers?
- Is there anything else in, on or near the building that is likely to hold water after a heavy rain?
- Is the trash compactor area maintained:
 - is trash spilled outside of the trash compactor promptly removed and placed into the trash compactor?
 - is the surrounding area cleaned?

Roofs

- Do leaves and debris collect easily on the roof or roof drainage systems?
- Is drainage system clear and working properly?
- Does water tend to pool anywhere on the roof or in the drainage system?

Fountain

- Is water in the decorative fountain moving or standing still?
- Is the water treated with the appropriate amount of chlorine?

Neighborhood

- Are there nearby construction sites that may have potholes or low-lying areas that would retain water after a heavy rain?
- Is there anything else (ex. Tires, birdbath) on an adjacent property that would be likely to hold standing water?

Appendix 2 – SOP for Tsunami

SOP for tsunami in ABSL-2 and BSL-2

1. If working in a Biosafety Cabinet (BSC)

- a. Seal all open cultures (this includes putting animal carcasses in a sealed or disinfectant filled container).
- b. Cover pipette trays.
- c. Carefully remove your outer gloves, and leave them in the BSC.
- d. Close the sash to the lowest possible position.
- e. If time permit, animals will be sacrificed as well as infected culture by autoclaving.

NOTE: If you believe that you are in immediate danger from tsunami, DO NOT perform the procedures described for the BSC and immediately exits the building. The Isocage™ systems, which house the animal, are waterproof and without power supply, the animal will die in 15 minutes due to suffocation. Freezer and incubator are waterproof. Therefore infected material will not spread into the environment. In worse case scenario when salt water can get into these equipment's, salt water will kill all these infected cultures and animals.

2. If you are working outside of a cabinet, close up any equipment/appliances you are working with.

3. Just prior to leaving the barrier:

- a. Animal suites: discard shoes, gloves, and mask
- b. Virology suites: discard lab coat, gloves

4. Proceed out of the building towards the designated exits according to your JABSOM evacuation plan.

6. Stay at the designated evacuation gathering areas and wait for further instruction from Emergency personnel.

7. If the situation is cleared, and the building can be re-occupied, return to your labs (under the appropriate conditions), and finish/clean up your work.

8. At your earliest possible convenience fill out an Incident Report if a potential exposure occurred.

Appendix 3 - Bomb Threat/Suspicious Package SOP

BOMB THREAT/SUSPICIOUS PACKAGE

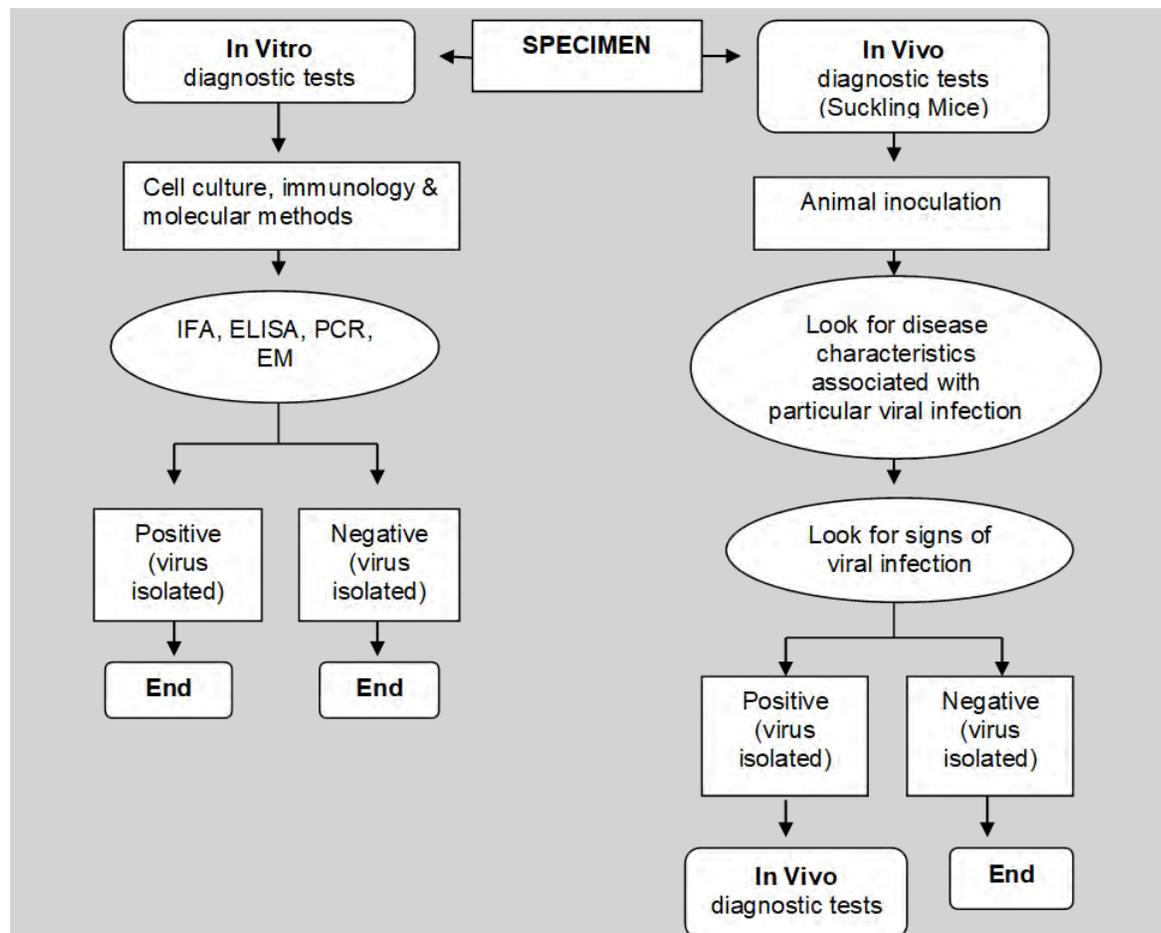
- Called in Bomb Threat
 - DO NOT hang up on caller
 - Keep them on phone for as long as possible and get as much info as possible
 - Once caller hangs up, contact Security
- Suspicious Package
 - DO NOT open or move package
 - Vacate area and notify Security and Biosafety Program

Experimental Procedure for Inoculation of SARS-CoV-2 into Mice and Cell Culture

All the procedural manipulation of mice and/or cell culture testing will be done inside a Class II Bio-safety Cabinet (BSC). Skilled and trained researchers will do all manipulation. Each investigator will have had prior experience working with animals and will be able to detect abnormal behavior and understand proper handling techniques of mice and cell culture. They will follow the safety regulations set by IACUC and University of Hawaii Biosafety office and Office of Research Compliance.

Suckling mice (pups) 2-4 days old will be used to grow the potential virus contained within the diagnostic samples obtained from humans, mosquitoes, and animals. Suckling mice are considered a highly sensitive method for virus isolation and inoculation of this age of mice is a standard, classical laboratory technique that has proven effective for decades of research. Most Arboviruses can replicate well only in a living animal host according to Topley and Wilson's Microbiology and microbial Infections 10th Edition vol.2, p1050.

In the diagnostic procedures to identify biological specimens, a two track parallel testing system will be employed which includes both and in vitro (in cell culture) and in vivo (in animals) methods for the isolation unknown agent as shown in Figure 1.



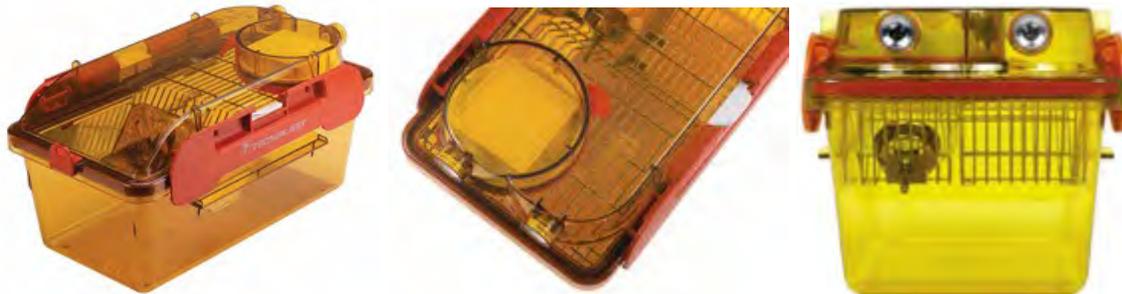
This dual, parallel approach assures the broadest coverage for isolation of virus regardless of the type of biological specimen submitted for screening and can be accomplished in a timely fashion. In the animal portion of this approach, the suckling mice will be inoculated intracranially. During this *in vivo* incubation period the investigators will be looking for signs of viral infection. Simultaneously the cell culture phase will include inoculation of both mammalian and arthropods cell systems and further testing of samples by Polymerase Chain Reaction (PCR) using broad group primers. Visual observation of viral activity can be seen in cell cultures by a microscope and further identification is possible with the aid of immunofluorescent staining, Enzyme-linked Immuno Sorbent Assay (ELISA) and Electron microscopy.

About 15-35 pregnant female Swiss Webster mice will be utilized for each investigation. These mice will either be purchased from a certified Specific Pathogen Free (SPF) vendor or will be bred in the Kaka'ako Vivarium Level 2 and transferred into the ABSL-3 when appropriate. Please see SOP # 2 for receiving pregnant females Mice from LAS and transfer into the ABSL-3. Prior to transfer into the ABSL-3, the mothers will be transferred to a total bio-containment, individually housed cage. Isocage™ information is detailed in Appendix 6 and in the Daily Husbandry and Observation Prior to Inoculations SOP #3. Two to three days after birth, the pups be will be inoculated intracranially (IC) with 20 uL of the suspected, unknown, viral sample (See SOP # 5 Inoculation). This type of inoculation will allow the virus, if present, to replicate in the animal host. After the inoculation procedure, pups will be gently returned back into the mother's Isocage™. The pups will be closely monitored twice daily post inoculation for any signs or symptoms of a viral illness. See SOP # 6 for Post Inoculation Observation and Husbandry and Daily Site Log.

If we find by either *in vivo* or *in vitro* methods that the agent isolated belongs to a family of viruses in a higher biosafety level, is a Select Agent, or if we cannot identify the agent, the research on this agent will cease immediately. Appropriate actions will be undertaken: the principal investigators will communicate and consult with Research Compliance, JABSOM Biosafety Officer, the IBC, and LAS within 24 hours of the determination. CDC, and/or APHIS, and Hawaii Department of Agriculture will be informed within 7 days, and a permit for the viral agent will be applied for if agent permit is not already in possession. The agent, and all cultures generated from this research, will be sent to the Special Pathogens Branch, CDC Atlanta or to the Boston National Laboratory in Boston. Please see Standard Operational Procedure # 8 detailing the packaging and shipping out of infectious agents. If after consultation among investigators, the Research Compliance Officer, the JABSOM Biosafety Officer, CDC, and USDA, the viral agent isolated is a Biosafety Level 4 agent, or deemed to pose too great a risk to continue to safeguard or ship to the previous listed agencies, then the materials

generated from the experiment will be destroyed and documented as such and witnessed by the Investigators, the Research Compliance Officer, and the JABSOM Biosafety Officer.

The inoculated sucking mice and their mothers will be housed in the ABSL-3 in the Isocage™ cage and rack system. The Isocage™ is a hermetically sealed, individually ventilated cage (IVC) that creates absolute containment comparable to that obtained by other types of isolators, while at the same time maintaining the simplicity and ease of use typical of IVCs. The Isocage™ features a HEPA filter on the exhaust valve protected by a pre-filter, in addition to a HEPA filter at the cage level, the air is then pulled through another pre-filter and HEPA filter at the rack level, **GUARANTEEING TRUE BIO-CONTAINMENT AT EVERY LEVEL!** The HEPA filter and the pre-filter can be removed and quickly changed when the cage is open and in a protected environment. The Isocage™ guarantees a stable, lasting hermetic seal under both normal working conditions and also when the cage is removed from the rack. The hermetic seal is so efficient, that if the cage is removed from the passive air flow of the rack system, air flow in the cage will cease, and the oxygen supply within the cage will be depleted within 15 minutes, which results in further reassurance of aerosol containment regardless of whether the cage is docked in the rack system.



If during the course of the research, three or more of the pups within a litter show signs of viral infection such as hunched, hyperactivity, hind limb paralysis, ataxia and failure to thrive, they will be humanely euthanized by cervical dislocation to prevent unnecessary pain and suffering. Immediately following death, animals will be placed into an ultra low temperature freezer. The carcasses will be thawed at a later date in order to harvest the brain or liver tissues (the former by means of needle/syringe aspiration the latter by use of forceps and scissors) from which the infectious virus will be extracted by homogenization in a diluent. All remaining infectious wastes generated from the ABSL-3 (animal tissues, contaminated bedding, unused feed, sharps, and other disposables) will be transported in a red biohazard containment bags and placed directly into the autoclave for immediate sterilization. If there are no visible signs and symptoms of illness and disease among the litter after two weeks, we will terminate the experiment by euthanizing all the animals using cervical dislocation technique. The carcass will be properly contained in a red biohazard containment bag, transported in a leak proof container, inventoried, and held in an ultra low temperature freezer until placed into the autoclave for immediate sterilization. Please see SOP # 7 for carcass and waste

disposal guidelines. The non-disposable surgical tools will be chemically neutralized in a 10% bleach solution for a minimum of 15 minutes, then rinsed in water and placed into a pan for autoclaving. The disposable surgical tools and sharps will also be chemically neutralized in 10% bleach solution for a minimum of 15 minutes, then placed in a rigid, biohazard sharps container, which once full, will be autoclaved and then disposed of in accordance with current EHSO guidelines (please see Kaka'ako High Containment Sharps Disposal Plan).

To validate the function of the autoclave and ensure proper sterilization by reaching appropriate temperature, pressure, for appropriate duration, a Class V Integrator will be placed in a minimum of two locations along with the waste during the autoclaving cycle. After the cycle is completed, the Class V Integrator strips are collected and verified for proper sterilization and stored in the autoclave log book.

Spills related to feed, feces, water, urine, bedding will be cleaned immediately as in SOP# 9. The ABSL-3 also will undergo weekly maintenance both sanitary and safety as noted in SOP#10. The specific routine for exit and entry of the ABSL-3 is also included in the following documents and is further separated into two types of entry and exit: active and passive, as determined by the activities conducted and the risk involved with such activities. This delineation will be shown mostly in the level and amount of personnel protection equipment (PPE) portion of these SOPs.

SOP #1: RECEIVING AN INFECTIOUS PACKAGE CONTAINING BIOSAFETY LEVEL 3 PATHOGEN

1. Email and voice communication from the researcher with Dr. Nerurkar concerning his/her finding about the shipping of the pathogen will be documented.
2. Either World Courier or FedEx will send Coronavirus to Hawaii. The sender and the carrier will follow all standard safety measures. The sender will provide us with a tracking number so that we can track the location of the package containing the agent at any given time.
3. The agent will be packed in an air sea Biopack. This container 4G/ class 6.2 is suitable for all infectious substances under I.C.A.O. class 6.2, US DOT and IATA. This container will be placed in another container and labeled with an infectious substance, universal biohazard symbol, and UN dry label and accompanied by documented paperwork.
4. The specific information about the arrival of the agent at Honolulu can be found electronically using the given tracking number. The airport quarantine office of Hawaii Department of Agriculture will call us as the packaged is cleared by inspection.
5. Arrival of the package to the Kaka'ako Biosciences Building:
 - a. The package will be delivered to Kaka'ako on working days between 8 AM and 5 PM by the courier. The mailroom personnel or building security personnel are not to receive, or in any way handle the package. Their only response is to notify Dr. Vivek R. Nerurkar at (808) 692-1668 or (808) 753-6961, or trained biocontainment personnel employed the Department of Tropical Medicine, Medical Microbiology, and Pharmacology. If neither Dr. Nerurkar is available, the package will be refused.
 - b. Alternatively, the package can be picked up by the airport regardless of the time or holiday.
 - c. The package must have the HDOA stamp of inspection on the package otherwise HDOA will be notified. We will place the packaged in a secure freezer in the JABSOM biocontainment and await instructions.
 - d. If the package is on dry-ice and is near empty, or noticed to have a low amount of dry-ice will open the outer package and replenish, store in a secure area, and wait for further instruction from HDOA.
6. The package now will be handled by the following methods regardless of the route of its arrival at the Kaka'ako Biosciences Building.
 - a. The package will be carried to the BSL-3 biocontainment facility. This will be done by the coordination of two authorized staff. One will carry the package and the other staff will open the doors leading to the BSL-3 biocontainment

facility. The package will be immediately brought to the BSL-3 biocontainment facility and placed directly in the interlocked pass through. The package remains there until it is picked up on the ABSL-3 side of the pass through after the surface of the packaged is chemically disinfected.

b. After personnel have donned appropriate PPE, the package will be carried through the other door secured by Edstrom lock system to get into the ABSL-3 and into suite A or suite B. The package then will be placed into a biosafety cabinet (BSC). The investigator working in the BSC will remove the outer wrap and packaging materials. The inner small package (4G/ 6.2) will be chemically disinfected by spraying the surface with a 10% bleach solution.

7. The 4G/6.2 packages will be placed in the locked freezer until the experimental procedures can be conducted. The outer package material left in the BSC will be placed in a red autoclave bag and placed directly into the autoclave in the ABSL-3 facility.

SOP #2 RECIEVEING PREGNANT FEMALE MICE FROM Animal and Veterinary Services (AVS)

1. Rodents will be procured from approved commercial vendors of known specific pathogen free (SPF) status.
2. All shipments received by Laboratory Animal Services (AVS) will be assigned a unique AVS number on the corresponding Historical Data Sheet (HDS) that will be provided by the AVS office. The AVS number will be noted on the Chain of Custody Form.
3. Animals will be tracked internally by AVS through Granite Cage Cards.
4. The mice used for experiments will be time-pregnant animals, and will be acclimated 1-3 days in the Vivarium after arrival for the purpose of physiological, psychological, and nutritional stabilization before their use.
5. AVS will have Isocages™ and bedding ready before the shipment and arrival of the pregnant female mice.
6. AVS will receive the mice in the shipping container and will disinfect the box at the Vivarium airlock.
7. When ready to receive the pregnant female into the ABSL-3 suite, the AVS Facility Supervisor or the designee will be contacted with at least 24hrs prior notice to arrange the date and time of transfer from the Vivarium into the ABSL-3.
8. Mice will be transferred into clean Isocages™ while in the vivarium just prior to be taken into ABSL-3.
 - a. The Isocages™ microisolator tops should not be placed tightly on the cage bodies until the cages are docked to their racks. Otherwise, because of the tight seal created by the microisolator top and the cage body, the mice will suffocate within 15 minutes of the microisolator top is secured while not docked to its air supply from the motor on the rack.
9. Prior to transport of the pregnant female mice to the dedicated ABSL-3 lab, the AVS staff will be consulted regarding the following:
 - a. Number of cages
 - b. Live animal labels on the cage
 - c. Granite cage cards present and accurate
 - d. Integrity of the cages (proper filters tops, holes , deformation, wetness
 - e. Record of Condition/Behavior of pregnant female mice
10. Pregnant female mice are then transported from the holding room into the ABSL-3 facility.
 - a. It is very important to note that any mice that have been accepted and transported to the ABSL-3 lab will not, for any reason, be returned back to the AVS holding area. The mice enter the ABSL-3 facility, and do not leave the ABSL-3 facility alive.

11. The Isocages™ will be immediately passed into the ABSL-3 lab via the shower/change hallway. A person wearing proper PPE should be ready to receive the animals inside the ABSL-3 lab in order to expedite the process.
12. Once inside the ABSL-3 lab, research personnel will inspect each cage and inspect the mice. The number of mice will be verified against the Granite cage card and the condition of the mice will be noted.
13. Personnel will secure the microisolator tops to the Isocages™ bodies and immediately dock it to its rack, ensuring that the motor is on and providing air supply to the cages. The cages containing the mice will remain until the completion of the experiment.
14. Once the pregnant female mice have given birth, the number of suckling mice will be recorded on the Granite cage card and on the husbandry log sheet. A 'Suckling Mouse Log' will also be maintained by the investigators and kept on record.

SOP #3 DAILY HUSBANDRY AND OBSERVATIONS PRIOR TO INNOCULATION

Daily husbandry and observations of animals must be recorded in the husbandry log sheet.

1. Check mice for vitality (healthy dieting, smooth coat, absence of injury, etc.) and note any abnormalities.
2. Ensure mice have eaten food daily and replenish feeders as they become low (3/4 empty). Feeders will not be near feces and urine and will be washed and sanitized bimonthly. Feed will be placed in a sterile container located at the housing site (See Feed Storage SOP #4).
3. Check water bottles daily and replenish with fresh water as they become low (1/2 empty). Water should be clear and will not be placed near feces and urine. To avoid microbial cross-contamination, water bottles will be replaced or refilled with potable, uncontaminated water and returned to the same cage from which they were removed. Water bottles will be washed and sanitized bimonthly.
4. The cages will be checked daily and will be changed after two weeks, depending on animal numbers cage sizes, urinary, and fecal output, and experimental conditions.
5. Cages will be decontaminated every two weeks.
6. Temperature and humidity levels will be monitored daily via the Edstrom Watchdog system, and logged on the housing site an electronic version of the Daily Husbandry Record daily. Room temperature should be 18-26°C and room humidity should be 40-70%. If temperature or humidity ranges are compromised, report to AVS immediately so a veterinarian can evaluate the impact on the animal's health and well-being.
7. Proper ventilation will be checked and maintained in the room via the Edstrom Watchdog system. At a minimum, the room should be receiving 10-15 fresh-air changes per hour. Record ventilation check on housing site log. Contact the AVS veterinarian and Facilities management if ventilation is poor.
8. Inspect all lighting fixtures to ensure working condition. Lighting should be adequate for vision and for neuron-endocrine regulation of diurnal and circadian cycles. If lighting is poor, gently move cages and mice to areas of better lighting and contact the AVS veterinarian and Facilities Management.
9. Listen to for any unnecessary noise that might startle the mice and appropriately take action to minimize it.
10. Any problems with maintaining the conditions specified in this SOP will be brought to the immediate attention of the Principle Investigator and the Attending Veterinarian.

SOP #4 FEED AND STORAGE

1. A 5 gallon sterile food container will be used to store a maximum of 20lbs of feed obtained from AVS. This container will remain at the preparatory area of the ABSL-3 at all times and will not be placed for any reason in the isolation suites.
2. Obtain rodent chow, such as Lab Rodent Diet 5001 from AVS and place into the sterile container and note the date received and expiration date on the Feed Storage Log.
3. Report to AVS and the attending Veterinarian if feed appears to be discolored, contaminated, or unusual.
4. Stock chow will be stored in a covered, labeled container including the milling date for the food, and kept in the Preparation Room of the ABSL-3 animal suites. Rodent food must be discarded if it is older than six months past the milling date. AVS will keep it filled as needed.
5. Each time feed is removed from the container, record the date of removal, the approximate amount of feed taken out, and the relocation of the feed to an appropriate cage onto the Feed Storage Log.
6. The rodent chow will be fed ad libitum, in quantities sufficient to last two days (at 5 grams of chow per day per adult mouse).
7. Sterilize the 5-gallon food container every month, removing or discarding any unused feed, and then cleaning with 10% bleach, made fresh daily or Quaternary Ammonium compound (refer to Maintenance of Cleanliness and Safety SOP) followed by sending the container to AVS for final washing by the cage washer. Use new trash bags when new feeds are added to the sterilized food container.

SOP #5 INNOCULATION

All inoculations and tissue harvesting of suckling mice will be conducted in an approved, certified biosafety cabinet. The inoculation of “unknown” diagnostic samples will be conducted in the Class II BSC. Appropriate personal protective equipment (PPE) will be used when entering the laboratory space. Refer to EHSO Infected Animal Policy for additional information regarding general procedures for the use of infectious agents.

1. Inoculate the pups when given volume (10-20uL) of specimen by intracranial (IC) route using a 0.5mL retractable sleeve syringe permanently attached to a 26-gauge 3/8” needle. Immediately after use and WITHOUT further manipulation the syringe will be discarded directly into a puncture resistant sharps container inside the BSC. The sharps container will be autoclaved and kept separate of regular trash
2. The injection is diagrammed below:



Note: Diagram shows injection site approximately 1cm away from optical nerve (as indicated by the + sign). Although not depicted above, appropriate PPE will be worn at all times in the Laboratory.

3. Return pups to the mother.

SOP #6 POST INNOCULATION OBSERVATIONS AND DAILY HUSBANDRY

1. Observe for any sign or symptom of illness post inoculation at least twice daily.
2. Record any changes in the appearance, activity, and size of the suckling mice on the daily record sheet (see Post Inoculation Daily Site Log).
3. Any pups showing signs of illness such as hunched, hyper activity, hind limb paralysis, ataxia, and failure to thrive will be euthanized by CO₂. If there are 3 or more pups showing the above symptoms, we will euthanize the entire litter to prevent unnecessary pain and suffering.
4. Euthanized pups will be frozen in ultra low temperature -80C freezer in the ABSL-3 freezer for future brain extraction. All pups that are frozen will be logged into the ABSL-3 freezer carcass logbook.

SOP #7 CARCASS WASTE AND DISPOSAL

1. On the completion of the experiment, all cages along with the bedding will be taken directly to the autoclave in red autoclave bags and autoclaved at 121 C and 18 psi for 1 hour. After the autoclave the cages will be placed on a cart in the autoclave area and the AVS staff will pick it up from there.
2. All remaining infectious wastes generated from the ABSL-3 (unused feed and other disposables) will be transported in a leak proof container and directly placed into the autoclave for immediate sterilization. All other non-consumables (forceps, surgical scissors, etc.) will be disinfected in 10% bleach after use, collected in a separate box and autoclaved for sterilization. Sharps such as needle etc. will also be autoclaved in separate sharps designated box.
3. Nozzles from the feeder bottles will be removed and the water from the water bottles will be discarded in 10% bleach. The bottles will then be placed in a rack and autoclaved along with the Isocages™.
4. After the brain dissection the carcass and animal tissues will be collected in a biodegradable autoclave bag safe to use in the tissue digester. The bag containing carcasses will be properly labeled with the following information before being placed in the -80C Ultra Low freezer located within the Preparation room in the ABSL-3:
 - a. Bag # (will link to a log book)
 - b. Room number
 - c. Date carcass placed in freezer
 - d. Principal Investigator (PI)
 - e. Type of animal waste
 - f. Number of animals
5. Arrangements and coordination must be made with the AVS staff 24 hours prior in preparation for carcass disposal in the tissue digester (see Carcass Waste SOP in JBF Biosafety Manual).
6. The Chain of Custody Form must be filled out by the PI or representative and then faxed out to AVS. The completed form will stay in the ABSL-3 binder to keep as record.
7. The frozen carcass waste will be transported from ABSL-3 in consultation with AVS staff and after AVS has received and accepted the completed Chain of Custody Form.

ABS and ABSL-3 personnel will place the carcasses in the tissue digester.

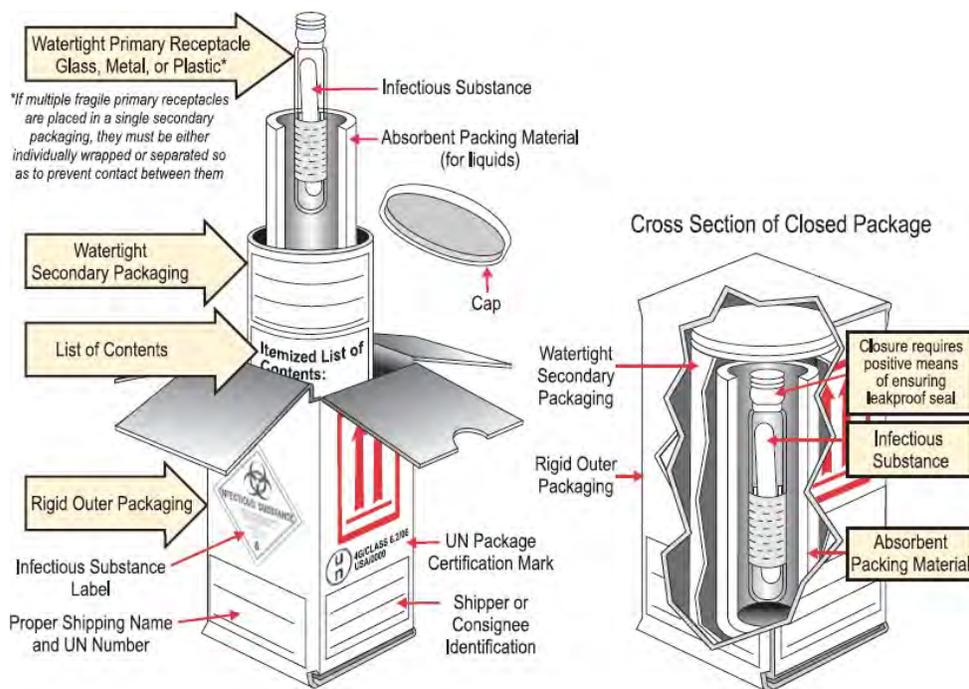
SOP #8 SHIPPING PACKAGES TO CDC

If we find that an agent belongs to a family of viruses in a higher biosafety level, a Select Agent, or we cannot distinguish the agent family by our techniques, the research on this agent will cease immediately.

The decision tree will be as follows:

Dr. Nerurkar will meet and discuss the data and come to the final decision whether or not the unknown agent should be sent to CDC in consultation with the Research Compliance Officer and the Biosafety Office. The consultation will take place within 24 hours. CDC, APHIS, and Hawaii Department of Agriculture will be notified within 7 days.

If the decision is to send to CDC, the infectious agent, animal tissue, and specimen for pathology, cell culture generated from the research will be sent to Special Pathogen Branch at CDC, Atlanta following the below packaging SOP.



"Transporting Infectious Substances Safely", PHMSA, DOT

Dr. Nerurkar will pack the 4G/ 6.2 containers in the BSC in either suite A or B of the ABSL-3 and transfer the container to a dry ice box in the Preparation Room. The package will be taken into the rear door of airlock room 126A. The package will be chemically disinfected and will be picked up from the front door of the airlock. The packages will then be transported back to the lobby of the BSB building where proper labeling, address, and phone numbers are attached to the box. Documented paperwork will accompany the package and an authorized carrier will pick up the package.

SOP #9 MAINTENANCE OF CLEANLINESS AND SAFETY

The ABSL-3 laboratory will undergo weekly sanitary and safety maintenance that will be conducted and logged as follows:

1. Disinfect bench tops and equipment with 10% hypochlorite solution (Clorox, made fresh daily) or Quaternary Ammonium Compound. This will be immediately followed by 70% Ethanol disinfection (stocks of these disinfectants kept under sink within Suite).
2. Disinfect floors by mopping with the Swiffer™ mop.
3. Inspect safety devices such as eyewashes and emergency showers for operability and document on log sheet.
4. Tidy and reorganize areas that appear cluttered and/or disorganized.
5. Hazardous biological, chemical, or physical agents WILL NOT BE STORED WHERE ANIMALS ARE HOUSED. Remove any of these agents if they are found.
6. Log activities and observations regarding cleanliness and safety (See Cleanliness and Safety Log)
7. Half-yearly disinfection of feed storage containers will be conducted as described above for bench tops and equipment.
8. See Spill Clean-up SOP regarding spills.
9. In the event of an emergency, quickly secure animals and experimentation and evacuate (See Emergency Procedure SOP).

SOP #10 SPILL CLEANUP

All mouse related dry and wet spills (feed, water, bedding, feces, and urine) in the ABSL-3 laboratory will be presumed infectious and will be cleaned immediately as followed:

1. Disinfect the spill with 10% hypochlorite solution (Clorox bleach, made fresh daily) or Quaternary Ammonium Compound and allow the disinfectant to soak with the spill for a minimum of 10 minutes.
2. Clean up the spill area with paper towels and dispose of the waste in an appropriate biohazardous waste bin.
3. Follow the spill area with fresh 10% hypochlorite solution (Clorox) or disinfectant solution and wipe immediately for disposal into a biohazardous waste bin.
4. Use 70% Ethanol in the spill area and wipe up with paper towels to complete disinfection.
5. For larger spills greater than 10 mL use the designated spill kits located in the ABSL-3 Preparation Room.

SOP #11 LIQUID WASTE MANAGEMENT

All liquid waste generated during manipulation within the Biosafety Cabinet is chemically neutralized with no less than 10% sodium hypochlorite solution, made fresh daily. Contact time with the chemical neutralizer is to be no less than 20 minutes. Once the effective neutralization period elapses, the solution is diluted with water to an appropriate neutral pH level as indicated by the use of pH strips located in the sink area, and disposed of down the drain in the Manipulation suite.

Before work begins and also upon completion of work within the Manipulation Suite, a 50 mL drain disinfectant (typically 5% quaternary ammonium compound solution) is placed in the sink traps to ensure that no infectious waste is able to reach the wastewater. The use of the disinfectant solution also provides the added assurance that no insects or unwanted pests could climb up through the drainpipes into the laboratory.

SOP #12.1 AND #12.2 ABSL-3 ENTRY PROCEDURES

12.1 ACTIVE ENTRY

ACTIVE Definition: all activities that involve opening of animal caging

Entrance into the ABSL-3 Anteroom

1. Show ID to Security and sign in the ABSL-3 Log book at the Security desk.
2. Pass keycard over reader at Vivarium hallway door and touch finger on biometric sensor.
3. Make sure to step firmly on the tacky matt once inside the door to remove dirt and contaminants.
4. Enter and pass through the Vivarium locker room.
5. Don the Vivarium PPE: yellow gown, booties, and bouffant over your clothes immediately after exiting the locker room and entering the Vivarium PPE corridor.
6. Enter your PIN to have access to the Vivarium, and proceed down the clean corridor to the ABSL-3 area.
7. Once at the door of the ABSL-3, sign the ABSL-3 Log sheet, noting the date, the time, your name, purpose of entry, the pressure reading of the Magnehelic, and the name of escort if applicable. If reading of Magnehelic is above -0.05, then do not enter until notification and permission granted from the Biosafety Officer (Hubert Olipares 285-7619) and the Level 3 Lab Director (Vivek Nerurkar 753-6961).
8. Pass keycard over reader at hallway door and place your palm onto the biometric reader to gain access into the Anteroom of the ABSL-3. Perform door check to ensure proper latch of door closure.
9. **NO PIGGYBACK POLICY ENFORCED.** Each person must use his or her own keycard to enter the ABSL-3 lab.
10. Enter the ABSL-3 Anteroom prior to shower area and doff the Vivarium gown and bouffant. Hang these items on hooks near door and save for exiting of the ABSL-3.
11. Doff Vivarium booties.
12. **Leave all personal devices on shelf.**
13. Remove any watches or jewelry that may interfere and effect PPE coverage and protection.
14. Change out of personal clothing into the ABSL-3 scrubs and designated shoes. Hang personal clothing on hooks in shower area.
15. Don primary layer of gloves (black gloves).
16. Don two pairs of ABSL-3 booties.
17. Don either a PAPR or wrap-around blue gown, N95, and hair bouffant.
18. Don sleeves.

Entrance into the ABSL-3 Preparation Room

1. Check for the negative pressure of ABSL-3 Prep Room by pressing the down arrow of the EDSTROM system and enter pressure in log with date and initials. If pressure is more positive than -0.05, then do not enter the ABSL-3 facility until notifying the Biosafety Officer (Hubert Olipares 285-7619) and Level 3 Lab Director (Vivek Nerurkar 753-6961) and obtaining further instruction.
2. Enter your PIN to have access to the ABSL-3 Prep Room. **NO PIGGYBACKING!**

REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.

3. Survey the room for any irregularities and lab cleanliness.
4. Check on autoclave, ultra-cold -80 freezer, and any other lab equipment located in the Preparation Room,
5. Make certain that telephone is working and Fax machine is turned on.
6. If you are the first ABSL-3 user of the day, pour 50 mL disinfectant into the drain of the Prep Room sink.
7. After finishing assigned tasks in the Prep Room, place items to be moved into your assigned Manipulation Suite into a closed carrier container or the Transport Cart.

Entrance into the two ABSL-3 Manipulation Suites

1. Sign in the logbook placed outside your assigned ABSL-3 Manipulation Suite note the date, time, name, and work to be done inside.
2. Check for any special PPE requirements posted at the door of your assigned Manipulation Suite.
3. Check for negative pressure of ABSL-3 Manipulation Suite by pressing the down arrow of the EDSTROM System. Also monitor the temp (should be between 70-74 degrees F), humidity (should be between 40-60%), and air flow (CFM, which should be).
4. Open metal plate on door and view interior of the suite to be entered to make certain that entry into the Manipulation Suite is safe and not interfering with any active manipulations being conducted.
5. Post Active Manipulation sign on Suite Door.
6. Enter your PIN to gain access to your assigned Manipulation Suite, remembering that there is **NO PIGGYBACKING**. **REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.**
7. Work within the Manipulation Suite can begin adhering to the guidelines and agent specific protocols that have received IACUC approval.

12.2 PASSIVE ENTRY

PASSIVE definition: all activities that DO NOT involve opening of cage

Entrance into the ABSL-3 Anteroom

1. Show ID to Security and sign in the ABSL-3 Logbook at the Security desk.
2. Pass keycard over reader at Vivarium hallway door and touch finger on biometric sensor.
3. Make sure to step firmly on the tacky matt once inside the door to remove dirt and contaminants.
4. Enter and pass through the Vivarium locker room.
5. Don the Vivarium PPE: yellow gown, booties, and bouffant over your clothes immediately after exiting the locker room and entering the Vivarium PPE corridor.
6. Enter your PIN to have access to the Vivarium, and proceed down the clean corridor to the ABSL-3 area.

7. Once at the door of the ABSL-3, sign the ABSL-3 Log sheet, noting the date, the time, your name, purpose of entry, the pressure reading of the Magnehelic, and the name of escort if applicable. If reading of Magnehelic is above -0.05, then do not enter until notification and permission granted from the Biosafety Officer (Hubert Olipares 285-7619) and the Level 3 Lab Director (Vivek Nerurkar 753-6961).
8. Pass keycard over reader at hallway door and place your palm onto the biometric reader to gain access into the Anteroom of the ABSL-3. Perform door check to ensure proper latch of door closure.
9. **NO PIGGYBACK POLICY ENFORCED.** Each person must use his or her own keycard to enter the ABSL-3 lab.
10. Enter the ABSL-3 Anteroom prior to shower area and doff the Vivarium gown and bouffant. Hang these items on hooks near door and save for exiting of the ABSL-3.
11. Retain Vivarium booties.
12. **Leave all personal devices (cell phones, I-pods, etc) on shelf.**
13. Remove any watches or jewelry that may interfere and effect PPE coverage and protection.

Entrance into the ABSL-3 Preparation Room

1. Check for the negative pressure of ABSL-3 Prep Room by pressing the down arrow of the EDSTROM system. If pressure is more positive than -0.05, then do not enter the ABSL-3 facility until notifying the Biosafety Officer (Hubert Olipares 285-7619) and Level 3 Lab Director (Vivek Nerurkar 753-6961) and obtaining further instruction.
2. Enter your PIN to have access to the ABSL-3 Prep Room. **NO PIGGYBACKING! REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.**
3. Survey the room for any irregularities and lab cleanliness.
4. Check on autoclave, ultra-cold -80° freezer, and any other lab equipment located in the Preparation Room,
5. Make certain that telephone is working and Fax machine is turned on.
6. If you are the first ABSL-3 user of the day, pour 50 mL disinfectant into the drain of the Prep Room sink.

Entrance into the two ABSL-3 Manipulation Suites

1. Sign in the logbook placed outside your assigned ABSL-3 Manipulation Suite note the date, time, name, and work to be done inside.
2. **Check for any special PPE requirements posted at the door of your assigned Manipulation Suite.**
3. Check for negative pressure of ABSL-3 Manipulation Suite by pressing the down arrow of the EDSTROM System. Also monitor the temp, humidity, and air flow (CFM).
4. Open metal plate on door and view interior of the suite to be entered to make certain that entry into the Manipulation Suite is safe and not interfering with any active manipulations being conducted.
5. Enter your PIN to gain access to your assigned Manipulation Suite, remembering that there is **NO PIGGYBACKING.** REMEMBER TO PULL DOOR CLOSED

BEHIND YOU AND PERFORM DOOR CHECK.

6. Enter the Manipulation Suite to perform duties that do not involve active manipulation.

SOP #13.1 AND 13.2 ABSL-3 EXIT PROCEDURES

13.1 ACTIVE EXIT

ACTIVE Definition: all activities that involve opening of animal caging

Exit Procedures for the ABSL-3 Manipulation Suite

1. When finished with any active manipulations, be sure to remove the manipulation sleeving and the secondary glove and disposing of directly in the Biohazardous Waste container nearest the BSC.
2. Clean BSC with 10 % bleach (made fresh daily) or 5 % quaternary ammonium compound, dry and wipe down with 70% alcohol, allowing for the appropriate contact time specific for each cleaning agent—10 MINUTES.
3. DO NOT turn on the UV light of the Baker Sterilguard Hood. This model hood should be left on so that the suite exhausts properly and the proper negative pressure is maintained.
4. Make certain that all waste generated for the day is contained within the Waste Container and that the lid is closed. Spray the Waste Container down with 70% Ethanol.
5. Note time finished in the BSC on the Logsheet.
6. Survey the area for any spilled bedding or irregularities in cleanliness. If something is detected, please treat as a Biological Spill and decontaminate as dictated in the Biological Spill SOP.
7. Add 50 mL disinfectant into sink drain to fill trap.
8. Survey and log all equipment in the Manipulation Suite before leaving—make special note that the Isocage™ unit is functioning properly, reading at -100 Pascals, all cages are docked properly (noting that all yellow tabs are not visible—yellow flag means docking is improper and must be addressed before exit), and mice are behaving normally.
9. Inspect PAPR for any signs of contamination. If contamination is suspected, spray surface with 10% bleach solution and wait for 10 minutes to allow for chemical neutralization. After appropriate contact time has elapsed, spray with
10. Doff outer layer of booties before removing outer gloves.
11. Remove outer gloves and place in Waste Container.
12. Check for signage on the door for any further special instructions before exiting suite.
13. Disinfect inner glove with 70% Ethanol.
14. Disinfect inner booties with 70% Ethanol spray just prior to exit.
15. Press release bar on the wall next to the door in order to open the door.

Exit Procedures for the ABSL-3 Preparation Room

1. Enter Preparation Room for decontamination. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.
2. Note the time exiting the Manipulation Suite on the Logsheet.
3. Remove Active Manipulation sign from Suite door.
4. Survey and log all equipment in the Prep Room.
5. Check status of autoclave.
6. If leaving late in the day, add 50 ml drain disinfectant into sink drain to fill trap.

7. Fax the appropriate husbandry logs, checklists, and laboratory notes.
8. Remove outer layer of booties, leaving only designated shoes or the Vivarium booties.
9. Remove inner gloves.
10. Wash hands before exiting.
11. Press the release bar and exit the Preparation Room. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.

Exit Procedures for the ABSL-3 Anteroom

1. Doff PAPR and fold, place in storage bin.
2. Proceed to the shower.
3. Depending upon Agent and SOP specifications, determine if shower is required.
4. Doff used scrubs and place in designated Waste Container for autoclaving and laundering. If confident that scrubs were not contaminated, they can be folded and stored in a large ziplock bag labeled with name, date, and agent and worn again.
5. Doff designated shoes.
6. Don personal clothing and shoes originally worn into the ABSL-3.
7. Don the Vivarium PPE: yellow disposable gown, booties and bouffant over personal clothing.
8. Make certain that the "clean" Vivarium booties originally worn into the Level 3 labs are again worn over shoes.
9. Exit shower.
10. Exit the ABSL-3 Anteroom, making certain to pull the door closed behind you. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.
11. Note time of exit on the Entry Logsheet.
12. Walk to the Vivarium exit, following the soiled corridor and reach the exit door which leads back to the Locker Rooms.
13. Press release bar and enter the PPE corridor.
14. Remove and dispose of gown, bouffant, and booties. Dispose of in the properly labeled containers.
15. Enter the Locker Room.
16. Wash hands inside Locker Room, then exit.
17. Exit the Vivarium
18. Return to the Security Desk and note time of exit in the ABSL-3 Logbook.

13.2 PASSIVE EXIT

Passive definition: all activities that DO NOT involve opening of cage

Exit Procedures for the ABSL-3 Manipulation Suite

1. Survey the area for any spilled bedding or irregularities in cleanliness. If

something is detected, please treat as a Biological Spill and decontaminate as dictated in the Biological Spill SOP.

2. Add 50 mL drain disinfectant into sink drain to fill trap.
3. Survey and log all equipment in the Manipulation Suite before leaving—make special note that the Isocage™ unit is functioning properly, reading at -100 Pascals, all cages are docked properly (noting that all yellow tabs are not visible—yellow flag means docking is improper and must be addressed before exit), and mice are behaving normally.
4. Inspect blue gown for any signs of contamination. If contamination is suspected, doff gown before exiting and replace with clean gown (clean PPE are available and stocked in a drawer in the Manipulation Suite).
5. Remove outer gloves and place in Waste Container. Check for signage on the door for any further special instructions before exiting suite.
6. Disinfect inner glove with 70% Ethanol.
7. Disinfect inner booties with 70% Ethanol spray just prior to exit.
8. Press release bar on the wall next to the door in order to open the door.

Exit Procedures for the ABSL-3 Preparation Room

1. Enter Preparation Room for decontamination. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.
2. Note the time exiting the Manipulation Suite on the Logsheet.
3. Survey and log all equipment in the Prep Room.
4. Check status of autoclave.
5. If leaving late in the day, add 50 ml disinfectant into sink drain to fill trap.
6. Fax the appropriate husbandry logs, checklists, and laboratory notes.
7. Remove outer layer of booties, leaving only designated shoes or the Vivarium booties
8. Remove inner gloves.
9. Wash hands before exiting.
10. Press the release bar and exit the Preparation Room. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.

Exit Procedures for the ABSL-3 Anteroom

1. Doff Blue Gown and fold with outer surface folded inward, place in storage bag, label with name.
2. Doff bouffant.
3. Proceed through the shower.
4. Doff designated shoes if worn and replace with personal shoes worn in.
5. Don the Vivarium PPE: yellow disposable gown, booties and bouffant over personal clothing.
6. Exit the ABSL-3 Anteroom, making certain to pull the door closed behind you. REMEMBER TO PULL DOOR CLOSED BEHIND YOU AND PERFORM DOOR CHECK.

7. Note time of exit on the Entry Logsheet.
8. Walk to the Vivarium exit, following the soiled corridor and reach the exit door, which leads back to the Locker Rooms.
9. Press release bar and enter the PPE corridor.
10. Remove and dispose of gown, bouffant, and booties. Dispose of in the properly labeled containers.
11. Enter the Locker Room.
12. Wash hands inside Locker Room, then exit.
13. Exit the Vivarium.
14. Return to the Security Desk and note time of exit in the ABSL-3 Logbook.

SOP #14 KAKA'AKO BSL-3 AND ABSL-3 SHARPS MANAGEMENT

1. Hypodermic syringes and needles will be issued only to authorized personnel, and must only be used for research purposes.
2. Stocks of hypodermic syringes and needles will be secured in a secure place (e.g., locked drawer, cabinet, or room) with controlled access. Hypodermic syringes and needles not in reserve, not in main stocks, and not in use must also be stored under suitable locked conditions.
 - a. All work will be conducted with only one uncapped hypodermic needle at a time. Keep uncapped needles and other sharps in view.
 - b. DO NOT place a needle cap in your mouth in order to remove the cap.
 - c. DO NOT leave sharps unattended.
3. Place a biohazard sharps container within an arm's reach of the area where sharps are used. Position the biohazard sharps container low enough in the work area so that you can readily visualize the opening. Biohazard sharps containers are available for purchase from laboratory supply companies (e.g., Fisher, VWR, etc.).
4. Immediately dispose of a used hypodermic syringe and needle, as a unit, directly into a sharps container, **without any further manipulation**. Avoid bending, breaking, shearing, or removing needles from syringes. Likewise, dispose of any broken glassware contaminated with biohazardous materials directly into a biohazard sharps container. Store reusable sharps in a puncture resistant container, to prevent accidental or unintentional contact. If contaminated with biohazardous materials, reusable sharps should be stored in disinfectant solution until processed.
 - a. Sharps MUST NOT be disposed in the regular trash.
 - b. If vacutainers are to be reused, secure the hub of the needle in a sharps container and unscrew it directly into the container.
5. DO NOT recap needles. Recapping of needles causes more injuries than it prevents. However, if it is absolutely necessary to recap needles, for example, as part of a protocol, you must use either:
 - a. A mechanical device such as forceps to replace the cap on the needle, *or*
 - b. Transport any recapped needles in secondary containers to prevent accidental inoculation.
6. Avoid handling any broken, contaminated glassware directly by hand, even if wearing gloves. Use a device such as tongs, forceps, brush and dustpan, or even two pieces of cardboard.
7. Biohazard sharps containers will be disposed when they are 3/4 full. Secure the containers to prevent leakage, punctures, and spillage during transport. Sharps containers must be disposed through the UH-EHSO program.
 - a. Sharps containers must not enter the regular solid waste stream.
 - b. DO NOT overfill biohazard sharps containers.
 - c. DO NOT force a sharps item into a container, or retrieve a discarded item.

SOP #15 EMERGENCY RESPONSES TO HVAC AND POWER FAILURE

Should a power outage or an HVAC failure occur at the University of Hawaii John A. Burns School of Medicine at Kaka'ako, these procedures will be followed:

POWER FAILURE

If a power outage does occur while you are working in the ABSL3 labs, these labs are designed to run on back-up emergency power so you should not be affected. The back-up power should maintain the negative pressure in the suites as well as in the Isocage™ system. Additionally, the Isocage™ system is an independent unit, which has its own back-up power—the UPS (Uninterrupted Power Supply) has the ability to supply power to the Isocage™ system for 3 to 6 hours, independent of the building systems, which will allow the Isocage™ to maintain negative pressure in the cages. If building power is not restored within the 3 to 6 hour timeframe, the exhaust fans of the Isocage™ will no longer function and the negative pressure of the Isocage™ will continue to draw in environmental air until the pressure is equalized (becomes static, NOT POSITIVE), at which point, the mice will have approximately 15 minutes of Oxygen, and will then suffocate and perish. Note that no air is being exhausted from the cage in this scenario and the DOUBLE HEPA filtration is still in place and functional.

HVAC FAILURE

The HVAC system is a redundant system consisting of two exhaust fans. When one fan becomes inoperable, the backup fan should engage and become operational in just moments. However, if both fans are not operating, the situation will be immediately noticeable, as the suites will no longer hold negative pressure. You will immediately hear the audible alarms, but also see the visual strobe alarms as well in all of the different rooms making up the ABSL3 Labs. In addition the BSCs will also sound their individual, independent alarms as well. The only exception will be seen in the Isocage™ system. The HVAC system failure will have NO effect on the Isocage™ itself. The Isocage™ system has complete containment and filtration independent of the building HVAC. The building HVAC serves as to help control the odors from the Isocages™ only, and is not necessary for Isocage™ biocontainment. In fact, there is a special "thimble" connection between the Isocage™ exhaust and the building HVAC specifically designed not to be airtight to prevent the interference of the building HVAC with the Isocage™ function. Again, it is important NOT to have an airtight connection between building exhaust and Isocage™ exhaust in order to prevent interference with the Isocage™ airflow rates and pressure balance.

RESPONSE

However, regardless of the nature of the failure, you should immediately stop working and start to secure any biological agents, animals, and/or chemicals. Depending upon the ongoing procedures following steps should be taken:

1. While conducting following procedures, it is mandatory to wear N95 mask.
 - a. **Inoculation:** While inoculation, diagnostic samples are prepared in a 0.5

mL syringe. In case of power failure immediately flush the syringe with 10% bleach. Place the animals back in the Isocage™ and seal them immediately with the lid. Spray and wipe it clean with 70% ethanol and immediately place them the Isocages™ in the Isocages™ cage rack. Discard the syringe in the sharps container. Close the BSC sash immediately and leave the suite. The diagnostic sample is decontaminated and contained at this point.

- b. **Euthanasia:** During this investigation mice are sacrificed followed by tissue harvesting and processing in chilled isopentane. If the power failure occurs before animal sacrifice, then immediately place the animals back in the cage. Seal the lid and wipe the cage with 70% ethanol from outside and place the cage in the Isocage™ rack. If the power failure occurs during sacrifice, then immediately spray the mice with 10% bleach, cover with paper towel and place in a red biocontainment bag. Dip surgical instruments in the bleach. In case the power failure occurs during tissue processing, discard any tissue harvested in the beaker with 10% bleach. Dip the surgical instruments used to process the tissues in the bleach solution. Close the BSC sash and leave the suite. The virus is contained and decontaminated at this point.
2. Remember to close all BSC sashes.
 3. Notify Security (692-0911 or 692-1911).
 4. Disconnect all equipment that could be damaged by a power surge when electricity is restored.
 5. Turn off all appliances and other energy users to reduce the power requirements for restoration.
 6. If animals are currently housed within the Isocage™ system DO NOT UNPLUG the unit, it has its own UPS and should not be unplugged.
 7. Do not evacuate the building unless instructed to do so by emergency services (HPD, HFD, and JABSOM Security). If you are instructed to evacuate the building, use the emergency EXITs and go to a designated Evacuation Gathering Area to await further instructions from emergency services. (See Diagram for Designated Evacuation Gathering Area below).
 8. If instructed to evacuate, follow SOP to exit the lab.

APPENDIX #1 – PEST MANAGEMENT PLAN SPECIFIC FOR KAKA’AKO BSL-3 AND ABSL-3

The Kaka’ako, JABSOM, BSL-3 and ABSL-3 facilities infrastructure meets the standards defined in the 5th edition of the BMBL. Similarly, all BSL-3 and ABSL-3 experimental practices, and containment practices will be adhered to as prescribed in the 5th edition of the BMBL. The standard operation procedure (SOP) for conducting research with Arboviruses is described in detail in the attached SOPs.

The encephalitic flaviviruses include West Nile, Murray Valley, and St. Louis encephalitis viruses. All are zoonotic viruses with birds as the natural vertebrate host and primarily *Culex* species mosquitoes as vectors.

Cx quinquefasciatus is a good vector of Arboviruses on the mainland, and has been involved in both enzootic and epizootic transmission to birds. It is not known what role it has played in transmission to humans. Arboviruses have been isolated from both *Ae. albopictus* and *Ae. Japonicis* in nature on the mainland, but neither species have been confirmed as vectors in nature.

The BSL-3 and ABSL-3 facilities at Kaka’ako are under negative pressure and are built according to the CDC and USDA standards as defined in the 5th edition of the BMBL. To enter the BSL-3 and ABSL-3, mosquitoes will have to cross seven doors, three of which are under negative pressure. None of the above mentioned mosquitoes will readily feed on in vitro cultures, and it is nearly impossible for them to access to Arboviral infected animals in the ABSL-3 facilities. Moreover, for all arboviruses and zoonotic agents research protocols, we will put several sticky mousetraps in the BSL-3 and ABSL-3 facilities and mosquito monitoring traps in the laboratory.

Following are the justifications for why wild mosquitoes cannot feed on infected cultures and animals.

BSL-3

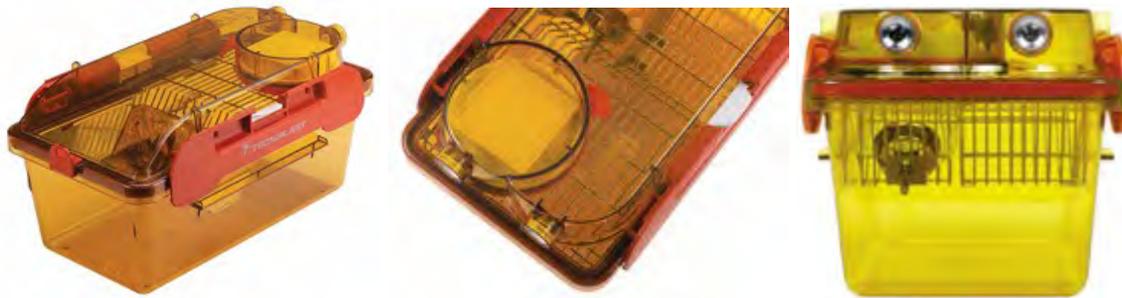
1. Viral infected cultures are always maintained in a closed system, such as covered plates or screw cap flasks.
2. All infected cultures are manipulated in a hard-ducked biological safety cabinet (BSC), which is under negative pressure and also generate air curtain at the opening of the BSC. Mosquito will not able to cross over the air curtain and in the rare case if they accidentally cross, it will be sucked in to the HEPA filter on the top of the BSC.
3. All infected cultures are maintained in closed plates and flasks, and are kept in a double-door secured incubator.

ABSL-3

1. Animals will be inoculated only in the BSC cabinet, which is under negative pressure and also generate air curtain at the opening of the BSC. Mosquito will not able to cross over the air curtain and in the rare case if they accidentally cross, it will be sucked in to the HEPA filter on the top of the BSC.
2. Isocages™, in which infected animals will be housed are hermetically sealed and secured. Moreover, Isocages™ will only be opened in the BSC (refer to Isocage™

instructions).

The ISOCAGE™ is a hermetic individually ventilated cage (IVC) that creates a total containment comparable to that obtained through isolators while at the same time not losing the advantages of simplicity of use typical of IVCs as shown in pictures below. The ISOCAGE™ features a HEPA filter on the Exhaust valve protected by a pre-filter, GUARANTEEING TRUE BIO-CONTAINMENT AT CAGE LEVEL! The HEPA filter and the pre-filter can be removed and quickly changed when the cage is open and in a protected environment. The Isocage™ guarantees a stable, lasting hermetic seal under both normal working conditions and when the cage is removed from the rack. With these physical barriers in place, mosquitoes cannot reach infected mice. In addition to physical barrier, a Pest Control Plan is implemented as described below. Pest control is best accomplished by maintaining good housekeeping. A good sanitation program is fundamental to the control of vermin and pests, which includes storage, collection, and disposal of solid wastes. Caulking of cracks and crevices in the room is also important. Submit a work request via the Facilities Management Office (<http://jabsom.hawaii.edu/jabsom/departments/WorkReqForm.doc>) to control vermin in strict accordance with applicable laws and regulations.



General Pest Management Plan

The following describes the JABSOM Kaka'ako Plan for minimizing the risk of insects and rodent vector transmission of hazardous agents from the Level 3 Facilities. Many pests can mechanically transmit disease pathogens and compromise the research environment. As such, integrated pest management (IPM) is an important part of managing a Research Facility. The Plan relies heavily on the education and assistance of JABSOM Facilities Staff who care for JABSOM buildings and grounds. Consequently, it is the policy of the JABSOM Facilities to reduce or eliminate the potential for pest breeding, harborage, and entrance to the research facility. Proper sanitation, good housekeeping, and good building maintenance are key factors to keeping insects and rodents from entering the buildings.

Insects

1. Users of ABSL-3 and BSL-3 will routinely inspect the labs for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the

surrounding campus grounds.

2. Facilities will contact a Licensed Pesticide Contractor on an as-needed basis to inspect, verify and take proper treatment to eradicate insects in the ABSL-3 and BSL-3 areas that are affected as well as other areas of the campus. The Contractor shall meet with EHSO to discuss the Pesticide to be used and application to ensure all EPA FIFRA requirements and guidelines are followed and to ensure the safety of the JABSOM Kaka'ako occupants. Pesticides may only be applied when the lab is closed down for maintenance, i.e. there are no active research being conducted.

Safety: Every effort must be made to insure that pesticide application/exposure is held to a minimum to insure the safety and welfare of JABSOM Kaka'ako Occupants and Research Projects.

Preventive applications of pesticides are not encouraged in any Research Facility. As such, pesticide application(s) are restricted to areas where pest populations cannot be controlled by other means.

3. Facilities shall monitor the Pesticide Contractor to insure treatment was administered effectively.

Rodents

1. If there are signs of rodent infestations in the Level 3 Labs, the Users shall inspect the areas and capture any rodents. Traps shall be placed throughout the lab. The rodent shall be contained in the Level 3 Lab until an investigation conducted by EHSO is concluded and decisions are made regarding testing the rodent for infection, destruction of the rodent, surveying the facility for ports of entry for rodents, decontamination of the facility, SOP evaluation and revisions as necessary.
2. Careful records of all animals shall be maintained and any unaccounted for rodents shall be reported to the Level 3 Manager and Supervisors, LAS, and EHSO immediately

Mosquitoes

1. JABSOM facilities shall maintain the buildings and grounds according to the general JABSOM Kaka'ako Pest Management Plan to prevent, identify, monitor, and eliminate mosquito-breeding sites and prevent wild mosquitoes from entering the research building. Refer to the General Plan. If wild mosquitoes are able to enter the building, there are several safeguards that prevent the wild mosquitoes from contacting infecting animals or inoculating cultures refer to specific protocol SOPs.

RECORD KEEPING AND PROGRAM EVALUATION

1. Visual sightings or other evidence of any pests shall be reported to the Lab

Manager/Supervisors and EHSO immediately and shall be documented.

2. Reports communicated verbally and in writing concerning pest activity will be recorded and kept on file by Lab Manager/Supervisors, Facilities, and EHSO.
3. The Laboratory Director, JABSOM Facilities, and EHSO shall also maintain inspection results for review.

Quality assurance and program review must be performed to provide an objective, ongoing evaluation of pest management activities. EHSO is responsible for evaluating the effectiveness of all pest control procedures implemented and approving or redirecting efforts to control pests found.

SPECIFIC PROTOCOL IPM

Specific IPM shall be protocol driven.

Arboviruses

1. Users of ABSL-3 and BSL-3 will routinely inspect the labs for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.
2. Hanging the sticky mosquitoes' trap is required
3. Users will keep the ABSL-3 and BSL-3 lab clean and make sure there is no standing water container in order to disrupt the reproductive cycle of the mosquitoes.
4. Animal inoculation will only be done in the BSC.

There are three potential Flaviviruses mosquito vectors in the Hawaiian Islands, *Culex quinquefasciatus*, *Aedes albopictus* and *Aedes (Ochlerotatus) japonicus*. The first two are ubiquitous and occur on all islands, including Oahu. *Ae japonicus* has recently been introduced to the Big Island, where its distribution is still relatively limited.

Moreover, JABSOM Facilities provide building, campus wide monitoring, and protection. The following is the Facilities Management Plan.

Many pests can mechanically transmit disease pathogens and compromise the research environment. As such, integrated pest management (IPM) is an important part of managing a Research Facility. Consequently, it is the policy of the JABSOM Facilities to reduce or eliminate the potential for pest breeding, harborage and entrance to the research facility.

JABSOM KAKA'AKO CAMPUS BUILDINGS AND GROUNDS

Building occupants should routinely inspect their work areas for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.

1. JABSOM Facilities will contact a Licensed Pesticide Contractor on an as-needed basis to inspect, verify and take proper treatment to eradicate insects in areas that are affected as well as other areas of the campus. The Contractor shall meet

with JABSOM EHSO to discuss the pesticide to be used and application to ensure all EPA FIFRA requirements and guidelines are followed and to ensure the safety of the JABSOM Kaka'ako occupants.

Safety: Every effort must be made to insure that pesticide application/exposure is held to a minimum to insure the safety and welfare of JABSOM Kaka'ako Occupants and Research Projects.

Preventive applications of pesticides are not encouraged in any University Facility. As such, pesticide application(s) are restricted to areas where pest populations cannot be controlled by other means.

2. JABSOM Facilities shall monitor the Pesticide Contractor to insure treatment was administered safely and effectively.
3. If there are signs of rodent infestations in the buildings or on the grounds, contact Facilities and complete a Work Order Request. All unaccounted for lab rodents shall be reported to EHSO, Security, and Facilities immediately.

REDUCING THE NUMBER OF MOSQUITOES ON THE JABSOM KAKA'AKO GROUNDS, NEAR BUILDING ENTRANCES, AND IN THE BUILDINGS

Proper sanitation, good housekeeping, and good building maintenance are key to keeping insects and rodents from entering the buildings.

Draining sources of standing water reduces possible breeding areas. In addition, larvicides (to control breeding areas) and other pesticides may be used to reduce mosquito populations.

- JABSOM Facilities shall respond to any standing water problems in the landscape on campus.
- JABSOM Facilities shall schedule preventive maintenance on gutters and downspouts and the fountain in front of the Medical Education Building.
- Potential mosquito breeding areas (wetter areas of landscaping, etc.) shall be inspected periodically and treated with pesticides when mosquito presence is reported. These "trouble" areas shall be monitored periodically to ensure there are no breeding mosquitoes.
- Trash, recyclables, and discarded equipment and materials must be contained in the trash compactor or promptly removed from all collection areas. Any spilled trash outside of the trash compactor shall be reported to JABSOM Facilities and Custodial staff shall promptly remove the trash.

4.

RECORD KEEPING AND PROGRAM EVALUATION

Visual sightings or other evidence of any pests reported to the Facilities shall be documented. Reports communicated verbally and in writing concerning pest activity will be recorded and kept on file by Facilities.

Quality assurance and program review must be performed to provide an objective, ongoing evaluation of pest management activities. Facilities is responsible for evaluating the effectiveness of all pest control procedures implemented and approving or redirecting efforts to control pest found.

APPENDIX #2 SOP FOR TSUNAMI IN ABSL-3 AND BSL-3

1. If working in a Biosafety Cabinet (BSC)
 - a. Seal all open cultures (this includes putting animal carcasses in a sealed or disinfectant filled container).
 - b. Cover pipette trays.
 - c. Carefully remove your outer gloves, and leave them in the BSC.
 - d. Close the sash to the lowest possible position.
 - e. If time permits, animals may be sacrificed and infected cultures may be autoclaved. **NOTE:** If you believe that you are in immediate danger from tsunami, DO NOT perform the procedures described for the BSC and immediately exit the building. The Isocage™ systems which house the animal are waterproof and without power supply, the animal will die in 15 minutes due to suffocation. Freezer and incubator are waterproof. Therefore infected material will not spread into the environment. In worse case scenario when salt water can get into these equipment's, salt water will kill all these infected cultures and animals.
2. If you are working outside of a cabinet, close up any equipment/appliances you are working with.
3. Meet at the designated evacuation points.
4. Stay at the evacuation point and ensure there is full accountability for all personnel that were in the facility. If individuals are missing do not re-enter the facility to find them, but notify police or fire personnel of the number and identity of individuals missing and where they were working in the facility. DO NOT LEAVE ; until you are given the clearance to do so from Emergency Management.
5. If the situation is cleared, and the building can be re-occupied, return to your labs (under the appropriate conditions), and finish/clean up your work.
6. At your earliest possible convenience fill out an Incident Report if a potential exposure occurred.

APPENDIX #3 R BOMB THREAT/SUSPICIOUS PACKAGE SOP

BOMB THREAT/SUSPICIOUS PACKAGE

- Called in Bomb Threat:
 - DO NOT hang up on caller
 - Keep them on phone for as long as possible and get as much info as possible
 - Once caller hangs up, contact Security
- Suspicious Package
 - DO NOT open or move package
 - Vacate area and notify Security and Biosafety Officer

List of SOPs included in this document

These SOPs are specific for SARS-CoV-2 research in the BSL-3. You must read and understand general SOPs in the JBF Biosafety manual to conduct research in the JBF.

SOP 1: Entry into the BSL3 laboratory

SOP 2: Exiting BSL3 laboratory

SOP 3: Working with SARS-Cov-2 in the BSL-3 Suites

SOP 4: SARS-CoV-2 infection and cell harvesting in the BSL3

SOP 5: Viability assay of SARS-CoV-2 infected cells

SOP 6: SARS-CoV-2 plaque assay and neutralization assay

SOP 7: Movement of viable and nonviable SARS-CoV-2 between suite and preparation room

SOP 8: SOP for emergency conditions

SOP 9: Daily decontamination procedure for liquid waste

SOP 10: Spill Clean up

SOP 11: Kakaako BSL-3 sharps management

SOP 12: Emergency responses to HVAC and power failure

Appendix 1: Pest management plan specific for Kakaako BSL-3

Appendix 2: SOP for tsunami

Appendix 3: Bomb threat/suspicious package SOP

SOP 1: ENTRY INTO THE BSL-3 LABORATORY

Entrance in to the BSL-3 Anteroom

1. Pass keycard over reader at hallway door and touch finger on biometric sensor.
2. Enter hallway and proceed to end of hall.
3. Before entry into the BSL-3 anteroom, check the Magnahelic gauge for a reading of -0.05 or greater (indicating increased *negative* pressure). Enter your name, date, time of entry, purpose of entry, and the current reading of the Magnahelic. Note that the pressure was appropriately negative and is a suitable range for entry. If the reading is not sufficiently negative, you must call your PI and/or JBF Supervisor (Eileen Nakano 692-1612) and inform them of the insufficient pressure and obtain approval and further instructions before entering.
4. Ring the bell twice and wait for 15 sec. Make sure that no one is exiting the BSL-3 prep suite before attempting to enter.
5. Place keycard on the biometric reader.
6. Place finger or thumb on top of biometric surface wait for green light to appear.
7. Once again, be aware of persons that may be coming out of the BSL-3 prep suite. Do not open the door if you see persons exiting the BSL-3 prep suite.
8. Open door and proceed to the anteroom.
9. Make sure that the door is closed.
10. **NO PIGGYBACK POLICY ENFORCED.** Each person must use their own keycard to enter the BSL-3 lab.

Please note: Do not bring personal items into the anteroom. NO BACKPACKS, NO PERSONAL LISTENING DEVICES, CELL PHONES, LAPTOPS, BOOKS, ETC. Cardboard is not allowed in the BSL3 facility. If using a cardboard box to transport items, transfer items and dispose of the cardboard immediately.

Entrance into the BSL-3 Prep room

1. Put on gown and shoe covers/designated shoes.
2. Check the Magnahelic which monitors the pressure of the Prep Room, making sure that airflow is negative (-0.020 to -0.05). Sign Entry Log Sheet: enter your initials, date, time, and pressure reading.
3. Place keycard next to the Biometric Palm reader.
4. Place your palm on Biometric reader to gain access into preparation room.
5. Open door and enter preparation room area.
6. Immediately don first layer of gloves.
7. Survey the room for any irregularities and lab cleanliness.
8. Check on autoclave, ultra-cold freezer (-80°C), refrigerator, and tissue culture incubator readings.
9. If you are the first BSL-3 user of the day, pour 50 mL disinfectant into the drains of the Prep Room sinks.
10. After finishing assigned tasks in the Prep Room, place items to be moved into your assigned Manipulation Suite into a closed carrier container or the Transport Cart.
11. Move tissue cultures or virus stock into an assigned Manipulation Suite where work is to be performed (refer to the SOP- *Movement of virus between Manipulation Suite and Prep Room*).

Entrance into the BSL-3 Manipulation Suite for SARS-CoV-2

1. Check signage at the entrance of your assigned Manipulation Suite for agent specific information.
2. Check Magnahelic to confirm negative pressure (approx) 0.05 inside the Manipulation Suite. Note initials, date, pressure, and time of entrance in the Manipulation Suite Logsheet, then enter the selected suite.
3. Place Keycard near biometric reader. **NO PIGGYBACKING!**
4. Enter Suite and place carrier container on to the counter. If using Transport Cart, move through the door with the cart and place near the end of the counter.
5. Immediately don secondary gloves and disposable sleeves over your gown once fully inside the Manipulation Suite.
6. Immediately wear N95 mask, bonnet and face shield.
7. Work can begin adhering to the guidelines of the Working in the BSL-3 Manipulation Suite SOP.

SOP 2: EXITING THE BSL-3 LABORTORY

1. Clean BSC with 10% bleach (made fresh daily), dry and wipe down with 70% alcohol.
2. Switch on the UV and leave on for 20 min to decontaminate the BSC.
3. Add 1% bleach to sink to fill trap.
4. Remove N95 masks and face shield.
5. Clean the face shield with 70% alcohol twice and wait for 3 min between each cleaning step. Start cleaning from inside out. Store face shield in a container in the SARS-CoV-2 suite.
6. Discard N95 mask if doing high-risk procedures. Save N95 mask appropriately if doing low-risk procedures. There is a shortage of masks and PPE. Consult your supervisor.
7. Remove sleeves and outer gloves and place in wastes container.
8. Now exit from SARS-CoV-2 suite into the preparation room
9. Remove inner gloves and booties. Wash hands with soap and water for minimum 30 sec.
10. Exit preparation room
11. Remove gown in the anteroom
12. Sanitize hands with waterless hand sanitizer just before exiting the BSL-3 anteroom
13. Exit BSL-3 anteroom.
14. Wash hands with soap and water in the IBR corridor rest room.
15. Exit hallway in the BSB lobby

SOP 3: WORKING WITH SARS-CoV-2 IN THE BSL-3 SUITES

1. Clean BSC with 10% bleach solution.
2. Dry and repeat cleaning with 70% alcohol and dry.
3. Switch on the UV in the BSC and UV-irradiate the BSC for 20 min.
4. Place supplies into the BSC; a covered trash pan, small beaker with 10% bleach, tissue culture plate, media etc.
5. Arrange all items in good configuration so that air flow will not be obstructed.
6. Wear N95 mask, bonnet and secure the face shield over bonnet.
7. The personnel, *BSC and the suites are now ready for the following virus manipulations.*

a. SARS-CoV-2 infection and cell lysate harvesting from infected cells (SOP 4)

b. Cell viability assays (SOP 5)

c. Plaque assay and neutralization assays (SOP 6)

SOP 4: SARS-COV-2 INFECTION AND CELL HARVESTING IN THE BSL3

Before working with the SARS-CoV-2, the lab worker must:

- have the approval of the PI who shall provide specific training according to this SOP
- complete UH lab safety training and JABSOM Kaka'ako hazardous waste generator training prior to working with any chemicals;
- sign this SOP as documentation that he/she understands the hazards and has been trained in how to complete the following tasks safely.

Statement of Understanding and Compliance

I confirm that I have read and understand this SOP and will comply with the procedures and policies.

Name:

Signature:

Date:

PPE Requirements & Special Practices: In addition to standard BSL3 Manipulation Suite PPE (booties, wrap-around blue gown, black primary gloves, manipulation sleeves, and secondary grey gloves), N95 mask, face shield and safety glasses shall be worn when working with the SARS-CoV-2 as per the entry SOP

Virus infection procedures:

1. In the prep room, carefully remove the vial of virus from the -80 freezer and place in secondary containment.
2. Take the vial in secondary containment into the suite and immediately place in BSC.
3. Carefully remove the tissue culture plates of cells from the incubator and place in the BSC.
4. Per the experiment design, infect the cells with the appropriate volume of thawed virus and return the plates to the incubator located in the suite. **INFECTED TISSUE CULTURES WILL BE INCUBATED IN THE ASSIGNED SUITE. NO INCUBATIONS OF INFECTED CULTURES WILL BE HOUSED IN THE PREP ROOM.**
5. Discard any remaining virus in the vial into the fresh 10% bleach solution and let sit for at least 20 minutes.
6. After infection, wash the cells in the tissue culture plate with 2X PBS.
7. Remove PBS wash with a pipet and carefully discard all the waste into the bleach solution.
8. Add fresh media over the cells and return to the incubator.
9. Determine if the virus waste has been in the bleach solution for at least 20 minutes. After the 20 minutes decontamination time, the virus is totally inactivated, i.e. not viable.
10. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
11. Pour the media waste down the sink drain followed with water for at least 1 minute.

12. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

Procedure of cell and supernatant harvesting:

1. After 24, 48 and 72 hours after infection, carefully take the plate out of the incubator and place it in the BSC hood.
2. Remove approximately 200-400ul media from each well and store in an Eppendorf tube. Label it with date, amount, virus details and store it in a 96-well cardboard box.
3. Carefully wash the cells with PBS and carefully discard all the waste into the bleach solution.
4. Now add cell lysis reagent in the wells and collect the lysate in the Eppendorf tubes. This lysate inactivates the virus and will be used for RNA extraction.
5. Wash plates with 10% bleach solution once and discard all the waste into the bleach solution container.
6. Carefully place the supernatant and lysate tubes in a 96-well box. Place this box in a secured secondary container and move it out to the prep room to store the samples in the -80°C freezer.
7. Determine if the virus waste has been in the bleach solution for at least 20 minutes. After the 20 minutes decontamination time, the virus is totally inactivated, i.e. not viable.
8. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
9. Pour the media waste down the sink drain followed with water for at least 1 minute.
10. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

SOP 5 : VIABILITY ASSAY OF SARS-CoV-2 INFECTED CELLS

Before working with the SARS-CoV-2, the lab worker must:

- have the approval of the PI who shall provide specific training according to this SOP
- complete UH lab safety training and JABSOM Kaka'ako hazardous waste generator training prior to working with any chemicals;
- sign this SOP as documentation that he/she understands the hazards and has been trained in how to complete the following tasks safely.

Statement of Understanding and Compliance

I confirm that I have read and understand this SOP and will comply with the procedures and policies.

Name:

Signature:

Date:

PPE Requirements & Special Practices: In addition to standard BSL3 Manipulation Suite PPE (booties, wrap-around blue gown, black primary gloves, manipulation sleeves, and secondary grey gloves), N95 mask, face shield and safety glasses shall be worn when working with the SARS-CoV-2 as per the entry SOP

Cell Viability assay:

1. Carefully remove the tissue culture plates of SARS-CoV-2 infected cells from the incubator and place in the BSC.
2. Add 20ul of One stop cell viability solution in each well and carefully return the plates in the incubator.
3. After 2hrs, take the plate out from the incubator, place it in a secondary container and take it to the plate reader.
4. Carefully place the plate in the plate reader and read the viability as per company's protocol settings.
5. Remove the plate after reading and place it in the secondary container. Carry the secondary container to the BSC
6. Carefully discard all the waste from the plates into the bleach solution.
7. Determine if the waste has been in the bleach solution for at least 20 minutes. After the 20 minutes decontamination time, the virus is totally inactivated, i.e. not viable.
8. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
9. Pour the media waste down the sink drain followed with water for at least 1 minute.
10. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

SOP 6: SARS-CoV-2 PLAQUE ASSAY AND NEUTRALIZATION ASSAY

Before working with the SARS-CoV-2, the lab worker must:

- have the approval of the PI who shall provide specific training according to this SOP
- complete UH lab safety training and JABSOM Kaka'ako hazardous waste generator training prior to working with any chemicals;
- sign this SOP as documentation that he/she understands the hazards and has been trained in how to complete the following tasks safely.

Statement of Understanding and Compliance

I confirm that I have read and understand this SOP and will comply with the procedures and policies.

Name:

Signature:

Date:

PPE Requirements & Special Practices: In addition to standard BSL3 Manipulation Suite PPE (booties, wrap-around blue gown, black primary gloves, manipulation sleeves, and secondary grey gloves), N95 mask, and a face shield shall be worn when working with the SARS-CoV-2 as per the entry SOP.

Virus infection procedures for plaque assay:

1. In the prep room, carefully remove the supernatant samples from the -80°C freezer and place in secondary containment.
2. Take the vials in secondary containment into the suite and immediately place them into the BSC.
3. Carefully remove the 6-well tissue culture plates of Vero E6 cells from the incubator and place them in the BSC, remove most of the culture media by aspiration leaving about 300ul of media.
4. Add 1 dilution (100µL) to each well ensuring that the cells are *not disturbed* when pipetting in the sample
5. Discard any remaining virus dilutions in the tubes into freshly prepared 10% bleach solution and let sit for at least 20 minutes.
6. Let the plates sit in the incubator for an hour and then add 3ml of the first overlay (containing DMEM and 1% agarose) over the cells in each well and swirl gently.
7. Return the plates to the incubator after the agarose is solidified.
8. Determine if the virus waste has been in the bleach solution for at least 20 minutes (after last waste was added). Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.

9. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
10. Pour the media waste down the sink drain followed by water for at least 1 minute.
11. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

Second Overlay

1. Second overlay is added after 3 days of infection with coronaviruses. Heat the second overlay containing 0.9% sodium chloride, neutral red and 1% agarose in a microwave.
2. Take the plates out of the incubator and add 1mL of the overlay in each well. Let the agarose solidify and then return the plates to the incubator.
3. Discard any waste in the 10% bleach solution.
4. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
5. Pour the media waste down the sink drain followed by water for at least 1 minute.
6. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

Plaque reading: 24hrs after application of the second overlay, take the plates out of the incubator and read the plaques using a plaque reader light box. Assay plates will be discarded into biohazard waste bags and decontaminated by autoclaving before disposal as non-infectious waste.

Alternative assay formats: As alternative to detection of plaques with neutral red using a solid overlay, the cells may be overlaid with a solid or semi-solid overlay and fixed using 4-6% formaldehyde followed by staining with crystal violet. Another, more rapid alternative is to fix the cell sheet with formaldehyde 12-24h after infection, the resulting spots on the cell sheet will then be detected using standard immunospot detection with a suitable monoclonal or polyclonal antibody followed by a conjugated secondary antibody and incubation with a solid substrate creating well defined immunospots that can be counted.

Plaque reduction neutralization assay: As a modification to the direct titration of viable virus from infection experiments, plaque reduction neutralization tests (PRNTs) will be conducted as an assay to determine the presence of functional antibodies in animal and human sera.

1. In brief, for this assay suitable dilutions of stock virus containing 50 pfu of SARS-CoV-2 in 50µL DMEM will first be incubated with or without serially diluted antibodies in a total volume of 100µL in 96-well U-bottom tissue culture plates for 1 hour at 37°C.
2. The mixture will be added into the 6- well plate seeded with Vero E6 cells after removing most of the culture medium and incubated for 1 hour at 37°C.
3. Then first overlay will be applied as described above and all remaining procedures of the standard plaque assay including various detection methods will be completed.
4. Assay results will be analyzed using non-linear regression to determine PRNT50 or PRNT80 titers.

SOP 7: MOVEMENT OF VIABLE AND NONVIABLE SARS-COV-2 BETWEEN SUITE AND PREPARATION ROOM

SARS-CoV-2 stock or supernatant collected from infected cells MUST NOT leave the suite without a secondary container. The vials MUST NOT be placed in only an eppendorf rack and taken outside. A secondary container (Tupperware of 2 sizes) will always be used to carry virus between suite and prep room. Reasons for moving viable virus from suite to prep room are be the following:

1. *Bring out the virus stock from -80°C in prep room and take it inside the suite for infection:*
 - a. Take the virus stock vial out of the -80°C and keep in a rack placed in the secondary container.
 - b. Lock the container and carry to the suite.
 - c. Place the container directly in the BSC, open in the BSC and take the vial out of the rack in the BSC.

2. *Bring the virus supernatant collected from infected cells or left over virus stock from the suite and store it in -80°C in the prep room.*
 - a. Collect the virus supernatant or cell lysates in 0.6, 1.5 or 2 mL Eppendorf tubes.
 - b. Keep the tubes in the freezer box or a rack and place this box/rack in a secondary container in the BSC.
 - c. Lock the container and carry to the prep room.
 - d. Open the -80°C freezer and place the vials/box in the designated rack of the freezer.

3. *Remove the 96 well plates with infected cells in it for taking readings using the Victor 3 instrument:* There will be some infection experiments which will be conducted in 96-well plates. The cells in the wells will be infected and then at designated time points the cells will be treated with solutions from kits such as viability assay (cell death) or ELISA kits. The experiments will be performed in the BSC and at the end of the experiment the stop solution will be added. The stop solution kills the cells and inactivates the virus. Such plates have to be moved out to the victor3 machine placed in the prep room for reading the substrate or end product of the kits.
 - a. Cover the plates with the plate cover, place in the secondary container and take out to the prep room.
 - b. Near the machine, open the secondary container and place the plates along with cover directly in the Victor3 reader.
 - c. Read the plates and place them back in the secondary container.
 - d. Clean the victor3 area by 5% bleach and 70% alcohol.
 - e. Bring the secondary container along with the plates back to the BSC, treat with 10% bleach for 30 min and then discard after neutralizing the solution.

SOP 8: SOP FOR EMERGENCY CONDITIONS

AT ANYTIME AFTER YOU ENTER THE BSL-3 LAB, OR IF YOU ARE IN THE MIDDLE OF MANIPULATING CULTURES IN THE BSC, IF YOU NOTICE A SUDDEN CHANGE IN THE LIGHTING OR IN THE SOUND OF THE AIRFLOW. IMMEDIATELY STOP WHAT YOU ARE DOING.

1. CHECK AIR INDICATOR STRIPS /MAGNAHELIC.
2. IF AIRFLOW IS DETERMINED TO BE STATIC OR POSITIVE LEAVE THE LOCTION AND EXIT LABORATORY.
3. CLOSE THE VIAL/FLASK/PETRIDISH ETC CONTAING LIVE VIRUS IN THE BSC. VIRUS CULTURES ARE ONLY MANIPULATED INSIDE THE BSC.
4. CLOSE THE BSC STASH.
5. CALL YOUR JBF SUPERVISOR AND FOLLOW THE EMERGENCY RESPONSE PHONE TREE.
6. IF AIR FLOW IS DETRMINED TO BE NEGATIVE; CONTINUE WITH THE WORK AS OUTLINED IN THE SOP.
7. ALWAYS WATCH THE MAGNAHELIC INDICATOR FOR NEGATIVE AIR PRESSURE.

SOP 9: DAILY DECONTAMINATION PROCEDURE FOR LIQUID WASTE

No liquid waste is to be discharged into sinks without prior decontamination;

1. All Liquid effluent waste in the containment area will be collected daily and decontaminated with fresh 10 % sodium hypochlorite solution.
2. Waste is treated for a minimum of 15 minutes before being neutralized with water.
3. Neutralized waste is discharged in the sink with additional copious amounts of water.
4. A 50 ml solution of Rocal disinfectant (quaternary ammonium) or similar type of disinfectant will be added to the sink trap before and after each use.

SOP 10: SPILL CLEAN UP

Biological Spill/Release inside a Biosafety Cabinet (BSC)

- Notify others in the area about the spill.
- Leave the BSC blower on.
- Secure any biological materials.
- If there is gross contamination of your PPE, wipe down with paper towels soaked in disinfectant solution, carefully remove and properly dispose of contaminated PPE. Don fresh PPE before beginning clean up.
- Remove any sharps that might be present in the spill area using forceps or tools. Do not use your hands, even if gloved.
- Cover spill with paper towels/absorbent material. Apply appropriate disinfectant proceeding from the outside toward the center. Allow to remain for the required contact time.
- Wipe down all surfaces and equipment in the BSC with appropriate disinfectant solution.
- Dispose of all contaminated materials into red biohazard bag. Change outer gloves after collecting materials.
- Autoclave/decontaminate waste.
- Notify your PI and JBF Supervisor regarding the spill, and then complete a JBF Incident Report.
- The JBF Supervisor will notify the appropriate individuals on the JBF Incident Response Phone Tree.
- The JBF Director will inform the BSO, Kaka'ako EHSO, AVS Manager/Manager (if applicable), and Facilities Director of the spill.

Biological Spill/Release outside a BSC

Any spill of SARS-CoV-2 material should have occurred in a BSC. Otherwise you have already violated these requirements.

A spill outside of a BSC is unacceptable and presents a number of problems. First, all staff members in the room where the spill has occurred are now considered potentially exposed and, thus, must be considered for a self-quarantine for 14 days. Second, the spill must be immediately decontaminated to prevent potential spread of infectious material. The survival of SARS-CoV-2 on surfaces is expected to be a number of hours so shoes, socks, pants, etc are all suspect in the event of a spill outside the BSC and must be removed carefully and bagged to minimize the chance of generating inhalable aerosols. Follow the JBF spill containment procedures.

If the spill is **SMALL** (<100 mL) and can be easily contained and cleaned up:

- Notify others in the area about the spill.
- Spray down any potentially contaminated PPE with decontamination solution and carefully remove and properly dispose.
- Don fresh PPE. Obtain spill kit materials.
- Remove any sharps present in the spill area using forceps or tools to collect sharp pieces. Do not use hands, even if gloved.
- Place absorbent material over the spill, starting from the outside and working toward the center. Add extra absorbent material beyond the edges of the spill.
- Soak the absorbent material, outside toward the center, with the appropriate disinfectant also spray area around spill.
- Allow the required time for absorbent material soaked with disinfectant to remain on the spill. Carefully collect and dispose of all contaminated materials into red biohazard bag
- Wipe down spill area again with disinfectant soaked paper towels.

- Disinfect any equipment, walls, or other areas around spill that might have been splashed. Discard paper towels used in cleanup/wipe down into a red biohazard bag.
- Change outer gloves after collecting materials.
- Autoclave/decontaminate waste.
- Notify your PI and JBF Supervisor that clean-up was completed and complete a JBF Incident Report.
- The JBF Supervisor will notify the appropriate individuals on the JBF Incident Response Phone Tree.
- The JBF Director will inform the BSO, Kaka'ako EHSO, AVS Manager/Manager (if applicable), and Facilities Director of the spill.

If a **LARGE** spill (greater than 100 mL) should occur and cannot be handled easily or contained:

- Immediately evacuate the laboratory.
- Post signs at the Suite and Anteroom entrances prohibiting entry.
- Notify your PI and JBF Supervisor once outside of the laboratory and complete a JBF Incident Report.
- The JBF Director will inform the BSO, Kaka'ako EHSO, AVS Manager/Manager (if applicable), and Facilities Director of the incident.
- The JBF Supervisor, JBF Director, JBSO, Kaka'ako EHSO, and JABSOM Facilities Director will discuss the situation, conduct a risk assessment, and determine the course of action.
- Once the plan has been discussed and approved, the spill will be cleaned up by approved staff.

Biological Spill/Release Inside a Centrifuge

- If a breakage or spill is known or suspected while the machine is running.
- Immediately stop the cycle and turn off the centrifuge.
- Allow the centrifuge to come to a complete stop.
- If the centrifuge is small and can be placed into the biosafety cabinet, (e.g., microcentrifuge) place it in the biosafety cabinet before opening. If it cannot be placed in the biosafety cabinet, contact your PI and JBF Supervisor, before proceeding.
- Do not open the centrifuge for at least 30 minutes to allow any aerosols to settle.
- Once approval has been given, use appropriate PPE (e.g., thick rubber gloves, safety goggles) to clean spill.
- Lay towels soaked in disinfectant over the spill area. Allow the required time for absorbent material soaked with disinfectant to remain on the spill.
- Use forceps, or cotton swabs held in forceps, to pick up small pieces of sharps.
- All broken tubes, sharps fragments, buckets, trunnions, and rotors must be properly decontaminated (treated with an appropriate disinfectant or autoclaved). If safety cups (sealed buckets) or sealed rotors were used, they must be opened in a biosafety cabinet.
- Unbroken, capped tubes can be disinfected in a separate container if the contents are to be recovered.
- All cleaning materials shall be collected and decontaminated.
- Contact the JBF Supervisor when cleanup is completed and document the incident by completing a JBF Incident Report.
- If, upon opening the rotors inside of the BSC, you notice evidence that a spill has occurred during centrifugation (e.g., cracks in the containers), follow the instructions for a spill inside of the BSC.
- The JBF Director will inform the BSO, Kaka'ako EHSO, AVS Manager/Manager (if applicable), and Facilities Director of the incident.

Spill or Release Outside of Containment

- Biological materials leaving the BSL-3 facility must be properly packaged as per Department of Transportation (DOT), the Federal Aviation Authority (FAA), and the International Air Transport Association (IATA) dangerous goods regulations. Federal and international regulations require that the shipper successfully complete job-specific training and be certified to ship infectious materials. If proper packaging fails and if there is a spill outside of containment, then follow the same rules and guidelines for response to Spill/Release outside of a BSC.

SOP 11 - KAKA'AKO BSL-3 SHARPS MANAGEMENT

1. For conducting research on SARS-CoV-2 hypodermic syringes and needles will be issued only to authorized personnel, and must only be used for research purposes. Risk assessment must be conducted with the JBF Director and the Biosafety Officer. Alternative methods must be taken into consideration before using needles. Buddy system must be followed.
2. Stocks of hypodermic syringes and needles will be secured in a secure place (e.g., locked drawer, cabinet, or room) with controlled access. Hypodermic syringes and needles not in reserve, not in main stocks, and not in use must also be stored under suitable locked conditions.
 - a. All work will be conducted with only one uncapped hypodermic needle at a time. Keep uncapped needles and other sharps in view.
 - b. DO NOT place a needle cap in your mouth in order to remove the cap.
 - c. DO NOT leave sharps unattended.
3. Place a biohazard sharps container within an arm's reach of the area where sharps are used. Position the biohazard sharps container low enough in the work area so that you can readily visualize the opening. Biohazard sharps containers are available for purchase from laboratory supply companies (e.g., Fisher, VWR, etc.).
4. Immediately dispose of a used hypodermic syringe and needle, as a unit, directly into a sharps container, **without any further manipulation**. Avoid bending, breaking, shearing, or removing needles from syringes. Likewise, dispose of any broken glassware contaminated with biohazardous materials directly into a biohazard sharps container. Store reusable sharps in a puncture resistant container, to prevent accidental or unintentional contact. If contaminated with biohazardous materials, reusable sharps should be stored in disinfectant solution until processed.
 - a. Sharps MUST NOT be disposed in the regular trash.
 - b. If vacutainers are to be reused, secure the hub of the needle in a sharps container and unscrew it directly into the container.
5. DO NOT recap needles. Recapping of needles causes more injuries than it prevents. However, if it is absolutely necessary to recap needles, for example, as part of a protocol, you must use either:
 - a. A mechanical device such as forceps to replace the cap on the needle, or
 - b. Transport any recapped needles in secondary containers to prevent accidental inoculation.
6. Avoid handling any broken, contaminated glassware directly by hand, even if wearing gloves. Use a device such as tongs, forceps, brush and dustpan, or even two pieces of cardboard.
7. Biohazard sharps containers will be disposed when they are 3/4 full. Secure the containers to prevent leakage, punctures, and spillage during transport. Sharps containers must be disposed through the UH-EHSO program.
 - a. Sharps containers must not enter the regular solid waste stream.
 - b. DO NOT overfill biohazard sharps containers.
 - c. DO NOT force a sharps item into a container, or retrieve a discarded item.

SOP 12 - EMERGENCY RESPONSES TO HVAC AND POWER FAILURE

Should a power outage or an HVAC failure occur at the University of Hawaii John A. Burns School of Medicine at Kaka'ako, these procedures will be followed:

POWER FAILURE

If a power outage does occur while you are working in the BSL3 lab, these labs are designed to run on back-up emergency power so you should not be affected. The back-up power should maintain the negative pressure in the suites as well as in the Isocage™ system. Additionally, the Isocage™ system is an independent unit, which has its own back-up power—the UPS (Uninterrupted Power Supply) has the ability to supply power to the Isocage™ system for 3 to 6 hours, independent of the building systems, which will allow the Isocage™ to maintain negative pressure in the cages. If building power is not restored within the 3 to 6 hour timeframe, the exhaust fans of the Isocage™ will no longer function and the negative pressure of the Isocage™ will continue to draw in environmental air until the pressure is equalized (becomes static, NOT POSITIVE), at which point, the mice will have approximately 15 minutes of Oxygen, and will then suffocate and perish. Note that no air is being exhausted from the cage in this scenario and the DOUBLE HEPA filtration is still in place and functional.

HVAC FAILURE

The HVAC system is a redundant system consisting of two exhaust fans. When one fan becomes inoperable, the backup fan should engage and become operational in just moments. However, if both fans are not operating, the situation will be immediately noticeable, as the suites will no longer hold negative pressure. You will immediately hear the audible alarms, but also see the visual strobe alarms as well in all of the different rooms making up the BSL3 Labs. In addition the BSCs will also sound their individual, independent alarms as well. The only exception will be seen in the Isocage™ system. The HVAC system failure will have NO effect on the Isocage™ itself. The Isocage™ system has complete containment and filtration independent of the building HVAC. The building HVAC serves as to help control the odors from the Isocages™ only, and is not necessary for Isocage™ biocontainment. In fact, there is a special "thimble" connection between the Isocage™ exhaust and the building HVAC specifically designed not to be airtight to prevent the interference of the building HVAC with the Isocage™ function. Again, it is important NOT to have an airtight connection between building exhaust and Isocage™ exhaust in order to prevent interference with the Isocage™ airflow rates and pressure balance.

RESPONSE

However, regardless of the nature of the failure, you should immediately stop working and start to secure any biological agents, animals, and/or chemicals. Depending upon the ongoing procedures following steps should be taken:

1. While conducting following procedures, it is mandatory to wear N95 mask.
2. Remember to close all BSC sashes.
3. Notify Security (692-0911 or 692-1911).
4. Disconnect all equipment that could be damaged by a power surge when electricity is restored.
5. Turn off all appliances and other energy users to reduce the power requirements for restoration.
6. Do not evacuate the building unless instructed to do so by emergency services (HPD,

HFD, and JABSOM Security). If you are instructed to evacuate the building, use the emergency EXITS and go to a designated Evacuation Gathering Area to await further instructions from emergency services. (See Diagram for Designated Evacuation Gathering Area below).

7. If instructed to evacuate, follow SOP to exit the lab.

APPENDIX-1: PEST MANAGEMENT PLAN SPECIFIC FOR KAKA'AKO BSL-3

The Kaka'ako, JABSOM, BSL-3 facilities infrastructure meets the standards defined in the 5th edition of the BMBL. Similarly, all BSL-3 experimental practices, and containment practices will be adhered to as prescribed in the 5th edition of the BMBL. The SOP for conducting research with SARS-CoV-2, is described in detail in the attached SOPs. The BSL-3 facilities at Kaka'ako are under negative pressure and are built according to the CDC and USDA standards as defined in the 5th edition of the BMBL.

General Pest Management Plan

The following describes the JABSOM Kaka'ako Plan for minimizing the risk of insects and rodent vector transmission of hazardous agents from the Level 3 Facilities. Many pests can mechanically transmit disease pathogens and compromise the research environment. As such, integrated pest management (IPM) is an important part of managing a Research Facility. The Plan relies heavily on the education and assistance of JABSOM Facilities Staff who care for JABSOM buildings and grounds. Consequently, it is the policy of the JABSOM Facilities to reduce or eliminate the potential for pest breeding, harborage, and entrance to the research facility. Proper sanitation, good housekeeping, and good building maintenance are key factors to keeping insects and rodents from entering the buildings.

Insects

1. Users of BSL-3 will routinely inspect the labs for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.
2. Facilities will contact a Licensed Pesticide Contractor on an as-needed basis to inspect, verify and take proper treatment to eradicate insects in the BSL-3 areas that are affected as well as other areas of the campus. The Contractor shall meet with EHSO to discuss the Pesticide to be used and application to ensure all EPA FIFRA requirements and guidelines are followed and to ensure the safety of the JABSOM Kaka'ako occupants. Pesticides may only be applied when the lab is closed down for maintenance, i.e. there are no active research being conducted.

Safety: Every effort must be made to insure that pesticide application/exposure is held to a minimum to insure the safety and welfare of JABSOM Kaka'ako Occupants and Research Projects. **Preventive applications** of pesticides are not encouraged in any Research Facility. As such, pesticide application(s) are restricted to areas where pest populations cannot be controlled by other means.

Facilities shall monitor the Pesticide Contractor to insure treatment was administered effectively.

Rodents

1. If there are signs of rodent infestations in the Level 3 Labs, the Users shall inspect the areas and capture any rodents. Traps shall be placed throughout the lab. The rodent shall be contained in the Level 3 Lab until an investigation conducted by EHSO is concluded and decisions are made regarding testing the rodent for infection, destruction of the rodent, surveying the facility for ports of entry for rodents, decontamination of the facility, SOP evaluation and revisions as necessary.
2. Careful records of all animals shall be maintained and any unaccounted for rodents shall be reported to the Level 3 Manager and Supervisors, LAS, and EHSO immediately

Mosquitoes

1. JABSOM facilities shall maintain the buildings and grounds according to the general JABSOM Kaka'ako Pest Management Plan to prevent, identify, monitor, and eliminate mosquito-breeding sites and prevent wild mosquitoes from entering the research building. Refer to the General Plan. If wild mosquitoes are able to enter the building, there are several safeguards that prevent the wild mosquitoes from contacting infecting animals or inoculating cultures refer to specific protocol SOPs.

SPECIFIC PROTOCOL IPM

Specific IPM shall be protocol driven.

Moreover, JABSOM Facilities provide building, campus wide monitoring, and protection. The following is the Facilities Management Plan.

Many pests can mechanically transmit disease pathogens and compromise the research environment. As such, integrated pest management (IPM) is an important part of managing a Research Facility. Consequently, it is the policy of the JABSOM Facilities to reduce or eliminate the potential for pest breeding, harborage and entrance to the research facility.

JABSOM KAKA'AKO CAMPUS BUILDINGS AND GROUNDS

Building occupants should routinely inspect their work areas for signs of insect infestations and notify JABSOM Facilities through a Work Order Request to investigate and trap or treat insects that are found in the building or the surrounding campus grounds.

1. JABSOM Facilities will contact a Licensed Pesticide Contractor on an as-needed basis to inspect, verify and take proper treatment to eradicate insects in areas that are affected as well as other areas of the campus. The Contractor shall meet with JABSOM EHSO to discuss the pesticide to be used and application to ensure all EPA FIFRA requirements and guidelines are followed and to ensure the safety of the JABSOM Kaka'ako occupants.

Safety: Every effort must be made to insure that pesticide application/exposure is held to a minimum to insure the safety and welfare of JABSOM Kaka'ako Occupants and Research Projects.

Preventive applications of pesticides are not encouraged in any University

Facility. As such, pesticide application(s) are restricted to areas where pest populations cannot be controlled by other means.

2. JABSOM Facilities shall monitor the Pesticide Contractor to insure treatment was administered safely and effectively.
3. If there are signs of rodent infestations in the buildings or on the grounds, contact Facilities and complete a Work Order Request. All unaccounted for lab rodents shall be reported to EHSO, Security, and Facilities immediately.

REDUCING THE NUMBER OF MOSQUITOES ON THE JABSOM KAKA'AKO GROUNDS, NEAR BUILDING ENTRANCES, AND IN THE BUILDINGS

Proper sanitation, good housekeeping, and good building maintenance are key to keeping insects and rodents from entering the buildings.

Draining sources of standing water reduces possible breeding areas. In addition, larvicides (to control breeding areas) and other pesticides may be used to reduce mosquito populations.

- JABSOM Facilities shall respond to any standing water problems in the landscape on campus.
- JABSOM Facilities shall schedule preventive maintenance on gutters and downspouts and the fountain in front of the Medical Education Building.
- Potential mosquito breeding areas (wetter areas of landscaping, etc.) shall be inspected periodically and treated with pesticides when mosquito presence is reported. These "trouble" areas shall be monitored periodically to ensure there are no breeding mosquitoes.
- Trash, recyclables, and discarded equipment and materials must be contained in the trash compactor or promptly removed from all collection areas. Any spilled trash outside of the trash compactor shall be reported to JABSOM Facilities and Custodial staff shall promptly remove the trash.

RECORD KEEPING AND PROGRAM EVALUATION

1. Visual sightings or other evidence of any pests shall be reported to the Lab Manager/Supervisors and EHSO immediately and shall be documented.
2. Reports communicated verbally and in writing concerning pest activity will be recorded and kept on file by Lab Manager/Supervisors, Facilities, and EHSO.
3. The Laboratory Director, JABSOM Facilities, and EHSO shall also maintain inspection results for review.

Quality assurance and program review must be performed to provide an objective, ongoing evaluation of pest management activities. EHSO is responsible for evaluating the effectiveness of all pest control procedures implemented and approving or redirecting efforts to control pests found.

APPENDIX-2: SOP FOR TSUNAMI

1. If working in a Biosafety Cabinet (BSC)
 - a. Seal all open cultures (this includes putting animal carcasses in a sealed or disinfectant filled container).
 - b. Cover pipette trays.
 - c. Carefully remove your outer gloves, and leave them in the BSC.
 - d. Close the sash to the lowest possible position.
 - e. If time permits, animals may be sacrificed and infected cultures may be autoclaved.
NOTE: If you believe that you are in immediate danger from tsunami, DO NOT perform the procedures described for the BSC and immediately exit the building. The Isocage™ systems which house the animal are waterproof and without power supply, the animal will die in 15 minutes due to suffocation. Freezer and incubator are waterproof. Therefore infected material will not spread into the environment. In worse case scenario when salt water can get into these equipment's, salt water will kill all these infected cultures and animals.
2. If you are working outside of a cabinet, close up any equipment/appliances you are working with.
3. Meet at the designated evacuation points.
4. Stay at the evacuation point and ensure there is full accountability for all personnel that were in the facility. If individuals are missing do not re-enter the facility to find them, but notify police or fire personnel of the number and identity of individuals missing and where they were working in the facility. DO NOT LEAVE ; until you are given the clearance to do so from Emergency Management.
5. If the situation is cleared, and the building can be re-occupied, return to your labs (under the appropriate conditions), and finish/clean up your work.
6. At your earliest possible convenience fill out an Incident Report if a potential exposure occurred.

APPENDIX-3: BOMB THREAT/SUSPICIOUS PACKAGE SOP

BOMB THREAT/SUSPICIOUS PACKAGE

- Called in Bomb Threat:
 - DO NOT hang up on caller
 - Keep them on phone for as long as possible and get as much info as possible
 - Once caller hangs up, contact Security
- Suspicious Package
 - DO NOT open or move package
 - Vacate area and notify Security and Biosafety Officer

These SOPs are specific for Coronavirus research in the BSL-2.

You must read and understand general SOPs in the BSL-2 Biosafety manual to conduct research in the Department of Tropical Medicine, Medical Microbiology and Pharmacology laboratories at the JABSOM Kakaako campus.

SOP 1: Infection and Cell Harvesting in BSL-2

SOP 2: Plaque assays in BSL-2

SOP-1: Coronavirus Infection and Cell Harvesting in the BSL2

Virus infection procedures:

13. Take the vial of virus stock from -80oC in secondary containment and take it to the BSL2 suite and immediately place in BSC.
14. Carefully remove the tissue culture plates of cells from the incubator and place in the BSC.
15. Per the experiment design, infect the cells with the appropriate volume of thawed coronavirus such as OC43 and 229E and return the plates to the incubator located in the BSL2 suite.
16. Discard any remaining virus in the vial into the fresh 10% bleach solution and let sit for at least 20 minutes.
17. After infection, wash the cells in the tissue culture plate with 2X PBS.
18. Remove PBS wash with a pipet and carefully discard all the waste into the bleach solution.
19. Add fresh media over the cells, and return to the incubator.
20. Determine if the virus waste has been in the bleach solution for at least 20 minutes. After the 20 minute decontamination time, the virus is totally inactivated, i.e. not viable.
21. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
22. Pour the media waste down the sink drain followed with water for at least 1 minute.
23. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

Procedure of cell and supernatant harvesting:

11. After 24, 48 and 72 hours after infection, carefully take the plate out of the incubator and place it in the BSC hood.
12. Remove approximately 200-400ul media from each well and store in an Eppendorf tube. Label it with date, amount, virus details and store it in a 96-well cardboard box.
13. Carefully wash the cells with PBS and carefully discard all the waste into the bleach solution.
14. Now add cell lysis reagent in the wells and collect the lysate in the Eppendorf tubes. This lysate inactivates the virus and will be used for RNA extraction.
15. Wash plates with 10% bleach solution once and discard all the waste into the bleach solution container.
16. Carefully place the supernatant and lysate tubes in a 96-well box. Place this box in a secured secondary container and move it out to the -80oC freezer.
17. After the 20 minute decontamination time, the virus is totally inactivated, i.e. not viable. Pour the media waste down the sink drain followed with water for at least 1 minute.
18. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

SOP-2: Coronaviruses plaque assays in the BSL-2

All procedures will be conducted in certified BSC's by operators wearing appropriate personal protective equipment as outlined in the BSL2 laboratory SOP's.

Virus infection procedures:

1. Take the vials of coronavirus samples tested for plaque assay from the -80°C freezer in secondary containment into the BSL2 suite and immediately place them in the BSC.
2. To establish viral titers over the expected range, dilute each sample 10-fold 3-6 times
3. Carefully remove the 6-well tissue culture plates of Vero E6 cells from the incubator and place them in the BSC, remove most of the culture media by aspiration leaving about 300ul of media.
4. Add 1 dilution (100µL) to each well ensuring that the cells are *not disturbed* when pipetting in the sample
5. Discard any remaining virus dilutions in the tubes into freshly prepared 10% bleach solution and let sit for at least 20 minutes.
6. Let the plates sit in the incubator for an hour and then add 3ml of the first overlay (containing DMEM and 1% agarose) over the cells in each well and swirl gently.
7. Return the plates to the incubator after the agarose is solidified.
8. Determine if the virus waste has been in the bleach solution for at least 20 minutes (after last waste was added). Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
9. Pour the media waste down the sink drain followed with water for at least 1 minute.
10. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

Second Overlay

1. Second overlay is added after 3 days of infection with coronaviruses. Heat the second overlay containing 0.9% sodium chloride, neutral red and 1% agarose in a microwave.
2. Take the plates out of the incubator and add 1mL of the overlay to each well. Let the agarose solidify and then return the plates to the incubator.
3. Discard any liquid waste in the 10% bleach solution.
4. Use a pH strip (located near the sink) to check the pH to ensure the solution is in the acceptable range of 5.5 and 9.5. If necessary, add water until the pH is within the acceptable range.
5. Pour the media waste down the sink drain followed by water for at least 1 minute.
6. Decontaminate the BSC and work surfaces as described in the *Clean-up SOP*.

Plaque reading: 24hrs after application of the second overlay, take the plates out of the incubator and read the plaques using a plaque reader light box. Assay plates will be discarded into biohazard waste bags and decontaminated by autoclaving before disposal as non-infectious waste.

Alternative assay formats: As alternative to detection of plaques with neutral red using a solid overlay, the cells may be overlaid with a solid or semi-solid overlay and fixed using 4-6% formaldehyde followed by staining with crystal violet. Another, more rapid alternative is to fix the cell sheet with formaldehyde 12-24h after infection, the resulting spots on the cell sheet will then be detected using standard immunospot detection with a suitable monoclonal or polyclonal antibody followed by a conjugated secondary antibody and incubation with a solid substrate creating well defined immunospots that can be counted.

Plaque reduction neutralization test: As a modification to the direct titration of viable virus from infection experiments, plaque reduction neutralization tests (PRNTs) will be conducted as an assay to determine the presence of functional antibodies in animal and human sera. In brief, for this assay suitable dilutions of stock virus containing 50 pfu of SARS-CoV-2 in 50µL DMEM will first be incubated with or without serially diluted antibodies in a total volume of 100µL in 96-well U-bottom tissue culture

plates for 1 hour at 37°C. Then, the mixture will be added into the 6- well plate seeded with Vero E6 cells after removing most of the culture medium and incubated for 1 hour at 37°C. Then first overlay will be applied and all remaining procedures of the standard plaque assay including various detection methods completed. Assay results will be analyzed using non-linear regression to determine PRNT50 or PRNT80 titers.

PQB NOTES: For reference, this attachment contains the information that was originally submitted by Dr. Nerukar and initially reviewed by the subcommittee, but then subsequently replaced based on the subcommittee review. To further identify the information that was deleted from the current submittal, it has been highlighted in grey.

The section below begins on page 4 and ends on page 24 of the submittal.

II. Information Provided by the Applicant in Support of the Application

PROJECT: A novel coronavirus was isolated in late 2019, early 2020 which caused sever pneumonia. Today that pneumonia is called COVID-19 (Coronavirus disease 2019). Its etiological agent is known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11, 2020, The World Health Organization (WHO) declared COVID-19 a pandemic. Within three months of its discovery, this infection has spread to more than 114 countries, adversely affecting nearly every social, economic, and health care system worldwide.

Since SARS-CoV-2 is a newly identified virus, there are several unknowns that hamper our ability to control virus spread and develop novel testing tools, therapeutics and vaccines. The projects described herein involve understanding basic epidemiology and pathogenic mechanism of SARS-CoV-2. Additionally, vaccine development projects and antivirals are anticipated.

- a. Basic epidemiology – genomic and antibody testing By understanding the relationship between the occurrence of positive genomic testing and positive antibody testing, a correlations can be identified.
 - Increase the number of genomic and antibody tests
 - Identify a correlation between the presence of total antibody and protective antibody.
 - Estimate the true number of COVID0-19 cases.
 - Rapidly identify COVID-19 cluster cases. In the absence of FDA approved antivirals, or an FDA approved vaccine, epidemiologists have said the key in defeating COVID-19 pandemic is to identify infected individuals and those they have infected and to quarantine them to severe the vicious cycle of infection. Extensive testing, thus, is a crucial step. It should be noted, the asymptomatic rate for COVID-19 has been reported to be as high as 85%. More importantly these asymptomatic individuals can transmit the virus.
- b. Basic pathogenic mechanism
 - Identify the effects of virus infection of various cell types and correlate these with known disease symptoms.

- Investigate the effects of various FDA approved drugs in virus replication in various cell types.
- Investigate the effect of virus replication and the observed cytokine storm.

c. Vaccine development

- Develop a safe and efficacious SARS-CoV-2 vaccine

Tropical Medicine, Medical Microbiology, & Pharmacology faculty employ an interdisciplinary approach to answer fundamental questions associated with the pathogenesis, immunology, and evolution of tropical diseases and to translate this new knowledge into the development of new diagnostics, drugs and vaccines. The Department staff and laboratories at Kakaako, thus, have the expertise and the equipment to address these problems provided that UH scientists are allowed to import pathogens to develop diagnostic assays and research tools for SARS-CoV-2 without posing any serious health risk or threat to laboratory personnel or the environment and population of the State of Hawaii. We request to import and work with SARS-CoV-2 and other human coronaviruses (229E and OC43 as comparative strains) to further our diagnostic and research capabilities, which would benefit not only the citizens of Hawaii, but the global population as well. The location of Hawaii at the hub of the Pacific, and having inhabitants and travelers from such a wide variety of countries, provides a unique opportunity to position the research conducted at UH at the forefront of exotic pathogen detection and diagnosis.

OBJECTIVE: Our objective is to join the global effort to combat COVID-19 disease. We propose to conduct experiments to:

a. Basic epidemiology – genomic and antibody testing

- Increase genomic SARS-CoV-2 and SARS-CoV-2 antibody detection capacity of the state
- Develop a sensitive and accurate quantitative ELISA
- Identify correlates between total antibody and protective antibodies

Turn-around time for the majority of nucleic acid based tests take more than 24 hours, while antibody based tests, although rapid, have been criticized for their lack of sensitivity and accuracy. Without effective, wide-spread accurate and rapid diagnosis, effective emergency response cannot be conducted.

b. Basic pathogenic mechanism

- Understand the cellular target of this virus
- Understand the pathogenesis mechanisms including how it causes damage in multiple organs
- Understand the mechanism of the cytokine storm

c. Vaccine Development

- Identify the most promising vaccine candidate and formulation
- Evaluate these candidates in small animal models and evaluate the elicited immune response both total antibody, protective antibodies, and cellular immune response
- Challenge immunized animals and determine if they are protected.

PROCEDURE:

a. Diagnostic procedures: Different clinical samples including blood, saliva, nasal wash, urine and stool will be used to diagnose virus and/or virus associated antibodies. These samples will be used to extract virus RNA using Qiagen kits and PCR will be run to detect presence or absence of the virus. For blood samples, plasma will be used to measure virus antibodies using different assays including ELISAs and Luminex assays. These diagnostic procedures require 1-3 days depending on the assays (2).

b. Virus infection of different human cell types: Different human cells will be cultured in 24-, or 12-well plates and grown to 80% confluency. The cells will then be infected with lower dose of different coronaviruses (MOI 0.01 to 1) for 1 h at 37°C. Following the infection, wells will be washed with PBS and replenished with fresh media. Supernatant will be collected every day up to day 5 of infection and cells will be washed with PBS and used to extract RNA and proteins for measuring different host responses as described below. These infection experiments will take between 2-5 days for sample collection before the plates are discarded. RNA and proteins samples will only contain inactive virus particles and will be safe to handle.

c. Virus measurement using plaque assay: Plaque assay using VeroE6 cells is a widely used method to measure infectious virus in the supernatant. Vero cells grown in 6-well plates will be incubated with the supernatant from infected cells at different time points and overlaid with 1% agarose as described in previous studies. The colonies will be counted after 3-4 days. Completion of this experiment takes total 5-6 days (3).

d. Cell viability assays: Death of cells caused by the virus at different days after infection will be measured using widely used cell viability kit as described in our previous studies. This experiment takes total 2-4 hrs.

e. Host response studies using inactive virus particles: Infected cells will be washed and RNA will be extracted using commercially available kit and cDNA will be used to run RT-PCR assays to profile host immune and inflammatory genes as described in our previous studies. Virus copy number will be also measured using commercially available coronavirus primers. After RNA extraction, these samples do not remain infectious and RNA can be stored in -80°C for months to run RT-PCRs.

f. Vaccine development: Various sequences of various candidate vaccine will be cloned into appropriate expression vectors, cells transfected, and protein analyzed using conventional molecular biology techniques. Protein will be purified using conventional chromatographic methods. Mice will be immunized with various subunit vaccine candidates and the vaccine formulation eliciting the highest level of total IgG antibody and neutralizing antibodies will be further evaluated in a small animal challenge model.

BSL-2 Biosafety Practices: Coronaviruses **EXCLUDING** SARS-CoV-2 will be used and stored at the JABSOM, Biosciences Building 3rd Floor, 651 Ilalo Street, Honolulu, Hawaii 96813. BSL-2 and ABSL-2 laboratories will be used to propagate the virus and subsequent experimentation using cell cultures and mice model. The ABSL-2 is located within the vivarium on the first floor of the Biosciences Building, 651 Ilalo Street, Honolulu, Hawaii 96813.

Viral stocks in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, are under the supervision of Dr. Vivek R. Nerurkar. The virus is only grown in closed lid cell culture vessels in CO₂ incubators, in secured labs that are only accessible by trained laboratory personnel authorized by Dr. Nerurkar. Culture vessels are only opened inside the Class II Biosafety Cabinet (BSC), using aseptic techniques. Viral stocks are transported in triple packaging, and typically no more than 3 mL of diluted virus is transported at a time for viral manipulations. All procedural manipulations of mice and/or cell culture testing will be done inside a BSC. All manipulation will be done by skilled and trained researchers. Each investigator will have had prior experience working with animals and will be able to detect abnormal behavior and understand proper handling techniques of mice and cell culture and will comply with the safety regulations set forth by UH

Institutional Animal Care and Use Committee and UH Biosafety Program and Office Research Compliance.

The Department of Tropical Medicine, Medical Microbiology and Pharmacology personnel are required to wear a laboratory coat and gloves. Researchers never conduct work with exposed skin surfaces on hands and arms and are discouraged from working with any deep wounds or cuts, not matter how well bandaged. Proper personal protection equipment practically eliminates any potential lab infection, except when handling sharps and needles. Activities involving the use of sharps are limited whenever possible. In the laboratory, in any unfixed tissue or organ (other than intact skin) from clinical samples, regardless of latent or convalescent coronavirus infection, in all materials derived from coronavirus culture, and in/on all equipment and devices coming into direct contact with any of these materials. Laboratory personnel take great care in decontaminating all of the above items when not involved in active manipulations.

Coronavirus infection from stock vial to human is not possible. The only plausible cause of infection in the laboratory setting is if a technician during active manipulation of the virus, accidentally pokes himself deep into the skin with a contaminated needle or sharp object, providing direct access of the virus to the bloodstream. Thus, we have designed our protocols and procedures including PPE to limit, and nullify if possible, the need for sharp in all but the inoculation protocol. Even when handling infected animals, there is no known case that the virus can be aerosolized from feces or urine of the infected animal, however, strict SOPs are in place to protect against any potential exposure by housing the infected animals in the ABSL-2, in the Isocage system, and only opening dirty cages in a certified BSC and the laboratorian wearing proper PPE and using BSC to manipulate the virus and animals. All wastes and cages are treated with chemical neutralizing agents such as sodium hypochlorite solution or quaternary ammonium compound solution.

With proper precautions in place, training of personnel, and strict adherence to SOP, not only is the risk of laboratory infection extremely unlikely, but accidental release is nearly impossible. Experiments and procedures are designed to limit the amount and concentration of virus. Stocks are aliquoted in small amounts and the virus is contained at all time points except for during direct manipulation. Typical viral manipulations, such as inoculations, only involve approximately 3 mL of virus to be used at one time. If an accidental spill were to occur in the lab, research technicians are trained to respond to isolate the spill immediately and chemically

neutralize the spill, virtually eliminating all possibility of adverse environmental and health effects. As mentioned above in the lab we handle limited quantity and concentration of the virus at any given time, therefore it is relatively easy to contain the virus spill. Additionally, all infected culture plates are placed in trays meant to contain any spills.

Specific receptors are required for the virus to bind and enter the cells, thus, skin provides an excellent primary barrier. Coronavirus and other similar viruses are transmitted by aerosols or need to be injected into the body to infect an individual. Furthermore, if an infected animal were to escape from the BSC, strict SOPs are in place so that technicians do not leave the room until the mouse is captured. If capture is impossible, then the room is fumigated to ensure that the infected animal does not leave the manipulation suite alive.

Proper inventories will be kept and just as with other permits granted to Dr. Nerurkar, all annual inventories will be submitted yearly to the Hawaii Department of Agriculture (HDOA).

BSL-2 Animal Inoculation: We will inoculate the virus in the 2-4 day old suckling mice model to generate quantities of the virus needed to complete aforementioned experiments. Suckling mice will be used to grow coronavirus obtained from either clinical samples or previously propagated cultures received from fellow collaborators. The virus may also be isolated from diagnostic samples obtained from humans, or animals. Suckling mice model is considered to be a highly sensitive method for virus isolation and inoculation of this age of mice is a standard, classical laboratory technique that has proven effective for decades of research. The coronavirus will then be further propagated in appropriate cell lines, including Vero, HCT-8, MRC-5 and LLC-MK2, and re-confirmed for identity using immunofluorescent assay (IFA) with type-specific monoclonal antibodies and by sequencing key regions of the coronavirus genome. Several molecular, cellular and pathogenesis studies will be conducted using techniques such as RNA and protein expression, cytokine expression, antibody production, and epidemiological comparisons. In addition, we will conduct vaccine development experiments in which we will challenge mice at various time points after administering coronavirus antigens.

Approximately 15-30 pregnant female C57 BL/6 mice will be purchased for each investigation from a certified Specific Pathogen (SPF) vendor. Please refer to SOP #2 (Attachment 6, page 2) for receiving pregnant female mice from Laboratory Animal Services

(LAS) upon verification from LAS that the mice are in good condition, the mothers will be transferred to a total bio-containment, individually housed cage called a microisolater. Isocage™ (microisolater) information is detailed in the Daily Husbandry and Observation Prior to Inoculations SOP #3 (Attachment 6, page 3). Two to three days after birth, the pups will be inoculated intracranially with 20ul of the suspected, viral sample (see SOP #5 inoculation, Attachment 6, page 6). This type of inoculation will allow the virus, if present, to replicate in the animal host. After the inoculation procedures, pups will be gently returned back into the mother's Isocage™. The pups will be closely monitored twice daily, post inoculation for any signs or symptoms of a viral illness. See SOP #6 (Attachment 6, page 7) for Post Inoculation Observation and Husbandry and Daily Site Log.

The inoculated suckling mice and their mothers will be housed in the ABSL-2 or ABSL-3 depending upon space availability, in the Isocage™ cage and rack system. If the ABSL-2 vivarium space is fully occupied with other investigations, then the option exists to conduct coronavirus inoculations in the BSL-3, not due to the need for higher containment, but simply to accommodate the experiments if no ABSL-2 vivarium space is available. The Isocage™ is a hermetically sealed, individually ventilated cage (IVC) that creates absolute containment comparable to that obtained by other types of isolators, while at the same time maintaining the simplicity and ease of use typical of IVCs. The Isocage™ features a HEPA filter on the exhaust valve protected by a pre-filter, in addition to a HEPA filter at the cage level, the air is then pulled through another pre-filter and HEPA filter at the rack level, GUARANTEEING TRUE BIO-CONTAINMENT AT EVERY LEVEL. The HEPA filter and the pre-filter can be removed and quickly changed when the cage is open in a protected environment. The Isocage™ guarantees a stable, lasting hermetic seal under both normal working conditions and also when the cage is removed from the rack. The hermetic seal is so efficient, that if the cage is removed from the passive air flow of the rack system, air flow in the cage will cease, and the oxygen supply within the cage will be depleted within 15 minutes, which results in further reassurance of aerosol containment regardless of whether the cage is docked in the rack system.

Infected animals are handled minimally and only with another highly trained technician present. All waste generated from the experiments and manipulations are autoclaved at 250°C, 18 PSI for 1 hour. Sharps and needles are inventoried and kept in secure locations and the contaminated sharps and needles are disposed of in rigid, biological sharps waste containers that are autoclaved at the aforementioned conditions before being disposed of by UH-

Environmental Health and Safety Office. All excess virus stocks and infected cultures are chemically neutralized with infected carcasses are autoclaved at 250°C, 18 PSI for 1 hour and then placed in the tissue digester for complete processing. If during the course of the research, three or more of the litters show signs of viral infection such as hunched, hyperactivity, hind limb paralysis, ataxia and failure to thrive, they will be humanely euthanized by cervical dislocation to prevent unnecessary pain and suffering. If we find by either in vivo or in vitro methods that the viral agent isolated belongs to a family of viruses in a higher biosafety level, is a select agent, or if we cannot identify the agent, the research on this agent will cease immediately.

BSL-3 Biosafety Practices: SARS-CoV-2 will be manipulated and stored in the JABSOM, Biosciences Building, JABSOM Biocontainment Facility (JBF), 651 Ilalo Street, Honolulu, Hawaii 96813. BSL-3 and ABSL-3 laboratories will be used to propagate the virus and subsequent experimentation using cell cultures and small animal model; initially in mice. The ABSL-3 is located within the vivarium on the first floor of the Biosciences Building, 651 Ilalo Street, Honolulu, Hawaii 96813.

SARS-CoV-2 viral stocks in the Department of Tropical Medicine, Medical Microbiology and Pharmacology, are under the supervision of Dr. Vivek R. Nerurkar. SARS-CoV-2 will be only grown in closed lid cell culture vessels in CO2 incubators, in secured labs that are only accessible by trained laboratory personnel authorized by Dr. Nerurkar. Culture vessels will be only opened inside the Class II Biosafety Cabinet (BSC), using aseptic techniques. Viral stocks will be transported within the laboratory in triple packaging, and typically no more than 3 mL of diluted virus is transported at a time for viral manipulations. All procedural manipulations of cell culture and clinical sample testing will be done inside a BSC. All manipulations will be done by skilled and trained researchers. Each investigator will have had prior experience working with BSL3 pathogens and will be able to detect abnormal behavior and understand proper handling techniques of the animals/viruses and will comply with the safety regulations set forth by UH Institutional Animal Care and Use Committee and UH Biosafety Program and Office Research Compliance. Once inside the A/BSL-3 SARS-CoV-2 will not leave the A/BSL-3. Virus will be chemically treated followed by autoclaving using SOP.

Personnel will undergo rigorous training and testing prior to entry into the BSL3 facility, and will be required to continue to train and keep abreast of training requirements, and new techniques. SARS-CoV-2 will only be manipulated in a Class II certified Biosafety Cabinet. The

Department of Tropical Medicine, Medical Microbiology and Pharmacology personnel working in the BSL3 laboratories with SARS CoV-2 will be required to wear following PPE:

- a long, wrap around gown that close in the back
- a double layer of gloves
- manipulation sleeves over gown and booties
- hair bonnet and safety glasses/goggles
- N95 respirator is required for all SARS-CoV-2 related activities
- Face shield will be used when conducting high-risk A/BSL-3 experiments

Researchers never conduct work with exposed skin surfaces on hands and arms and are discouraged from working with any deep wounds or cuts, not matter how well bandaged. Proper personal protection equipment practically eliminates any potential lab infection. Activities involving the use of sharps are avoided whenever possible. In the laboratory, virus will be presumed to be present in all blood or other clinical specimens like urine or saliva, in any unfixed tissue from clinical samples, in all materials derived from SARS-CoV-2 culture, and in/on all equipment and devices coming into direct contact with any of these materials. Laboratory personnel will take great care in decontaminating all of the above items when not involved in active manipulations.

The most common routes of laboratory acquired infection (LAI) are inhalation (particularly by aerosols), percutaneous inoculation (needlestick injuries, broken glass injury, and/or animal bites or scratches), direct contact between contaminated surfaces (gloves, hands), and mucous membranes as well as through ingestion – for example by smoking, eating, or accidental aspiration through a pipette. SARS-CoV-2 requires specific receptors to bind and enter the cells that are not present on the skin. Thus, skin provides an excellent primary barrier. Infection is via inhaled respiratory droplets from a cough leading to infection of nasal or upper respiratory cells directly (1). The risk of an LAI are minimal in cell culture experiments where the use of sharps are very limited. In the cell culture setting, the only risk of infection is the generation of aerosols during sonication of infected tissue. Thus, we have designed our protocols and procedures to avoid any sonication procedures and limit, and nullify if possible, the need for sharps. However, strict SOPs and use of N95 masks during handling of any type of virus cultures will be in place to protect against any potential exposure. All wastes will be treated with chemical neutralizing agents such as sodium hypochlorite solution or quaternary ammonium compound solution.

With proper precautions in place, training of personnel, and strict adherence to SOP, not only is the risk of laboratory infection extremely unlikely, but accidental release is nearly impossible. Experiments and procedures are designed to limit the amount and concentration of virus. Stocks are aliquoted in small amounts and the virus is contained at all time points except for during direct manipulation. If an accidental spill were to occur in the lab, due to the limited quantity and concentration, the risk of virus spread would be minimum. Moreover, research technicians are trained to respond to isolate the spill immediately and chemically neutralize the spill, virtually eliminating all possibility of adverse environmental and health effects.

BSL-3 Animal Inoculation: We will inoculate the virus in the 2-4 day old suckling mice model to generate quantities of the virus needed to complete aforementioned experiments. Suckling mice will be used to grow SARS-CoV-2 obtained from either clinical samples or previously propagated cultures received from fellow collaborators. The virus may also be isolated from diagnostic samples obtained from humans, or animals. Suckling mice model is considered to be a highly sensitive method for virus isolation and inoculation of this age of mice is a standard, classical laboratory technique that has proven effective for decades of research. The SARS-CoV-2 will then be further propagated in appropriate cell lines, including Vero, HCT-8, MRC-5 and LLC-MK2, and re-confirmed for identity using immunofluorescent assay (IFA) with type-specific monoclonal antibodies and by sequencing key variable and conserved regions of the SARS-CoV-2 genome. Several molecular, cellular and pathogenesis studies will be conducted using techniques such as RNA and protein expression, cytokine expression, antibody production, and epidemiological comparisons. In addition, we will conduct vaccine development experiments in which we will challenge mice at various time points after administering SARS-CoV-2 antigens.

Approximately 15-30 pregnant female C57 BL/6 mice will be purchased for each investigation from a certified Specific Pathogen (SPF) vendor. Please refer to SOP #2 (Attachment 5, page2) for receiving pregnant female mice from Laboratory Animal Services (LAS) upon verification from LAS that the mice are in good condition, the mothers will be transferred to a total bio-containment, individually housed cage called a microisolater. Isocage™ (microisolater) information is detailed in the Daily Husbandry and Observation Prior to Inoculations SOP #3 (Attachment 6, page 3). Two to three days after birth, the pups will be inoculated intracranially with 20ul of the suspected, viral sample (see SOP #5 inoculation Attachment 6, page

6). This type of inoculation will allow the virus, if present, to replicate in the animal host. After the inoculation procedures, pups will be gently returned back into the mother's Isocage™. The pups will be closely monitored twice daily, post inoculation for any signs or symptoms of a viral illness. See SOP #6 (Attachment 6, page 7) for Post Inoculation Observation and Husbandry and Daily Site Log.

The inoculated suckling mice and their mothers will be housed in the ABSL-3, in the Isocage™ cage and rack system. The Isocage™ is a hermetically sealed, individually ventilated cage (IVC) that creates absolute containment comparable to that obtained by other types of isolators, while at the same time maintaining the simplicity and ease of use typical of IVCs. The Isocage™ features a HEPA filter on the exhaust valve protected by a pre-filter, in addition to a HEPA filter at the cage level, the air is then pulled through another pre-filter and HEPA filter at the rack level, GUARANTEEING TRUE BIO-CONTAINMENT AT EVERY LEVEL. The HEPA filter and the pre-filter can be removed and quickly changed when the cage is open in a protected environment. The Isocage™ guarantees a stable, lasting hermetic seal under both normal working conditions and also when the cage is removed from the rack. The hermetic seal is so efficient, that if the cage is removed from the passive air flow of the rack system, air flow in the cage will cease, and the oxygen supply within the cage will be depleted within 15 minutes, which results in further reassurance of aerosol containment regardless of whether the cage is docked in the rack system.

Infected animals are handled minimally and only with another highly trained technician present. All waste generated from the experiments and manipulations are autoclaved at 250°C, 18 PSI for 1 hour. Sharps and needles are inventoried and kept in secure locations and the contaminated sharps and needles are disposed of in rigid, biological sharps waste containers that are autoclaved at the aforementioned conditions before being disposed of by UH-Environmental Health and Safety Office. All excess virus stocks and infected cultures are chemically neutralized with infected carcasses are autoclaved at 250°C, 18 PSI for 1 hour and then placed in the tissue digester for complete processing.

If during the course of the research, three or more of the litters show signs of viral infection such as hunched, hyperactivity, hind limb paralysis, ataxia and failure to thrive, they will be humanely euthanized by cervical dislocation to prevent unnecessary pain and suffering. If we find by either in vivo or in vitro methods that the viral agent isolated belongs to a family of viruses in a higher biosafety

level, is a select agent, or if we cannot identify the agent, the research on this agent will cease immediately.

Equipment use for research: Equipment commonly used for live virus culture are described below. Only inactive virus samples containing virus RNA is used for PCRs and other assays.

Basic equipment for live virus culture and for inactivated virus

- Class II biosafety cabinet
- Incubator (humid CO2 incubator)
- Water bath
- Centrifuge with “O” ring buckets
- Refrigerator and freezer (–20°C and -80°C)
- Cell counter (Countess® Automated Cell Counter or hemacytometer)
- Inverted microscope
- plate reader for ELISA and cell viability assays
- autoclave to decontaminate waste

Supplies: Identification of specific function of components of protein synthesis machinery will allow focusing on drug targets which will be effective for drug resistant strains and also improve existing drug therapy. Basic science proposed by Dr. Priscic will take about 5 years, but drug development will take up to 10 years and will be conducted in collaboration with clinical researchers.

DISCUSSION:

PQB NOTES: Only the sections from the original submittal that contained changes are included here. For reference, the “Safeguard Facility and Practices” section begins on page 24 and “Effects on the Environment” begins on page 28 of the submittal respectively.

1. **Safeguard Facility and Practices:** Non-select agent SARS-CoV-2 will be used and stored in the JABSOM BioContainment facilities (JBF; BSL-3 and ABSL-3 containment) located in the Biosciences Building First Floor, 651 Ilalo Street, Honolulu, Hawaii 96813. BSL-3 laboratory will be used to propagate the virus and subsequent experimentation using cell cultures as described below.

Coronavirus assigned BSL-2 status by the HDOA will be stored in the BSL-2 laboratories located in the Biosciences Building Third Floor, 651 Ilalo Street, Honolulu, Hawaii 96813.

Specifically:

BSL-2 storage – BSB rm 331 or 334

BSL-2 manipulation – BSB rm 303, 336

BSL-2+ manipulation – BSB rm 332, 333, 324B

JBF storage – BSL-3 preroom freezer or ABSL-3 preroom freezer

JBF manipulation – BSL-3 manipulation rooms or ABSL-3 manipulation rooms

JBF room numbers will be provided only to the HDOA inspectors in a separate document

- JBF**
- a. Directions to the facility: Driving from H-1 West Take Exit 23 to Merge onto Lunalilo Street Turn Left on Ward Avenue Continue onto Ilalo Street Driving from H-1 East Take Exit 21A Turn Left onto Aala Street Turn Left onto N Beretania Street then Turn Right onto River Street Turn Right onto HI-92 W then make a Sharp Left onto HI-92 E Turn Right on Coral Street then Left on Ilalo Street.
 - b. Pictures of the facility: See attachment
 - c. Containers in which the virus will be stored: See attachment

- 6. Effects on the Environment:** There will be no additional impact of the import of this virus and research at JABSOM facility on the environment. With proper precautions in place, training of personnel, and strict adherence to SOP, not only is the risk of laboratory infection extremely unlikely, but accidental release is nearly impossible. Experiments and procedures will be designed to limit the amount and concentration of virus. Stocks will be aliquoted in small amounts and the virus will be contained at all time points except for during direct manipulation. Typical viral manipulations, such as infection, only involve approximately 0.5 - 1 mL of virus to be used at one time. If an accidental spill were to occur in the lab, due to the limiting of quantity and concentration, taking care of the spill over will not be a problem. A spill kit is always available for use in case of any spill of small quantity of virus as per CDC and WHO guide of taking care of spills (4). The research technicians are trained to respond to isolate the spill immediately and chemically neutralize the spill, virtually eliminating all possibility of adverse environmental and health effects. Based on the fact that there is no evidence of this virus affecting any plants, there will be no effect of this virus on native plants. Similarly, there is no evidence so far that SARS-CoV-2 outbreak in Hawaii has affected any native or endemic bird species or ocean animals. A recent study from China showed that domestic poultry were unlikely to have been the reservoir, or associated with dissemination, of SARS coronavirus in the animal markets of southern China (9). Based on these reports we speculate that this virus will not infect native Hawaiian birds. Further, although there have been few reports of virus RNA present in sewage and wastewater but no study have shown the presence of infectious virus in wastewater or ocean water as yet. Therefore, there will be minimum or no additional economic or environmental impact on natural resources.