**Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART)**
**Governance Protocol for Pacific Islander Biospecimens**

This governance protocol is a resource that consists of the set of authorities, processes, and procedures guiding key operational decisions regarding the storage of and access to biospecimen (saliva) samples from the Pacific Islander Biospecimen Education and Collection (PIBEC) Project. The PIBEC saliva samples represent Pacific Islander community members from Southern California who identify as Chamorro, Marshallese, Native Hawaiian, Samoan, and Tongan.

WINCART developed this governance protocol to ensure appropriate access to the biospecimens as well as community approved custodial relationships and responsibilities. WINCART believes that biospecimen resources, defined as the storage location of samples and related data and all associated processes and policies, should demonstrate accountability to promote public trust by accepting all of the required custodial responsibilities associated with governance.

**Principal Investigator:** Dr. Sora Park Tanjasiri and Dr. Paula Healani Palmer

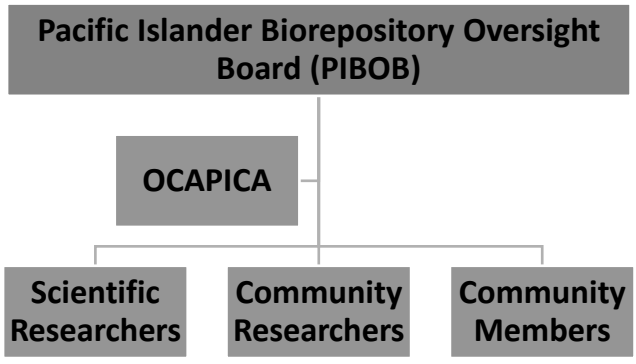
**Project Title:** Pacific Islander Biospecimen Education and Collection (PIBEC) Project (a supplementary project of Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART))

**Name of the Biospecimen Resource:** Multiple resources: (1) Claremont Graduate University (CGU) and California State University, Fullerton (CSUF), (2) Orange County Asian and Pacific Islander Community Alliance (OCAPICA), and (3) a university biorepository (to be named).

A. **Name of Custodian.** Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART)
B. **Summary of Project.** The purpose of the PIBEC Project is to educate Pacific Islander adults on biospecimen donation, collect, and store Pacific Islander saliva samples. The purpose of this governance document is to establish a set of processes and protocols for the storage and access of Pacific Islander biospecimens.
C. **Governance Structure.** The governance structure outlined below pertains to the storage of, and access to, PIBEC samples. Protocols and procedures that guide the education, recruitment, and consent of study participants, prior to the biospecimen collection, are outlined in the PIBEC Project plan and executed with the oversight of the Principal Investigators and the project's established committee structures, as approved by the CGU and CSUF Institutional Review Boards.

    1. **Structure**
    The biospecimen samples will be under the care of the Pacific Islander Biorepository Oversight Board (PIBOB). The PIBOB will be managed and administered by the OCAPICA. It will be made up of 2 researchers and 7 community stakeholders from various Pacific Islander backgrounds.

**PIBOB Structure**



2. **Oversight Board Make-Up**
   The PIBOB will be made up of representatives from the following stakeholder groups based on their expertise and contribution to a balanced and informed governing body. The proposed board will be made up of a minimum of 2 researchers, 5 representatives from Pacific Islander-serving community-based organizations with cancer disparities research experience, and 2 Pacific Islander community members.
   a) **Cancer Researcher** with Pacific Islander cancer disparities research experience – *currently represented by WINCART Principal Investigator, Dr. Sora Park Tanjasiri.*
   b) **Researcher** with Pacific Islander cultural background - *currently represented by WINCART Principal Investigator, Dr. Paula Healani Palmer*
   c) **Chamorro representative –** *currently represented by Guam Communications Network*
   d) **Hawaiian representative –** *currently represented by Pacific Islander Health Partnership*
   e) **Marshallese representative –** *currently represented by Pacific Islander Health Partnership*
   *f)* **Samoan representative –** *currently represented by Samoan National Nurses Association*
   g) **Tongan representative –** *currently represented by Tongan Community Service Center and/or Union of Pan Asian Communities*
   h) **Past research study participant** from Pacific Islander community – *no current representative*
   i) **Community member** from Pacific Islander community – *no current representative*
3. **Roles and Responsibilities.** The PIBOB shoulders the responsibilities for the PIBEC Project biospecimens which extend from storage to eventual research use, as follows:
   a) Implementing overall operational, ethical, and legal policies based on feedback from individuals and the community, where feasible and appropriate.
   b) Deciding on a biorepository for long-term storage of the PIBEC samples.
   c) Ensuring appropriate scientific assessment of access requests and proposed research use as well as managements of conflicts of interest.
   d) Providing requested advice regarding publications and dissemination of research data that are potentially stigmatizing or discriminating to groups. Others, including the investigators, Institutional Review Boards, and possibly the groups studied, may share this responsibility.
   e) Educating the public and obtaining their feedback, where feasible, through the biospecimen resource's public web site or alternative mechanism.
4. **Protocol and Process for Informed Discussions**
   a) Regular (at least once per year) PIBOB meetings will be held to discuss requests for access to the samples and/or any research conducted with the samples over the past year, maintain communication with PIBOB members and any external audiences, and continue education about the community, research, and biospecimen. These meetings will be separate from any meetings called to determine access request applications.

**D. Integrity of Biospecimens and Data**

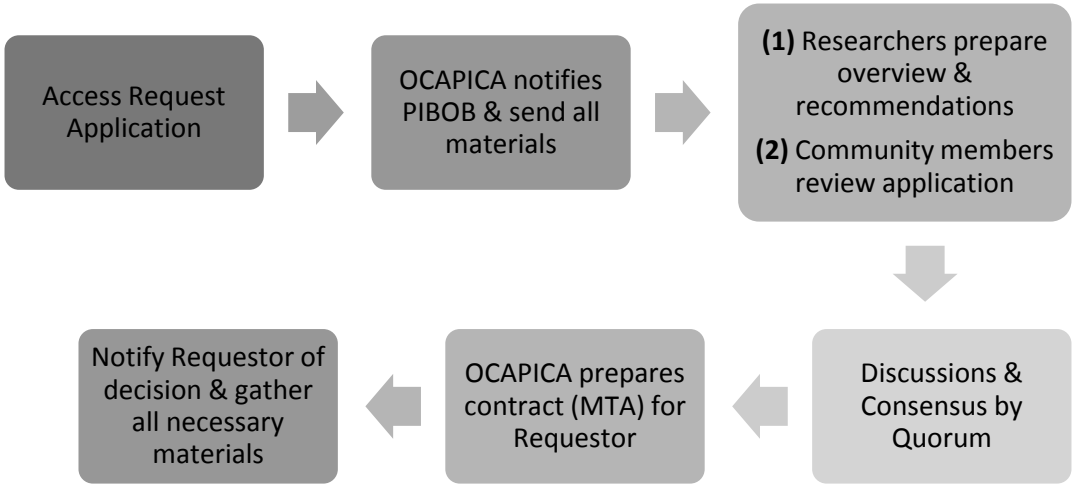
1. All biospecimen collections are coded and studies are conducted under an Institutional Review Board and HIPAA guidelines in accordance to all federal, state, and local statutes and regulations pertaining to privacy.

2. The WINCART principal investigators (Drs. Tanjasiri and Palmer) and their respective research staff members will implement procedures to minimize the risk of loss of confidentiality for PIBEC participants.
    a) All PIBEC biospecimen (saliva) samples, informed consent documents, and survey data collected and compiled will be identified only by a unique numeric study ID code, not participant names.
    b) Identifying information will not be connected to data generated from any of the saliva samples.
    c) The list linking a participant's ID codes with his/her name will be stored in a password-protected file on a separate study computer, accessible only to the principal investigators and selected research staff.
    d) All study data will be stored in computerized form in password-protected files behind a firewall.
3. Biospecimen samples with codes only will be temporarily stored under lock and key at CGU School of Community and Global Health with direct access by research staff under the authorization of, and direct supervision of, Drs. Tanjasiri and Palmer, until a permanent storage facility is decided upon by the PIBOB.
4. Access to the research participants' identities and medical, social, and personal histories are restricted to only biospecimen resource staff members, who need to access such records as part of their assigned duties or those persons permitted access by law.
5. The number of personnel allowed to access links and re-identify information is kept to a minimum and access is appropriately monitored to ensure compliance.

E. **Access to Biospecimens and Data.** Biospecimen samples and de-identified data are available to researchers with priority given to entities whose work directly impacts Pacific Islander communities.
    1. Processes for **access to biospecimens** and data are as follows:
        a) Access to biospecimens and data from the biorepository requires submission of an access request application to the PIBOB via OCAPICA. Such a request should include a scientifically sound and appropriate research plan. The application can be accessed from the WINCART website or can be requested by contacting OCAPICA.
        b) Upon receipt of the access request application, OCAPICA will send all information to each member of the PIBOB. A review and decision meeting will be called and coordinated. All members are expected to review the application.
        c) The researchers on the PIBOB will prepare an overview of the application, which will include a summary of the research, risks and benefits for the Pacific Islander community, and any recommendations they have for the application.
        d) The application will be presented by the researchers for discussion with the remainder of the PIBOB. Quorum must be met in order for final decisions to be made. Consensus among the group must be met in order for any decisions to accept, deny, or clarify.
        e) If an application is accepted, the lead investigator will be notified by OCAPICA along with all necessary documents and materials.
        f) In order to establish that an access request application is legitimate, the requesting principal investigator and an institutional official authorized to make legal binding agreements must sign the Materials Transfer Agreement (MTA).
        g) Decisions made on samples accompanied by data will be made based on recommendations of the researchers on the PIBOB. No identifying information will be released in association with data. Any special consideration will be assessed through the application process and indicated on consent and authorization forms.

h) Once an access request application is formally approved, the PIBOB will contact the to-be-named biorepository with details regarding release of the samples and any additional information.

**Process for Decisions to Access to Biospecimens**




2. **Guiding principles for access** to biospecimen and data decisions. The following principles should be considered by the PIBOB when reviewing applications for access to biospecimens and/or data.
    a) Timely, equitable, and appropriate access to human specimens without undue administrative burden.
    b) Scientific merit and institutional research qualifications, proven investigator experience with the proposed methods, and a research plan appropriate to answer the study question.
    c) Pacific Islander community attitudes, benefits, and ethical/legal considerations regarding biospecimen research.
    d) Fair, transparent, and clearly communicated access procedures.
    e) Appropriate allocation of biospecimens based on the nature of the scientific investigation (e.g. discovery, prevalence, initial validation, and hypothesis testing) and the need for annotation. The level of identifiability of the biospecimen and related transfer documents should be appropriate for the proposed research.
    f) A mechanism for addressing disputes over allocation decisions.
    g) An investigator agreement covering confidentiality, use, disposition, and security of biospecimens and associated data.
    h) The parties' written agreement in an MTA or other appropriate document that is consistent, as applicable, with the NIH Research Tools Policy and other applicable NIH sharing policies.
3. MTA and other **contractual agreements** must be established and may stipulate that the recipient of the specimens:
    a) will not attempt to identify subjects;
    b) will abide by relevant regulations;

c) will not sell or share the specimens and/or data with third parties;
d) will only use the specimens and/or data for the proposed research use;
e) will not use specimens for testing in humans;
f) will follow appropriate biohazard precautions for handling specimens;
g) will acknowledge the PIBEC Project in publications, which helps the PIBEC Project document its contributions and ultimately to get funding;
h) will indemnify the PIBEC Project;
i) will abide by any collaborative agreements in place;
j) will return research data to the PIBEC Project if required;
k) and will abide by any other conditions specified by the PIBOB.

The agreements may also include requirement for disposition of unused specimens or destruction of specimens and/or data at the end of the research period. They may stipulate any intellectual property and publication rights of the providers of the specimens and/or data and the recipient researcher and/or institution.

**F. Release of Research Results**

1. Any results of research involving biospecimen and data from biospecimen should be published and disseminated to the public. When, and if, community partners are involved and contribute to the study interpretation, they must be included as authors and contributors to the study and acknowledged on all publications resulting from the study.
2. All publications, presentations, reports, materials, or dissemination opportunities must acknowledge the PIBEC Project as the source of samples and/or data.
3. All publications, presentations, reports, materials, and final reports of projects that utilized samples and/or data from the project must be shared with the PIBEC Project.
4. All studies and acknowledgements of sample/data use from the project will be published on the WINCART website for public reference and in accordance to data sharing policy.

**G. Legacy and Contingency Plans**

1. Plans for the following time points will be discussed and determined by the PIBOB.
    a) *End of the budget period of the grant*
    b) *Loss of management or termination of funding*
    c) *Accomplishment of the specific research objectives of the study*
    d) *Depletion of biospecimens*
    e) *Achievement of critical data end points*
2. Retention of Biospecimens, Data, and Records – Plans for retention of biospecimen, data, and records will be discussed and determined by the PIBOB.

## APPENDICES

### APPENDIX I: ACCESS REQUEST APPLICATION

Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART):
**ACCESS REQUEST APPLICATION** FOR PACIFIC ISLANDER BIOSPECIMEN SAMPLES

*Please complete the following form and submit it to **{INSERT OCAPICA CONTACT EMAIL}** along with your Curriculum Vitae and a 1-page summary of the proposed project that includes a description of potential relevant community attitudes/benefits/ethical issues.*

**Investigator:** _____
**Institution:** _____
**Address:** _____
**Email:** _____ **Phone:** _____

**Project Title:** _____
**Grant Title:** _____
**Funding Source:** _____

1. **What is the purpose/scientific rationale of your request?** *Please provide a brief summary of the data/research that supports your hypothesis. You may attach documents to provide this information.*

2. **What type of tissue and/or data are you requesting?** *Please give a rationale for the type and quantity you're requesting.*

3. **Please provide a justification of the number of specimens requested, including statistical analysis or justification supporting this.**

4. **Please provide details of your study logistics.** *Clearly outline the details of your study logistics and methodology and what assays and analysis you will be conducting on the sample.*

5. **What potential impact will your proposed project have?** *Please explain its relevance to the Pacific Islander community.*

**6. How do you plan to share your results or data back with the Pacific Islander Biorepository?**

Signed: _____

Print Name: _____

Date: _____

**APPENDIX II: MATERIAL TRANSFER AGREEMENT** *(adapted from NCI Best Practices for Biospecimen Resources)*

This Material Transfer Agreement (the "Agreement") is by and between *WINCART* ("Provider") and _____ ("Recipient") regarding the transfer of human biospecimens, with or without associated data, from the *Pacific Islander Biospecimen Education and Collection (PIBEC) Project* to approved third-party end users for research purposes as further defined below. Throughout this Agreement, Provider and Recipient are collectively referred to as the "Parties." This Agreement will become effective upon the date of the last signature affixed below.

The Provider and Recipient agree as follows:

1. **DEFINITIONS.** Within this Agreement, the following terms will have the same meaning and effect as those used in the Standards for Privacy of Individually Identifiable Health Information set for in the 45 CFR Parts 160 and 164 ("HIPAA Privacy Rule"). These terms are repeated here for convenience:
    a. "De-identified" information is information that formerly contained individually identifiable health information but which has had all unique identifying information, numbers, characteristics, and codes removed such that the information a record contains cannot be used alone or in combination with other information to identify the individual who is the subject of the information (45 CFR 164.514). Identifying information includes, but is not limited to, the 18 categories of identifiers described in 45 CFR 164.514(b)(2).
    b. "Protected Health Information" or "PHI" means any information, whether oral or recorded in any form or medium: (i) that relates to the past, present, or future physical or mental condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual, and (ii) that identifies the individual or with respect to which there is a reasonable basis to believe the information can be used to identify the individual (45 CFR 164.103).
2. **DESCRIPTIOIN OF MATERIAL AND DATA.** The Provider will transfer to the Recipient the following biospecimens and/or derivatives ("MATERIAL"): _____

    _____

    with the following data ("DATA"): _____
3. **COLLECTION OF MATERIAL AND DATA.** The MATERIAL and DATA were collected and/or processed from human biospecimens as part of _____ accordance with appropriate Federal and local laws, Assurances, And Institutional Review Board approvals related to human subjects research, as appropriate.
4. **TRANSFER OF MATERIAL AND DATA.** The MATERIAL and DATA provided by Provider will be de-identified and all PHI, as defined by the Federal Health Insurance Portability and Accountability Act (HIPAA, 45 CFR 164) will have been removed.
5. **RESPONSIBILITIES AND AUTHORIZATIONS OF RECIPIENT**
    a. Recipient agrees to use the MATERIAL and DATA for the approved research project only and will not use the MATERIAL and DATA for any unapproved commercial purposes, including selling or transferring to a third party for commercial purposes.
    b. Recipient is responsible for obtaining any necessary Human Subjects research approvals or exemptions required to use the MATERIAL and DATA at the respective institution. The MATERIAL and DATA will be used by the Recipient in compliance with all applicable Federal, state, and local statutes and regulations.

c. Recipient will allow the use of MATERIAL and DATA only by _____ ("Recipient Investigator") and Recipient Investigator's research team that are under the direct supervision of Recipient Investigator, and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any transfer of MATERIAL And DATA to other than Recipient Investigator's research team requires the advanced written approval of the Provider.
d. It is acknowledged that the Recipient may already have in its possession or will obtain from another source, PHI related to the MATERIAL and DATA, and to which the Recipient may be subject to additional restrictions or obligations under separate agreement. Recipient shall notify subject to additional restrictions or obligations under separate agreement. Recipient shall notify Provider in writing within five (5) working days of its discovery of any unauthorized use or disclosure of PHI related to the MATERIAL and DATA of which Recipient, its officers, employees, or agents become aware. Recipient shall take (i) prompt corrective action to cure any deficiencies or (ii) any action pertaining to such unauthorized disclosure required by applicable federal law.
e. Recipient agrees to not identify or contact any donor, or living relative of a donor, who may have provided the MATERIAL or any DATA received by Recipient under this Agreement from Provider.
f. Recipient agrees to report data, inventions, and publications resulting from use of the MATERIAL and/or DATA to Provider.

6. **THE MATERIAL AND DATA ARE NOT FOR USE IN HUMAN SUBJECTS OR FOR UTHE TREATEMEN OR DIAGNOSIS OF HUMAN SUBJECTS.**
7. **DISCLAIMER.** Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKS NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESSED OR IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COMPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. To the extent allowed by law, Recipient assumes lability for claims for damages against it by third parties which may arise for its use, storage, processing, distribution, or disposal of the MATERIAL except that, to the extent permitted by law, Provider shall be liable to Recipient when the damage is caused by the gross negligence or willful misconduct of Provider.
8. **TERMINATION AND DISPOSAL.** Either Party may terminate this Agreement within sixty (60) days written notice to the other Party. When the Research Project is completed or this Agreement is terminated, whichever comes first, any unused MATERIAL and DATA will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Provider as requested by the Provider.
9. **ACKNOWLEDGEMENT.** In all oral presentations or written publications resulting from the use of the MATERIAL and DATA, the Recipient will acknowledge the *PIBEC Project* as the source of the MATERIAL and DATA, unless requested otherwise by Provider, as follows:

"Biospecimens {and/or Derivatives} and associated data were provided by the Pacific Islander Biospecimen Education and Collection (PIBEC) Project, a supplementary project of Weaving an Islander Network for Cancer Awareness, Research, and Training (WINCART), a Community Networks Program Center of the National Cancer Institute, grant number U54CA153458."

10. **COST AND SHIPPING.** The MATERIAL and DATA are provided at no cost to Recipient. Provider will notify Recipient when the MATERIAL and DATA are ready for shipment. Recipient will be responsible for the pick-up and shipment, including shipping costs, of the MATERIALS and DATA.

The Parties have executed this Agreement by their respective duly authorized officers on the day and year hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed.

**Signature for Provider**

Provider Scientist:
Provider Organization:
Address:

Name of Authorized Official:
Title of Authorized Official:

---

**Signature of Authorized Official** Date

Certification of Provider Authorized Official: This Agreement __has/__has not been modified. If modified, the modifications are attached.

**Signature of Recipient**

Recipient Scientist:
Recipient Organization:
Address:

Name of Authorized Official:
Title of Authorized Official:

---

**Signature of Authorized Official** Date

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL and DATA.

---

**Scientist Receiving Material** Date