PALAU INSTITUTIONAL REVIEW BOARD
APPLICATION FOR IRB APPROVAL OF HUMAN SUBJECTS RESEARCH
P.O. Box 6027
Koror, Republic of Palau 96940
Tel.: (680) 488-4773 Fax: (680) 488-4701

Date : _____ **Title of Study:** _____

Name of Principal Investigator: _____
Mailing Address: _____
Phone: _____ Email Address: _____
Cell Phone: _____ Fax #: _____

Names of Other Investigators or Study Coordinator (if any) – List all other project personnel including co-investigators, and anyone else who has contact with subjects or identifiable data from subjects. **Include email address for each who should receive electronic copies of IRB correspondence to PI):**

Name of Co-Investigator/Others: _____
Mailing Address: _____
Phone: _____ Email Address: _____
Cell Phone: _____ Fax #: _____

Collaborating centers, institutes or departments:
Name: _____
Mailing Address: _____
Phone/Fax: _____ Email Address: _____

Name of funding source or sponsor (please do not abbreviate):
Not Funded ☐ Federal ☐ State ☐ Industry ☐ Foundation ☐
Private ☐ Other (specify): _____

For industry sponsored research (if applicable):
Sponsor's master protocol version #: _____ Version Date: _____
Investigator Brochure version #: _____ Version Date: _____
Any other details you need documented on IRB approval:
Brief Summary. Provide a brief non-technical description of the study, which will be used in IRB documentation as a description of the study:
Purpose:

Participants/Subjects (inclusion/exclusion criteria; special populations; recruitment inducements and costs to subjects):

Procedures (methods):

Benefits to subjects and/or society:

Full description of risks and measures to minimize risks:

Logistics (proposed calendar of the study, including any needs such as local staff, costs to be borne by subjects, if any):

Data Considerations:

Confidentiality of the data: Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect data from access by those not authorized. How will data be transmitted among research personnel? Where relevant? Describe procedures for maintaining confidentiality of the data you will collect or will receive. Describe how you will protect the data from access by those not authorized. How will data be transmitted among research personnel? Where relevant, discuss the potential for deductive disclosure (i.e., directly identifying subjects from a combination of indirect ID's).

Data sharing: With whom will *identifiable* (contains any of the 18 identifiers listed in question A.4.9 above) data be shared outside the immediate research team? For each, explain confidentiality measures. Include data use agreements, if any.	**Data security for storage and transmission:** Please check all that apply.
No one Coordinating Center Statisticians Consultants Other researchers: Registries: Sponsors: External labs for additional testing: Journals: Publicly available dataset: Other:	*For electronic data:* Secure network Password access Encryption Other (describe): Portable storage (e.g., laptop computer, flash drive) *Describe how data will be protected for any portable devise:* *For hardcopy data (including human biological specimens, CDs, tapes, etc.):* Data de-identified by research team (stripped of the 18 identifiers listed in question A.4.9 above) Locked suite or office Locked cabinet Data coded by research team with a master list secured and kept separately Other (describe):

Post-study disposition of identifiable data or human biological materials. Describe your plans for disposition of data or human biological specimens that are identifiable in any way (directly or via indirect codes) once the study has ended. Describe your plan to destroy identifiers, if you will do so.

Commitment to Good Practices in Palauan communities:
I certify that, as a researcher involved in Palauan communities, I have considered the following "good practices":

- To respect the culture, traditions and knowledge of Palauans;
- To conceptualize and conduct research with the Palauan community as a partnership;
- To consult members of the community who have relevant expertise;
- To involve the community in the design of the project;
- To examine how the research may be shaped to address the needs and concerns of the community;
- To make best efforts to ensure that the emphasis of the research, and the ways chosen to conduct it, respect the many viewpoints of different segments of the community question;
- To provide the community with information respecting the following:
    - Protection of the Palauan community cultural estate and other property;
    - The availability of a preliminary report for comment;
    - The potential employment by researchers of members of the community appropriate and without prejudice;
    - Researcher's willingness to cooperate with community institutions;
    - Researcher's willingness to deposit data, working papers and related materials in an agreed-upon repository.
- To acknowledge in the publication of the research results the various viewpoints of the community on the topics researched; and
- To afford the community an opportunity to react and respond to the research findings before the completion of the final report, in the final report or even in all relevant publications.

Considering the Palauan peoples' right to react to the research findings, I will give such matters due consideration. If disagreement persists, I shall afford the group an opportunity to make its views known, or will accurately report any disagreement about the interpretation of the data in their reports or publications.

_____ _____

Signature of Principal Investigator Date

Principal Investigator: I will personally conduct or supervise this research study. I will ensure that this study is performed in compliance with all applicable laws, regulations and institutional policies regarding human subject research. I will obtain IRB approval before making changes or additions to the project. I will notify the IRB of any other changes in the information provided in this application. I will provide progress reports to the IRB at least annually, or as requested. I will report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. I will follow the IRB approved consent process for all subjects. I will ensure that all collaborators, students and employees assisting in this research study are informed about these obligations. All information given in this form is accurate and complete.

_____ _____

Signature of Principal Investigator Date

Conflict of Interest Questions and Certification

The following questions apply to all investigators and study staff engaged in the design, conduct, or reporting results of this project and/or their immediate family members. For these purposes, "family" includes the individual's spouse and dependent children. "Spouse" includes a person with whom one lives together in the same residence and with whom one shares responsibility for each other's welfare and shares financial obligations.

A.3.1 Currently or during the term of this research study, does any member of the research team or his/her family member have or expect to have: (a) A personal financial interest in or personal financial relationship (including gifts of cash or in-kind) with the sponsor of this study?	Yes	No
(b) A personal financial interest in or personal financial relationship (including gifts or cash or in-kind) with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	Yes	No
(c) A board membership of any kind or an executive position (paid or unpaid) with the sponsor of this study or with an entity that owns or has the right to commercialize a product, process or technology studied in this project?	Yes	No
A.3.2 Has any institution or foundation received cash or in-kind gift from the sponsor of this study for the use or benefit of any member of the research team?	Yes	No
A.3.3. Has any institution or foundation received a cash or in-kind gift for the use or benefit of any member of the research team from an entity that owns or has the right to commercialize a product, process or technology studied in this project?	Yes	No

If the answer to ANY of the questions above is *yes*, the affected research team member(s) must complete and submit to the Ministry of Health the form accessible at http://pirb.webs.com. List name(s) of all research team members for whom any answer to the questions above is *yes*:

_____

Certification by Principal Investigator: By submitting this IRB application, I (the PI) certify that the information provided above is true and accurate regarding my own circumstances. I understand that as Principal Investigator I am obligated to ensure that any potential conflicts of interest that exist in relation to my study are reported as required by the Palau IRB.

_____ _____

Signature of Principal of Investigator Date

Checklist of Items to Include with Your Submission (2 copies of each):

Check	Item
	1. This application. One copy must have original PI signatures.
	2. Research Protocol (Research Project)
Included Not Applicable	3. Consent (official Palauan translations if needed) and assent forms, fact or information sheets; include phone and verbal consent scripts.
Included Not Applicable	4. All recruitment materials including scripts, flyers and advertising, letters, emails.
Included Not Applicable	5. Questionnaires, focus group guides, scripts used to guide phone or in-person interviews, etc
Included Not Applicable	6. Investigator Brochure if a drug study