STUDY PROTOCOL

Project Title: Puipuia le Ola: Increasing reach and uptake of COVID-19 testing among Pacific Islanders in Hawaii and Guam

IRB Protocol No: 2020-00825

Sponsor: National Institutes of Health (3P30GM114737-05S1)

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Human Subjects Involvement and Study Design

This project aims to develop and evaluate culturally tailored, community-engaged strategies to increase the reach, access, uptake and impact of COVID-19 testing among non-Native Hawaiian Pacific Islanders (PI) in Hawaii and on Guam (Fig. 1). Human subjects will be recruited using the Respondent Driven Sampling (RDS) method. Study participants will complete a questionnaire and pre- and post-surveys, and take part in education and information awareness sessions on COVID-19 testing. Study participants who are willing to undergo COVID-19 testing will provide a nasopharyngeal swab or nasal swab or saliva specimen for FDA-approved or emergency use authorization (EUA) COVID-19 test, and blood for SARS-CoV-2 antibody testing.

Inclusion criteria: Adults (18 years and older), who self-identify as PI, who will be on Oahu or Guam for at least 3 months, and who have not previously had a positive COVID-19 diagnostic (RT-PCR) test, will be eligible to participate in the study.

Exclusion criteria: An individual, who is younger than 18 years old, not able to give verbal and/or written consent, does not self-identify as a Pacific Islander, will not be on Oahu or Guam for at least 3 months, has had a positive COVID-19 diagnostic (RT-PCR) test result, has a bleeding problem or disorder, has an immune deficiency disorder, or has an autoimmune disease, will be ineligible from participating in the study.

Target Enrollment: 4,000 Pacific Islanders in Hawaii and 800 Pacific Islanders on Guam.

Sampling and Recruitment Plan: Using the RDS method, a total of 12–15 “initial seeds”, who fulfill the eligibility criteria as study participants from each study site, will be selected in consultation with the Community Field Coordinator. Seeds are defined as community members who take the survey, and who go on to recruit additional community members to take the surveys. These recruits take the survey and in turn become seeds, who recruit community members, and so forth. On Oahu (State of Hawaii), the seeds will be selected from settings where many PI live and pray: public housing and churches. Other seeds will be identified through networks of project partners, including members of the Community and Scientific Advisory Board, who represent education, young adults (college students), and advocacy. These initial recruitment areas of contact should provide a broad representation of the PI community.

Each seed will be contacted by a Community Field Researcher via phone or email to schedule consenting, enrollment, and administration of the pre-survey. Information for all documents will be translated into the appropriate PI language (e.g., Samoan, CHamoru, Chuukese, Marshallese, etc). Once scheduled, the seed participants will have the study explained, including human subjects protection, to obtain informed consent.

Assuming continued physical distancing, and the survey questions do not ask for sensitive information verbal consent may be sufficient. If a written signed consent is needed, the Project Coordinator and/or Community Field Researcher will text, email or drop off the forms. Enrollment information (e.g., name, contact information) will be obtained orally followed by an oral administration of the pre-survey. The Community Field Researchers will enter survey data electronically (using a laptop computer or tablet) into the REDCap system. Upon completion of the survey, the process of additional recruitment requested of the seeds will be explained. Each seed will recruit up to three eligible study participants from their own networks. The Community Field Researchers will remain in touch with the seeds to encourage recruitment of their friends and family, who will in turn contact the Community Field Researchers to complete the process of consenting, enrolling, and surveying.

With the RDS procedure, the waves of recruitment will expand the number of study participants as follows: Wave 1 = 15 x 3, Wave 2 = 45 x 3, Wave 3 = 135 x 3, Wave 4 = 405 x 3, Wave 5 = 1,215 x 3, Wave 6 =3,645 for a total N= 5,460 with 5% dropout and 5% sample error, leaving approximately 4,914 for the final analysis.

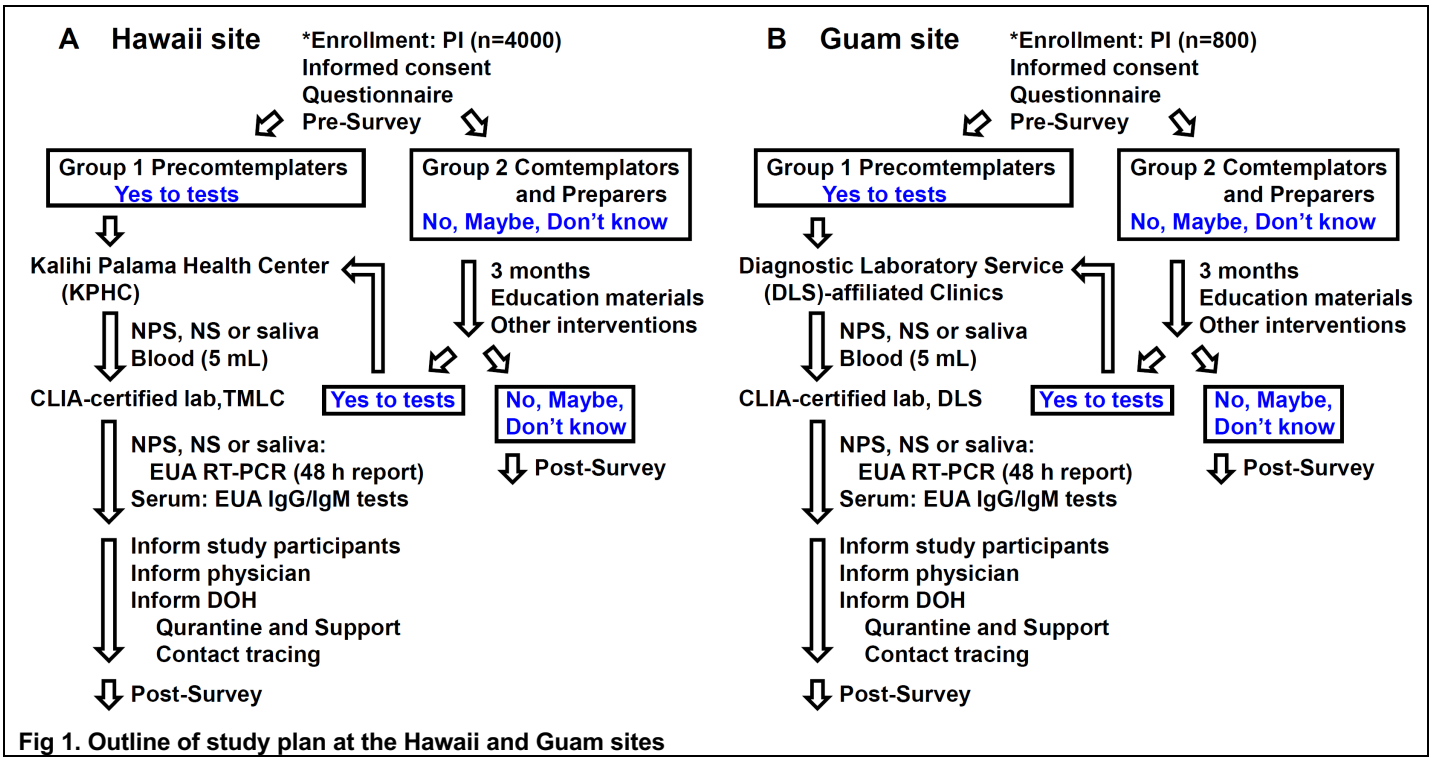

Fig 1. Outline of study plan at the Hawaii and Guam sites

Taking part in the study: The study will consist of two surveys and/or one visit for collecting samples, if the study participant agrees to take the COVID-19 test. Also, the study participants will join a small group and receive health education information about COVID-19 testing. In the health education session, the study participants will meet in a small group virtually or in-person (depending on the current COVID-19 safety guidelines in Hawaii and Guam). It is likely that participants will know other study participants.

In the first survey:

- The study participant will sign (electronically) an **informed consent form,** complete the **questionnaire,** and then fill out **the first survey.** The survey will consist of 23 multiple choice and open-ended questions and take about 30 minutes to complete. The survey and questionnaire will be accessible through a website or over the phone by the Community Field Researcher.
- The study participant could ask up to three family members or friends to take part in this project.
- If the study participant is willing to **take the COVID-19 test**, the Community Field Coordinator will schedule the test (See **COVID-19 test** below).

Between the first and second survey:

- The study participants will attend one formal 60-minute small-group educational information session. The study participants also have the option of attending additional health education and project events (e.g.,

performances or entertainment, special talks) virtually, arranged by the Community Field Researcher, to understand more about COVID-19 and COVID-19 testing in the community. The study participants will meet other participants during these sessions.

- If the study participants do not want to participate in small group virtual heath education, the Community Field Researcher will arrange for individual one-on-one sessions over the phone. The Community Field Researcher will mail or drop off the hardcopy materials to the study participants at the requested location, church or other familiar location.
- If the study participant decides to **take the COVID-19 test**, the Community Researcher will schedule the test (See **COVID-19 test** below).

In the second (final) survey:
About 3 months after the first survey, the study participants will be asked to complete a **second survey** with the same questions as the first survey.

COVID-19 tests:

- The **COVID-19 test** includes a respiratory specimen (nasopharyngeal swab, nasal swab or saliva) and blood sample (5 mL). For study participants in Hawaii, the Community Field Coordinator will schedule the sample collection at the Kalihi-Palama Health Center or the Clinics at Kakaako on Oahu. The type of respiratory specimens collected and the type of testing platform will follow the recommendation from the Testing Technology domain of the RADx-UP Coordination and Data Collection Center (CDCC). A consent form of sample storage and future use will be signed. The respiratory samples will be shipped to the Tropical Medicine Clinical Laboratory (a CLIA-certified lab), at the John A. Burns School of Medicine, of the University of Hawaii, for COVID-19 RT-PCR test using an EUA-approved test (TagPath COVID-19 Combo Kit, Thermo Fisher Scientific). For COVID-19 antibody test, serum will be tested using an EUA-approved IgG test (Abbott SARS-CoV2 IgG assay). For equivocal samples, a neutralization test based on SARS-CoV-2 pseudotype reporter virus will be performed.
- For study participants on Guam, the Community Field Coordinator will schedule sample collection at the American Medical Center. The respiratory specimen will be tested by an EUA-approved test (TagPath COVID-19 Combo Kit, Thermo Fisher Scientific) at the Diagnostic Laboratory Service (DLS) (a CLIA-certified commercial lab) on Guam. Blood samples will be processed at DLS and shipped to the University of Hawaii for COVID-19 antibody testing, as described above.
- All data will be entered into a secure database system (REDCap) managed by a Database Manager. The Consortium Data Reporting will be led by Co-I Wei-Kung Wang.
- The results of COVID-19 RT-PCR test will be reported by the CLIA-lab within 48 hours. Positive test results will be referred to study participant and to public health authorities, namely Hawaii State Department of Health or Guam Department of Public Health and Social Services, for contact tracing and to primary care physicians at Kalihi-Palama Health Center in Hawaii and American Medical Center on Guam for medical care. Community Field Coordinators will assist test-positive participants to get food or temporary housing. In addition, Co-I Tina Tauasosi-Posiulai will work closely with the Lieutenant Governor of Hawaii and Governor of Guam to streamline processes for obtaining comprehensive medical and social services.