Appendix B

INFORMED CONSENT DOCUMENT

Project Title: Title

Investigator(s): List the full names of all individuals (include degrees where appropriate, such as Ph.D.) who will obtain Informed Consent from the research subjects. Include the name of the Principal Investigator and all other key investigative personnel.

PURPOSE

This study involves research. The purpose of the research is…include a 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: 1. have been diagnosed with lung cancer 2. are taking an introductory psychology class 3. are teachers in the Honolulu City school district 4. are joggers 5. 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

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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 to your research.

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 must be noted. Describe how the alternatives will be presented to the study subject.

COSTS AND COMPENSATION

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

Subjects will / will not (select one) 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* 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. *If the research includes drug/device studies, list **U.S. Food and Drug Administration** after "federal government regulatory agencies…" The next sentence should describe the methods that will be used to ensure confidentiality, for example: 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 or choose the phrase (1, 2, or 3) that applies to your study.

1) In the event of research related injury, medical treatment is available at (insert the name of the Affiliated Medical Center here) and will be paid for by the sponsor, (insert the name of the sponsor here), 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.

2) 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.

3) 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.

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 irbchair@hpu.edu)

Subject's name (printed): _____

_____ _____
(Signature of Subject) (Date)

Include a Legally Authorized Representative signature line if applicable to your study. For more information see "Informed Consent FAQs" under "Informed Consent".

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

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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 all 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.

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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 IRB Chair; irbchair@hpu.edu, 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 name and describe the method of security here. 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 COMPENSATIONADDITIONAL 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 initial