HAWAIʻI PACIFIC UNIVERSITY
INSTITUTIONAL REVIEW BOARD

POLICY AND PROCEDURES FOR RESEARCH WITH HUMAN SUBJECTS

Revised 06/07/02

POLICY ON RESEARCH WITH HUMAN SUBJECTS

Many forms of research in which human beings participate as subjects must be approved by the Institutional Review Board (IRB) of Hawai'i Pacific University (HPU). Specific exemption criteria may apply to some research (see page 8, Exempt Review). For research requiring IRB approval, these policies and procedures apply and approval must be obtained prior to involving subjects and prior to distributing any information or written materials to subjects. They also apply to all research sponsored by external funding agencies, to University sponsored research and to unsponsored research. They apply to all research conducted under University auspices or as a part of an investigator's professional activities as an employee of the University. It does not apply to research entirely unrelated to the University. However, employees may choose to submit unrelated research for IRB review.

HPU's human subjects policy was developed in accordance with the Federal Policy for the Protection of Human Subjects, published in the *Federal Register* on June 18, 1991, as a final common rule for participating federal agencies (*Institutional Review Board Guidebook* and *Belmont Report*). HPU's policy, like the federal policy, is designed to safeguard the rights and well being of human subjects, and to ensure that the principles of respect for persons, beneficence, and justice are met by proposed activities involving human subjects.

DEFINITIONS (as defined in the federal policy)

Beneficence: an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Human Participant: a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

Informed Consent: a person's voluntary agreement based upon adequate knowledge and understanding of relevant information, to participate in research.

Interaction: includes communication or interpersonal contact between investigator and subject.

Intervention: includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Minimal Risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Principal Investigator: the scientist or scholar with primary responsibility for the design and conduct of a research project.

Private Information: includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information is individually identifiable when the identity of the subject is or may be readily ascertained by the investigator or associated with the information.

Research: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Vulnerable Subjects: Federal regulations requires that IRB give special consideration to protecting the welfare of particularly vulnerable subjects such as children, prisoners, pregnant women, mentally disabled persons and economically or educationally disadvantaged persons.

PRINCIPLES

A. Research on human subjects serves to advance the study of human thought, behavior, and physical make up and ultimately the knowledge base of science. This positive outcome of research is defined as one form of beneficence. However, research also has potential risks and hazards to human subjects. The purpose of the Institutional Review Board is to evaluate all research proposals, to determine what risks may be present for subjects, and to assess how these balance against benefits to subjects and the advancement of knowledge.

B. The IRB requires that researchers recognize and practice the principle of respect for persons, that is, upholding their choice about whether to participate in any proposed research and their right to be properly informed about the nature and conduct of such research. Potential subjects must be given the opportunity to choose whether to participate through an informed consent process. An informed consent document ordinarily signals their awareness of the research to be performed and their understanding of the potential risk to them. In the case of minors or others not capable of giving true informed consent, their legal representative must be consulted for informed consent. The IRB will review all proposals, including informed consent documents (where applicable), to insure that the participation of subjects is voluntary and their consent is based on adequate information about the project.

C. Both the benefits and burdens of participation in research must be distributed fairly across all populations to ensure justice. Researchers must take care not to overburden vulnerable populations who, by virtue of their status, may be coerced

to participate. These populations include fetuses, pregnant women, children, prisoners, physically or mentally disabled persons, persons with acute or severe physical illness, persons who are economically or educationally disadvantaged, or persons subject to military discipline. The IRB will assure that the subjects are selected fairly and appropriate selection procedures are followed so that no one group is disproportionately burdened.

D. The University's policy places primary responsibility for the protection of human subjects with the Principal Investigator.

RESPONSIBILITY

The Principal Investigator has the responsibility to bring research proposals that involve human subjects to the IRB. In accordance with federal regulations, approval of a project extends one full year from the anticipated start time. If the project extends beyond that date, the Principal Investigator must request a review 30 days prior to the end of the first and any subsequent years or permission to conduct the event will be suspended. If the project changes or there is unexpected harm to human subjects, the Principal Investigator must apprise the IRB of those changes immediately.

SCOPE OF AUTHORITY

The IRB shall have authority to approve, require modifications in (to secure approval), or disapprove the research, and to conduct continuing review of the research at intervals appropriate to the degree or risk, but not less than once per year. The IRB reserves the right at any time to seek clarification from the investigator and/or require alteration and resubmission.

The IRB shall have authority to require that information given to subjects as part of informed consent is in accordance with the requirements for informed consent, listed below, (see p.12, Informed Consent) and if necessary for the protection of human subjects, to observe or have a third party observe the consent process and the research.

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's actions and shall be reported promptly to the Principal Investigator, appropriate institutional officials, and the appropriate granting agency official. Suspension or termination of the research project will be immediate.

MEMBERSHIP

The IRB shall be comprised of a minimum of seven standing members with a quorum of five persons and alternates as the chair deems necessary: six representatives of the University (one academic dean, four faculty members and one who may be a member of either the faculty or staff), one student member, and one community member. The University representatives (faculty or staff) and the community member are selected for three-year terms by the President or Vice President for Academic Administration (VPAA) with input from the Faculty. The student member is appointed annually by the VPAA.

The members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The IRB shall be qualified through the experience and expertise of its members, and the diversity of its members' backgrounds. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, communities and their members, applicable law, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas. If the IRB regularly reviews research that involves a vulnerable category of subjects, the IRB shall include one or more individuals who are primarily concerned with the welfare of these subjects. The IRB may not consist entirely of men, women, or of members of one profession.

The IRB shall include at least one member whose primary concerns are not in any scientific area, (including the social sciences), for example: a lawyer, an ethicist, or a member of the clergy. The IRB shall include at least one member who is not affiliated with the University and who is not part of the immediate family of any person who is affiliated with the University. The IRB may not have a member participating in the IRB's initial or continuing review of any project in which the member has a conflicting interest. A member with a conflicting interest will excuse herself or himself from the review of that research.

The IRB may invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

CRITERIA FOR APPROVAL OF RESEARCH

The HPU Institutional Review Board is designed to protect human subjects of research by making decisions based upon risks and benefits. It is not to offer an opinion on the merits of a research proposal's design or execution apart from this narrow question of risks and benefits. The Institutional Review Board should strive for consensus rather than a simple majority. The Board should function as a jury ascertaining facts and applying standards rather than as a legislature representing diverse interests and creating policy.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized:

   a. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and

   b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research components (as distinguished from risks and benefits subjects would experience if not participating in the research.) The IRB should not consider possible long range effects of applying knowledge gained in the research (for example, the possible effects of research on public policy) as among those research risks or benefits that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with the requirements for informed consent.

5. Informed consent will be appropriately documented, in accordance with the requirements for informed consent.

6. Where appropriate, there are adequate provisions for monitoring the data collected to ensure the safety of subjects.

7. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards are required in the study to protect the rights and welfare of these subjects. (See PRINCIPLES C., p.4)

CATEGORIES OF RESEARCH REVIEW

All research involving human subjects must be submitted to the IRB. There are three categories of review: **Exempt**, **Expedited** and **Full**. The **Exempt** review determines whether or not the proposed research meets the requirements for Exempt status, or whether the project should be submitted for review under another category. Exempt category does not apply to any research with children and other vulnerable subjects. The **Expedited** review is applicable in instances of renewal, minor changes in previously reviewed research and in special cases of limited human involvement with minimal risk. The **Full** review is required for all new research proposals that do not meet the requirements for Exempt status or Expedited review. Research proposals requesting funding from Health and Human Services agencies are required by the agencies to receive Full review if they are not eligible for Expedited review.

Course Requirement Review

Many of our courses require students to engage in research as part of the regular academic experience. While the majority of student research falls into categories which in no way may be construed as exposing subjects to more than minimal risk, HPU wants to insure that all student researchers are cognizant of the need to obtain informed consent and to protect those subjects from risk.

Faculty who allow or require research projects involving human subjects should follow the procedures outlined below and should allow sufficient time for IRB review. Members of the IRB are available to meet with students or classes to discuss the process and its role in protecting human subjects.

Sections A. to C. below provide further information related to the three categories of review. Research that has already been reviewed by the IRB of another institution is also normally determined to be Exempt.

A. Exempt Review

Certain categories of research which have nil or minimal risk are exempt from review by the IRB as a whole. Categories of research that are generally exempt include the following. However, research involving children under 18 years or pregnant women or other vulnerable subjects is not eligible for Exempt review. Please see the section on Special Considerations (p. 11).

1. Research involving educational practices and outcomes, such as:

    a. institutional and internal research about the students, faculty, and staff of Hawai'i Pacific University that involves data collection on the opinions and preferences of the University community or surveys about ways to improve University services. These projects do not require approval if they are part of the institution's own quality control, program assessment, and effectiveness monitoring programs and do not involve material that is likely

to be stressful. Examples of these include end-of-semester course evaluations, faculty evaluations by students or peers, and graduation or postgraduation surveys.

b. research on instructional strategies. Examples of these include research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

c. educational testing as part of the assessment of an individual student, for example to identify strengths and weaknesses for course placement purposes, is not considered to be research.

If possible, data in these categories should be collected without identifying information that can be tied to an individual student (e.g, name, Social Security number.) Should identifying information be collected, the confidentiality of the data should be protected.

Identifying information should not be released to anyone else within the University (e.g., Alumni Office) unless students are informed of this possibility and given the right to withhold the identifying information.

Data collection that consists entirely of material in this category does not require the submission of an IRB Project Application (see Appendix A). The IRB Co-chairs are available for consultation if desired. Research in all other categories must be reviewed and approved, via a Project Application, before the project begins.

2. Data gathering as part of a classroom exercise which is intended to familiarize students with existing instruments and procedures or to explicate concepts presented in the classroom, and which is not designed to test a research hypothesis or answer a research question is not considered research. Therefore, it does not come under the purview of the IRB. This may include hypothesis testing, providing the intent is a classroom exercise in which the data do not go beyond the classroom. If the exercise goes beyond the classroom and involves other human subjects, it is research and falls under these guidelines.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, attitudinal, achievement), surveys, interviews or observation of public behavior:

   a. that is unlikely to elicit emotion,

   b. that is unlikely to place subjects at risk of civil or criminal liability or damage to their reputation, financial standing, academic status, or employability, and

c. that have data recorded in a manner that the human subjects cannot be identified, directly or through identifiers linked to the subjects.

4. Research involving the study or analysis of existing data, documents, records, or specimens, if these are publicly available or if the information has been recorded in such a manner that subjects cannot be identified.

5. Taste and food quality evaluation and consumer acceptance studies;

   a. if wholesome foods without additives are consumed or

   b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Services of the U.S. Department of Agriculture.

6. Research that has been approved by the IRB of another institution, as long as the project is in compliance with that institution's requirements and the HPU IRB is informed of any adverse effects. A Project Application should be submitted to the HPU IRB, with a copy of the other IRB's approval attached.

The Co-chair or other person approving research as Exempt from Full review will inform the Principal Investigator promptly in writing, and will make this information available to other IRB members upon request.

B. Expedited Review

Expedited review procedures may be used for certain types of research involving no more than minimal risk. The review may be carried out by the IRB Co-chair or by one or more IRB members designated by the Co-chair. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the Full review procedure set forth below. Reviewers may also refer the proposal to a Full review by the IRB if they believe that a full discussion is warranted. The Principal Investigator will be informed in writing whether the proposed research has been approved or referred for Full review. All members of the IRB will receive written notification of this action from the person performing the Expedited review.

Expedited review can also be used for minor changes in previously approved research during the period for which approval has been authorized.

Expedited review is appropriate for the following risk categories:

1. Data collection methods that do not involve invasive procedures, deception, or more than minimal stress.

2. Research involves only noninvasive, painless, and non-disfiguring collection of physical samples, such as hair, sweat, and excreta.

3. There is no use of vulnerable subjects.

4. Data are recorded using noninvasive, painless, and non-disfiguring sensors or equipment, such as EKG, weighing scales, or voice/video recording.

5. Research involving physical exertion requires only moderate levels of exercise in healthy volunteers.

6. The research does not involve ingestion of drugs or use of hazardous devices.

7. If existing data, documents, records, or specimens with identifiers are used, procedures are in place to ensure confidentiality.

C. Full Review

Any research not covered under the Exempt or Expedited review categories is referred to the IRB for Full review. The investigator is welcome to attend the review in order to answer any questions that may arise, and may bring others if desired. The research is either approved, approved pending modifications that must be verified by committee members, or not approved. The IRB will be expeditious in its review and decision-making. Investigators will be notified in writing about the IRB decision.

SPECIAL CONSIDERATIONS

A. Children as Subjects in Research

The range of activities that may be approved by Exempt or Expedited review is reduced when children are involved as subjects in research. Specifically, research involving survey or interview procedures and research involving the observation of public behavior where the investigator is a participant in the activities being observed may not receive Exempt or Expedited review when these research activities involve persons under the age of 18 (hereinafter, “child” or “children”).

Written permission is required of both parents or the child’s guardian(s) for each child under the age of 18 who will be the subject of research. The permission of one parent is sufficient if: (a) the other parent is not reasonably available or is incompetent; (b) only one parent has legal responsibility for the care and custody of the child; or (c) the research is such that it either does not involve more than minimal risk to the child or involves more than minimal risk but also presents the prospect of direct benefit to that child. The requirement for written permission may be waived by the review committee where it is not a reasonable requirement to protect the subjects (for example, neglected or abused children).

Assent: In addition to the written permission required of parents, it is necessary to acquire the assent of children, when they are capable of providing assent. “Assent” means a child’s affirmative agreement to participate in research; mere failure to object should not be construed as assent. Ordinarily for children 14 years and older, written assent is required. For children under 14, verbal assent may be obtained. The Principal Investigator must submit to the IRB the methods that will be used to obtain and document assent. The ages, maturity, and psychological state of the children should be taken into account in deciding whether assent must be obtained and how it will be documented.

Children who are wards of the state or of any other entity may be included in research involving greater than minimal risk and no prospect of direct benefit to the individual children only if the research is related to their status as wards or is conducted in schools, camps, hospitals, or other similar settings in which the majority of children involved as subjects are not wards. An individual must be appointed as advocate for the wards; the advocate may not be associated with the research, the investigators, or the guardian organization. The advocate must have the background experience to act in the best interests of the children for the duration of their participation in the research. It is suggested that the Principal Investigator identify a suitable advocate and secure his or her consent to serve prior to review by the IRB. Advocates for child wards are not required for research involving no more than minimal risk or research presenting the prospect of direct benefits to the individual children.

B. Research involving Fetuses, Pregnant Women, or Human In Vitro Fertilization

Additional protection and limitations are placed on research involving pregnant women, fetuses in utero, or fetuses exutero. Please contact one of the Co-chairs of the IRB for additional information.

C. Research Involving Prisoners

Additional protection and limitations are placed on research on prisoners. Please contact one of the Co-chairs of the IRB for additional information.

D. Fieldwork or Ethnographic Research

The foregoing fall into the category of special populations that require additional protection and oversight by the IRB. By the same token, there may be circumstances that imply less rather than more oversight. *The IRB Guidebook (Section 5.5)* developed by the National Institute of Health recognizes that fieldwork or ethnographic research commonly conducted in the field of anthropology is a type of method in which the use of a consent form may not be appropriate. The IRB should keep in mind the possibility of granting a waiver of informed consent.

INFORMED CONSENT

A. General Requirements For Informed Consent

Informed consent is a written agreement made between an investigator and a freely participating subject, that describes in easily understandable language: (a) the subject's role in the investigation, (b) the potential risks and benefits associated with study participation, (c) the confidential nature of all information obtained in the investigation, and (d) the provision for voluntary withdrawal without necessity for explanation by the participant. Additionally, no informed consent, whether oral or written, may include any language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

The basic elements of informed consent include:

(1) a description of the proposed study that includes the purpose, the procedure, and the expected duration of the subject's participation;

(2) a description of foreseeable risks (i.e., physical, psychological, social, legal) that could be associated with study participation;

(3) a description of benefits that could be associated with study participation;

(4) a disclosure of any appropriate alternative procedures that might be advantageous for the subject;

(5) a statement describing the extent to which confidentiality of records identifying the subject will be maintained;

(6) a related explanation for research involving more than minimal risk that describes whether any compensation and/or medical treatment will be available if injury occurs and, if necessary, a description of the compensation and/or medical treatment and information about the associated availability;

(7) an explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject;

(8) a statement that describes participation as voluntary and assures that refusal to participate will not involve penalty or loss of benefits to which the subject is otherwise entitled; and,

(9) a statement that discontinuation of participation at any time will not involve penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, any of the following additional elements of informed consent should be included:

(1) a statement that the treatment or procedure to be used may involve risks which are currently unforeseeable;

(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without the subject's consent;

(3) any additional costs to the subject which may result from participation in the research;

(4) the consequences of the subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and,

(6) the approximate number of subjects involved in the study.

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) the research involves no more than minimal risk to the subjects;

(2) the waiver or alternation will not adversely affect the rights and welfare of the subject;

(3) the research could not practicably be carried out without the waiver or alteration; and

(4) the subjects will be provided with additional pertinent information after participation, whenever appropriate.

The IRB may consult with the University attorney(ies) about the legal requirements for informed consent, and should consider doing so in complex cases and cases where substantial risk exists, and must do so in cases where physical touch (i.e., potential battery, e.g., surgery) is involved.

B. Documentation of Informed Consent

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. (See Appendix B for a sample form)

An IRB can waive the requirement for the investigator to obtain a signed consent form for some or all subjects if any of the following apply:

(1) that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

(2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context;

(3) that, as the case of ethnographic fieldwork, the researcher can, by virtue of the probability of his or her long term presence and participation in the lives of people, achieve a personal rapport with people that would be disrupted by the use of a consent form;

(4) that, in case of covert research, there are no apparent risks and the research project would be seriously compromised by disclosure of the research in progress.

C. Waiver of Signed Informed Consent

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

PROCEDURE FOR SUBMITTING A RESEARCH PROJECT FOR REVIEW

A. All proposals requiring IRB review should be sent to one of the Co-chairs of the IRB.

B. The IRB meets as frequently as necessary to meet the needs of University researchers. Investigators submit all information well in advance of the anticipated start date of data collection and, in the case of sponsored research, in advance of submission of the proposal to the agency.

C. Investigators should request the type of review most appropriate for their study using the IRB Project Application Form. Proposals are first reviewed by one of the IRB Co-chairs. If there is any disagreement with the type of review requested, the investigator will be contacted, the reasons for the disagreement explained, and any additional material necessary to continue the review process requested.

D. All research involving human subjects must be submitted to the IRB. There are three categories of review: Exempt, Expedited and Full.

E. Faculty who allow or require research projects by their students (when such projects involve the use of human subjects) should submit an IRB Project Application

(Appendix A) for review every fall semester, or as needed, provided the research objectives and methodology are not changed.

F. The following information should be submitted to the IRB:

Required Form	**Number of Copies**		
	Exempt	Expedited	Full
IRB Project Application (Appendix A.)	2	2	6
Informed Consent Form, if appropriate (Appendix B.)	2	2	6
Instruments (survey, etc.)	2	2	6
Progress Report, if renewal (Appendix C.)	2	2	6
Full Grant Proposal, if applicable	1	1	1

G. The IRB's actions, comments, and recommendations will be sent to the Principal Investigator. If a proposal is disapproved, the Principal Investigator may request to attend the next IRB meeting.

H. Any changes in a proposal or consent form must be promptly reported in writing to one of the IRB Co-chairs. In most cases these will received an Expedited review.

I. All adverse reactions and unexpected side effects must be reported immediately, in writing to the IRB.

J. Interim progress reports should be submitted if requested by the IRB to insure that the rights and well being of subjects are protected.

K. Annual renewals are mandatory. (See Human Subjects Project Amendment/Modification/Renewal Form, Appendix C.)

APPEALS

The Principal Investigator may request that the IRB reconsider the decision made. A rationale must accompany that request.

If the IRB sustains its decision, the Principal Investigator may appeal to the VPAA. The VPAA may, but need not, convene an ad hoc review panel to review all materials and make a recommendation back to the VPAA. The VPAA's decision is final.

ANNUAL RENEWAL PROCEDURES

Thirty days before the anniversary of the last approval date, the following should be submitted (two of each for Expedited, six of each for Full review):

A. Human Subjects Project Amendment/Modification/Renewal Form (Appendix C.)

B. If any changes have been made, submit instruments, with any changes noted, and the consent form(s) and written explanation of study, with changes highlighted.

COMPLETION OF RESEARCH

When a project is completed, withdrawn, or past the phase involving human subjects, please inform the IRB Chair in writing.

RECORD KEEPING

The following records must be maintained by the IRB for three years:

A. Copies of all research proposals reviewed; scientific evaluations, if any, that accompanied the proposal; approved sample consent documents; progress reports and renewals submitted by investigators; and reports of injuries to subjects.

B. Minutes of IRB meetings which should be in sufficient detail to show attendance at the meeting, action taken; the vote on these actions including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a summary of the discussion of disputed issues and their resolution.

C. Records of continuing review activities.

D. Copies of all correspondence between the IRB and the Principal Investigators.

E. A list of the IRB members detailing their names, earned degree, representative capacity, indications of experience sufficient to describe each members' chief anticipated contribution to the IRB, and any employment or other relationship between the member and HPU (e.g. full-time employee).

F. A statement of significant new findings provided to subjects, as required by the policy on informed consent, discussed above.

Hawai‘i Pacific University
Institutional Review Board
Project Application

Please print, complete, and submit form and a copy to the IRB chair: Send to irbchair@hpu.edu.

Study title:

Investigator:

Name:_____
(Please check one)
☐ Faculty ☐ Student ☐ Outside Investigator

Phone:_____

Email:_____

Sponsoring HPU Faculty Member:
(if Investigator is not an HPU faculty member)

Please attach a brief summary of the project. This should include an explicit statement of methods, data collection, and how confidentiality of subjects/data will be protected including consent form.

Category for Review:

Check one level of review (Exempt, Expedited, Full) for which you believe the project qualifies, and each criterion that your project meets.

____ **Exempt from review (nil or minimal risk study, or already reviewed by an IRB)**

____ Research involves ONLY investigation into or comparison of normal instructional strategies.

____ Tests, interviews, and surveys are unlikely to elicit emotion or place subjects at risk of civil/criminal liability or damage to their reputation, financial standing, employability, etc. AND information will not be recorded in such a way that subjects can be identified.

____ Research involves only the study or analysis of existing data, documents, records, or specimens that are publicly available or recorded in such a way that subjects cannot be identified.

____ If study involves ingestion of food: only wholesome food without additives in excess of USDA recommended levels is consumed.

____ Brief informed consent will be done (except in the case of existing data, etc.).

____ No use of vulnerable subjects (children, prisoners, pregnant women, mentally ill, etc.).

____ Has already been approved by IRB at ________________________________.
(Include copy of signed IRB approval form.)

____ Expedited review (minor risk study)

____ Research and data collection methods are unlikely to elicit strong emotion and deception is not involved.

____ Research involves only noninvasive, painless, and non-disfiguring collection of physical samples, such as hair, sweat, excreta.

____ No use of vulnerable subjects (children, prisoners, pregnant women, mentally ill, disabled, etc.).

____ Data are recorded using noninvasive, painless, and non-disfiguring sensors or equipment, such as EKG, weighing scales, voice/video recording.

____ Research involves only moderate levels of exercise in healthy volunteers.

____ Research does not involve ingestion of drugs or use of hazardous devices.

____ If existing data, documents, records, or specimens with identifiers are used, procedures are in place to ensure confidentiality.

____ Informed consent process will be done (attach copy of informed consent form).

____ Data will be kept confidential and not reported in identifiable fashion.

____ Full review required (more than minor risk)
Attach a statement that describes the use of vulnerable subjects or the study procedures and conditions that place subjects at risk. Describe the precautions that will be taken to minimize these risks. Attach a copy of the informed consent form that will be used.

Certification by Principal Investigator: The above represents a fair estimate of risks to human subjects.

__________________________ ______________________________ ________________
Name Title Date

- -

FOR IRB USE ONLY

Certification by IRB Co-chair: I have read this application and believe this research qualifies as:
____ Exempt from IRB review
____ Appropriate for expedited review, and
    ____ approved
    ____ disapproved
____ Appropriate for review by the full IRB

____ _______________
IRB Co-chair Date

Appendix B

INFORMED CONSENT DOCUMENT

Project.Title: [Title]

Investigator(s): **[List all individuals (name and degree) who will obtain Informed Consent from subjects, including Principal Investigator and other key personnel]**

PURPOSE

This study involves research. The purpose of the research is **[general description of the project - what is being investigated, what knowledge is to be gained].**

We are inviting people to participate in this research because they **[complete this sentence by describing why people reading the consent are possible subjects for your project. For example, ... they have been diagnosed with lung cancer, ...they are taking an introductory psychology class, ... they are teachers in the Honolulu City school district, ...they are joggers, ...they are healthy adults in the community, etc.]. [If appropriate, indicate the total number of subjects expected to participate in the study.]**

This project will last for **[length of time for one subject's participation. If more than one contact is involved in the study, length of time for each contact, and how long in between each contact].**

PROCEDURES

Those agreeing to participate can expect the following to occur. **[Describe, step by step, what is going to happen to the research subject if he/she decides to participate. Describe any procedures that are experimental. Use subheadings as appropriate. For complex protocols, consider including a table showing which procedures/tests are performed at each visit.]**

RISKS

The possible risks associated with participating in this research project are as follows. **[Describe the risks - psychological, physical, pain, drug toxicity, emotional, legal, privacy issues, etc. If there are no known risks, state that there are no foreseeable risks to participating.]**

BENEFITS

There **[may be / will be - select the appropriate phrase]** no personal benefit for participating in this study. However it is hoped that in the future, society could benefit from this study by **[describe the possible benefits to society. Note that compensation is not a benefit and should be described in the Costs and Compensation section.].**

ALTERNATIVE TREATMENT [For treatment/therapy projects - omit if not applicable]

Instead of participating in this study, the alternative treatments are: **[List the alternative treatments. If the subject can receive the same intervention without participating in the research, that fact should be noted. Describe how the alternatives will be presented to the study subject.]**

COSTS AND COMPENSATION

There **[will / will not]** be any costs to the subject for participating in this research project. **[Clearly describe any monetary costs to the subject, if there are any. If there are costs that might be covered by a medical or hospital insurance carrier, consider adding a sentence regarding checking with the insurance carrier prior to deciding whether to participate.]**

Subjects **[will / will not]** be compensated for their time and inconvenience for participating in this research project. **[Clearly describe the monetary (total amount, average total amount, amount per visit, amount per hour, etc.) or non-monetary compensation. If compensation is pro-rated when a subject withdraws prior to completing the study, explain how it is pro-rated.]**

CONFIDENTIALITY

Records of participation in this research project will be maintained and kept confidential to the extent permitted by law. However, federal government regulatory agencies **[for drug/device studies, add: the U.S. Food and Drug Administration,]** and the Hawai'i Pacific University IRB may inspect and copy a subject's records pertaining to the research, and these records may contain personal identifiers. **[Describe the methods that will be used to ensure confidentiality, e.g., coded names or identification numbers, removal of all identifying information, secure storage area, etc.]** In the event of any report or publication from this study, the identity of subjects will not be disclosed. Results will be reported in a summarized manner in such a way that subjects cannot be identified.

RESEARCH RELATED INJURY [This section may be eliminated if it does not apply.]

- In the event of research related injury, medical treatment is available at **[Affiliated Medical Center]**

- No compensation for treatment of research related injury is available from Hawai'i Pacific University unless the injury is proven to be the direct result of negligence by a University employee.

- The cost of treatment for any research-related illness or injury is the responsibility of the research subject and/or his/her medical or hospital insurance carrier.

-- **OR -- (CHOOSE THE PHRASE THAT APPLIES TO YOUR STUDY)**

will be paid for by the sponsor, **[name of sponsor],** to the extent that these costs are not covered by the research subject's medical or hospital insurance carrier. **[If the sponsor will not provide complete coverage, or if there are other restrictions, explain what will be covered.]**

VOLUNTARY PARTICIPATION

All participation is voluntary. There is no penalty to anyone who decides not to participate. Nor will anyone be penalized if he or she decides to stop participation at any time during the research project. **[If appropriate, describe the consequences of a subject's withdrawal and the procedures for withdrawing.]**

QUESTIONS

Questions are encouraged. Questions about this research project and questions about the rights of research subjects or research related injury may be addressed to the IRB Chair (Dr. Trish Ellerson at 566-2467 or pellerson@hpu.edu)

Subject's name (printed): _____

_____ _____
(Signature of Subject) (Date)

[Include Legally Authorized Representative signature line only if applicable to your study – see instructions at beginning of this document.]

INVESTIGATOR STATEMENT

I have discussed the above points with the subject or the legally authorized representative, using a translator when necessary. It is my opinion that the subject understands the risks, benefits, and obligations involved in participation in this project.

_____ _____
(Signature of Investigator) (Date)

STANDARD LANGUAGE FOR SPECIFIC ISSUES

If the project involves any of the following circumstances, add this language to the appropriate section(s) of the basic Informed Consent Document.

RISKS

UNFORESEEABLE, DRUG RISKS

Drugs often have side effects. In addition, there is the risk of very uncommon or previously unknown side effects occurring. The drug(s) used in this study may cause all, some, or none of the side effects listed below. **[List side effects.]**

NEW INFORMATION

If new information related to a subject's willingness to continue to participate develops during the
course of this study, subjects will be promptly informed.

USE OF PLACEBO

Subjects in this study may receive a placebo (an inactive substance). This means that it is possible that no medication will be received while participating in this study.

TERMINATION OF STUDY BY INVESTIGATOR/SPONSOR

Under certain circumstances, the subject's participation in this research study may be ended without the subject's consent. This might happen because **[describe why the study might be ended without the subject's consent].**

WOMEN OF CHILDBEARING POTENTIAL

Women of childbearing potential will be asked to have a pregnancy test before beginning this study. Subjects in this study must use effective birth control methods and try not to become pregnant. There may be long-term effects of this treatment, which may increase the risk of harm to an unborn child.

WOMEN AND RADIATION EXPOSURE

Women may not participate in this study if they are pregnant. For women who are capable of becoming pregnant, a pregnancy test will be performed before any exposure radiation. Women subjects must inform the research team if there is a chance that they may have become pregnant within the previous 14 days. In that case, the radiation procedure can not be done because the pregnancy test is unreliable earlier than 14 days after conception.

GENETIC RESEARCH

Participation in this study may reveal that you or a member of your family is a carrier of the specific gene under study. You may be unable to obtain health insurance or may be denied benefits for this condition if this information becomes known outside the research study. The results of this study **[will / will not - select the appropriate phrase]** be placed in your medical record. We will not release information about you

unless you authorize us to do so or unless we are required to do so by law. However, insurance companies commonly have access to medical records.

CONFIDENTIALITY

AUDIO/VISUAL TAPING

By initialing in the space provided, subjects verify that they have been told that audio/visual materials will be generated during the course of this study. These recordings will be used for **[describe designated use].**

_____Subject's initials

CERTIFICATE OF CONFIDENTIALITY [Please contact the Human Subjects Office for information on how to obtain this Certificate.]

A. Certificate of Confidentiality has been issued for this project by the Department of Health and Human Services (DHHS). This Certificate will protect the investigator(s) from being forced, even under a court order or subpoena, to release any research data in which subjects are identified. Subjects may receive a copy of this certificate upon request.

REGISTRY INFORMATION

Information regarding medical and research information will be maintained in a registry. This registry will contain information including subjects' names, addresses, ages, and diagnoses. This information will be kept on file so that we may contact subjects in the future regarding this or other research studies. This information will be kept secure by **[method of security].** Subjects may have their personal information removed from this file at any time by contacting the investigator.

STUDIES FOCUSING ON VIOLENCE, ABUSE, OR SELF-INFLICTED INJURY

All information gathered during this research project is confidential to the extent permitted by law. However, Hawaii law requires the research staff to disclose to the proper authorities any information shared with them concerning child abuse, child sexual abuse, family violence, or anticipated injury to oneself or others.

COSTS AND COMPENSATION

ADDITIONAL COSTS TO SUBJECTS

Subjects **[will / will not - select the appropriate phrase]** be charged for any tests that are being performed for the purposes of this study. Subjects and/or their insurance provider will be responsible for all other medical care expenses.

STUDIES INVOLVING PRISONERS AS SUBJECTS

Participation does not affect or influence the duration of the sentence, parole or any other aspects of incarceration for any prisoners who chose to take part in this study. In the event that a prisoner completes his/her sentence, the study will continue to be available. However, costs, other than those detailed in the information summary (i.e. transportation and lodging) will not be covered.

_____Subject's initials

Appendix C

HAWAI‘I PACIFIC UNIVERSITY
HUMAN SUBJECTS PROJECT
AMENDMENT/MODIFICATION/RENEWAL FORM

This form is to be completed and attached to changes made to a research project. This includes any changes, in content or form, to the protocol, consent form, or any supportive materials (such as advertisements, revised instruments, etc.). Please submit two complete sets (original and one copy) of completed amendment/modification form and applicable materials to the IRB Chair (Dr. Trish Ellerson,1166 Fort Street Mall, Honolulu, Hawaii 96813

Date_____

Principal Investigator_____

Co-Investigators_____

Faculty Advisor (if student)_____

Department_____Phone #_____

Protocol #_____

Project Title:_____

Current Status of Project: (check one)
_____Currently in Progress (Subjects Entered)
_____Closed to Subject Entry (Remains Active)
_____Project Not Yet Started (No Subjects Entered)
_____Inactive/Cancelled

THE PROJECT HAS BEEN CHANGED AS FOLLOWS:
_____Protocol Modified
_____Study Methods
_____Study Instruments

Appendix C

_____Modified Consent Form
_____Change of Investigator[1]
_____Additional Investigators/Key Personnel[2]
_____Protocol Amendment
_____Addendum (New) Consent Form
_____Additional Funding (If proposal submitted to a federal agency, submit one copy of the *Research Plan/Project Description* section of the grant application. **NOTE:** If the funding title differs from the Human Subjects Protocol Title or additional investigators will be added to the project, the Modification Form must clarify these changes.
_____Other (Specify)_____

1. For "change in principal investigator," the signatures of both new and old P.I. are required on this form and attach an additional letter from new P.I. indicating the change in responsibility of the research.
2. Include a brief description of background, expertise, and involvement in the project. Do the changes affect subject participation (e.g. procedures, risks, costs, etc.)? If YES, and the project is in progress or not yet started, the consent form must reflect these changes. NOTE: Indicate in bold or highlight changes on modified consent form(s).

BRIEF SUMMARY OF PROPOSED CHANGE(S) (Attach additional pages as necessary.):

REASON FOR PROPOSED CHANGE(S):

_____
Signature of Principal Investigator(s) & Date

_____
Signature of Faculty Advisor (For student protocols) & Date

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TO BE COMPLETED BY IRB

Date Received_____
Comments:

IRB APPROVAL_____DATE:_____