

CALIFORNIA STATE UNIVERSITY, EAST BAY

DESIGNATION CODE: 2007-08 CR 5

DATE SUBMITTED: May 15, 2008

TO: The Academic Senate

FROM: The Committee on Research

SUBJECT: Policy on Training for Investigators doing Research Using Human Subjects

PURPOSE: Action by the Academic Senate

ACTION REQUESTED: That the Academic Senate approve the attached proposed CSUEB policies on Training for Investigators doing Research Using Human Subjects; effective upon the signature of the President.

BACKGROUND

INFORMATION: The Office of Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS), which oversees research that utilizes human subjects, recommends that a) Institutional Review Board (IRB) members and staff complete relevant educational training before reviewing human subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research. Further, the Chancellor of the California State University, in Executive Order 890 states that campus policy shall incorporate provisions for adequate training of research personnel and for multi-institutional Sponsored Programs.

CSUEB needs to develop a policy to meet the Chancellor's requirements. The Assurance of Compliance that CSUEB files with the Department of Health and Human Services must be updated to reflect the new policy.

Via an email vote ending May 14, 2008, the Committee on Research approved the attached Policy, the associated Procedures, and modifications to the Assurance of Compliance that CSUEB files with the DHHS. The Committee on Research then voted to send the documents to the Senate for final adoption.

In the interest of brevity, the changes to the Assurance of Compliance are as follows:

Add to Section 3.0 Ethical Principles:

3.15 Investigators conducting human subjects research must undergo appropriate training as well as periodic updates to that training as specified by the AVP.

Add to Section 5.0 The Institutional Review Board, Subsection 5.1 Membership:

All members shall undergo appropriate training as well as periodic updates to that training as specified by the AVP.

Modifications to Section 5.0 The Institutional Review Board, Subsection 5.4 Meetings:

~~The IRB shall meet at least four times each academic year. The IRB shall meet as needed in order to review research protocols in a timely manner. The Director shall convene an organizational meeting of the Board early each Fall Quarter. At this meeting, a Chair, who must be an employee of CSUH, and a Secretary shall be elected and a schedule of meetings developed for the remainder of the year. This schedule shall be widely disseminated in the CSUH academic community and printed in The View. When the Chair position is vacant, the AVP shall convene an organizational meeting of the Board. At this meeting, a Chair, who must be an employee of CSUEB, shall be elected. Emergency meetings of the IRB may be called by the Chair or by the AVP.~~
Director.

California State University, East Bay

ASSURANCE OF COMPLIANCE WITH DEPARTMENT OF HEALTH AND HUMAN SERVICES REGULATIONS ON PROTECTION OF HUMAN SUBJECTS

- 1 California State University, East Bay will comply with the Department of Health and Human Services regulations on Protection of Human Subjects (45 CFR 46), and the implementing guidelines of this policy statement. Accordingly:
- 2 This institution will comply with the decisions of the California State University, East Bay's Institutional Review Board, to which Board this institution will submit all projects and activities involving human subjects for review and approval. The Board shall determine for each activity as planned and conducted whether subjects will be placed at risk and if risk is involved whether:
 - the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant a decision to allow the subject to accept these risks;
 - the rights and welfare of any such subjects will be adequately protected;
 - legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provision of the regulation; and the conduct of the activity will be reviewed at timely intervals.
- 3 This institution will provide for Board reviews to be conducted objectively and in a manner to ensure the exercise of independent judgment of the members. Members will be excluded from review of projects or activities in which they have an active role or conflict of interest.
- 4 This institution will encourage continuing constructive communication between the Board and Project Director as a means of safeguarding the rights and welfare of the subjects.
- 5 This institution will have established procedures for referring subjects to appropriate professionals for treatment of physical, psychological, or other injury suffered as a result of participation in an activity.
- 6 This institution acknowledges that it will bear responsibility for the proper performance of all work and services including the use of human subjects under each grant or contract covered by this assurance including continuing compliance with pertinent state or local laws, particularly those concerned with informed consent.
- 7 This institution will maintain appropriate and informative records of the Board's review of applications and activities, of documentation of informed consent, and of other documentation that may pertain to selection, participation, and protection of subjects and to the review of circumstances that adversely affect the rights or welfare of individual subjects.
- 8 This institution will at least annually reassure itself through appropriate administrative overview that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied and are consistent with the regulations and with the implementation of this assurance as accepted by the Department of Health and Human Services.

Appended hereto are: (a) the implementing guidelines of California State University, East Bay, and (b) the list of current members of the Institutional Review Board responsible for review of projects and activities involving human subjects for this institution.

1.0 Preamble

This document sets forth the policies and procedures for the protection of human subjects in research, development, and related activities conducted at or sponsored by California State University, East Bay. It also serves to implement the specific requirements of the United States Department of Health and Human Services (45 Code of Federal Regulations Part 46, as revised FR 40, 11854-58, March 13, 1975, FR 40, 33528-30, August 8, 1975, FR 43, 56173-56198, November 30, 1978, and 58 FR 28012, 28022 June 18, 1991). This statement supersedes all previous East Bay policy statements.

2.0 Application

The policies and procedures described herein apply to all research, development, and related activities involving human subjects, irrespective of source of funding or fact of funding, for which California State University, East Bay is responsible. (For further details, see 4.1 below.)

3.0 Ethical Principles

California State University, East Bay accepts as basic principles the following:

- 3.1 No human being is to be exposed to unreasonable risk to health or well being.
- 3.2 The rights and welfare of all subjects involved in research, development, and related activities who are subject to risk shall be adequately protected.
- 3.3 The risks to an individual must be outweighed by the potential benefit to him or her or by the importance of the knowledge to be gained.
- 3.4 Adequate, appropriate, and legally effective informed consent must be obtained in those cases where human subjects are put at risk.
- 3.5 If publication of research results is done, any assurances concerning publication that an investigator has given to a human subject are to be carried out.
- 3.6 No information concerning a project may be withheld from a potential subject in order to increase the willingness of the subject to participate in the project.
- 3.7 Whenever possible or relevant, any hazard to health conceivably resulting from procedures utilizing human subjects must be first investigated through animal research.
- 3.8 Whenever medicines, surgical, other medical procedures, or exposures to hazardous environmental conditions are used or are likely to occur, the activity must be performed in conformity with high standards of clinical medical practice.
- 3.9 If in the course of an activity an investigator discovers unanticipated risks to a subject that derive directly from the activity, the investigator must obtain the advice of the Associate Vice President of Research and Sponsored Programs (hereinafter referred to as the AVP) on how to deal with such risks, and the latter must inform the sponsoring agency about both the risks and his or her advice. If in the course of a biomedical activity the investigator discovers in a subject an unanticipated symptom or disorder requiring treatment that derives from factors unrelated to the activity, the investigator must bring such information to the attention of the subject's own physician; if the latter cannot be identified, the investigator must inform the subject of the condition and advise the subject to seek medical assistance.
- 3.10 Subjects may be paid, provided that the payment is not so large as to constitute an improper inducement.
- 3.11 If participation as a subject is part of the academic work of a student, it must not be a coercive or mandatory requirement, and appropriate informed consent must be obtained. Instructors using students as research subjects must assign to those not wishing to participate a reasonable alternative academic activity.

- 3.12 The subject's personal privacy must be respected, and the investigator must take steps, when appropriate, to insure the confidentiality of research data.
- 3.13 Research involving vulnerable populations--the mentally or physically infirm, children, prisoners, parolees, addicts, and others in conditions of dependency, helplessness, or deprivation-- will likely require additional precautions to assure protection of the rights of human subjects.
- 3.14 When research takes place in a foreign culture, the investigator must consider the ethical principles of that culture in addition to the principles listed above.
- 3.15 Investigators conducting human subjects research must undergo appropriate training as well as periodic updates to that training as specified by the AVP.

4.0 Definitions

4.1 Research, Development, and Related Activities

Research, development, and related activities include all investigative efforts by faculty and staff that are intended, or used, as contributions to knowledge.

Research, development, and related activities also include all activities by students that meet the above condition and whose results are intended, or used for publication, distribution, or use outside a specific instructional setting, such as presentation at professional and disciplinary conferences. Theses and dissertations that are made available to the public through library copies, microfilm service, or comparable devices count as publications.

Also included as research, development, or related activities are student investigations within instructional settings which meet the above conditions and in which the data are to be used by instructors or other faculty or staff researchers in their own research, development, or related activities.

Research, development and related activities do not include demonstrations and service activities. Nor do they include classroom, laboratory or field exercises conducted by students which result in information that is used only in instructional settings. However, in reviewing the research proposals of students they are advising or instructing, as well as in preparing their own research proposals, faculty should not accept procedures which violate the ethical principles listed in Section 3.0, Ethical Principles.

4.2 Human Subject Involvement

There is human subject involvement when human beings or identifiable human groups are asked to participate physically in an activity or to donate their tissue, organs, fluids, and other bodily material; when information is sought from them directly (as through interview, questionnaire) or indirectly (as through observation); when information concerning specific, individually identifiable human beings or identifiable human groups is asked for from third parties--whether through access to files, data banks, or other means--or through direct inquiry of third parties concerning the individuals in question.

Purely statistical research does not involve human subjects when the data being analyzed are anonymous and not traceable to individuals by the researcher. There is also no human subject involvement when data used in research are taken from the public domain. No human subjects are involved in a research, development, or related activity by use of secondary statistical data from which no individual can be identified by the researcher or other persons.

Involvement exists or does not exist from the outset, and is not affected by any assurances the investigator may provide (e.g. assurance of anonymity) once human subjects are involved. If there is involvement, the Institutional Review Board must review the project to make the initial determination of whether or not risk exists.

4.3 University Responsibility

The University is responsible for activities involving human subjects conducted at the University or using University funds or facilities, sponsored by the University as part of the University's program or

activities, or engaged in by University investigators in the course of their employment. The University is not responsible for privately conducted research activities which do not utilize University facilities, students or staff, are not part of a University program, and which are outside of the scope of employment of the investigators. Such research activities are still subject to all federal and state laws governing the use of human subjects in research. Faculty members engaging in non-University sponsored activities must avoid suggesting by use of their University titles, or in any other way, that these are University sponsored activities.

4.4 Subject At Risk

A subject is at risk if, as a participant in a research, development, or related activity, he or she may be exposed to the possibility of harm--physical, psychological, or social--which exceeds the ordinary risks of public or private living, including the recognized risks inherent in a chosen occupation or field of service, and the application of those established and accepted methods necessary to meet the subject's needs.

Based on the protocol submitted by the principal investigator, the Institutional Review Board is charged with determining the degree of physical, psychological, or social risk, if any, in each case. Physical, psychological, and social risks include the following:

4.4.1 Physical Risks

Physical risks are those present when a substance is injected or ingested into a subject's body or some other physical intervention is performed on the subject's body, or the subject's body is in any way unduly stressed. A physical risk may involve unusual physical activity or strong aversive stimulation. Engaging a subject in a social situation which could involve violence may also create a physical risk.

4.4.2 Psychological Risks

Psychological risks are those present when there is the possibility that a subject will undergo a significant degree of psychological damage or discomfort directly or indirectly as a consequence of participating in an experiment or project.

4.4.3 Social Risk

Social risk exists when there is the possibility that the research may cause the subject to suffer a loss of personal reputation or material possessions, or be put in legal jeopardy, or suffer personal degradation in the eyes of other persons. Ordinarily, such risks can be minimized if the researcher safeguards the confidentiality of the files and conceals the identities of the subjects in the published findings. Additional safeguards may be required if circumstances warrant.

4.5 Informed Consent

Informed consent means the knowing consent of an individual (or of his or her legally authorized representative) to participate in a research, development, or related activity. The individual, or an authorized representative, must be so situated as to be able to exercise free power of choice without undue inducement or any element of fraud, deceit, force, duress, or other form of constraint or coercion. No informed consent, oral or written, shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his or her legal rights, including any release of the University or its agents from liability for negligence. (See Section 7.0 for consent procedures.)

The basic elements of informed consent, all of which must be addressed in research protocols, are:

- (1) a fair and understandable explanation of the nature of the activity, its purpose, and the procedures to be followed, including identification of any procedures which are experimental;
- (2) an understandable description of any attendant discomforts and risks reasonably to be expected;
- (3) an understandable description of any benefits reasonably to be expected;

- (4) an understandable disclosure of any appropriate alternative procedures that might be advantageous for the subject;
- (5) an offer to answer any questions about the procedures;
- (6) an instruction that the person is free to withdraw his or her consent and to discontinue participation in the activity or project at any time prior to its termination without prejudice to the subject;
- (7) an explanation, in the case of research which may result in physical injury, as to whether compensation and medical treatment are available, and if so, what they consist of or where further information about them may be obtained; and
- (8) the Office of the AVP, Research and Sponsored Programs (California State University, East Bay, California 94542, telephone no. 510/885-4212) and Chair of the IRB shall receive and consider expressions of concern from any source regarding adequacy of protection for human subjects involved in research, development, or related activities conducted at or sponsored by CSUEB.

4.6 Legally Authorized Representative

A legally authorized representative is an individual or a judicial or other body authorized under law to consent on behalf of a prospective subject to such subject's participation in the particular activity or procedure.

5.0 The Institutional Review Board

5.1 Membership

California State University, East Bay's IRB shall be a standing subcommittee of the Committee on Research. Its membership shall consist of eleven or more members of varying backgrounds to assure complete and adequate review of research and related activities commonly conducted by the University. The membership shall vary in discipline, profession, racial background, and sex. One member of the IRB must be a community representative and, as such, may not be an employee or related to an employee of the University. The AVP or his/her designee will serve as the IRB Coordinator and an ex officio member of the IRB. The Medical Director of Student Health Services or the Medical Director's designee, and the Chair of the Committee on Research shall be ex officio members of the IRB. The remaining members shall serve by appointment. One shall be a faculty or staff member who has current skills in, and is licensed to provide, psychological counseling. There shall be an equal number of alternate members to serve when a regular member is absent from a meeting. Alternate members will meet the same criteria, and have the same qualifications to serve as do the regular members. All members shall undergo appropriate training as well as periodic updates to that training as specified by the AVP.

5.2 Appointment Procedures

When appropriate, the Committee on Research shall select nominees for the IRB and forward them to the Executive Committee of the Academic Senate. The Executive Committee shall review the nominees, add additional names if it wishes, and forward all nominations to the AVP of Research and Sponsored Programs. The AVP shall select the appointed members of the IRB from among these nominees, except in those instances in which he or she finds the list inadequate in any respect. In such cases, the AVP shall ask the Committee on Research to forward, through the Executive Committee, the names of additional nominees. The AVP shall also have the authority to appoint special members to the IRB in those instances when the Board is considering cases in which Federal regulation requires unique expertise, e.g. experiments with new drugs or research with prisoners. All appointments to and changes in IRB membership shall be reported to the Department of Health and Human Services (hereinafter referred to as DHHS).

5.3 Terms of Service

Appointed members of the IRB shall serve for three years, commencing in a Fall Quarter, except that at the time the Board is initially constituted, half the appointed members shall be named to two-year terms and the other half to three-year terms.

5.4 Meetings

The IRB shall meet as needed in order to review research protocols in a timely manner. When the Chair position is vacant, the AVP shall convene an organizational meeting of the Board. At this meeting, a Chair, who must be an employee of CSUEB, shall be elected. Emergency meetings of the IRB may be called by the Chair or by the AVP.

5.5 Quorum and Voting

A quorum of the IRB shall be a majority of the total membership, and in order to conduct official business, the Board must have a quorum. No member of the Board can vote regarding any activity in which he or she has a conflicting interest. All members and alternates are notified of each meeting and may attend any meeting. An alternate may vote only when substituting for an absent member.

5.6 Committee Review Procedures

Protocols (see Sect. 6.0) should be submitted to the AVP at least two weeks before the next scheduled meeting of the IRB. Normally, the review process will be completed within four weeks after the scheduled meeting of the IRB. Emergency meetings may be called under unusual circumstance. (Note: DHHS requires that IRB certification be submitted within 60 days following the proposal submission date.)

5.6.1 Initial Screening

An initial screening is made by the IRB Chair to determine whether or not human subjects are involved in the activity. (This is a determination of involvement only, not of risk.) If human subjects are obviously not involved, the review process is concluded, the proposal is approved and certified, and is forwarded to the potential sponsor or returned to the investigator. In cases which are not obvious, the IRB Chair consults with the AVP, and if the AVP finds any possibility of human subject involvement, the protocol is reviewed by the Chair as specified in 5.6.2.

5.6.2 Initial Review

The IRB Chair conducts a preliminary review of each protocol, proposal, and related documents to determine whether the materials submitted (particularly the protocol) are sufficiently informative and complete to constitute a basis for a knowledgeable and fair review by the entire IRB. An inadequate protocol will be returned to the investigator until the protocol conforms to the specifications given in Section 6.0. The IRB Chair determines whether a protocol is exempt from review, is eligible for expedited review or requires full board review.

5.6.3 Board Review

In evaluating a project, the IRB makes four basic determinations:

- (1) whether or not the subjects are at risk, and if they are, whether the risks are so outweighed by the potential benefit to the subjects themselves or by the importance of the knowledge to be gained as to warrant a decision to allow them to accept those risks.
- (2) whether the rights and welfare of the subjects are adequately protected;
- (3) whether informed consent is being obtained by adequate, understandable, and appropriate methods (see Sections 4.5, 7.0, and 7.1); and
- (4) whether the conduct of the activity is to be reviewed at timely intervals (see Section 5.6.4).

Investigators are notified in writing of the decisions of the IRB. For approved projects requesting extramural funding, a certification of IRB approval is forwarded to the agency. A project that is disapproved by the IRB is done so without prejudice for resubmission at a later date, and the reasons for such disapproval are conveyed in full to the investigator. Investigators wishing to appeal decisions to modify or disapprove a protocol may, in writing, explain their reasons and request a hearing.

5.6.4 Continuing Review

Projects extending beyond a period of one year require continuing review and approval by the IRB.

The IRB may specify a shorter period for continuing review of a given project. If the research protocol remains unchanged, investigators are required to provide the IRB with a copy of the protocol which they are currently following, and assure the IRB, in writing, that the actual use of human subjects has been conducted in accordance with the approved protocol and conditions, if any, imposed by the IRB, and that no changes are intended. If changes are planned, investigators are required to specify them in their protocol, and obtain approval of these changes or additions.

Continuing review may also involve the preparation of scheduled progress reports or it may involve the establishment of ad hoc committees to conduct project site visits; in rare, although conceivable, instances it may involve the appointment of an independent ad hoc committee which would have the sole function of protecting the subjects' interests.

If in the conduct of research, problems involving risks to human subjects arise which were not foreseen in the protocol approved by the IRB, the investigator must report such problems to the IRB. In the case of projects involving adverse reactions (for example, to drugs or to medical services) the IRB will promptly report such problems to the DHHS, or other sponsoring agencies.

5.6.5 Support Services for the IRB

Meeting rooms, secretarial services, and related logistic support for the IRB shall be provided by the Office of Research and Sponsored Programs.

5.6.6 Annual Report

The Chair of the IRB shall report annually in writing to the AVP and through the Chair of the Committee on Research to the Chair of the Academic Senate. The annual report will include the following information derived from IRB meeting minutes and other records:

- (1) The dates of all IRB meetings and the attendance.
- (2) The total number of projects and activities reviewed, including statistics on expedited reviews, approvals, rejections and deferred protocols.
- (3) The current membership of the Board with terms of appointment indicated.
- (4) A citation of current, relevant legislation and regulatory requirements which govern the actions of the IRB.
- (5) Notes on developments at the national, state, local community and university levels that may require policy revisions to provide assurance as defined by Federal regulations, changes or addenda or other administrative attention or action.
- (6) Recommendations for administrative or Academic Senate actions for maintaining an effective institutional review function for the purpose of protecting the rights and welfare of human subjects.

5.6.7 Additional Procedures

The IRB may adopt additional procedures subject to the approval of the Committee on Research, the Executive Committee of the Academic Senate and the President of the University. Such procedures may cover, but are not limited to, criteria for calling emergency meetings, expedited reviews, and the like.

5.7 Cooperative Activities

California State University, East Bay assumes full responsibility for human subject protection for any project sponsored by this campus regardless of possible co-sponsorship by or cooperation with any other institution. Thus, every such project is subject to review by the CSUEB IRB. The Provost and Vice President, Academic Affairs may waive the requirement for a complete review of a cooperatively sponsored project upon receiving a recommendation to so waive from both the AVP and the Chair of the IRB.

5.8 Expressions of Concern and General Information

The Office of Research and Sponsored Programs (California State University, East Bay, California 94542, telephone no. 510/885-4212) and the Chair of the IRB shall receive and consider expressions of concern from any source regarding adequacy of protection for human subjects involved in research, development, or related activities conducted at or sponsored by CSUEBH. The AVP and the Chair of the IRB shall also provide investigators with information regarding all regulations and procedures affecting protection of human subjects in research, development and related activities.

5.9 Research on Fetuses, Pregnant Women, and In Vitro Fertilization

Research in these categories will be reviewed and monitored in conformance with DHHS regulations, Paragraph 46.205, FR 40, 33529, August 8, 1975 as amended at 43 FR 1759, January 11, 1978.

5.10 Investigational New Drug 30-Day Delay Requirement

Where DHHS requires a certification (Part 46, Title 45, CFR amended March 13, 1975, under Paragraphs 46.11, 46.12, 46.13, or 46.14) and the application or proposal involves an investigational new drug within the meaning of The Food, Drug, and Cosmetic Act, the drug shall be identified in the certification together with a statement that the 30-day delay required by 21 CFR 312.1(a) (2) has elapsed and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects; or that the Food and Drug Administration has waived the 30-day delay requirement: except that in those cases in which the 30-day delay interval has neither expired nor been waived, a statement shall be forwarded to DHHS upon such expiration or upon receipt of a waiver.

6.0 Protocols

A protocol is a statement by the investigator which conforms to provisions 6.1 through 6.10 below.

A protocol must be prepared for all research, development, or related activities in which human subjects are involved or in which there is a question of involvement, and submitted to the IRB. A research proposal may serve as a protocol, but proposals often are lengthy while not answering all of the concerns of the IRB. Eleven copies of a protocol must be provided, either when initially submitted or after having passed the initial review (see Section 5.6.2).

A protocol must contain the following information:

- 6.1 A brief summary of the nature and purpose of the research, development, or related activity.
- 6.2 A description of the subjects and how they are selected, indicating explicitly whether any are minors (under the age of 18 under California Law) or otherwise members of "vulnerable" populations (the mentally or physically infirm, prisoners, or other individuals whose ability to give voluntary informed consent may be in question). The protocol must indicate if any subjects are California State University, East Bay students.
- 6.3 A description of how the subjects are to be used.
- 6.4 A description of the benefits, if any, to the human subjects, and of the benefits to knowledge.
- 6.5 A description of the risks, if any, to the subjects. Such risks may be physical, psychological, social (see Section 4.4).
- 6.6 A description of the means to be taken to minimize such risks, including the means by which the subject's personal privacy is protected and the confidentiality of the information obtained from him or her maintained.
- 6.7 If human subjects are to be put at risk, a description of the procedures to be used in obtaining and documenting the informed consent of the subjects. If written consent forms are to be used, a copy of the consent form and a verbatim copy of any accompanying oral instructions should be attached to the protocol (see Sections 4.5 and 7.1 for the nature of such forms and oral instructions and the

circumstances associated with their use).

- 6.8 If a waiver from the requirement of written informed consent is sought, the justifications for the waiver should be specified (see Section 7.1).
- 6.9 If questionnaires or interview schedules are to be used in the project, a copy of each should be attached. If they are not available at the time of submission, an informative description of their content and manner of administration should be included in the protocol, along with an assurance that when completed they will be filed with the IRB.
- 6.10 The protocol must be signed by the investigator and the appropriate department chair. If the investigator is a student, the signature of the faculty sponsor is also required. If the investigation is part of a larger project or training program, the title and identifying number of the latter should be provided.

7.0 Consent

Any investigator proposing to place any subject at risk is obligated to obtain and document legally effective informed consent. No such informed consent, oral or written, shall include any exculpatory language through which the subject is made to waive, or to appear to waive, any of his or her legal rights, including any release of the Institution or its agents from liability for negligence.

7.1 Documentation of Informed Consent

The documentation of consent will employ one of the following three forms:

(a) Provision of a written consent document embodying all of the basic elements of informed consent. This may be read to the subject or to his or her legally authorized representative, but in any event the subject or legally authorized representative must be given adequate opportunity to read it. This document is to be signed by the subject or his or her legally authorized representative. Sample copies of the consent form as approved by the IRB will be retained in its records.

(b) Provision of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to the subject or his or her legally authorized representative. Written summaries of what is to be said to the subject are to be approved by the IRB. The short form is to be signed by the subject or a legally authorized representative and by an auditor witness to the oral presentation and to the subject's signature. A copy of the approved summary, annotated to show any additions, is to be signed by the persons officially obtaining the consent and by the auditor witness. Sample copies of the consent form and of the summaries as approved by the IRB will be retained in its records.

(c) Modifications of either of the primary procedures outlined in paragraphs (a) and (b) of this section. The IRB will grant permission to use modified procedures only if: (1) the risk to any subject is minimal, (2) use of either of the primary procedures for obtaining informed consent would surely invalidate objectives of considerable immediate importance, and (3) any reasonable alternative means for attaining these objectives would be less advantageous to the subjects. The IRB's reasons for permitting the use of modified procedures will be individually and specifically documented in its minutes and reports. All such modifications will be regularly reconsidered as a function of continuing review and as required for annual review, with documentation of reaffirmation, revision, or discontinuation, as appropriate.

7.2 Retention of Signed Consent Forms

Because signed consent forms may have evidentiary importance in respect to University liability, they must be stored in the files of the appropriate unit (department, organized research unit, or school). These will be considered privileged institutional records and protected for confidentiality of information on individual subjects to the extent authorized by law.

8.0 Presidential Authority

The President of California State University, East Bay reserves authority to prohibit or suspend any research,

development, or related activity he or she finds not in compliance with these procedures or with current federal and state laws and regulations regarding the protection of human subjects. All such actions will be reported to the IRB and to the Chair of the Academic Senate.

California State University, East Bay

Institutional Review Board

POLICY ON TRAINING REQUIREMENTS FOR INVESTIGATORS USING HUMAN SUBJECTS**BACKGROUND:**

The Office of Human Research Protections (OHRP) of the Department of Health and Human Services (DHHS), which oversees research that utilizes human subjects, recommends that a) IRB members and staff complete relevant educational training before reviewing human subjects research; and b) research investigators complete appropriate institutional educational training before conducting human subjects research¹. Further, the Chancellor of the California State University, in Executive Order 890 states that campus policy shall incorporate provisions for adequate training of research personnel and for multi-institutional Sponsored Programs².

The CSUEB Institutional Review Board (IRB) is charged, in its review of human subjects research protocols, with determining that all personnel conducting research using human subjects are appropriately qualified and trained.

POLICY:

It is the policy of California State University East Bay (CSUEB) that all faculty, students, and staff who conduct non-exempt research involving human subjects receive training in the protection of human subjects in research. Faculty, students, and staff who conduct exempt research are strongly encouraged to complete training as well. The IRB makes the determination as to whether a research project is exempt or not after the Primary Investigator (PI) submits a research protocol.

The IRB has established the following policy on training requirements for researchers conducting non-exempt research using human subjects:

1. Prior to the start of any research activity or recruitment of subjects, all research personnel (faculty, students, and/or staff) who will interact with the human subjects or artifacts resulting from the human subjects research which contain private, identifiable information about the subjects (e.g., audio or videotapes, completed surveys, observation notes) must receive training in the basic principles of human subjects research.
2. It is the responsibility of the PI to ensure that all research personnel listed above receive the required training in human subjects research principles. This training must be documented in writing.
3. All faculty, students, and staff who conduct research using human subjects are required to update their human subjects training at least once every three years to ensure that they remain current on laws, regulations, guidelines and policies.

It is also the policy of CSUEB that all Institutional Review Board (IRB) members receive training prior to beginning review of research protocols, and ongoing education opportunities.

1. Prior to reviewing any human subjects research protocols, IRB members must receive training in the basic principles of human subjects research. It is the responsibility of the

chair of the IRB to ensure that all IRB members receive the required training and maintain documentation of such completed training.

2. All IRB members are required to update their human subjects training at least once every three years to ensure that they remain current on laws, regulations, guidelines and policies.

¹ Office of Human Research Protections (OHRP), Department of Health and Human Services (DHHS), Federalwide Assurance (FWA) for the Protection of Human Subjects, Section A, Subsection 12 Educational Training, January 6, 2005.

² California State University, Office of the Chancellor, "Executive Order 890", Section 3.4.2 Human Subjects Research, January 7, 2004.

California State University, East Bay
Institutional Review Board

TRAINING PROCEDURES FOR INVESTIGATORS USING HUMAN SUBJECTS

I. Training/Ongoing Education of Principal Investigator and Research Team

One component of a comprehensive human research protection program is an education program for all individuals involved with research subjects. Investigators must review core training documentation including the CSUEB *Policies and Procedures for Human Research Protection* and the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. CSUEB maintains a subscription to the web-based “**CITI Course in the Protection of Human Research Subjects**” sponsored by the Collaborative Institutional Training Initiative (CITI) and the University of Miami at <http://www.citi.org>.

To satisfy the initial education requirement, investigators must complete either the Social and Behavioral Research modules or Biomedical Research modules as appropriate with an overall competency level of 80%. It is the responsibility of the PI to ensure that all research personnel receive the required training in human subjects research principles. For student researchers, the faculty advisor is responsible for ensuring that they receive the required training. New research protocols and applications for continuing review will not be approved until investigators and applicable members of their team have completed the required training and provided documentation of such completion to the IRB office in the Office of Research and Sponsored Programs (ORSP). ORSP will maintain a database of individuals who have completed training.

Waiver of Initial Education - If investigators or members of their research team can verify that they have successfully completed human subjects research training equivalent to that required by IRB, they may request a waiver of the requirement. For example, certification of attendance at one of PRIM&R’s *IRB 101 On the Road* workshops or completion of the Department of Veterans Affairs training, *Overview of Good Clinical Practice and Human Subjects Protection*, could qualify as equivalent training and could satisfy the requirement. The IRB reserves the right to review the training and experience of those conducting the research project.

Continuing Education and Recertification - All PIs, staff, students and research personnel who conduct research using human subjects are required to update their human subjects training at least once every three years to ensure that they remain current on laws, regulations, guidelines and policies. This must be accomplished by taking the on-line “refresher course” offered by CITI through CSUEB. PIs should submit documentation of the successful completion of the refresher course by all personnel involved in human subjects research to the Office of Research and Sponsored Programs.

Additional Resources

1. Human research protection information will be made available on the ORSP web page on an ongoing basis to ensure that the University research community is apprised of current regulatory and policy requirements and training opportunities.
2. Training workshops offered by the ORSP.
3. The website for the federal Office of Human Research Protections is <http://www.hhs.gov/ohrp/>.

II. Training/Ongoing Education of IRB Chair and Board Members in Regulations and Procedures

A vital component of a comprehensive human research protection program is an education program for the institution. CSUEB is committed to providing training and an on-going educational process for IRB members and alternates related to ethical concerns and regulatory and institutional requirements for the protection of human subjects.

Orientation

New IRB members, including alternates, have the opportunity to meet with the IRB Chair for an orientation session. At the session, the new member will be shown:

- The ORSP web site that incorporates the IRB pages.
- Navigation of the web site to find the protocol application, training materials, and other relevant information.
- Records pertinent to the IRB kept in the Office of Research and Sponsored Programs.
- Federal regulations relevant to IRB.

Initial Education

CSUEB maintains a subscription to the web-based “**CITI Course in The Protection of Human Research Subjects**” sponsored by the Collaborative IRB Training Initiative (CITI) and the University of Miami at <http://www.citiprogram.org>. IRB members must complete the group of modules named “IRB Member” which covers history, regulations, review processes, research with children, and IRB member responsibilities. All modules are available for further education.

To satisfy the initial education requirement, the IRB Chair and the IRB members must complete the required course with an overall competency level of at least 80%.

Continuing Education

To ensure that oversight of human research is ethically grounded and the decisions made by the IRB are consistent with current regulatory and policy requirements, training is continuous for IRB members throughout their service on the IRB. Board members must update their human subjects training at least once every three years by taking the on-line “refresher course” offered by CITI through CSUEB. Board members should submit documentation of the successful completion of the refresher course to the Office of Research and Sponsored Programs.

Additional, optional educational activities include, but are not limited to:

- In-service training at IRB meetings.
- Training workshops.
- IRB forum listserv at <http://www.irbforum.org>.
- Dissemination of current events articles relevant to human research protection.
- Unlimited access to the IRB office resource library.