Prepared by the Office of Research Services
This is a REVISED Procedure.

A5.503 (Revised 11/97) PROTECTION OF HUMAN SUBJECTS

1. Purpose

To set forth general policies and principles for the protection of humans to be involved in research and training projects conducted by the University of Hawaii.

2. Background

In 1966 the Surgeon General of the United States initiated the first federal regulations concerning the use of humans as subjects of research. Where humans are involved, all federal agencies will not make an award, or permit expenditure of funds, prior to the approval of the project by an Institutional Review Board of the grantee institution. It is for this purpose that the University's Institutional Review Board, the Committee on Human Studies (CHS), was formed and expanded its jurisdiction to include all projects, regardless of the absence or presence of support, and regardless of who else may have reviewed them.

3. Responsibility

The Office of Research Services (ORS) is responsible for the administration of the CHS. Under Department of Health and Human Services (DHHS) regulations, the CHS is charged with safeguarding the rights and welfare of humans involved as subjects, and must determine:

a. Whether humans involved will be placed at risk. Risk means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject or contributor, directly or indirectly, in any research, development or related activity, including training;

b. If at risk, whether the sum of the benefits to be expected of the project will outweigh the risks;

c. Whether the rights and welfare of the humans will be adequately protected; and

d. Whether legally effective informed consent of all humans to be involved will be obtained and adequate records maintained.

4. Multiple Assurance

The University of Hawaii has signed an assurance that it will abide by the DHHS regulations involving humans in research and/or training activities and has been assigned Multiple Assurance Number M1217 by the DHHS. The text of this assurance is provided under Attachment A of this section.

5. Procedure

The principal investigator submits form CHSAPP, "Application for Approval of Studies Involving Human Subjects," for new applications; and SRF2.WP5, "Status Report Form," for continuing applications to the CHS. See Attachments B and C, respectively, of this section. Forms are available at the Office of Research Services.

UNIVERSITY OF HAWAI'I

Office of Research Services

Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects

The University of Hawai'i, hereinafter known as the "institution," hereby gives assurance, as specified below, that it will comply with the Department of Health and Human Services (DHHS) regulations for the protection of human research subjects, 45 CFR Part 46, as amended to include provisions of the Federal Policy for the Protection of Human Subjects (56FR28003) as Subpart A, and as may be further amended during the approval period for this Assurance.

PART 1 - PRINCIPLES, POLICIES, AND APPLICABILITY

I. Ethical Principles

A. This institution is guided by the ethical principles regarding all research involving humans as subjects, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"], regardless of whether the research is subject to Federal regulation or with whom conducted or source of support (i.e. sponsorship).

B. All institutional and non-institutional performance sites for this institution, domestic or foreign, will be obligated by this institution to conform to ethical principles which are at least equivalent to those of this institution, as cited in the previous paragraph or as may be determined by the DHHS secretary.

II. Institutional Policy

A. All requirements of Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46) will be met for all applicable externally funded research, and all other human subject research regardless of sponsorship, except as otherwise noted in this Assurance. Federal (all departments and agencies bound by the Federal Policy) funds for which this Assurance applies may not be expended for research involving human subjects unless the requirements of this Assurance have been satisfied.

B. Except for those categories specifically exempted or waived under Section 101(b)(12-6) or 101(i), all research covered by this Assurance will be reviewed and approved by an Institutional Review Board (IRB) which has been established under a Multiple Project Assurance (MPA) with OPRR or as may be otherwise agreed to by OPRR. The involvement of human subjects in research covered by this Assurance will not be permitted until an appropriate IRB has reviewed and approved the research protocol and informed consent has been obtained from the subject or the subject's legal representative, unless properly waived by the IRB under Section 116(c),(d) or by any

applicable waiver under Section 101(i).

C. This institution assures that before human subjects are involved in nonexempt research covered by this Assurance, the IRB will give proper consideration to:

1. the risks to the subjects;
2. the anticipated benefits to the subjects and others;
3. the importance of the knowledge that may reasonably he expected to result; and
4. the informed consent process to be employed.

D. Certification of IRB review and approval for all Federally-sponsored research involving human subjects will be submitted to the Office of Research Administration (ORA) for forwarding to the appropriate Federal department or agency. Compliance will occur within the time and in the manner prescribed for forwarding certifications of IRB review to DHHS or other Federal departments or agencies for which this Assurance applies.

As provided for under section 118, applications and proposals lacking definite plans for involvement of human subjects will not require IRB review and approval prior to award. However, except for research exempted or waived under Section 101 (b) or (i), no human subjects may be involved in any project supported by such awards until IRB review and approval has been certified to the appropriate Federal department or agency. As required under Section 119, the IRB will review proposed involvement of human subjects in Federal research activities undertaken without prior intent for such involvement, but will not permit such involvement until certification of the IRB's review and approval is received by the appropriate Federal department or agency.

E. Institutions that are not direct signatories to this Assurance are not authorized to cite this Assurance. This institution will ensure that such other institutions and investigators not bound by the provisions of this Assurance will satisfactorily assure compliance with 45 CFR 46, as required, as a prior condition for involvement in DHHS-sponsored human subject research which is under the auspices of this institution. Institutions that have entered into an Inter-Institutional Amendment (IIA) to this Assurance must submit a Single Project Assurance (SPA) to the Office for Protection from Reasearch Risks (OPRR) for DHHS-sponsored research, on request, when that research is not conducted under the auspices of a signatory institution to this Assurance.

F. This institution will ensure that any collaborating entities (i.e. those entities engaged in human subject research by virtue of subject accrual, transfer of identifiable information, and/or in exchange of something of value, such as material support [e.g., money, drugs, or identifiable specimens], coauthorship, intellectual property, or credits) materially engaged in the conduct of nonfederally sponsored research involving human subjects will possess mechanisms to protect human research subjects that are at least equivalent to those procedures provided for in the ethical principles to which this institution is committed.

G. This institution will comply with the requirements set forth in Section 114 of the regulations regarding cooperative research projects. When research covered by this Assurance is conducted at or in cooperation with another entity, all provisions of this Assurance remain in effect for that research. This institution may accept, for the purpose of meeting the IRB review requirements, the review of an IRB established under another DHHS MPA. Such acceptance must be (a) in writing, (b) approved and signed by an official of this institution's Office of Research Administration, and (c) approved and signed by correlative officials of each of the other cooperating institutions i.e., a Cooperative Amendment to this MPA). The original of the signed understanding will serve as an addendum to this Assurance and will be forwarded to the OPRR of DHHS by the ORA for OPRR approval.

H. This institution will exercise appropriate administrative overview to insure that the institution's policies and procedures designed for protecting the rights and welfare of human subjects are being effectively applied in compliance with this Assurance.

I. Description of this institution's policy for the protection of human subjects is contained in its internal written procedures which are available to OPRR and other Federal departments or agencies, upon request. Appendix D to this Assurance abstracts pertinent organizational, personnel, and reporting procedures sufficient to describe the substance and relative prominence conferred upon the protection of subjects.

III. Applicability

A. Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under Section 101(b)(1-6) or 101(i), this Assurance applies to all externally funded research involving human subjects, and all other activities which even in part involve such research, regardless of sponsorship, if one or more of the following apply:

1. the research is sponsored by this institution; or
2. the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities; or
3. the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution; or
4. the research involves the use of this institution's non-public information to identify or contact human research subjects or prospective subjects.

B. All human subject research which is exempt under Section 101(b)(1-6) or 101(i) will be conducted in accordance with: (1) the Belmont Report, (2) this institution's administrative procedures to ensure valid claims of exemption, and (3) orderly accounting for such activities.

C. Components of this institution are bound by the provisions of this Assurance. Those components which can be expected to participate in human subject research sponsored by DHHS or other Federal departments or agencies for which this Assurance will apply are identified in Appendix A. Appendix A will be revised as changes occur and revisions forwarded to OPRR.

D. This Assurance must be accepted by other Federal departments or agencies that are bound by the Federal Policy for the Protection of Human Subjects when appropriate for the research in question and therefore applies to all human subject research so sponsored. Externally funded research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in Section 102(e) must be reviewed and approved, in compliance with Sections 101,102, and 107 through 117.

PART 2 - RESPONSIBILITIES

I. Institution

A. This institution acknowledges that it bears full responsibility for the performance of all research involving human subjects, covered by this Assurance, including complying with Federal, state, or local laws as they may relate to such research.

B. This institution will require appropriate additional safeguards in research that involves: (1) fetuses, pregnant women, or human ova in vitro fertilization, (2) prisoners, (3) children, (4) the cognitively impaired, or (5) other potentially vulnerable groups.

C. This institution acknowledges and accepts its responsibilities for protecting the rights and welfare of human subjects of research covered by this Assurance.

D. This institution is responsible for acquiring appropriate Assurances or Amendments, when requested, and certifications of IRB review and approval for federally sponsored research from all its affiliates and Assurances or Agreements for all others, domestic or foreign, which may otherwise become affiliated on a limited basis in such research.

E. This institution is responsible for ensuring that no performance site cooperating in the conduct of federally sponsored research for which this Assurance applies does so without Federal department or agency approval of an appropriate assurance of compliance in whatever appropriate form, and satisfaction of IRB requirements.

F. In accordance with the compositional requirements of Section 107, this institution has established the IRB listed in the attached roster (see Appendix C). Certain research supported by the U.S. Department of Education will be reviewed in accordance with the requirements of Title 34 CFR Parts 350 and 356 which require that the IRB include one person who is primarily concerned with the welfare of handicapped children or mentally disabled persons.

G. This institution will provide both meeting space and sufficient staff to support the IRB's review and recordkeeping duties.

H. This institution recognizes that involvement in research activities of any OPRR-recognized Cooperative Protocol Research Program (CPRPs) will involve additional reporting and recordkeeping requirements related to human subject protections.

I. This institution is responsible for ensuring that it and all its affiliates comply fully with all applicable Federal policies and guidelines, including those concerning notification of seropositivity, counseling, and safeguarding confidentiality where research activities directly or indirectly involve the study of human immunodeficiency virus (HIV).

II. Office of Research Administration for Human Subject Research (ORA)

A. The ORA will receive from investigators, through their supervisors, all externally funded research proposals which involve human subjects, keep investigators informed of decisions and administrative processing, and return all disapproved protocols to them.

B. The ORA is responsible for reviewing the preliminary determinations of exemption by investigators and supervisors and for making the final determination based on Section 101 of the regulations. Notice of concurrence for all exempt research will be promptly conveyed in writing to the investigator. All nonexempt research will be forwarded to the appropriate IRB.

C. The ORA will make the preliminary determination of eligibility for expedited review procedures (see Section 110). Expedited review of research activities will not be permitted where full board review is required (e.g., provision of emergency medical care which also constitutes the conduct of more than minimal risk research).

D. The ORA will review all research (whether exempt or not) and decide whether the institution will permit the research. If approved by the IRB, but not permitted by the ORA, the ORA will promptly convey notice to the investigator and the IRB Chair. Neither the ORA nor any other office of the institution may approve a research activity that has been disapproved by the appropriate IRB.

E. The ORA will forward certification of IRB approval of proposed research to the appropriate Federal department or agency only after all IRB-required modifications have been incorporated to the satisfaction of the IRB.

F. The ORA will designate procedures for the retention of signed consent documents for at least three years past completion of the research activity.

G. The ORA will maintain and arrange access for inspection of IRB records as provided for in Section 115.

H. The ORA is responsible for ensuring constructive communication among the research administrators, department heads, research investigators, clinical care staff, human subjects, and institutional officials as a means of maintaining a high level of awareness regarding the safeguarding of the rights and welfare of the subjects.

I. The ORA will arrange for and document in its records that each individual who conducts or reviews human subject research has first been provided with a copy of this Assurance, as well as with ready access to copies of 45 CFR 46, regulations of other Federal departments or agencies as may apply, the Belmont Report, and all other

pertinent Federal policies and guidelines related to the involvement of human subjects in research.

J. The ORA will report promptly to the IRB, appropriate institutional officials, the Office for Protection from Research Risks (OPRR), FDA, and any other sponsoring Federal department or agency head:

1. any injuries to human subjects or other unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with the regulations or requirements of the IRB; and
3. any suspension or termination of IRB approval for research.

K. The ORA will ensure (a) solicitation, (or confirmation where applicable assurance to comply already exists) receipt, and management of all assurances of compliance (whatever the appropriate format), and certifications of IRB review (where appropriate) for all performance sites to this institution, and (b) subsequent submission of new documents to the proper Federal department or agency authorities as a condition for involvement in human subject research activities sponsored by DHHS or any other Federal department or agency for which this Assurance applies.

L. The ORA will ensure that all affiliated performance sites that are not otherwise required to submit assurances of compliance with Federal regulations for the protection of research subjects at least document mechanisms to implement the equivalent of ethnical principles to which this institution is committed.

M. When an IRB of this institution accepts responsibility for review of research which is subject to this Assurance and conducted by any independent investigator who is not otherwise subject to the provisions of this Assurance, the ORA will either: (a) obtain and retain a Noninstitutional Investigator Agreement (NIA) for CPRP activities (with copy to the investigator and the authorizing CPRP) or (b) obtain an Agreement for an Independent Investigator (AII) for review and approval by the appropriate Federal department or agency for non-CPRP activities to document the investigator's commitment to abide: (1) by the same requirements for the protection of human research subjects as does this institution and (2) the determinations of the IRB.

N. The ORA assumes responsibility for ensuring conformance with special reporting requirements for any OPRR-recognized Cooperative Protocol Research Programs in which the signatory institution participates.

O. The ORA will be responsible for procedural and recordkeeping audits not less than once every year for the purpose of detecting, correcting, and reporting (as required) administrative and/or material breaches in uniformly protecting the rights and welfare of human subjects as required at least by the regulations and as may otherwise be additionally required by this institution.

P. The ORA will ensure compliance with the requirements set forth in this Assurance and Section 114 regarding cooperative research projects. In particular, where the IRB of another institution with a DHHS MPA is relied upon, the ORA will ensure documentation of this reliance will be (a) in writing, (b)approved and signed by the ORA, (c) approved and signed by the correlative officials of each of the other cooperating institutions, and (d) retained by the ORA for at least three years past completion of the research project, if limited in scope to a specific research project or retained as a permanent addendum to the MPA if not restricted to a specific project. For all Cooperative Agreements (CAs), the ORA will forward the original of the required signed understanding to OPRR for approval and inclusion in this Assurance as an addendum.

III. Institutional Review Board (IRB)

A. The IRB will review and have authority to approve, require modification in, or disapprove all externally funded research activities, including proposed changes in previously approved human subject research. For approved research, the IRB will determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

B. IRB decisions and requirements for modifications will be promptly conveyed to investigators and the ORA in writing. Written notification of decisions to disapprove will be accompanied by reasons for the decision with provision of an opportunity for reply by the investigator, in person or in writing.

C. Initial and continuing convened IRB reviews and approvals will occur in compliance with 45 CFR 46 and provisions of this Assurance for each project unless properly found to be exempt (Section 101[b] and [i]) by the Office of Research Administration. Continuing reviews will be preceded by IRB receipt of appropriate progress reports from the investigator, including available study-wide findings.

D. The IRB will observe the quorum requirements of Section 108(b). This institution's IRB has effective knowledge of subject populations, institutional constraints, differing legal requirements, and other factors which can foreseeably contribute to a determination of risks and benefits to subjects and subjects' informed consent and can properly judge the adequacy of information to be presented to subjects in accordance with requirements of Sections 103(d),107(a), lll, and 116.

E. The IRB will determine, in accordance with the criteria found at 45 CFR 46.111 and Federal policies and guidelines for involvement of human subjects in HIV research, that protections for human research subjects are adequate.

F. The IRB will ensure that legally effective informed consent will be obtained and documented in a manner that meets the requirements of Sections 116 and

117. The IRB will have the authority to observe or have a third party observe the consent process.

G. Where appropriate, the IRB will determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45 CFR 46. The IRB will notify OPRR promptly when IRB membership is modified to satisfy requirements of 45 CFR 46.304 and when the IRB fulfills its duties under 45 CFR 46.305(c).

H. Scheduled meetings of the IRB for review of each research activity will occur not less than every 12 months and may be more frequent, if required by the IRB on the basis of degree of risk to the subjects. The IRB may be called into any interim review session by the Chairperson at the request of any IRB member or institutional official to consider any matter concerned with the rights and welfare of any subject.

I. The IRB will prepare and maintain adequate documentation of its activities in accordance with Section 46.115 and in conformance with the Office of Research Administration requirements.

J. The IRB will forward to the Office of Research Administration any significant or material finding or action, at least to include the following:

1. injuries or any other unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with the regulations or requirements of the IRB; and
3. any suspension or termination of IRB approval.

K. In accordance with Section 109, the IRB will have the authority to suspend or terminate previously approved research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

L. The IRB for this institution will ensure effective input (consultants or voting or nonvoting members) for all initial and continuing reviews conducted on behalf of the performance sites where there will be human research subjects. IRB minutes will document attendance of those other than regular voting members.

M. The IRB will act with reasonable dispatch, upon request, to provide full board review of protocols of OPRR-recognized Cooperative Protocol Research Programs (CPRP). The IRB will not employ expedited review procedures for CPRP protocols when they are to be entered into for the purpose of research. Although emergency medical care based on such protocols is permitted without prior IRB approval, patients receiving emergency care under these conditions will not be counted as research subjects and resultant data will not be used for research purposes.

N. Certification of IRB review and approval will be forwarded through the Office of Research Administration to the appropriate Federal department or agency for research sponsored by such departments or agencies.

IV. Research Investigator

A. Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research subjects and for complying with all applicable provisions of this Assurance.

B. Research investigators who intend to involve human research subjects will not make the final determination of exemption from applicable Federal Regulations or provisions of this Assurance.

C. Preparation of protocol.

1. Research investigators shall prepare a protocol giving a complete description of the proposed research. In the protocol, research investigators shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed. This requirement is applicable even in cases where the research is exempt under 45 CFR 46.101.

2. Research investigators shall include samples of proposed informed consent forms with the protocol.

D. Scientific merit and ethical consideration review.

1. Research investigators shall, upon the IRB's request, substantiate the scientific merit and ethical adequacy of proposed research.

E. Submission of protocol to ORA.

1. Research investigators shall be responsible for ensuring that protocols for all funded research involving human subjects are submitted to the ORA.

F. Submission of a supplement to an original protocol to the ORA.

1. Research investigators shall be responsible for submitting a supplement and the original protocol to the ORA when:

(a) it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects; or

(b) it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects;

or

(c) it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by the IRB.

G. Complying with IRB decisions.

1. Research investigators shall be responsible for complying with all IRB decisions, conditions and requirements.

H. Obtaining informed consent.

1. Research investigators are responsible for obtaining informed consent in accordance with 45 CFR 46.116, and for ensuring that no human subject will be involved in the research prior to the obtaining of the consent.

2. Unless otherwise authorized by the IRB, research investigators are responsible for ensuring that legally effective informed consent shall:

(a) be obtained from the subject or the subject's legally authorized representative;

(b) be in a language understandable to the subject or the representative;

(c) be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and

(d) not include exculpatory 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 research investigator, the sponsor, the institution or its agnets from liability for negligence.

I. Providing basic elements of informed consent.

1. Unless otherwise authorized by the IRB, research investigators at a minimum shall provide the following information to each subject:

(a) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(b) a description of any reasonably foreseeable risks or discomforts

to the subject;

(c) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(d) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(e) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(f) for research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

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

(h) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

J. Providing additional elements of informed consent.

1. When required by the IRB, the research investigator shall provide one or more of the following additional elements of information to each subject:

(a) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(b) anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;

(c) any additional costs to the subject that may result from participation in the research;

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

(e) 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

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

K. Documentation of the informed consent.

1. Research investigators shall be responsible for ensuring that informed consent is 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, unless this requirement is specifically waived by the IRB.

2. Research investigators shall ensure that each person signing the written consent form is given a copy of that form.

3. Research investigators may use a consent form which is either:

(a) a written consent document that embodies the elements of informed consent required by 45 CFR 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the research investigator shall give either the subject or the representative adequate opportunity to read the form before signing it; or

(b) a "short form" written consent document stating that the elements of informed consent required by 45 CFR 46.116 have been presented orally to the subject or the subject's legally authorized representative. When the "short form" is used, research investigators shall ensure that:

(1) a witness is present at the oral presentation;

(2) the short form is signed by the subject or the representative;

(3) the witness signs both the short form and a copy of the written summary of the oral presentation;

(4) the person obtaining consent signs a copy of the summary;

(5) a copy of both the short form and summary is given to the subject or the representative; and

(6) the written summary of what is to be said to the subject or the representative receives the prior approval of the IRB.

L. Retention of signed consent documents.

1. Research investigators are responsible for placing the consent documents signed

by human research subjects in an appropriate repository.

M. Submission of progress reports on the research.

1. Research investigators are responsible for reporting the progress of the research to the ORA, as often as and in the manner prescribed by the IRB but no less than once a year.

2. Progress reports are to be made in the form of any application for annual review, unless the IRB imposes different or additional requirements.

N. Submission of injury reports and reports of unanticipated problems involving risks.

1. Research investigators are responsible for reporting promptly to the IRB any injuries to human subjects.

2. Research investigators are responsible for reporting promptly any unanticipated problems which involves risks to the human research subjects or others.

O. Reporting changes in research.

1. Research investigators are responsible for reporting promptly to the IRB proposed changes in a research activity that directly or indirectly affect the role of human subjects.

2. Changes in research during the period for which IRB approval has already been given shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

P. Reporting of noncompliance.

1. Research investigators are responsible for reporting promptly to the ORA and the IRB any serious or continuing noncompliance with the requirements of this assurance or the determinations of the IRB. Department heads who learn of any such noncompliance shall assure that it is reported promptly to the ORA and the IRB.

Q. Attending IRB meetings.

1. To facilitate the review of research and the protection of the rights and welfare of human subjects, research investigators or designate should attend IRB meetings when invited by the IRB.

R. Notifying the ORA concerning investigational new drugs.

1. The research investigators shall be responsible for notifying the Food and Drug Administration (FDA) and the ORA whenever it is anticipated that an

investigational new drug or device exemption will be required.

S. Research investigators are responsible for providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement.

T. No research investigator who is obligated by the provisions of this Assurance, any associated Inter-Institutional Amendment, or Noninstitutional Investigator Agreement will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law. However, such activities will not be counted as research nor the data used in support of research.

U. Research investigators will advise the IRB, Office of Research Administration and the appropriate officials of other institutions of the intent to admit human subjects who are involved in research protocols for which this Assurance or any related Inter-Institutional Amendment or Noninstitutional Investigator Agreement applies. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OPRR-approved Assurance prior to involvement of such persons as human subjects in those research protocols.

V. Affiliated Institutions and Investigators

A. Each performance site to this institution that is involved in federally-sponsored research activities must provide to the Office of Research Administration an appropriate written Assurance of compliance with the Belmont Report and the Federal Policy, to include Subparts B, C, and D or 45 CFR 46 where appropriate(or equivalent protections if a foreign site), for review and approval, as specified by the sponsoring Federal department or agency (e.g., by OPRR for DHHS), prior to involvement of human subjects or expenditure of funds or other support to do so.

B. Each institutional performance site must respond to a request by the Office of Research Administration of this institution for an Inter-Institutional Amendment, SPA, or CPA as appropriate, whichever is most suited to the circumstances.

C. Each non-institutional performance site (e.g., a private practice physician not otherwise an employee of this institution or who otherwise would not ordinarily be bound by the provisions of this Assurance or any other applicable institutional Assurance) who is involved in human subject research of this institution must respond to a request by the Office of Research Administration of this institution for either an Agreement for an Independent Investigator or a Noninstitutional Investigator Agreement, as appropriate, depending on the nature of the research activity.

D. Performance sites that are legally separable from this institution (whether an institutional or non-institutional performance site) are not authorized to cite this Assurance.

PART 3 - SIGNATURES

I. Institutional Endorsement

The official signing below assures that any research activity conducted, supported, or otherwise subject to DHHS or other Federal departments or agencies that are authorized to rely on this Assurance (Parts 1,2,3 and Appendices) or any other sources provided for in this Assurance, will be reviewed and approved by the appropriate IRB(s) in accordance with the requirements of all applicable Subparts of Part 46, Title 45 of the Code of Federal Regulations, with this Assurance, and the stipulations of the IRB(s).

A. Primary Signatory Institution

1. AUTHORIZED INSTITUTIONAL OFFICIAL

Signature: Marvin S. Enokawa Date: 10.29.97
Name: Marvin S. Enokawa
Title: Director of Research Services
Institution
and Address: University of Hawai'i
Office of Research Services
2530 Dole St., Sakamaki D200
Honolulu, HI 96822

Phone: (808) 956-7800
Fax: (808) 956-9081
E-Mail: enokawa@hawaii.edu

2. PRIMARY CONTACT

Signature: SAME Date: _____
Name: _____
Title: _____
Institution
and Address: _____
_____
_____
_____
_____
Phone: _____
Fax: _____
E-Mail: _____

FOR DHHS USE ONLY

II. Office for Protection from Research Risks (DHHS Approval)

A. DHHS RECOMMENDING OFFICIAL

Signature: Katherine Duncan Date: Nov 5.1997
Name: Katherine Duncan, M.D.
Title: Adjunct Medical Officer
Address: Division of Human Subject Protections
Office for Protection from Research Risks(OPRR)
6100 Executive Boulevard, Room 3B01 (MSC 7507)
Rockville, Maryland 20892-7507
Phone: 301-496-7005 x207
Fax: 301-402-0527
E-mail: kd41f@nih.gov

EFFECTIVE DATE OF ASSURANCE: Nov 1 1997

EXPIRATION DATE OF ASSURANCE: Oct 31, 2002

B. DHHS APPROVING OFFICIAL

Signature: Freda E. Yoder Date: 11/12/97
Name: Freda E. Yoder
Title: Assurance Coordinator, Assurance Branch
Address: OPRR, OER, OD, NIH (MSC 7507)
6100 Executive Boulevard, Suite 3B01
ROCKVILLE MD 20892-7507
Phone: Phone: (301) 402-5793
Fax: Facsimile: (301) 402-0527
E-mail: Email: fy9r@nih.gov

DHHS MPA# 1217
Date: October 30, 1997

Appendix A

COMPONENTS WHICH ARE LEGALLY INSEPARABLE FROM EACH DESIGNATED SIGNATORY INSTITUTION AND PARTICIPATE IN HUMAN RESEARCH OF THE SIGNATORY

Names, Cities, and States

Signatory Institution #1:	University of Hawai'i at Mānoa
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	University of Hawai'i at Hilo
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	West Oahu College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Windward Community College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Leeward Community College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Honolulu Community College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Hawai'i Community College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Kapiolani Community College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Maui Community College
Components Authorized to Cite MPA	Entire Campus
Signatory Institution #1	Kauai Community College
Components Authorized to Cite MPA	Entire Campus

DHHS MPA#: 1217
Date: October 30, 1997

Appendix B

STANDING AFFILIATES WHICH ARE LEGALLY SEPARATE FROM EACH DESIGNATED SIGNATORY INSTITUTION AND POSSESS OPRR-APPROVED INTERINSTITUTIONAL AMENDMENTS

Names, Cities, States

MPA Signatory Institution #1(Primary): University of Hawai'i at Mānoa

	Name:	City:	State:
Affiliate Institutions:	Kapiolani Health	Honolulu	Hawaii

MPA Signatory Institution #2: _____

Affiliate Institutions:			

MPA Signatory Institution #3: _____

Affiliate Institutions:			

MPA Signatory Institution #4: _____

Affiliate Institutions:			

MPA Signatory Institution #5: _____

Affiliate Institutions:			

☐ Please check here if there are no suitable standing affiliates for entry.

Appendix C

[Please Resubmit as Changes Occur]

IRB NO: 01
ASSURANCE NO: M-1217
DATE: October 29, 1997
SCOPE: General

INSTITUTIONAL REVIEW BOARD (IRB) MEMBERSHIP(1)

NAME(S) OF SIGNATORY INSTITUTION(S)

MEMBER NAME FIRST	M.I.	LAST	HIGHEST DEGREES EARNED	PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY	AFFILIATION WITH INSTITUTION(S)(2) (YES/NO; IF YES, WHICH ONE(S))
*Alan	R.	Katz	MD	Public Health	Associate Professor
David	T.	Horio	MD	Pathology	Assistant Professor
M. Casey		Jarman	LLM	Law	Associate Professor
Gertraud		Maskarinec	MD	Cancer research	Assistant Researcher
Dennis		McDougall	EdD	Special Education	Assistant Professor
Sarah	D.	Miyahira	PhD	Counseling Psychology	Community Member
Linda	B.	Nahulu	MD	Psychiatry	Assistant Professor
Anita	M.	Sasaki	RPh	Pharmacy	Community Member
Anne		Verderber	PhD	Nursing	Professor
** (for Katz) Frederick	D.	Miller,IV	PhD	Public Health	Professor
** (for Horio) Venkataraman		Balaraman	DM	Pediatrics	Associate Professor
**Hazel (for Jarman)	G.	Beh	JD	Law	Associate Professor
** Bruce F. Chorpita(Miyahira)			PhD	Psychology	Assistant Professor
** Amelia A. Jenkins(McDougall)			PhD	Special Education	Assistant Professor
** Andrea Macleod (Sasaki)			PharmD	Pharmacy	Community Member
** Kathryn Patterson(Verderber)			PhD	Nursing	Associate Professor
** Thomas M. Vogt (Maskarinec)			MD	Cancer research	Researcher
** Noelle Y. Yuen (Nahulu)			MD	Psychiatry	Assistant Professor

ADDRESS AND PHONE NUMBER FOR CHAIRPERSON ONLY

IRB CHAIR NAME: Alan R. Katz, M.D.

ADDRESS: University of Hawaii at Manoa
School of Public Health
1960 East-West Road
Honolulu, HI 96822

PHONE: (808) 956-5781/8577
FAX: (808) 956-4585
E-MAIL: katz@hawaii.edu

SIGNATURE:

RESTRICTION CODES ARE PRESENTED AS A SUFFIX TO THE MULTIPLE PROJECT ASSURANCE "M" NUMBER. A RESTRICTION IS BASED ON THE COMPOSITION OF THE IRB(S) AND INDICATES THAT ADDITIONAL EXPERTISE ON THE IRB IS NECESSARY FOR PARTICULAR ACTIVITIES.

AN XM SUFFIX INDICATES AN INSUFFICIENT NUMBER OF MEDICAL MEMBERS (MINIMUM IS 2).

AN XB SUFFIX INDICATES THAT THE IRB HAS AN INSUFFICIENT NUMBER OF BEHAVIORAL SCIENCE EXPERTS (MINIMAL NUMBER IS 2).

WHEN AN APPLICATION OR PROPOSAL *GOES BEYOND* THE SCOPE OF A RESTRICTED IRB, THE IRB MUST ADD ADDITIONAL MEMBERS TO OFFSET THE RESTRICTION, THEIR NAMES AND QUALIFICATIONS MUST BE REPORTED TO AND APPROVED BY OPRR PRIOR TO THE AWARD OF FUNDS.*(3)*

* DENOTES CHAIRPERSON
** DENOTES ALTERNATES (IF ANY, DENOTE MEMBER FOR WHOM ALTERNATE WILL SERVE
^ DENOTES NON-VOTING MEMBERS

NOTES

(1) EACH SIGNATORY INSTITUTION MUST CONTRIBUTE ONE OR MORE VOTING MEMBERS TO THE IRB UPON WHICH IT RELIES FOR REVIEWS. EACH AFFILIATE INSTITUTION MUST BE REPRESENTED BY AT LEAST ONE IDENTIFIED CONSULTANT OR NONVOTING MEMBER TO THE RELIED UPON IRB WHO IS KNOWLEDGEABLE ABOUT THE AFFILIATE'S SITUATION.

(2) AFFILIATION MAY TAKE THE FORM OF FULL OR PART-TIME EMPLOYMENT, MEMBER OF GOVERNING PANEL OR BOARD, STOCKHOLDER, OR PAID OR UNPAID CONSULTANT (FOR PURPOSES OTHER THAN IRB FUNCTIONS).

(3) *IRB MINUTES SHOULD DOCUMENT THOSE CONSULTANTS WHO PARTICIPATE IN REVIEWS THAT FALL WITHIN THE APPROVED SCOPE OF AN IRB BUT EXCEED EXISTING EXPERTISE.*

A5.503
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Committee on Human Studies
2540 Maile Way, Room 253
Honolulu, HI 96822
PHONE: 956-5007
FAX: 956-9232

PLEASE READ BEFORE COMPLETING THE APPLICATION / STATUS REPORT FORM

1. **Please TYPE the application. Handwritten applications are not accepted.**

2. **Make sure that all questions are answered. If a question is not applicable to your project, state "not applicable" or N/A.**

3. **Make sure that all of the required attachments are included with your application.**

4. **If you have additional information, such as explanations which may help clarify matters in your application, please attached a separate sheet or a memo.**

5. **Incomplete or illegible applications may be returned to you without processing.**

Remember, the Committee is not as familiar with your project as you are. Providing sufficient detail and explanation in your application will help to avoid delay in the review and approval of your project.

If you have any questions or require assistance, call the Executive Secretary at the number above. We will be happy to assist you in this process.

The CHS Staff

COMMITTEE ON HUMAN STUDIES (CHS)

TO: The Principal Investigator (PI)

FROM: The U.H. Committee on Human Studies (CHS)

SUBJECT: Protection of Humans to be Involved in your Extramural Research/Training Project

This is a very brief summary of information for each PI. The current Federal regulations which govern this subject extend to several pages, but here we will attempt to provide some background and other helpful information.

The University of Hawaii frequently seeks extramural support for its research and training ideas. Federal agencies constitute the most attractive and available funding sources -- in fact, they furnish nearly 90% of all outside support.

In 1966, the Surgeon General of the United States initiated the first Federal regulations for the protection of human subjects. They have been expanded over the years and apply to all who propose to use Federal money appropriated to the U.S. Department of Health and Human Services (DHHS) to conduct research/training projects involving humans. Responsibility for initial review and approval of such proposals was placed upon each institution requesting funds. Since then, DHHS and other Federal agencies have increased their concern, spurred by Congress and others.

Where humans are involved in research no Federal agency will make an award, or permit expenditure of funds, prior to the approval of the project by an Institutional Review Board (IRB) of the grantee institution, in our case, the Committee on Human Studies (CHS).

The President of our University has signed an assurance that UH will abide by the DHHS regulations involving humans in research/training activities. The UH policies and procedures, and membership of its CHS, are subject to review by DHHS. DHHS has approved the UH policies and procedures, and they apply throughout the University of Hawaii system.

Under DHHS regulations, the CHS is charged with safeguarding the rights and welfare of humans involved, and must determine:

- Whether humans involved will be placed at risk. Risk means any individual who may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject or contributor, directly or indirectly, in any research, development or related activity including training.
- If at risk, whether the sum of the benefits to be expected of the project will outweigh the risks.
- Whether the rights and welfare of the humans will be adequately protected.
- Whether legally effective informed consent of all humans to be involved will he obtained and adequate records maintained.

It is recommended that the PI submit research/training plans which involve humans to the CHS for review by the 13th of the month, in order for the review to be completed in about five weeks. DHHS urges that CHS approval accompany each research/training application for such a project. If this is not possible, the DHHS regulations permit review and approval to follow the proposal no later than 60 days after dispatch.

The UH CHS is composed of nine senior people of professional competence, from diverse disciplines and backgrounds, selected for maturity, experience, and expertise. After several years of CHS operation, the attached forms have been prepared to assist the Pl in presenting complete information to the CHS to permit prompt review and approval for such plans. Please call the CHS Executive Secretary, 956-5007, for any additional information on this subject.

Attachments

- Application requirements
- PI memo
- Basic Elements Necessary to Informed Consent
- Submittal for New Proposals Form (Please remove, complete and submit to CHS)
- Elements of an Accceptable Consent Form
- Venipuncture wording
- Student Research Policy

UNIVERSITY OF HAWAII

COMMITTEE ON HUMAN STUDIES (CHS)

INSTRUCTIONS FOR THE PREPARATION OF A CONSENT FORM

In response to many queries, attached are CHS models for preparation of a consent form, keyed to DHHS regulations. The model on Schedule A of the attached sheet represents a "written" consent document embodying all of the basic elements of informed consent. Both the "written" form and the "oral" form (Schedule B) must contain the information in Sections 1, 111, IV of the sample forms.

The material to be presented verbally in conjunction with the "oral form" must contain all the basic elements of consent, that is, must include the information given in Section II of the sample "written" form. The "oral" consent document, when submitted to the CHS must be accompanied by written summary of the information to be presented orally to the subject or authorized representative.

It is initial that subjects be informed about compensation policies. The following represents suggested consent form wording for informing subjects on compensation and medical treatment if there are physical risks: "I understand that in the event of physical injury resulting from the research procedure, *medical treatment for injuries or illness is available* OR *only immediate and essential medical treatment is available* OR *hospitalization is available. In addition, monetary compensation is available or wages lost because of injury* OR *financial compensation is not available, but medical treatment is provided free of charge* OR *I understand that if I am injured in the course of this research procedure, I alone may be responsible for the costs of treating my injuries.*" etc.

All P.I.'s should endeavor to make sure that consent forms are written in PLAIN, EASY TO UNDERSTAND,LANGUAGE.

Signatures of minor subjects seven (7) years of age and older must be obtained in addition to the signature of the authorized legal representative.

CHS # _____

APPLICATION FOR APPROVAL OF STUDIES INVOLVING HUMAN SUBJECTS

University of Hawaii, Committee on Human Studies (CHS)
Spalding Hall 253, 2540 Maile Way, Honolulu, Hawaii 96822
Telephone: (808) 956-5007

Date: _____

Principal Investigator: _____ SS #: _____

Title & Department: _____

Bldg/Room No.: _____ Phone: _____

Supervising Professor: _____ Phone: _____
(If student project)

Project Title: _____

Proposed Sponsoring Agency: _____ Project Start Date: _____

Complete Agency address: _____

_____

Proposal Submitted to ORS: [ ] NO [ ]YES, when _____ Proposal #: _____
(if known)

If your proposal is a renewal or continuation, please use the "Status Report Form" which can be obtained at the CHS office.

1. Summarize your proposed research. Outline objectives and methods.

2. Summarize all involvement of humans in this project (who, how many, age, sex, length of involvement, frequency, etc.) and the procedures they will be exposed to. Attach survey instrument, if applicable.

Check whether any subject of your research will be selected from the following categories:

_____	Minors	_____	PregnantWomen	_____	Mentally Disabled
_____	Fetuses	_____	Abortuses	_____	Physically Disabled
_____	Prisoners				

3. Research involving humans often exposes the subjects to risks:

For the purpose of this application, "risk" is defined as exposure of any person to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field or service.

a. Check all the risks to human subjects that apply to your project:

_____ Physical trauma or pain
_____ Side effects of medications
_____ Contraction of disease
_____ Worsening of illness
_____ Psychological pain
_____ Other -- explain

_____ Experimental diagnostic procedures
_____ Experimental treatment procedures
_____ Deception
_____ Loss of privacy
_____ Loss of legal rights

b. Check procedures that will be used to protect human participants from risks:

_____ M.D. or other appropriately trained individuals in attendance
_____ Sterile equipment
_____ Precautions in use of stressor or emotional material (explain below)
_____ When deception used, subjects fully informed as to nature of research at feasible time (explain below)
_____ Procedures to minimize changes in self-concept (explain below)
_____ Anonymity of subjects maintained via code numbers and protected files
_____ Others-- explain

Explanations:

c. Risk to human subjects involving injuries requiring medical treatment:

Has provision been made to assure Human Subjects will be indemnified for expenses incurred for treating these injuries?

_____ Not applicable
_____ No -- The following language should appear in the written consent form:

I UNDERSTAND THAT IF I AM INJURED IN THE COURSE OF THIS RESEARCH PROCEDURE, I ALONE MAY BE RESPONSIBLE FOR THE COSTS OF TREATING MY INJURIES.

_____ YES, explain:

d. Are there non-therapeutic tests that the research subjects may be required to pay?

_____ Not applicable
_____ No
_____ Yes explain:

If yes, the following language should appear in the written consent form:

I UNDERSTAND THAT I MAY BE RESPONSIBLE FOR THE COSTS OF PROCEDURES THAT ARE SOLELY PART OF THE RESEARCH PROJECT.

4. Describe mechanism for safety monitoring:

   How will you detect if greater harm is accruing to your subjects than you anticipated? What will you do if such increased risk is detected?

5. Briefly describe the benefits that will accrue to each human subject or to mankind in general, as a result of the individual's participation in this project, so that the committee can access the risk benefit/ratio.

6. Indicate how you will obtain informed consent:

   _____ Subject (or Parent/Guardian) reads complete consent form & signs ("written" form)
   _____ Oral briefings by PI or project personnel, with simple consent form ("oral" form)
   _____ Explain below the reason why a written consent form is not used

   _____ Other-- explain

   PARTICIPATION MUST BE VOLUNTARY: THE PARTICIPANTS CANNOT WAIVE LEGAL RIGHTS, AND MAY WITHDRAW AT ANY TIME WITHOUT PREJUDICE. Attach consent forms to be signed by each participant (these must remain as part of your project records, subject to committee review). Attach a summary of all verbal information to be read to each subject. All subjects must receive a copy of the consent form unless waived by CHS.

7. I affirm that the attached drug sheet(s) submitted to CHS for this project have been checked and confirmed to be accurate and current. If changes in a CHS-approved drug sheet have been made to insure accuracy and currency these changes have been listed on the attached. I understand the CHS will send this protocol to two (2) independent reviewers before review is made by the Committee as a whole.

8. Are there any local IRB's reviewing this proposal also? [ ] YES [ ] NO Location: _____

Signed: _____ Date: _____
Principal Investigator

Signed: _____ Date: _____
Supervising Professor (if applicable)

Submit the ORIGINAL plus 12 copies of this form with the following attachment:

Three (3) copies of proposal
Thirteen (13) copies of all consent forms
Thirteen (13) copies of verbal information to be given if short form is used
Thirteen (13) copies of the survey instrument
(Please consult with the CHS Executive Secretary if providing the survey instrument is a problem.)

Section I: Title* Schedule A

AGREEMENT TO PARTICIPATE IN

_____

(Title of Project)

_____

(Principal Investigator's name, address, and phone number)

Section II: Project Description*

1. Description of project including purpose and procedures need only give enough detail to allow informed consent and should be in plain English. Jargon should be avoided. Elaborate background information is usually not necessary. Include in procedures: duration of project, frequency, location and length of participation, e.g., 2 years; 6 times a year for 2 hours, etc. Include identification of those which are experimental.

2. All invasive procedures, including those for which consent is not normally obtained during diagnostic and therapeutic procedures, must be described. For example, venipuncture should be mentioned and the discussion should include the amount of material removed in ordinary measurements, e.g., 10 mL-2 teaspoon, 50 mL-3 tablespoons. Under any circumstances. a listing of all complications and risks should be Specified in plain language.

3. The consent form should include assurances of confidentiality, the possibility of embarrassment and the opportunity for voluntary withdrawal, where appropriate.

4. Benefits to be expected from project, to individual and/or to basic science, should be indicated.

5. Any appropriate alternative procedures advantageous to individual must be Identified.

6. If there are risks of physical injury, advice to subjects regarding compensation and medical treatment for injury resulting from such research must be included; see instructions for sample wording.

7. Any other information on matters specifically pertaining to your project, including whether the results of the research will be made available to the subject, should be included as warranted.

Section III: Certifications*

[The following material should be included verbatim in all consent forms. Items in italics should be tailored to fit the circumstances of your particular project.]

I certify that I have read and that I understand the foregoing, that I have been given satisfactory answers to my inquiries concerning project procedures and other matters and that I have been advised that I am free to withdraw my consent and lo discontinue participation in the project or activity al any time without prejudice.

I herewith give my consent to participate OR, *I consent to the participation of my minor child* OR *minor ward*, OR *adult ward* in this project with the understanding that such consent does not waive any of my legal rights, nor does it release the principal Investigator or the institution or any employee or agent thereof from liability for negligence.

Section IV: Signatures* [Include those signatures appropriate to your project.]

Signature of Minor (if appropriate) _____ Signature of individual participant(or authorized legal representative, if appropriate)

Date _____ Date _____

(If you cannot obtain satisfactory answers to your questions or have comments or complaints about your treatment in this study, contact: Committee on Human Studies, University of Hawaii, 2540 Maile Way, Honolulu, Hawaii 96822. Phone: (808) 956-8658.)

cc: Signed copy to subject

* Do not include section headings in actual form.
** If necessary, see instructions.

Section I: Title* **Schedule B**

AGREEMENT TO PARTICIPATE IN

_____

(Title of Project)

_____

(Principal investigator's name, address and phone number)

Section II: Project Description*
[To be given verbally, attach a copy of oral briefing to be used for committee review.]

Section III: Certifications*

[The following material should be included verbatim in all consent forms. Items in italics should be tailored to fit the circumstances of your particular project.]

I certify that I have been told of the possible risks involved in this project, that I have been given satisfactory answers to my inquiries concerning project procedures and other matters and that I have been advised that I am free to withdraw my consent and to discontinue participation in the project or activity at any time without prejudice.

I herewith give my consent to participate ***OR****, I consent to the participation of my minor child,* ***OR*** *minor ward,* ***OR*** *adult ward* in this project with the understanding that such consent does not waive any of my legal rights; nor does it release the principal investigator or the institution or any employee or agent thereof from liability for negligence.

Section IV: Signatures* [Include only those signatures appropriate to your project.]

_____ _____

Signature of Witness (If appropriate) Signature of individual participant
(or authorized Legal representative, if appropriate)

Date_____ Date_____**

Signature of Minor (If appropriate)

Date _____

(If you cannot obtain satisfactory answers to your questions or have comments or complaints about your treatment in this study, contact: Committee on Human Studies, University of Hawaii, 2540 Maile Way, Honolulu, Hawaii 96822. Phone: (808) 956-8658.)

cc: Signed copy to subject

*Do not include section headings in actual form.
**If necessary, see instructions.

FOR VENIPUNCTURE ASSOCIATED WITH PARTICIPATION IN RESEARCH STUDIES

The following has been approved by the UH Committee for Human Studies for use in consent forms used in research studies where venipuncture is proposed.

Example of Wording Used by Cancer Research Center. Epidemiology Program:

"We are asking you to give __cc of blood (about __tablespoons). The risks are minimal and are only those of having blood drawn. This might include mild pain or a bruise at the place where blood is taken. Risk of infection is slight since only sterile one-time equipment will be used.

Question: Should we request that research participants also be informed that they might faint (experience syncope) when this procedure is done?

Suggest Wording(underlined):

"We are asking you to give __cc of blood (about __tablespoons). The risks are minimal and are only those of having blood drawn. This might include mild pain or a bruise at the place where the blood is taken. Occasionally, a person may faint or feel faint when blood is drawn for a blood test. Risk of infection is slight since only sterile one-time equipment will be used."

UH COMMITTEE ON HUMAN STUDIES
STUDENT RESEARCH
POLICY

These guidelines are established by the University of Hawaii Committee on Human Studies (CHS) to assist faculty and students in preparing and conducting University research activities which involved UH students. Further information can be obtained from the Office of Research Services (ORS) at Spalding Hall, Room 253, (phone: 956-5007). Individual University departments, particularly those that routinely involve students in research-related educational activities, are encouraged to develop their own internal policies in this area.

The CHS encourages student involvement in research activities, both as researchers and as subjects. Participation is an integral part of the education process and enables students to become familiar with procedures and requirements applicable to research involving human subjects.

STUDENTS AS RESEARCHERS

The CHS policy is that student applications will be reviewed by standards designed to meet the UH's obligations under Human Subjects regulations. As a rule, all applications (student/nonstudent) to the CHS will be reviewed by the same standards and procedures. Feedback is often provided to students as a means of assistance and encouragement. The purpose of this policy is to provide practical experience to students learning about the research process.

UH policy requires that all University-related research activities involving human subjects must, at a minimum, comply with the ethical principles stated in the Belmont Report. Copies of the Belmont Report may be obtained from ORS. A three-part series of videocassettes on the topic of human research subjects has been produced by the National Institutes for Health and is also available for loan from ORS.

Funded Research

The UH Assurance with the U.S. Department of Health and Human Services requires that all funded research proposals be reviewed by the CHS. Those student research projects which will be supported, even in part, by external funding, must be submitted to the CHS for review, and approved, prior to commencement of the project. Nonfunded projects, such as dissertation or thesis research, are generally not required to be reviewed by the CHS. Nevertheless, the CHS welcomes submittal of such projects for review.

Non-Funded Activities

Special care should be taken when students will be conducting research activities outside of the classroom. Although nonfunded research activities are not required to be submitted to the CHS, students should be aware that the principles of the Belmont Report and proper consent procedures must be followed. If such projects are submitted to the CHS, a full review will be done and feedback will be provided to the student and/or faculty advisor.

If University-related research activities will be conducted outside of UH facilities, will involve persons not associated with the UH, or will involve more than minimal risk to the participants, it is recommended that such activities be submitted to the Committee for review to ensure compliance with human subject regulations and to assist the student in developing procedures which will safeguard and protect the subjects involved in the research.

STUDENTS AS RESEARCH SUBJECTS

Instructional/Educational Purpose

Student participation as subjects in classroom activities which are designed for instruction or educational purposes and primarily benefit the students, is encouraged. This allows students to experience research activities from the perspective of the research subject. Course instructors are encouraged to include consent procedures and explain the fundamental rights of human research subjects and obligations of researchers.

Non-Instructional/Educational Purposes

A. Outside Researcher

A course instructor who permits an outside researcher to conduct research involving his/her students has primary responsibility for the welfare of his/her students. The instructor should ensure that:

- the researcher has obtained all necessary University approvals and will abide by University policy in conducting the research.
- participation of the students is voluntary.
- risks to the students are minimized and disclosed.
- informed consent procedures are followed.
- ensure that students' confidentiality is protected, particularly if breach of confidentiality could be potentially embarrassing or harmful to students.

B. Instructor as Researcher

In those instances when an instructor chooses to involve his/her students in his/her research activities which will primarily benefit that instructor and not the students, the instructor should:

- recruit subjects from the general student population if possible (e.g., advertise in the student newspaper) If not possible, then recruitment should be from classes or courses with which the instructor is not involved. Recruitment of student subjects from the researcher's classes is discouraged.
- ensure that student participation is voluntary.
- inform the students of the instructor's interest in the research.
- minimize and disclose any risks to the students.
- ensure that the students' confidentiality is protected, particularly if breach of confidentiality could be potentially embarrassing or harmful to the students.

Incentives to students for participating in research activities, such as extra credit or bonus points, must be carefully considered. The Committee recognizes this practice as a means of encouraging student participation, but recommends that alternative opportunities for extra credit be offered to those students who choose not to participate in non-educational research activities. The intent is to minimize coercion in student participation. Extra credit alternatives should be comparable to the effort involved in participating in the research activity.

Please feel free to contact the Committee on Human Studies through the Office of Research Services for further information or assistance.

COMMITTEE ON HUMAN STUDIES

STATUS REPORT FORM

Instructions

To meet the obligation for periodic review of approved research involving human subjects, the Committee on Human Studies requires the completion of the attached Status Report Form in time for CHS review prior to the expiration of the current approval period.

CLOSED PROJECT:

1. Complete the standard information of the Status Report Form.
2. Answer Question #1, 3, and 5.
3. Attach a brief summary of results.
4. Sign the Status Report Form and return to CHS.

INACTIVE/ACTIVE PROJECT:

Without Changes:

1. Complete the entire Status Report Form.
2. Submit **ORIGINAL**, in addition to **12** copies of the Status Report Form.
3. Attach one copy of the currently dated Consent Form.
4. Upon approval by CHS, a DHHS Form 310 will be issued and valid for one year.

With Changes:

1. Complete the entire Status Report Form
2. List the changes for the protocol into two categories:
   a. Changes to Human Subjects
   b. Changes in Technical Matters
3. Submit **ORIGINAL** plus **12** copies of the Status Report Form
   13 copies of the List of Changes
   (The List of Changes can be in a memorandum format or on separate pages.)
   13 copies of the currently dated Consent Form
   3 copies of the Amendment to the protocol or revised protocol
   13 copies of the survey instrument and pertinent material(s).
   (Please consult with the CHS Executive Secretary if providing the survey instrument is a problem.)
4. Upon approval by CHS:
   a. A DHHS Form 310 will be issued and is usually valid for one year or;
   b. a memorandum of approval will be issued for the current approval period.

Be advised that incomplete submissions will be returned to the investigators and will delay the review of submittal.

The Committee on Human Studies convenes once a month, on the second Friday; therefore, it is imperative that you submit the Status Report Form for review by the 13th day of each month previous to the next month's meeting to keep your CHS approval current.

Should you have questions, please call Paul Kakugawa at 956-8658.

STATUS REPORT FORM

University of Hawaii, Committee on Human Studies (CHS)
Spalding Hall 253, 2540 Maile Way, Honolulu, Hawaii 96822
Telephone: (808)956-5007

Date: _____

PRINCIPAL INVESTIGATOR: _____ SS #: _____

TITLE & DEPARTMENT: _____

BLDG/ROOM NO: _____ Phone: _____

SUPERVISING PROFESSOR: _____ Phone: _____
(If student project)

PROJECT TITLE: _____

SPONSORING AGENCY: _____ Project Start Date: _____

AGENCY ADDRESS: _____ Proposal / Award No.: _____

_____

Continuation Proposal Submitted to ORA: [ ] NO [ ] YES, when _____

Check one: ____ Renewals with changes ____ Renewals w/out changes ____ Changes within current approval period

Previous CHS # _____ Date approved _____

To meet its obligation for periodic review of approved research involving human subjects, the Committee on Human Studies asks you to answer the following questions:

1. Is this project still active? If NO, please indicate date of termination and attach a brief summary of results.

   Yes ____ No ____ Project End Date: _____

2. If this project is active, indicate the anticipated date of completion. Date: _____

3. How many subjects or patients have been studied to date at this location? _____

4. Currently, do your procedures involve any activity which is different from that described in the last approved protocol?

   Yes ____ No ____

   IMPORTANT: *Federal regulations require that the committee be informed of even minor changes. If YES, please describe on additional pages or attach a copy of the protocol or consent form with changes highlighted or underlined.*

5. Have any of the subjects at this location been injured by participating or been subjected to unanticipated problems which involve risks? If YES, please describe on additional pages and attach; include <u>any</u> deaths which could be even remotely related to the study.

   Yes ____ No ____

Please sign below and submit with other required forms listed on the instructions and any other attachments you deem relevant to the Office of Research Administration, CHS.

SIGNED: _____ _____
Principal Investigator Date