**U N I V E R S I T Y O F H A W A I ‘ I**

**Human Studies Program**

**IRB Continuing Review Application**

UH Biomedical IRB and Social & Behavioral Sciences IRB

CHS Number:       Initial IRB Approval Date:       Current Expiration Date:

Study Title:

Principal Investigator (PI) Name:       PI email:       PI phone:

Administrative Contact (name):       Admin email:       Admin phone:

For UH students, name of faculty advisor:       Advisor email:

1. Study Enrollment: Please answer a. through d. below for all sites operating under UH Human Studies Program approval:

1. Enrollment status:  [ ]  / open [ ]  / closed  [ ]  / not applicable
2. IRB-approved enrollment target:
3. Number of participants screened: during this review period =      ; total screened to date =
4. Number of participants enrolled : during this review period =      ; total enrolled to date =

2. Check **all** that apply:

a. [ ]  Initial review of this study was performed under expedited review category number:

b. [ ]  This research is permanently closed to enrollment; all subjects have completed research-

 related interventions and the research remains active only for long-term follow-up of participants *(expedited category 8a)*.

c. [ ]  No participants have been enrolled and no additional risks have been identified *(8b)*.

d. [ ]  Remaining research activities are limited to data analysis *(8c)*.

3. Was a consent form approved by the IRB for this study? [ ]  Yes [ ]  No

**In a 12-point or larger font, provide a summary-level response to the following:**

1. Describe the study purpose and objectives.

1. Briefly describe study methods.

1. Are members of vulnerable populations (see attached glossary) enrolled in this study?

[ ]  No

[ ]  Yes: What additional safeguards are being provided to protect them?

1. Is private identifiable information being collected or retained?

[ ]  No

[ ]  Yes: Describe methods being used to ensure confidentiality.

1. Have you encountered any problems that have delayed the progress of this study (these may involve study participants, staffing, funding, or other issues)?

 [ ]  No

 [ ]  Yes: Describe these problems and their impact on the study.

1. Have you received any complaints from participants about the study?

[ ]  No

[ ]  Yes: Indicate how many and describe the nature of these complaints.

1. Have any participants withdrawn from the study?

 [ ]  No

 [ ]  Yes: Indicate how many and summarize the reason(s) for these withdrawals.

1. Has any new information been produced or obtained during the review period that indicates risk(s) to participants that was previously unknown or not recognized?

[ ]  No

[ ]  Yes: Summarize the new information and indicate whether it changes the risk/ benefit ratio of the study

1. Were any changes (e.g., modifications, revisions or amendments) made to this study or to any of the IRB-approved study documents during the review period?
2. [ ]  No [ ]  Yes: Summarize these changes.
3. Are there any changes that have not been approved by the IRB?

 [ ]  No [ ]  Yes: Submit a completed, *Request for IRB Approval of a Study Modification,* available on the Human Studies Program website.

1. Did any major or minor protocol violations (see attached glossary) occur during the review period?

[ ]  No

[ ]  Yes: Provide a summary of the violation(s), attaching a separate report, as necessary.

1. Have any unanticipated problems (see attached glossary) occurred during the review period?

 [ ]  No

 [ ]  Yes: Provide a summary of the problems, attaching a separate report, as necessary.

1. Append to this application:
2. The current version of any IRB-approved consent form(s) and assent form(s).
3. Any audit, inspection, multi-center trial, and DSMB (Data and Safety Monitoring Board) reports received during the period.
4. Proposed study modifications (please submit using the *Modification Request Form*).
5. Documentation of training requirements completed during the review period.
6. Documents that provide information requested above (e.g., summary of protocol violations, unanticipated problems, etc.)

Certification: I certify that the information provided in this continuing review application is accurate and complete to the best of my knowledge, and I agree to conduct this study in compliance with applicable federal regulations, Human Studies Program policies and IRB determinations.

PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**UH Human Studies Program**

**Continuing Review Application – Biomedical IRB and Social & Behavioral Sciences IRB**

**Instructions and Glossary of Key Terms**

**Instructions:** Provide succinct answers to all questions on the application form. If you have questions, call the Human Studies Program office at 956-5007. Please submit your application for continuing review, with appendices, to the Human Studies Program at least one month before the study expiration date.

Please email your continuing review application to uhirb@hawaii.edu. In the subject line, write “Continuing Review Application” and the CHS number. Also, provide hard copies following the guidance at this link: <https://manoa.hawaii.edu/researchcompliance/policies-guidance> to the University of Hawaii Human Studies Program, 2425 Campus Road, Sinclair 10, Honolulu, HI 96822. All applications must include the signature of the PI.

**Glossary of Key Terms**

**Protocol Violation:** Any deviation, change or departure from the IRB-approved protocol that does not have prior approval by the IRB unless the change is necessary to remove an apparent immediate hazard to one or more study participants. For additional information on protocol violations, see Standard Operating Policy and Procedure (SOPP) 104, *Reporting Protocol Violations to the IRB*, available on the website at <https://manoa.hawaii.edu/researchcompliance/policies-guidance>.

**Minor Protocol Violation:** A protocol violation that does not impact the safety or welfare of study participants, compromise the integrity of study data, or affect participants’ willingness to participate in the study.

**Major Protocol Violation:** A protocol violation that may impact the safety or welfare of study participants, compromises the integrity of study data, or affects participants’ willingness to participate in the study.

**Unanticipated Problem (UP):** Any incident, experience, or outcome that meets all of the following criteria:

* Unexpected (in terms of nature, severity, or frequency) given:
	+ (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and consent form; and
	+ (b) the characteristics of the subject population being studied.
* Related or possibly related to participation in the research protocol where “possibly related”means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures or interventions involved in the research; and
* Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Examples of UPs include occurrences of breaches of confidentiality, accidental destruction of study records, unaccounted for study drug, or one or more serious adverse events. For additional information on reporting UPs to the IRB, see Standard Operating Policy and Procedure (SOPP) 101, *Reporting and Reviewing Unanticipated Problems*, available on the website at <https://manoa.hawaii.edu/researchcompliance/policies-guidance>.

**Vulnerable Populations:** Children/minors, prisoners, pregnant women, neonates, substance abusers, individuals with a serious impairment or illness, or anyone else who may be vulnerable to coercion or undue influence.