

## California State University, East Bay Institutional Review Board Procedures

(This document is a living document and will be revised as federal, state, local, or other regulations protecting human subjects evolve. Revision dates will be duly noted above.)

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## 1. Mission

Cal State East Bay (officially, the California State University, East Bay, abbreviated as CSUEB) fosters a research environment that promotes the respect for the rights and welfare of individuals recruited for, or participating in, research conducted by or under the auspices of the University. In the review and conduct of research, actions by CSUEB will be guided by the principles (i.e., respect for persons, beneficence, and justice) set forth in the ***Ethical Principles and Guidelines for the Protection of Human Subjects of Research*** (often referred to as the Belmont Report) and will be performed in accordance with the Department of Health and Human Services (DHHS) policy, and regulations at 45 CFR 46, and the Federal Policy for the Protection of Human Subjects as revised effective January 21, 2019, (also known as the [revised Common Rule](#)). For the purposes of this policy, all references to the Common Rule or revised Common Rule will cite the regulations in 45 CFR 46, keeping in mind that each agency and department has its own CFR section.

The actions of CSUEB will also conform to all other applicable federal, state, and local laws and regulations regarding the conduct of research with human subjects.

To conduct this responsibility effectively, the University maintains an Institutional Review Board (IRB) to review research protocols involving human subjects and to evaluate both risk and protection against risk for those subjects. It is the function of the IRB to:

1. determine and certify that all projects reviewed by the IRB conform to the regulations and policies set forth in the pre-2018 Common Rule or revised Common Rule, as applicable, regarding the health, welfare, safety, rights, and privileges of human subjects; and
2. assist the investigator in complying with federal and state regulations.

CSUEB adheres to the CSUEB Assurance of Compliance with Federal Regulations on Protection of Human Subjects.

### 1.1. Introduction

These written procedures of ***the CSUEB Institutional Review Board*** were designed with consideration of a sampling of written procedures from other Institutes of Higher Education. Much appreciation is provided to Cal Poly Pomona IRB for their permission granted to CSUEB to create this document with modifications to the Cal Poly Pomona policies and procedures. The Cal Poly Pomona policies were based on a model created by Dr. Jeffrey M. Cohen CIP, JRP Associates, Inc. to whom acknowledgement is also given.

The IRB also expresses its appreciation to the research community associated with CSUEB in complying with the CSUEB Assurance and these written procedures designed to assure the protection of humans. It is they who contribute to the advancement of scientific understanding and derive benefit from this document.

The CSUEB Assurance and the written procedures are guided by the federal regulations and the [DHHS Institutional Review Board Written Procedures: Guidance for Institutions and IRBs](#). These procedures are designed to meet federal, state, and local regulations governing research with human subjects and the requirements for submitting research proposals for review by the CSUEB IRB and apply to all research involving human subjects, regardless of sponsorship and performance site, where any CSUEB faculty, staff, students, or facilities are involved.

As the field of human research protection evolves, sections of this manual may be subject to change. The Institutional Review Board at CSUEB will keep the University's research community apprised of all developments. For further information contact the CSUEB IRB Coordinator at [irb@csueastbay.edu](mailto:irb@csueastbay.edu).

The CSUEB Assurance and Procedures are available on the [CSUEB IRB website](#).

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 cited within this document or as may be determined by the US Department of Health and Human Services (DHHS) Secretary.

## 1.2. Ethical Principles: The Belmont Report

### The Belmont Report

It is the duty of the CSUEB IRB to review and make decisions on all protocols for research involving human subjects. The primary responsibility of the IRB is the protection of research subjects from undue risk and from deprivation of personal rights and dignity. This protection is best assured by consideration of **three principles**, which are the touchstones of ethical research:

- (1) that voluntary participation by the subjects, indicated by free and informed consent, is assured;
- (2) that an appropriate balance exists between the potential benefits of the research to the subject or to society, and the risks assumed by the subject; and
- (3) that there be fair procedures and outcomes in the selection of research

subjects. These principles are summarized as **respect for persons**, **beneficence**, and **justice**.

### Respect for Persons: Voluntary Participation and Informed Consent

Assurance of voluntary informed consent is one of the most important elements in any research involving human research subjects.

- Any person who is to be a research subject, whether designed for their own direct benefit or for the advancement of scientific knowledge in general, must understand as completely as possible what is to be done and what the potential risks and benefits are. They must give their consent freely, without pressure or inappropriate inducement. The IRB at CSUEB will carefully review the recruitment and consent processes as well as the informed consent documents to ensure voluntary informed consent of research subjects.
- The informed consent concept is extended to those studies in which the subjects are not able to give personal consent for themselves. Here the consent document is addressed to those who have been designated responsible for the research subject's well-being (e.g., parents of children, guardians of those with impaired decision-making capability). The IRB review will verify that the consent process and documents will likely assist participants and in making an informed decision.
- The capacity for truly informed and voluntary participation in research varies widely among study populations. At one extreme there may be ample understanding and manifest freedom from coercion; at the other, there may be degrees of understanding and freedom that affect the consent of potential subjects. The IRB must exercise special care when considering subjects whose ability to give free and informed consent may be compromised in any way.

### Beneficence: The Risk-Benefit Ratio.

The IRB is charged with deciding, for any proposed activity that falls under its jurisdiction, whether the "risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

- The assessment of the risk/benefit relation is a complex task.
  - There are risks of injury or discomfort to the individual that can be physical, psychological, and/or social.
  - There can be potential benefits to the individual, to a group to which the individual belongs, and/or to society.
  - When reviewing applications, members of the IRB must carefully assess the types and degrees of both risks and benefits for a given subject population, as well as the investigator's communication of these risks and benefits in the consent process and form.
  - The design of the study must be sound, and the nature and likelihood of all risks and benefits must be made clear in any application to the IRB. While the IRB is not charged with reviewing scientific design per se, it must sometimes do so in order to assess the risk/benefit ratio. If a study design does not seem adequate to attain the stated aim of the investigation, then no benefit can be anticipated from conducting the study, and there is no justification for placing any research subject at risk, however minimal.

## **Justice: The Fair Selection of Research Subjects.**

Both the risks and the potential benefits of research should be spread fairly among potential individual research subjects and research subject groups. Study design and selection of subjects should avoid bias for or against particular social, racial, sexual, or ethnic groups.

- **Sharing Research Risks.** The guiding principle in the ethical selection of research subject groups is that any risks of the research should fall upon the groups who might benefit from the research.
  - If the results of a risky protocol might benefit the general population, it would be unethical to focus subject recruitment on vulnerable or disadvantaged groups (e.g. institutionalized people or prisoners; patients at free clinics primarily patronized by people unable to afford other medical care) simply because they are easily accessible or can be persuaded to participate.
  - An undue share of research risks should also not burden groups already burdened by other factors. A fair sampling of the populations who might benefit from the study should be included.
  - When research involves persons whose autonomy is compromised, it is expected that the research bears some direct relationship to the conditions or circumstances of the research subject population. In addition, groups fully able to consider research risks and informed consent should be asked to face research risks before more vulnerable populations.
  - Investigational drugs are usually tested in adults before being tested in children. Certain investigational drugs and procedures may be tested in healthy volunteers before patients.
- **Sharing Research Benefits.** It is prudent to include various groups in research.
  - As individuals and through advocacy groups, many patients have come to insist on access to experimental treatments that may potentially provide the best medical care available.
  - Researchers, ethicists, and public officials have recognized that because many clinical trials focused primarily on white middle-class research subject groups, the results of some trials were of questionable value for members of other social, racial, sexual, and ethnic groups.
  - Federal agencies now require that study design include a broad range of research subjects and that data be analyzed to uncover responses that differ between groups.
    - E.g., Where women of child-bearing potential and pregnant and nursing women previously were routinely excluded from new drug trials, it is now required that whenever possible these women be asked to make their own choices after being fully informed of the risks of the research.

## **2. Definitions (as used for the purposes of these procedures)**

**Assent** – A child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

**Assurance** – Federal regulations require that each entity that applies for a grant, contract, or cooperative agreement under 45 CFR part 46 for any project or program that involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application for such grant, contract, or cooperative agreement an assurance that it has established in accordance with regulations a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects conducted at or supported by such entity in order to protect the rights of the human subjects of such research.

**AVP** – Associate Vice-President

**Certification** - The official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

**Children** – Children are individuals who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Residents under 18 years of age are considered minors in California, unless they are "emancipated" by court order. For research with children in other jurisdictions, such as foreign countries, the investigators may be asked to clarify the age of being an adult.

**CSUEB** – California State University, East Bay; also known as CSUEB

**Dead Fetus** – A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

**Delivery** – Complete separation of the fetus from the woman by expulsion or extraction or any other means.

**DHHS** – Department of Health and Human Services (a federal agency)

**EH&S** – Environmental Health and Safety, at CSUEB

**Exempt review** – Once a protocol has been reviewed and deemed Exempt, it is known to have received Exempt review. Studies that receive an exemption determination from IRB are exempt from the specific regulations and requirements in Title 45, Part 46 of the Code of Federal Regulations. They are, however, still considered human subject research. The Cal State East Bay IRB initially reviews all human subjects research to determine whether it is Exempt or Non-Exempt.

**Expedited Review** – Expedited Review is the process of protocol review by one to four members of the IRB rather than the full board because the study has potentially minimal risk to the human subjects. Expedited does not necessarily mean a rapid review, though it usually requires less time to complete than a full board review. What constitutes expedited review is extensively defined by federal regulation. Types of research that may be reviewed using the Expedited Review method are listed in and defined by federal regulation.

**Federalwide Assurance (FWA)** – FWA provides assurance that the institution receiving HHS support will follow HHS regulations for human subjects found in 45CFR46. The OHRP website provides decision charts and other guidance to determine if a research project is considered human subjects research.

**Fetus** – A fetus is the product of conception from implantation until delivery.

**Full Board review** – the process by which a study involving human subjects, due to high levels of risk, must be evaluated. The IRB conducts the review "full," meaning at a convened face-to-face in-person or

online meeting with quorum. What constitutes a full review is defined by federal regulation.

**Generalizable Knowledge** – Generalizable Knowledge is knowledge gained from a study that may be or is intended to be applied to populations outside of the specific study population and institution, to inform policy, other researchers, and the public.

#### **HRPP** – Human Research Protections Program

**Human Subject** – A living individual about whom an investigator (whether professional or student) conducts research:

1. Obtains information or biospecimens through intervention<sup>a</sup> or interaction<sup>b</sup> with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information<sup>c</sup> or identifiable biospecimens.

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

<sup>b</sup> Interaction includes communication or interpersonal contact between investigator and subject. This includes survey and questionnaires, even if there is no direct contact between the investigator and subject.

<sup>c</sup> Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, medical records or student records). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.]

**Human Subjects Research** – “Human subject research” is defined in 45 CFR 46.102(f). In addition, student research, if it involves human subjects as defined in 45 CFR 46.102(f) is included, even if the activity does not meet the definition of research in the same section.

1. Under 45 CFR 46.102(f), research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components, which constitute research activities under this definition.

**Institutional Official (IO)** – The IO has oversight of the University’s human research protections program, including appointment of members to the IRB, signature authority for documents provided to DHHS (Assurance Signatory Official), and resource allocations to the IRB. The IO has no voting privileges on the IRB).

**Investigator** – (sometimes referred to as a “Principal Investigator” or PI) is any individual who actually conducts the research project and who, typically, submits a human subject protocol to the IRB.

- In the event of an investigation conducted by a team of individuals, the investigator is the leader and person directly accountable for supervising the research at CSUEB.
- An investigator may be a CSUEB faculty member (including lecturers, emeriti, and faculty on Faculty Early Retirement Program (FERPs), staff member, or administrator.
- CSUEB students may be investigators with the oversight of a CSUEB responsible investigator (RI), who sponsors and/or mentors the work of the student and assumes ultimate responsibility for the conduct of the approved protocol.
- Off-campus persons may be investigators using the resources of the CSUEB campus with a RI (responsible investigator) from CSUEB engaged in the research or with approval from the CSUEB IRB, and must submit evidence of IRB approval from their “home” institution.
- All investigators must show familiarity with the research discipline and for non-exempt research much show appropriate evidence of training in human subject protection.

**Note:** The term "investigator" as defined and used by CSUEB may not be equivalent to the definition or use of that term by grant and contract agencies. The status of persons having a role in the conduct of research, but who do not fit within any of the above definitions will have their status evaluated on a case-by-case basis by the CSUEB IRB.

**IRB** – An Institutional Review Board established in accord with and for the purposes expressed in the IRB policy.

**IRB Approval** – The determination of the IRB that the research has been reviewed and may be conducted at or in association with the institution within the constraints set forth by the IRB and by other institutional and federal requirements.

**IRB Coordinator** – The staff position at CSUEB responsible for administrative support to the IRB. Duties include, but may not be limited to, the first review of protocols, communications with PIs and IRB members, meeting coordination, IRB meeting minutes, IRB training program tracking, and IRB and program record keeping. The IRB Coordinator is an ex-officio member of the IRB.

**Legal Guardian** – A Legal Guardian is an individual authorized under applicable State or local law to consent on behalf of a child to general medical care.

**Legally Authorized Representative (LAR)** – An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**Limited Review** – The process of reviewing a protocol, typically by the chair of the IRB or their designee, that is not subject to either expedited review or full review, as defined in regulations and further in this document.

- Federal regulations require that the IRB reviews certain research for Limited review, and that the IRB reviews all research that falls into several Exempt categories rather than have the Principal Investigator make the determination. In such cases, Limited Review or Exempt review is required at the minimum to ensure provision for the privacy of the subjects and confidentiality of the data.
- At CSUEB, an initial limited review may be completed for all Exempt-category research and will include review of all protocol elements required for Expedited Review.
- Protocol applications with surveys that collect data, whether anonymous or not, are often reviewed by the Limited Review method, and the review may be Expedited.

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

- For research involving college students for example, "minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in their daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

**Neonate** – A neonate is a newborn.

**Nonviable Neonate** – A neonate that is living after delivery, but not expected to live long is known as nonviable.

**OHRP** – Office of Human Research Protections, an agency within DHHS that has federal oversight of human subject research and administering programs.

**ORSP** – The Office of Research and Sponsored Programs at CSUEB is tasked with providing support to the IRB and is overseen by the AVP Research and Sponsored Programs.

**Permission** – Permission is the agreement of parent(s) or a legal guardian to the participation of their child or ward in research.

**Parent** – The term parent is used for a child's biological or adoptive parent.

**Pregnancy** – encompasses the period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

**President** – Refers to the president of Cal State East Bay.

**Prisoner** – The term prisoner is used for any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Protocol** – A protocol is the document completed by the PI(s) that describes the how, what, when, where, who, and why of a proposed study. It is submitted as an application of the proposed research study to the IRB for review.

- The protocol for human subject research includes, but is not limited to the following:
  - how the research came about (the background)
  - who will conduct the study and the human subject activity and their training
  - who the subjects are and how they will be recruited
  - how the data will be collected, for example the survey instruments
  - how the data and the human subjects' privacy will be protected
  - what measures will be in place to provide notice of and protection against any risks, for example the consent, assent, and permission forms
  - what potential conflicts of interest may be perceived or actual and how will they be mitigated

The IRB may ask for additional material to explain and clarify the study. No work can begin on a protocol until it has been reviewed and approved by the IRB.

**Quorum** – A quorum of the IRB consists of a simple majority of the voting membership in attendance at an IRB meeting or vote-by-email, including at least one member whose primary concern is in a non-scientific area.

**Reliance Agreements** – A human subject research reliance agreement is a signed authorization agreement between institutions engaged in human subject research that cedes review of the research activities to the Institutional Review Board (IRB) of one of the institutions.

**Student** – The term is inclusive of all students: undergraduate and graduate students; senior scholars; McNair scholars; and Doctorate of Education students (EdD) in conjunction with other institutions.

- At CSUEB students may submit protocols, but they must be supervised or mentored by a faculty member who acts as their advisor and is the Principal investigator ultimately responsible.
- At CSUEB the Cayuse Human Ethics (IRB) system is used for submission of protocols. When submitting the protocol the research team lists the faculty as Principal Investigator and the Student as Co-PI.

**Systemic Investigation** – A systemic investigation is an investigation that involves a prospective research plan which incorporates data collection, quantitative, qualitative, or both, and data analysis to answer a research question. Systemic investigations designed to develop or contribute to **generalizable knowledge** are those designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations outside of the specific study population), inform policy, or generalize findings.

**Viable** – Viable as it pertains to the neonate means being able to survive after delivery (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

### **3. Institutional Authority**

The President of Cal State East Bay has designated the Associate Vice President (AVP) from the Office of Research and Sponsored Programs (ORSP), who is the Chief Research officer, as the responsible institutional official (IO) for oversight of the University's human research protections program. The ORSP facilitates sponsored research on the CSUEB campus, and provides grant and contract pre-award and post-award services related to research, creative activity, and sponsored programs.

The CSUEB IRB has jurisdiction over all human subject research (as defined below) conducted under the auspices of the institution, which includes research:

- conducted at CSUEB,
- conducted by or under the direction of any employee or agent of CSUEB (including students) in connection with their institutional responsibilities,
- conducted by or under the direction of any employee or agent of CSUEB using any property or facility of CSUEB, or
- involving the use of CSUEB's non-public information to identify or contact human subjects.

#### **3.1. Assurance of Compliance**

California State University, East Bay holds a Federalwide Assurance (FWA) approved by the Office for Human Research Protections (OHRP). The FWA is an institutional assurance through which CSUEB commits to complying with the requirements of 45 CFR 46 for the protection of human subjects.

Under its FWA, CSUEB designates one or more IRBs (internal or external) that are authorized to review human subjects research conducted under the auspices of the institution.

#### **3.2. Cal State East Bay IRB Office**

The CSUEB IRB Office is assisted by the IRB Coordinator, who reports directly to the CSUEB ORSP AVP. The IRB Coordinator serves as the initial and primary point of contact at CSUEB for the Office of Human Research Protections (OHRP), Department of Health and Human Services.

#### **3.3. State Law**

CSUEB and its IRB rely on the counsel of the California State University Office of Risk Management for the interpretations and applications of California State law as it applies to human subjects' research.

#### **3.4. 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 that do not utilize University facilities, students or staff, are not part of a University program, and that 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.

#### **3.5. Ethical Principles**

CSUEB accepts the following as basic principles:

1. No human being is to be exposed to unreasonable risk to health or wellbeing.
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. The risks to an individual must be outweighed by the potential benefit to them or by the importance of the knowledge to be gained.
4. Adequate, appropriate, and legally effective informed consent must be obtained in those cases where human subjects are put at risk.
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.
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.
7. Whenever possible or relevant, any hazard to health conceivably resulting from procedures utilizing human subjects must be first investigated through animal research.
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 with the highest standards of practice.
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 (AVP) ORSP on how to deal with such risks. The AVP ORSP must inform the sponsoring agency of the risks and their 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.
10. Subjects may be paid, provided that the payment is not so large as to constitute an improper inducement.
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.
12. The subject's personal privacy must be respected, and the investigator must take steps, when appropriate, to insure the confidentiality of research data.
13. Research involving vulnerable populations—children, prisoners, parolees, addicts, persons with impaired decision-making capacity, economically or educationally disadvantaged persons, and others in conditions of dependency, helplessness, or deprivation—will likely require additional precautions to assure protection of the rights of human subjects.
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.
15. Investigators conducting human subjects research must undergo appropriate training as well as periodic updates to that training as specified by regulations and the AVP.

## **4. Cal State East Bay IRB**

The CSUEB IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under its auspices.

- CSUEB has one designated IRB with the authority to review, approve, disapprove, and/or require changes in research activities involving human subjects. This IRB has been established in accordance with the requirements of current federal rules.
- The IRB periodically reviews its activity and the institution's IRB policies and procedures.
- The IRB reserves the right to create subcommittees for various purposes such as to evaluate human protections on campus, to establish additional policies and procedures, and to represent the principles of human subject protections.

### **4.1. Authority of the IRB**

The CSUEB IRB reviews and has authority to approve, require modifications in, or disapprove all human subjects research activities conducted under the auspices of CSUEB.

- The IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects [45 CFR 46.111]. In fulfilling these responsibilities, the IRB is expected to review all research documents and activities that bear directly on the rights and welfare of the subjects of the proposed research. Examples of documents that the IRB reviews includes, but is not limited to, the following:
  - the protocol
  - the consent/assent document(s)
  - surveys and interview questions
  - for studies conducted under the Investigational New Drug (IND) regulations, the investigator's brochure are examples of documents that the IRB reviews
  - methods and materials that investigators propose to use to recruit subjects
- Before any human subject is involved in research in relationship to this institution, an IRB will give proper consideration to:
  - the risks to the subjects
  - the anticipated benefits to the subjects and others
  - the importance of the knowledge that may reasonably be expected to result
  - the informed consent (or assent) process to be employed
- The IRB has the authority to suspend, place restrictions upon, or terminate the approval of research activities that fall within its jurisdiction that are not being conducted in accordance with IRB requirements or that have been associated with unexpected adverse events.
- The IRB has the authority to observe or have a third party observe the consent process and the conduct of the research if the IRB determines it to be indicated.

### **4.2. Jurisdiction of the IRB**

The IRB jurisdiction extends to **all** research (funded and not funded) involving human subjects conducted at CSUEB, as well as research conducted elsewhere by CSUEB and/or its faculty, staff, and students.

- Any IRB Chair, member, or staff person who believes that the IRB has been unduly influenced by any party shall have the opportunity to make a confidential report to either the AVP or President, depending on the circumstances. The institution will conduct a thorough investigation and corrective action will be taken to prevent additional occurrences.
- CSUEB, as part of its Federalwide Assurance, has agreed to protect the welfare of all human

subjects involved in research, whether or not the research is conducted or supported by a federal department or agency. Therefore, the CSUEB IRB has jurisdiction over all human subject research conducted at this institution, regardless of funding.

#### **4.3. IRB Relationships and Reliance Agreements**

The IRB functions independently of, but in coordination with, other institutional regulatory committees such as the Environmental Health and Safety office (EH&S) and ORSP. The IRB, however, makes its independent determination to approve or disapprove a protocol based upon whether human subjects are adequately protected. The IRB has review-jurisdiction over all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that has adopted the human subjects' regulations.

- Research that has been reviewed and approved by the IRB may be subject to review and disapproval by officials of the institution. For example, if the campus is not equipped to conduct cancer studies in clinical trials, then an IRB-approved study may not be authorized by the administration. On the other hand, by federal regulation, a decision by the IRB to not approve a human subject study may not be overruled and approved by the administration.
- The CSUEB IRB meets, as necessary, with other University officials such as the provost, the IO, college deans, and academic departments.

**Relationships with other institutions:** CSUEB may choose, on a case-by-case basis, to provide human research protection oversight for another institution. In order for the University to provide this oversight, a formal relationship must be established between the University and the other institution through a Reliance Agreement (see next section)..

- In the conduct of cooperative research projects each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with applicable federal regulations.
- When a cooperative project exists, CSUEB may enter into a joint review arrangement, rely on the review of another qualified IRB, allow another IRB to rely upon the CSUEB IRB review, or make similar arrangements for avoiding duplication of effort.
  - When doing so, CSUEB will ensure that the review arrangement is approved, as required, by the IRB and/or by the appropriate officials of the institutions involved, and that the particular characteristics of its local research context are considered, either (i) through knowledge of its local research context by CSUEB IRB or (ii) through subsequent review by appropriate designated institutional officials, such as the Chair and/or other IRB members.
  - As IO has the authority to approve such reliance agreements.
  - CSUEB may also receive the decision of the IRB review of a protocol from another institution for review when a portion of the investigation involves CSUEB.
    - In evaluating the submission for approval, the CSUEB IRB may, at its discretion: review the paperwork; mandate the creation of a consent form specific to, and meeting the policies of, CSUEB; mandate additional human subjects training; and/or ask for other supporting documentation and information.
- When CSUEB is the coordinating lead center for a multi-center protocol, the Cal State IRB will act as lead IRB for a single IRB, known as sIRB and will require that the submitted protocol includes all required information from all participating institutions or, when not prohibited by federal mandate, may require the CSUEB principal investigator (PI) to ensure (and demonstrate) that IRB approval has been obtained at each participating site prior to initiation of the research at that site.
  - At the time of the initial review, the IRB will assess the procedures for dissemination of protocol information (e.g. unanticipated problems involving risks to participants or others, protocol modifications, interim findings) to all participating sites.

**Reliance Agreements:** A human subject research reliance agreement is a signed authorization agreement

between institutions engaged in human subject research that cedes review of the research activities to the Institutional Review Board (IRB) of one of the institutions.

- Reliance agreements may be referred to by different names depending on an institution's practice, e.g., IRB Authorization Agreement or Interagency Agreement.
- A reliance agreement is not required unless one institution agrees to rely upon another institution's IRB for review of human subject research activities.
- The Institutional Review Board (IRB) is charged with protecting the rights of human subjects who participate in research on or through this campus. This includes research conducted by CSUEB faculty, staff, or student investigators, and also research by investigators from other institutions or agencies working in conjunction with CSUEB in any capacity. The IRB is responsible for ensuring that human subjects are informed about and protected from unnecessary risks that may be associated with participating in research.
- Each institution determines whether they will maintain an Institutional Review Board (IRB) to review and provide oversight of the institution's human subject research. An institution's IRB may decide to review all of that institution's research or to allow reliance agreements in certain scenarios to cede review to another IRB.
- CSUEB's procedure is that all research involving human subjects, exempt and non-exempt, must be reviewed initially by the [CSUEB Review Board \(IRB\)](#) or by [the IRB Office](#).
- The Cal State IRB supports the use of reliance agreements when circumstances allow and such use would be reasonable and prudent
- When a study is deemed Exempt by one of the institutions, and the collaborating institutions concur, then a reliance agreement is usually not warranted, because the study is Exempt from the Common Rule.

Prior to collecting human subject research data, each Principal Investigator (PI) must notify their institution of their research and data collection plans and follow the institution's human subject research policy, which usually entails submitting a full IRB protocol for review.

- When the research involves collaboration with another institution, each Principal Investigator (PI) must notify their home institution of their plans and follow the institution's human subject research "IRB" policy.
- If either collaborating party determines they would like to request a reliance agreement in order to rely on the other institution's IRB for review and oversight of the human subject research, then each PI notifies their home IRB office of that intention and follows the instructions of their respective institutions.
  - The standard approach is that each institution submits a full IRB protocol to their home institution's IRB for review. In their protocol they describe the human subject activity their own campus will do, and they can describe their request for a reliance agreement.
  - Depending on the human subject activities and where they will occur, a full IRB protocol may need to include a copy of the collaborating PI's IRB protocol and IRB approval letter.
  - When the situation warrants it or as prescribed by [federal regulations for a single IRB \(sIRB\)](#), one institution may be asked to be the IRB reviewer for one or more PIs at other institutions, and if so the institutions of the other PIs may request a signed reliance agreement be issued to confirm their reliance on the lead IRB.

#### **Examples:**

##### **CSUEB PI**

- CSUEB (CSUEB) PI plans to conduct human subject research. The CSUEB PI submits an [IRB Protocol](#) to the CSUEB IRB for review.

##### **Cal State East Bay PI with Funding from Another Institution**

- CSUEB PI plans to conduct human subject research under a subaward, service agreement, or other form of funding, from an external agency or institution.
  - The CSUEB PI would plan to submit a full protocol to the CSUEB IRB. If there is a collaborating PI at the lead institution, then both PIs submit full protocols to their institutions.
  - If, however, the CSUEB PI's data will be collected at an awarding institution or there is another reason for the lead institution to have IRB review responsibility over all of the project's Human Subject Research, then each PI involved might agree to request a reliance agreement if their institutions allow. If so, then each PI should notify their home institution of their intent to request the single Reliance Agreement. The CSUEB PI submits their notification through Cayuse.

### **Cal State East Bay Providing Funding to Another Institution**

- CSUEB provides a subaward to or otherwise funds another institution for a project that includes human subject research activities.
  - If the funding is from or related to a CSUEB PI's project, then the CSUEB PI submits an [IRB Protocol](#) to the CSUEB IRB for review, and the PI of the awardee institution submits an IRB protocol to their institution's IRB for review.
  - If the two PIs agree they would like one of the institutions to be the IRB reviewer over both the human subject activities of both PIs, then each PI should include in their protocols that notification of their intent to request the single Reliance Agreement.

For all human subject research projects, review and approval by the IRB depends on many variables, including, but not limited to the specific human subject activities, study population, and where and how the activities will be conducted.

When a CSUEB Investigator requests a Reliance Agreement, the CSUEB PI should create an IRB protocol on Cayuse, providing basic but sufficient details about the research study, and indicating which institution is requesting to be the relying institution and which institution will be providing the IRB review and approval.

## **4.4. Roles and Responsibilities**

### **Chairperson of the IRB**

In consultation with the IRB and IRB Coordinator and with majority approval from the IRB members, the IO will appoint a Chair of the IRB. Any change in appointment, including reappointment or removal, requires written notification to the Chair, the IRB members, and the IRB Coordinator

- When the Chair position is vacant, the IO shall convene an organizational meeting of the Board.
  - To be eligible to serve as Chair, the individual must have served for at least one year on the CSUEB IRB.
  - Whenever possible, the Chair will be a tenured CSUEB faculty member.
  - The Chair is a voting member of the IRB and contributes to establishing quorum.
- The Chair manages the IRB and any matters brought before it. Specific functions include, but may not be limited to:
  - conducting IRB meetings
  - acting as a signatory for correspondence generated by the IRB
  - assigning IRBs for review to IRB members, or consulting with the IRB Coordinator on such assignments.
  - advising the CSUEB IO about IRB member performance and competence.
- The Chair is empowered to perform the following actions:
  - Review and make determinations on protocols which require limited or expedited review. The Chair may delegate the gathering of pertinent information to the IRB Coordinator.
  - Review and make determinations on protocols and reliance agreements with other IRBs.

These determinations are then provided to the IO for approval.

- Review and approve renewals of protocols in which there are no substantial changes to methods or subject handling.
- Review and approve modifications to protocols in which there is no substantial change to risks posed to the subject.
- The Chair may designate other IRB members to perform duties, as appropriate, such as for review, signature authority, and other IRB functions.
  - The Chair or designee may delegate protocol review to an IRB member, including the original reviewer(s).
  - The Chair may delegate the process of pertinent information gathering to the IRB Coordinator.

### **Acting Chair of the IRB**

The Chair may designate an acting Chair in anticipation of their absence. The IO may designate an acting Chair when the Chair is unable to do so. The acting Chair has the same authority and duties as the Chair.

### **Subcommittees of the IRB**

The Chair may create a subcommittee to perform duties, as appropriate, for protocol review, signature authority, and other IRB functions. When appropriate, individuals outside of the IRB membership may be included in subcommittees.

**Duties of a subcommittee** may include the following:

1. Serve as designees to the IRB Chair for the **expedited review** of new or continuing protocols, and/or modifications of continuing protocols. The subcommittee must be experienced in terms of seniority on the IRB, and must be matched as closely as possible with their field of expertise to the study.
2. **Review and approve the revisions** submitted by investigators for a protocol given provisional approval, i.e., "Approval Pending Revisions" by the convened IRB.
3. **Ensure fairness and expertise of an inquiry process.** A subcommittee is appointed consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise of an inquiry process (See Section 11.3 for a discussion of the inquiry process) The subcommittee is given a charge by the IRB, which can include any or all of the following:
  - a. Review of protocol(s) in question;
  - b. Review of FDA audit report of the investigator, if appropriate;
  - c. Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of their study involving human subjects;
  - d. Interview of appropriate personnel if necessary;
  - e. Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting;
  - f. Recommend actions if appropriate.
4. **Conduct on-site review.** Determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis. For example, for an investigator who is performing particularly risky research, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by an IRB subcommittee might occur or approval might be subject to an audit of study performance after a few months of enrollment, or after enrollment of the first several subjects.
5. **Observe the consent process.** When appropriate, the IRB may appoint a subcommittee to observe the consent process being used in a research project.
6. **Establish policy for the campus.** As it pertains to human subject protection, a sub-committee may be constituted to develop and recommend a policy or procedure to the full board.

#### **4.5. Resources for IRB**

The ORSP under the IO at CSUEB provides resources to the IRB and IRB Coordinator, including adequate meeting and office space, staff for conducting IRB business, and funds for professional travel and training related to improvement of the IRB functions at CSUEB. Office equipment and supplies, including technical support, file cabinets, computers, internet access, and copy machines, will be made available to the IRB and staff. The resources the IO provides to the IRB through ORSP will be reviewed during the annual budget review process.

#### **4.6. Reporting & Conduct of Quality Assurance/Quality Improvement Activities for IRB Operation**

The Chair of the IRB shall report annually in writing to the IO, who in turn shares the reporting with the Committee on Research and 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.

The IO and through appropriate mechanisms, will monitor and review the processes and procedures of the IRB to ensure effectiveness, efficiency, and compliance with federal regulations, institutional policy, and these procedures.

In collaboration with the IO, the Risk Management Director of Compliance and Audits, and the Academic Affairs Director of Compliance and Standards, the CSUEB IRB Coordinator or staff designated by the IO will conduct investigations and audits of ongoing research when the IRB directs an audit to be conducted or a complaint or allegation of non-compliance is received.

## 5. IRB Membership

### 5.1. Composition of the IRB

- CSUEB's IRB is designated as a standing subcommittee of the Committee on Research, but with oversight provided by the IO. Its membership shall consist of eleven or more regular members of varying backgrounds and disciplines to assure complete and adequate review of research and related activities commonly conducted by the University. A list of alternate members will cover primary members.
- The AVP ORSP is a non-voting ex-officio member of the IRB. At CSUEB the AVP ORSP is the IO providing the oversight of the IRB.
- ORSP provides the IRB Coordinator as support for the IRB. The IRB Coordinator is a non-voting ex-officio member of the IRB.
- The Medical Director of Student Health Services or the Medical Director's designee, shall be a voting ex-officio member of the IRB.
- The remaining members shall serve by appointment.
- The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
- The IRB will include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.
- There shall be a list 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 IO.
- The IRB will be sufficiently qualified through the experience and expertise of its members, and the **diversity of the members**, including consideration of discipline, profession, race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
- In addition to possessing the **professional competence necessary to review specific research activities**, the IRB will be able to ascertain the acceptability of proposed research in terms of institutional policies and regulations, applicable law, and standards of professional conduct and practice. The IRB will therefore include persons knowledgeable in these areas or call on such expertise when needed.
- If the IRB regularly reviews research that involves a vulnerable category of subjects (e.g., children, prisoners, pregnant women, or persons with physical or mental disabilities), consideration will be given to the inclusion of one or more individuals on the IRB who are knowledgeable about and experienced in working with these subjects.
- Every nondiscriminatory effort will be made to **ensure that the IRB does not consist entirely of one gender identity**, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB shall not consist entirely of members of one profession.
- Any member may satisfy more than one membership category.

## **5.2. Appointment of Members to the IRB**

When positions are open on the IRB, the IRB Chair and the IRB Coordinator will work together to issue an announcement to notify the IO and the CSUEB faculty through the Academic Senate and additional campus communication channels to allow for faculty members to indicate their interest in serving on the board.

- The IRB chair shall select nominees for the IRB from the names received and will forward them to the Committee on Research for review.
- The Committee on Research (CR) will review the list, remove names from it or add to the list and then forward the list to the Executive Committee of the Academic Senate (Ex Com).
- The Executive Committee will review the nominees, add additional names if it wishes, and forward all nominations to the IO
- The IO shall select the appointed members of the IRB from among these nominees provided by the Executive Committee, except in those instances in which they find the list inadequate in any respect. In such cases, the IO will request additional names from the CR and Ex Com, who will subsequently provide additional nominees to the IO.
- The IO 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.

Appointed members of the IRB shall serve for three years, commencing in a Fall Semester. Any change in appointment, including reappointment or removal, requires written notification to the member, the IRB Chair, and the IRB Coordinator. IRB members may resign by written notification to the IRB Chair.

- **Alternate members.** The appointment and function of alternate members is the same as that for primary (or regular) IRB members, and the alternate's expertise and perspective are comparable to those of the primary member.
- The IRB membership roster identifies the primary member(s) for whom each alternate member may substitute.
- Alternates may attend IRB meetings and are encouraged to attend as many meetings as possible.
- The alternate member will not be counted as a voting member unless the primary member is absent. However, the alternate member may freely participate in the discussion.
- When an alternate member substitutes for a primary member, the alternate member will receive and review the same materials prior to the IRB meeting that the primary member received or would have.
- The IRB minutes will document when an alternate member replaces a primary member.
- The alternate in attendance at a meeting is empowered to vote on the approval of minutes when approved electronically even when not serving as the primary member as long as they attended the meeting in question.
- The IRB chair and the IRB coordinator may assign IRB protocols to alternate members for Expedited or Limited Review as applicable.

## **5.3. Use of Consultants (Outside Reviewers)**

The IRB may, at its discretion or when required by federal regulation, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals do not vote with the IRB.

- Prior to committing to review, consultants will be informed of the [CSUEB conflict of interest policy](#) (see also <http://www.csueastbay.edu/orsp/compliance/policy/conflict-of-interest.html>). Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor or sponsorship of the research will not be invited to provide consultation.
- Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality and that is in compliance with the CSUEB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular investigator and research protocol).

#### **5.4. Conflict of Interest – IRB Members**

No IRB member will participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. IRB members are expected to self-identify conflicting interests. A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB staff who will re-assign the protocol. See also the website:

<http://www.csueastbay.edu/orsp/compliance/policy/conflict-of-interest.html>

An IRB member is considered to have a conflicting interest when the IRB member or an immediate family member of the IRB member encounters one of the following conditions:

1. Is an Investigator (PI or Co-PI) or other member of the research team on a research protocol submitted to the CSUEB IRB
2. Has a financial interest in the research whose value cannot be readily determined, whose value may be affected by the outcome of the research, or that exceeds \$10,000
3. Has received or will receive any compensation whose value may be affected by the outcome of the study
4. Has a proprietary interest in the research (property or other financial interest in the research including, but not limited to, a patent, trademark, copyright or licensing agreement)
5. Has received payments from the sponsor that exceed \$10,000 per year
6. Is an executive or director of the agency/company sponsoring the research
7. Is the advisor or mentor, or serves on the project or thesis committee, of a protocol submitted by a student (defined above) submitted to the IRB
8. Any other situation where an IRB member believes that another interest conflicts with his or her ability to deliberate objectively on a protocol.
  - In accordance with CSUEB Conflict of Interest policy, all IRB members who are CSUEB faculty or staff will have submitted annual disclosure forms, such as conflict of interest, to the ORSP, as appropriate when in a position identified to do so or when obtaining external funding through grants and contracts.
  - Letters of appointment to the IRB shall include wording addressing the concerns for conflict of interest.
  - For IRB members who are not CSUEB faculty or staff, the IRB will maintain documentation (such as the CSUEB IRB Policy or these procedures) that all IRB members and alternates are aware of and committed to compliance with the IRB policy regarding conflicts of interest.

#### **5.5. Duties of IRB Members**

Members are expected to perform the following activities:

- review meeting materials and protocol materials (agenda, submission materials, protocols, proposed informed consent forms, continuing review forms and other appropriate documents including research materials) in a timely fashion
- participate fully in the review of each proposed protocol designated for review
- attend meetings of the IRB
- review protocols critically holding to the principles of human subject protection and the policies of CSUEB
- receive appropriate training in human subject research regulations and ethical standards
- treat the research proposals, protocols, and supporting data confidentially, destroying hard copies and deleting electronic copies and supporting material
- participate in policy making discussions
- self-identify when there is a conflict of interest
- promote the principles of human subject protections

#### **5.6. Attendance Requirements**

Primary members should attend all meetings for which they are scheduled. If a member is unable to attend a scheduled meeting, he/she should inform their alternate and the IRB Chair or the IRB Coordinator. A prolonged absence (sabbatical, 'FERP' status, medical, etc.) should be discussed with the Chair or the IRB Coordinator to discuss options to maintain compliance with regulations dictating IRB composition.

## **5.7. Training and Ongoing Education of Chair & IRB 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, alternates, and staff of CSUEB IRB Office 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 and/or IRB Coordinator for an informal orientation session. At the session, the new member will be shown the following:

- 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
- The Cayuse IRB system through which protocols are submitted
- Records pertinent to the IRB, kept in the IRB Coordinator's office and secured online.
- Federal regulations relevant to IRB.

### **Initial Education**

CSUEB IRB Office maintains a subscription to the web-based **“CITI Course in The Protection of Human Research Subjects”** sponsored by the Collaborative IRB Training Initiative (CITI), [www.citiprogram.org](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%.
- New members are required to complete the “Initial Education” requirement for IRB members before they may serve as a Primary Reviewer.

### **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. Educational activities include, but are not limited to:

- in-service training at IRB meetings
- training workshops
- dissemination of current events articles relevant to human research protection
- 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.
- IRB members must complete the group of modules named “IRB member” on the CITI site at least once every three years.
- The IO may provide support for the IRB chair and possibly other IRB members to attend the annual CSU IRB workshop and possibly the annual PRIM&R/ARENA conference on human research protections.

## **5.8. Liability Coverage for IRB Members**

CSUEB will indemnify and defend University faculty and staff performing within the course and scope of their employment with regard to IRB responsibilities. This coverage extends to those under the supervision of faculty and staff (i.e., students and medical residents) and volunteers (i.e., unaffiliated IRB members) for the University.

*California statute (Government Code) 995. Except as otherwise provided in Sections 995.2 and 995.4, upon request of an employee or former employee, a public entity shall provide for the defense of any civil action or proceeding brought against him, in his official or individual capacity or both, on account of an act or omission in the scope of his employment as an employee of the public entity.*

### **5.9. Review of IRB Member Performance**

Service on the IRB is an important contribution to the University and its research program involving human subjects. The professional pursuits of faculty and students, federal regulations and campus policies, and the impact on subjects are all affected when a member cannot or does not serve the IRB effectively. The Chair and IO may evaluate the board-related performance of the IRB members on an annual basis, provide feedback, and take appropriate action that may include removal from the board or other actions as needed to ensure effective protection of human subjects.

## 6. IRB Records

The IRB must prepare and maintain adequate documentation of the IRB's activities including the following:

- copies of all items reviewed,
  - including but not limited to research proposals,
  - recruitment materials;
  - scientific evaluations (if any) that accompany the proposals;
  - approved consent documents;
  - approved HIPAA Authorization document, if separate from the informed consent,
- any proposed modifications and the IRB action on each modification;
- progress reports submitted by investigators;
- reports of injuries to subjects and serious and unexpected adverse events;
- documentation of protocol violations; and documentation of non-compliance with applicable regulations.

IRB records must also include:

- continuing review and modification review activities;
- copies of all correspondence between the IRB and investigators;
- statements of significant new findings provided to subjects must be maintained with the related research protocol, and when reviewed at an IRB meeting, must be documented in the minutes.

### 6.1. Minutes of an IRB Meeting

The IRB Coordinator takes the meeting minutes of a convened meeting and makes them available for review by the next regularly scheduled IRB meeting date. The minutes can be approved electronically, whereby the minutes are circulated to all members (both full and alternates) using email. Two-thirds (2/3) of those actually in attendance at the meeting must approve the minutes (records to be kept), allowing for minor changes (typographical errors, grammar, etc.). If less than two-thirds approve or there is a matter of significance, then the minutes are to be placed on the next agenda for further discussion. Once approved by the members, the minutes must not be altered by anyone, including a higher authority.

Per regulations, minutes of IRB meetings shall contain sufficient detail to show the following:

- Attendance at the meetings including those members or alternate members who are participating through videoconference or teleconference and documentation that those attending through videoconferencing or teleconferencing received all pertinent material prior to the meeting and were able to actively and equally participate in all discussions;
- Alternate members attending the meeting and, if voting, for whom they are substituting;
- The presence of a quorum throughout the meeting, including the presence of one member whose primary concern is in a non-scientific area;
- Actions taken by the IRB for protocols requiring full review by the convened IRB.
- Separate deliberations, actions, and votes for each protocol undergoing continuing review by the convened IRB; including the number of members voting for, against, and abstaining;
- Documentation that the research meets the four required criteria [45 CFR 46.116(f)] when approving a consent procedure that does not include or that alters some or all of the required elements of informed consent, or when waiving the requirement to obtain an informed consent;
- Documentation that the research meets the required criteria [45 CFR 46.117(c)] when the requirements for documentation of consent are waived;
- When approving research that involves populations covered by Subparts B, C, or D of 45 CFR 46, the minutes will document the IRB's justifications and findings regarding the determinations stated in the Subparts or in reference to the IRB's approval of the protocol details presented by the investigator on the IRB protocol.
- Notations indicating that when an IRB member has a real or potential conflict of interest relative to the proposal under consideration, that the IRB member was not present during the deliberations or voting on the proposal (and that the quorum was maintained);
- The basis for requiring changes in or disapproving research and documentation of resolution of

- these issues when resolution occurs;
- A written summary of the discussion of controversial issues and their resolution;
- Review of additional safeguards to protect vulnerable populations if entered as study subjects when this is not otherwise documented in IRB records;
- The determination of the level of risk, if not recorded elsewhere in IRB records;
- The frequency of continuing review of each proposal, as determined by the IRB, if not recorded elsewhere in IRB records;
- Documentation, as required by 45 CFR 164.512(i)(2), indicating the approval of a waiver or alteration of the HIPAA Authorization.

## **6.2. Membership Rosters**

The membership list of IRB members is maintained and kept current and will be posted on the IRB Web Pages.

- The membership roster will identify members by their academic departments and disciplines.
- Information contained on the membership roster will include the following:
  - the member's name,
  - earned degrees,
  - affiliated or non-affiliated status,
  - status as a scientist (physician-scientist, other scientist, non- scientist or social behavioral scientist);
  - regular/full/primary (voting) or alternate status, and status as Chair.

## **6.3. Records Retention Requirements**

The above detailed records are stored securely and retained for at least three (3) years after the completion of the research. All records are made accessible for inspection and copying by authorized representatives of the federal OHRP and other authorized entities at reasonable times and in a reasonable manner.

Records are maintained in locked file cabinets in the IRB Coordinator's office or digitally on CSUEB servers and are available only to IRB members (including the Chair), IRB office staff, the IO, the Director-Compliance and Standards, and persons with justified need (because they are confidential, this is determined on a case-by-case basis).

Examples of records maintained include those mentioned in previous sections above and for example:

- logs of protocol applications submitted for review
- a summary of the protocol review, the type of review, and who reviewed it
- the date of protocol approval
- files of protocol applications with pertinent paperwork, marked as CSUEB-IRB-20XX-###, meaning the four-digit year and a sequential number starting at 001 each calendar year
- copies of approval memos to PIs
- agendas and minutes of meetings
- training files of members.

## **6.4. Written Procedures and Guidelines**

The CSUEB Assurance of Compliance with Federal Regulations on Protection of Human Subjects and this document, the California State University, East Bay Institutional Review Board Procedures, comply with federal policies and regulations governing research with human subjects.

The IRB must follow these written procedures, including the procedures here in for

- conducting its initial and continuing review of research, and for reporting its findings and actions to the investigator and the institution;
- determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review;

- ensuring prompt reporting to the IRB of proposed changes in a research activity;
- and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject;
- and for ensuring prompt reporting to the IRB, appropriate institutional officials, and the federal Department or Agency head of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB suspension or termination of IRB approval.

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

## 7. Review Process

These procedures apply to all research involving human subjects, regardless of sponsorship and performance site, conducted under the auspices of CSUEB.

### 7.1. Human Subjects Research Determination

The investigator is responsible for understanding whether an activity constitutes human subjects research. Because the University must hold the investigator responsible for unapproved human subjects, research investigators are urged to request a determination that an activity does not constitute human subjects research from the CSUEB IRB before proceeding with research that includes human subjects. When the investigator submits a protocol for review, the request must be submitted through the Cayuse Human Ethics (IRB) system and include sufficient documentation of the activity to support the determination. Formal submissions will be responded to in writing, and a copy of the submitted materials and the emailed determination letter will be kept on file.

### 7.2. Exempt Research

Research determined to be exempt under 45 CFR 46.104 is exempt from certain regulatory requirements but remains subject to applicable ethical principles and institutional policies.

At CSUEB, exemption determinations are made by the IRB Chair or a designated reviewer, not by investigators. For exempt research categories that require limited IRB review under the regulations, the IRB will conduct such review to ensure appropriate protections for privacy and confidentiality.

The IRB or its designee may require additional protections or review procedures as appropriate based on the nature of the research.

Students may assume roles as Co-Principal Investigators (co-PIs) conducting exempt category research as long as they have a faculty advisor to serve as the Principal Investigator.

Approval of research approved through Exempt or Limited Review does not expire, except in cases where the IRB has specified an approval period and documented the reasons for limiting the approval period as required by 45 CFR 46.110(b)(1)(i).

#### Limitations on research subjects:

##### Vulnerable Populations:

- Children: Exemption for research involving survey or interview procedures or observations of public behavior does NOT apply, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. (See Section 10.1.1 for the definition of a child.) The Common Rule does not permit the exemption of research with children that includes identifiable information and is reviewed under a limited IRB review. Research under exemptions 1, 4, 5, 6, 7, and 8 are allowed. See 45 CFR 46 Subpart D for more information.
- Individuals with impaired decision-making capacity, or mentally-disabled economically- or educationally-disadvantaged persons: There are no restrictions on the inclusion of individuals with impaired decision-making capacity, or mentally-disabled economically- or educationally-disadvantaged persons in exempt research. The IRB is instructed, however, to more carefully examine protocols including these populations to ensure that subject selection is equitable, and that additional safeguards have been included in the study to protect the rights and welfare of these subjects. Such projects may be determined by the IRB to require expedited or full board review.
- Prisoners: No exemptions apply except for research involving a broader subject population which only incidentally includes prisoners, or secondary research of information or biospecimens from subjects who may be prisoners if that research is not seeking to examine prisoners as a subpopulation. The Common Rule allows subjects to continue in their exempt research if they become prisoners during a study. See 45 CFR 46 Subpart C for more information.
- While not specified as vulnerable populations by federal regulation, exempt category research with

pregnant women, fetuses or neonates may be determined by the IRB to require expedited or full board review. There are no restrictions on the inclusion of pregnant women, fetuses or neonates in exempt research. See 45 CFR 46 Subpart B for more information about research with these populations.

### **7.2.1. Categories of Research Permissible for Exemption**

With the above exceptions, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB convened review, but require limited review, at CSUEB:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness or comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
  - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
  - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
3. (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
  - (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
  - (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
  - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
- (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided those criteria are met, examples of such benign behavioral interventions

would include having the subjects play an online game or having them solve puzzles under various noise conditions.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that they will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

- (i) If wholesome foods without additives are consumed, or
- (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following are met:
  - (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);
  - (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;
  - (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

### **7.2.2. Additional protections**

Although research determined to be Exempt is not covered by the federal regulations, such research is not exempt from the ethical guidelines of the Belmont Report and must undergo at least expedited review by the IRB. The IRB chair or designee making the determination of exemption may require additional protections for subjects in keeping with the guidelines of the Belmont Report.

### **7.3. IRB Meetings**

Except when an initial, limited, or expedited review procedure is used (See Sections 7.2 and 7.7), the IRB must review proposed research at convened meetings (also known as **Full-Board meetings**) at which a **quorum** (see below) is present.

#### **7.3.1. Schedule of IRB Meetings**

The IRB at CSUEB is scheduled to meet during the academic year, at least once per semester, with meetings convened by the Chair.

#### **7.3.2. Quorum**

A quorum of the IRB consists of a simple majority of the voting membership **present at a convened IRB meeting**, including at least one member whose primary concerns are in a non-scientific area. Convened meetings may occur in person or via videoconference or teleconference, provided all members can actively and equally participate in the discussion.

**Votes on IRB actions requiring convened review must occur during a convened meeting.** Email or electronic communications may be used to distribute materials or collect comments but may not substitute

for discussion and voting at a convened meeting.

- The IRB Chair, with the assistance of the IRB Coordinator, will confirm that an appropriate quorum is present before calling the meeting to order.
- A quorum must be maintained for each vote to occur. If a quorum is not maintained, the proposal must be deferred or the meeting must be terminated.
- All members present at a convened meeting have full voting rights, except in the case of a conflict of interest (see below).
- In order for the research to be approved, it must receive the approval of a majority of those voting members present at the meeting. A member who leaves a meeting for conflict of interest still counts in establishing quorum.
- It is strongly recommended that members of the IRB be physically present at the meeting. If physical presence is not possible, a member may be considered present if participating through teleconferencing or videoconferencing. In this case the member will have received all pertinent material prior to the meeting and must be able to participate actively and equally in all discussions.
- Alternate members are encouraged to attend convened meetings and participate, but cannot vote unless replacing the regular, full member.
- Opinions of absent members that are transmitted by mail, telephone, facsimile, or email may be considered by the attending IRB members, but may not be counted as votes or to satisfy the quorum for convened meetings.

### **7.3.3. New Protocol Applications**

At CSUEB protocols are submitted for review by the Investigator(s) using the Cayuse Human Ethics (IRB) system and are first screened by the IRB Coordinator, then reviewed by the IRB Chair or designee for completeness and regulatory compliance prior to their distribution or placement on the agenda.

The Protocol must provide thorough details and must include or address the following. (The IRB may request additional information for adequate review of the application):

- Title of the study
- Purpose of the study
- Sponsor of the study
- Results of previous related research as needed
- Subject inclusion/exclusion criteria
- Recruitment procedures
- Justification for use of any special/vulnerable subject populations
- Study design (including, as needed, a discussion of the appropriateness of research methods)
- Description of procedures to be performed
- The possible/potential risks to the subjects
- Provisions for minimizing risks/managing adverse reactions
- The anticipated benefits of the research
- An assessment of the risk/benefit ratio
- Circumstances surrounding the consent procedure
  - Setting
  - Subject autonomy concerns
  - Language difficulties
  - Vulnerable populations
  - Procedures for documenting informed consent
  - Obtaining assent from minors
  - Using witnesses and/or translators

- Document storage
- Compensation to subjects for their participation, if any (rare)
- Compensation for injuries to research subjects (high risk studies)
- Costs to subjects for their participation in the study, if any
- Costs to third-party payers because of subject's participation
- Provisions for protection of data and human subjects' privacy
- Description of the resources available to protect research subjects, including supervision, number and training of staff, appropriate support services
- Training and experience with human subjects and conduct of research with human subjects

**Primary Reviewer:** The IRB Chair may act as or may assign a primary reviewer from the members of the IRB for all protocols requiring full IRB review. Reviewers are typically assigned protocols based on their related expertise, but may also be assigned a protocol outside of their field. When making reviewer assignments, the IRB Coordinator, with prior chair consultation, takes into consideration the vulnerable populations involved in the research and assigns the protocol to at least one individual who has experience with this population. The primary reviewer receives the following documentation, as applicable:

1. Protocol, including the description of the study
2. Proposed consent and/or parental permission/assent form(s)
3. Recruitment materials/subject information (including all surveys and questionnaires)

For sponsored research only:

1. Grant application(s), contract, or scope of work
2. Budget(s) or confirmation of payment to human subjects, if any are funded

Other IRB Members receive the following documentation:

1. Protocol application, including the description of the study
2. Recruitment materials/subject information (including all surveys and questionnaires)
3. Proposed consent and/or parental permission/assent form(s)

Copies of the full materials will be made available for any optional review at the request of any IRB member.

**NOTE:** Investigators who have other individuals write their protocols and responses to the IRB must recognize that the ultimate responsibility of any study lies with the Principal Investigator (PI). It is incumbent upon the PI to check all material that is submitted to the IRB for review.

#### **7.3.4. Pre-Meeting Distribution of Documents**

The place and time of the meeting is set forth on the agenda cover sheet distributed to all IRB members, including alternates.

- The agenda, with review assignments, and all protocols and supporting documentation to be reviewed are provided to all IRB members approximately two weeks prior to each meeting.
- Before the meeting, each protocol application (including background information, project protocol, and informed consent) is to be carefully reviewed by the primary reviewers.
- At the meeting, the IRB Chair, or the Primary Reviewer if one has been assigned, presents an overview of the goals, design, study procedures, safety procedures, and qualifications of the investigators.
  - Particular attention is paid to the risk/benefit ratio of the investigation and the adequacy of the consent form in conveying human subjects' concerns.
  - Problems identified by the Primary Reviewer or by other IRB members are discussed and suggestions for any necessary changes are agreed upon by the IRB. These issues are considered in the vote to decide IRB action.
  - Length of discussion can vary from a few minutes to over an hour when investigators make

formal presentations or information from outside experts is required.

- At the discretion of the IRB, the Principal Investigator(s) may be invited to the IRB meeting to answer questions about their proposed or ongoing research. If the PI attends, they may present the protocol elements listed in the previous paragraph in lieu of the chair doing so.

### **7.3.5. Consultants**

When necessary, the IRB may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

- The consultant's findings will be presented to the full board for consideration in person, by electronic means, or through documentation supplied to all board members in attendance.
- When in attendance, they will provide consultation but will not participate in or observe the vote.
- Prior to committing to review, consultants will be informed of the IRB conflict of interest policy. Individuals who have a conflicting interest or whose spouse or family members have a conflicting interest in the sponsor of the research will not be invited to provide consultation.
- Ad hoc or informal consultations requested by individual members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality and that is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research protocol).

### **7.3.6. Conflicts of Interest**

As noted in Section 5.4, no IRB member will participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

- IRB members are expected to self-identify conflicting interests.
- A primary reviewer or expedited reviewer with a conflict of interest must notify the IRB Coordinator who will re-assign the protocol.
- Except when their presence is requested by the IRB, IRB members will absent themselves from the meeting room when the IRB reviews research in which they have a conflicting interest.
- The Chair will allow for Board discussion once the conflicted member has recused themselves. The absent member is not counted toward quorum and their absence during the discussion and vote on the protocol will be noted in the IRB meeting minutes.

### **7.3.7. Possible IRB Actions Taken by Vote**

The CSUEB IRB recognizes the following options for voting on protocols:

**Approval** - the study is approved as submitted.

**Conditional Approval Pending Revisions** - the protocol and/or consent form require minor revisions. The needed revisions are agreed upon at the meeting. These revisions are presented to the Principal Investigator for incorporation by simple concurrence. Within the Cayuse System, conditional approval will be granted, with a letter generated indicating the agreed upon conditions. The IRB Chair, a designated IRB member, a subcommittee of the IRB, or the IRB Coordinator, may approve the study upon receipt and approval of the revisions without further action by the IRB. Upon such approval, the IRB Coordinator will ensure generation of a final letter of IRB approval and maintain documentation in the Cayuse system.

**NOTE:** Approval of the study protocol will not be granted and certification will not be issued until all deficiencies, if any, are corrected to the satisfaction of the IRB.

The date of approval is the earlier date the fully-convened IRB approved the protocol rather than the date that the minor changes were later reviewed and approved by the IRB Chair or the IRB Coordinator.

**Deferred for Substantive Issues** regarding the protocol and/or consent form must be addressed.

This action is taken if substantial modification or clarification is required, or insufficient information is provided to judge the protocol application adequately (e.g., the risks and benefits cannot be assessed with the information provided). IRB approval of the proposed research must not occur until subsequent review of the material the PI submitted by the convened IRB.

If the application is deferred the following will occur:

1. The IRB Chair, IRB Coordinator, or other designee informs the investigator in writing of the IRB's decision, questions, and concerns.
2. The investigator should enter the modification or additional information directly into the Cayuse Human Ethics (IRB) system, and if questions can contact the IRB Coordinator or Chair @ [irb@csueastbay.edu](mailto:irb@csueastbay.edu).
3. In order to receive approval for a deferred protocol, it must be submitted for full IRB review at a subsequent, convened meeting. The IRB Coordinator provides the IRB with the investigator's response, the revised protocol, and the previously submitted protocol, or may direct the IRB Members to the Cayuse system to review the documents online. The item is placed on the agenda for the following meeting.
4. The protocol application is given full IRB review again.
5. The outcome of the IRB's deliberations is once again communicated to the investigator in writing.
6. The IRB's determination concerning the subsequent amended submission will be documented in the minutes of that meeting.

**Disapproved** - questions are of such significance that the IRB feels approval of the study is unwarranted. Approval of a previously disapproved protocol requires full IRB review.

**Approval in Principle** [45 CFR 46.118] -- There are two circumstances in which the IRB may grant approval required by a sponsoring agency without having reviewed all of the study procedures and consent documents.

- o One is if study procedures are to be developed during the course of the research, but human subjects approval is required by the sponsoring agency.
- o The other is if the involvement of human subjects depends on the outcomes of work with animal subjects. (Research studies with animals must be approved by the Institutional Animal Care and Use Committee [IACUC]).

Approval in principle is granted to satisfy sponsoring agency requirements or to allow investigators to have access to funding to begin aspects of the project that do not involve human subjects.

In those two situations, the IRB may grant Conditional approval without having reviewed the as-yet undeveloped recruitment, consent, and intervention materials, but the approval only authorizes the proposal for funding to be submitted, or the development or other non-human subject work to begin. If the sponsored programs proposal is funded, the Principal Investigator must submit the remaining required protocol information and documents for approval at least 60 days before recruiting human subjects into the study, or into any pilot studies or pre-tests. See also "Conditional Approval Pending Revisions" above.

### 7.3.8. Determination of Risk

A subject is at risk if, as a participant in research, development, or a 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 study 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:

- o **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 that could involve violence may

also create a physical risk.

- 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.
- Social Risks: 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.

At the time of initial and continuing review, the IRB will make a determination regarding the risks associated with the research protocol.

- Risks associated with the research will be classified as either “minimal” or “greater than minimal” based on the “absolute” interpretation of minimal risk.
- The meeting minutes will reflect the IRB’s determination regarding risk levels.

### **7.3.9. Period of Approval**

At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research protocol.

- All protocols requiring full board review will be reviewed by the IRB at intervals appropriate to the degree of risk but no less than once per year.
- In some circumstances, a shorter review interval (e.g., biannually, quarterly, or after accrual of a specific number of participants) may be required.

The following factors will determine which studies require review more frequently than on an annual basis:

7. The probability and magnitude of anticipated risks to subjects.
8. The likely medical condition of the proposed subjects.
9. The overall qualifications of the Principal Investigator and other members of the research team.
10. The specific experience of the Principal Investigator and other members of the research team in conducting similar research.
11. The nature and frequency of adverse events observed in similar research at this and other institutions.
12. The novelty of the research making unanticipated adverse events more likely.
13. Any other factors that the IRB deems relevant.

- In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a maximum number of subjects either studied or enrolled.
  - If a maximum number of subjects studied or enrolled is used to define the approval period, it is understood that the approval period in no case can exceed 365 days and that the number of subjects studied or enrolled determines the approval period only when that number of subjects is studied or enrolled in less than 365 days.
- The meeting minutes will reflect the IRB’s determination regarding review frequency.

### **7.3.10. Independent Verification Regarding Material Changes**

Protecting the rights and welfare of subjects sometimes requires that the IRB verify independently, utilizing sources other than the investigator, information about various aspects of the study including but not limited to

- adverse event reporting,
- information in the scientific literature,
- reports of drug toxicity,
- drug approval status,
- and that no material changes occurred during the IRB-designated approval period.

The IRB will consider the following factors in determining which studies require such independent verification:

14. The probability and magnitude of anticipated risks to subjects.
15. The likely condition of the proposed subjects.
16. The probable nature and frequency of changes that may ordinarily be expected in the type of research proposed.
17. Prior experience with the Principal Investigator and research team.
18. Any other factors that the IRB deems relevant.

In making determinations about independent verification, the IRB may prospectively require that such verification take place at predetermined intervals during the approval period, may retrospectively require such verification at the time of continuing review, or may require such verification at any time during the approval period in the light of new information.

### **7.3.11. Consent Monitoring**

In reviewing the adequacy of informed consent procedures for proposed research, the CSUEB IRB may on occasion determine that special monitoring of the consent process by an impartial observer (consent monitor) is required in order to reduce the possibility of coercion and undue influence.

- Such monitoring may be particularly warranted where the research presents significant risks to subjects, or if subjects are likely to have difficulty understanding the information to be provided.
- Monitoring may also be appropriate as a corrective action where the IRB has identified problems associated with a particular investigator or a research project.

### **7.3.12. Reporting IRB Actions**

All IRB actions are to be communicated [45 CFR 46.109(d), 46.113] to the Principal Investigator (PI), or designated primary contact person for the protocol, in writing within ten (10) working days of the determination by the CSUEB IRB Coordinator or the Chair of the IRB. The IRB will notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity or of modifications required to secure IRB approval of the research activity.

For approved research, investigators are informed that:

- **modifications to approved projects** must be reviewed and approved by the IRB before they are initiated;
- **unexpected adverse events/reactions** must be reported to the IRB within ten working days of receipt.
- **monitoring** may occur. The frequency of monitoring will be determined by the IRB at the time of initial or continuing review, and investigators will be informed.

If the IRB decides to disapprove or require modifications to secure approval of a research activity, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

The IRB reports its findings and actions to the institution in the form of its minutes, which are available upon request by CSUEB institutional officials and are stored permanently and securely in the CSUEB IRB Coordinator's office, within the ORSP Office, or on the CSUEB secure servers (as applicable).

## **7.4. Continuing Review of Active Protocols (Renewals)**

Research approved through full board review is subject to continuing IRB review at least yearly, or more frequently if specified by the IRB [45 CFR 46.109(e) and (f)], but not sooner than 30 days prior to the protocol termination (expiration) date.

- The continuing review must take place **before the approval expiration date**;
- any lapse in approval will result in suspension of subject recruitment/enrollment and, if the research is DHHS-sponsored, notification to the funding agency.
- The approval date and the termination (expiration) date are clearly noted on all IRB communications

- sent to the PI and must be strictly adhered to.
- It is the investigator's responsibility to ensure that the continuing review of ongoing research is requested and approved prior to the expiration date. The PI must allow sufficient time for the review and re-approval process to be completed before the current approval expires.
- Retrospective approval for work done after the expiration date cannot be granted. By federal regulation, **no** extension to that date can be granted.

Research activities that have occurred are subject to internal audit and verification from sources other than the investigator. This is to assure that no material changes have occurred since the last IRB review.

The IRB Chair may choose to use expedited review procedures to renew a protocol with minor or no changes [45 CFR 46.110(b)(1)(ii)] or refer it to the IRB (in whole or part) for a *de novo* review.

#### 7.4.1. Continuing Review Process

When the IRB approves a study, it provides the Principal Investigators with an approval letter that indicates whether the study approval will expire and an expiration date if so. It is the Principal Investigators' responsibility to track when their protocol expires and to seek continuing review as needed or to request closure of a study.. The IRB may remind the PIs about expiring protocols, but if the PI does not receive a reminder it does not remove responsibility from the PI.

In accordance with Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and at 46.115(a)(3), continuing review by the convened IRB, with recorded vote on each study, is required except as given in (45 CFR 46.109(f)(1)):

Unless an IRB determines otherwise, continuing review of research is not required in the following circumstances:

- (i) Research eligible for expedited review in accordance with 45 CFR 46.110;
- (ii) Research reviewed by the IRB in accordance with the limited IRB review described in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8);
- (iii) Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:\*
  - (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

\*Once a study progresses to the point in which private information has been destroyed and only data analysis of de-identified data is occurring or a publication being prepared, the PI may request that the IRB close the active protocol. If the research team may decide to restart data collection or still has access to private identifiable information, however, the study protocol should not be closed. Once an IRB Protocol expires, the IRB may close the study protocol, keeping appropriate documentation on file.

DHHS regulations at 45 CFR 46.111 set forth the criteria that must be satisfied in order for the IRB to approve research. These criteria include, among other things,

- determinations by the IRB regarding risks,
- potential benefits,
- informed consent,
- and safeguards for human subjects.

The IRB must ensure that these criteria are satisfied at the time of both initial and continuing review.

The procedures for continuing review by the convened IRB may include a primary reviewer system.

When requesting continuing review of research, investigators should submit a protocol request through Cayuse (i.e., description of study) and a status report on the progress of the research, including the following information from the past year (cumulative data must also be included after the first renewal):

- the number of subjects enrolled;
- number of subjects who withdrew prematurely and reason(s) for their withdrawal
- a current copy of the description of study;
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- minor modifications to the protocol made since the last review;
- proposed modifications to the protocol (see Section 7.5);
- summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research;
- a copy of the current informed consent document and any newly proposed consent document, and
- a copy of the current HIPAA Authorization document (if applicable).

If full board review is to be conducted, the IRB Coordinator will release to the IRB members the continuing review request submitted through Cayuse.

If an expedited review is to be conducted, the IRB Coordinator will assign the review to a set of IRB members specified by the IRB Chair or the IRB Coordinator.

At least one member of the IRB (i.e., a primary reviewer or the IRB chair) also should receive a copy of the complete protocol including any modifications previously approved by the IRB.

Upon request, any IRB member may also have access to the complete IRB protocol file and relevant IRB minutes prior to or during a convened IRB meeting.

When reviewing the current informed consent document(s), the IRB should ensure the following:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with DHHS regulations at 45 CFR 46.116(c)(5).
- Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but **informed consent documents should be reviewed whenever new information becomes available** that would require modification of information in the informed consent document.

#### **7.4.2. Expedited Review of Continuing Review**

Generally, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review, except in limited circumstances described by expedited review categories (8) and (9) at 63 FR 60364-60367 (see "Expedited Review Categories"), or as given in 45 CFR 46.109(f)(1)(iii).

- It is also possible that research activities that previously qualified for expedited review in accordance with 45 CFR 46.110, have changed or will change, such that expedited IRB review would no longer be permitted for continuing review.

#### **7.4.3. How is the Continuing Review Date Determined?**

Department of Health and Human Services (DHHS) regulations at 45 CFR 46.108(b) and 109(e) require, respectively, that:

1. The IRB must review proposed research requiring full board review at convened meetings at which a majority of the members of the IRB is present, including at least one member whose primary concerns are in nonscientific areas; and
2. The IRB must conduct a continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year.

The IRB assigns the expiration date or frequency of continuing review for each study protocol as necessary to ensure the continued protection of the rights and welfare of research subjects.

- At CSUEB, determination of the review interval and the need for additional supervision and/or participation is made by the IRB on a protocol-by-protocol basis.
  - For example, for an investigator who is performing particularly risky research, or for an investigator who has recently had a protocol suspended by the IRB due to regulatory concerns, an on-site review by a subcommittee of the IRB might occur or approval might be subject to an audit of study performance after a few months of enrollment, or after enrollment of the first several subjects.
- Several scenarios for **determining the date of continuing review** apply for protocols reviewed by the IRB at a convened meeting. The date by which continuing review must occur depends on the date of the convened meeting at which IRB approval occurs. (These examples presume the IRB has determined that it will conduct a continuing review no sooner than within 1 year).

**Scenario 1:** The IRB reviews and approves a protocol without any conditions at a convened meeting on October 1, 2022. Continuing review must occur within one year of the date of the meeting, that is, by October 1, 2023.

**Scenario 2:** The IRB reviews a protocol at a convened meeting on October 1, 2022, and approves the protocol contingent on specific minor conditions the IRB Chair or their designee can verify. On October 31, 2022 the IRB Chair or designee confirms that the required minor changes were made. Continuing review must occur within one year of the date of the convened IRB meeting at which the IRB reviewed and approved the protocol, that is, by October 1, 2023.

**Scenario 3:** The IRB reviews a study at a convened meeting on October 1, 2022, and has serious concerns or lacks significant information that requires IRB review of the study at subsequent convened meetings on October 15 and October 29, 2022. At their October 29, 2022, meeting, the IRB completes its review and approves the study. Continuing review must occur within one year of the date of the convened meeting at which the IRB reviewed and approved the protocol, that is, by October 29, 2023.

- For a study approved under expedited review, for which the IRB determined a continuing review should be required, the continuing review must occur within one year of the date the expedited reviewer gives final approval to the protocol.
- Review of a change in a protocol ordinarily does not alter the date by which continuing review must occur. This is because continuing review is a review of the full protocol, not simply a change to it.

The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Therefore, continuing review and re-approval of research must occur on or before the date when IRB approval expires.

- When continuing review occurs annually and the IRB performs a continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur. This would be, for example, October 1, 2023, in the above scenarios 1 and 2, and October 29, 2023, in Scenario 3, even if the continuing reviews took place up to 30 days prior to these dates.

#### 7.4.4. What occurs if there is a Lapse in Continuing Review?

The IRB and investigators must plan ahead to meet required continuing review dates.

- If an investigator has failed to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the research must stop, unless the IRB finds that it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of IRB approval.
- The continuation of research after expiration of IRB approval is a violation of the regulations and CSUEB policy. Please see section 11.3 on Non-Compliance for required actions.
- If an investigator wishes to resume research for which the IRB approval has lapsed, they must submit a new research protocol to the IRB providing the information requested in section 7.4.1, and a statement as to whether research was conducted after the expiration of approval.

#### **7.4.5. Studies that are Approved but Never Started**

When the IRB approves a study which requires continuing review, continuing review should be performed at least annually.

- For the purposes of continuing review, the review date is determined by the date of initial IRB approval.
- Written progress reports should be received from the investigator for all studies that are in approved status prior to the date of expiration of IRB approval.
- If subjects were never enrolled, the investigator's progress report would be brief. Such studies may receive continuing IRB review using expedited procedures.
- If the study is finally canceled without subject enrollment, records will be maintained for at least three years after cancellation.

#### **7.5 Modification of an Approved Protocol**

Investigators may wish to modify or amend their approved applications. **Investigators must seek IRB approval before making any changes in approved research**, even though the changes are planned for the period for which IRB approval has already been given, unless the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once).

- When requesting modification review of research, investigators must submit a summary of the proposed changes using the CSUEB designated online system. It is helpful for investigators to also submit a status report on the progress of the research, including the following information reflecting data since the last review:
  - the number of subjects enrolled;
  - number of subjects who withdrew prematurely and reason(s) for their withdrawal;
  - a current copy of the description of study;
  - a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
  - minor modifications to the protocol made since the last review;
  - proposed modifications to the protocol (see Section 7.5);
  - a description of any changes to the risk to the subjects which would occur given the proposed modifications;
  - summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
  - any relevant multi-center trial reports;
  - any other relevant information, especially information about risks associated with the research;

- a copy of the current informed consent document and any newly proposed consent document;
  - a copy of the current HIPAA Authorization document (if applicable).
- Modifications may be approved administratively by the IRB chair if they are within the scope of what the IRB originally authorized and are non-substantive.
  - The IRB chair is authorized to evaluate how to proceed to approve the request. For example, if research personnel are to be added to a protocol which underwent limited review initially, or non-substantive changes to recruitment or consent documents are proposed, the IRB chair may require no further action than documenting the modification.
- The IRB Chair may use Limited Review procedures to review minor modifications to protocols that were originally approved through Limited Review.
- An IRB may use expedited review procedures to review minor changes in ongoing previously-approved research during the period for which approval is authorized [45 CFR 46.110; 63 FR 60364-60367, November 9, 1998].
  - For example, if a researcher wishes to add a population to an existing study, or wishes to modify a procedure, an expedited review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the IRB Chair from among members of the IRB.

**When a proposed change in a research study is not minor** (e.g., procedures involving increased risk or discomfort are to be added), then the IRB Chair must evaluate the proposed changes in light of 45 CFR 46.110 to determine if expedited or full board review are required before the change can be implemented.

- The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. In such a case the IRB Chair should be promptly informed of the change before or immediately following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.
- At least one member of the IRB (i.e., a primary reviewer or the IRB chair) also should receive a copy of the complete protocol including any modifications previously approved by the IRB.
- Furthermore, upon request, any IRB member also should have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

When reviewing the current informed consent document(s), the IRB should ensure the following:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with DHHS regulations at 45 CFR 46.116(c)(5).

## 7.6 Adverse Events and Unanticipated Problems

An adverse event is an event that occurs during the period of an approved research protocol that causes or increases the risk of physical or psychological harm to the participant, or results in a loss of privacy and/or confidentiality to the research participant or others.

### Adverse events may be:

- **Anticipated:** An adverse event that is reasonably expected in nature, severity, and frequency, and is included in the protocol and consent form as a possible risk of participating in the research
- **Unanticipated:** An adverse event whose nature, severity, or frequency was not identified in the protocol and consent form as a possible risk of participating in the research.
- **Related:** For PHS-funded projects, only adverse events that are caused by or affect the study design or procedures of the research need to be reported to the Office for Human Research Protections (OHRP).

### **Adverse events may be:**

- **Serious:** adverse events defined by 21 CFR 312.32, including death, a life-threatening adverse experience, hospitalization or prolongation of hospitalization, a persistent or significant disability or incapacity, or a congenital abnormality/birth defect. Serious adverse events must be reported to the IRB as soon as possible for the protection of the participant, but at least within 5 working days and, if federally funded, may need to be reported to the federal Office for Human Research Protections (OHRP).
- **Significant:** adverse events not specified by federal code, but that CSUEB considers grave, requiring immediate attention. These would include e.g., a psychotic or schizophrenic break not requiring hospitalization; a suicide attempt that does not result in hospitalization; suicide threat; a serious breach of confidentiality or privacy of research subjects or others by the researcher or focus group members that results in or could result in, e.g., deportation, arrest, expulsion, suspension, loss of job, loss of family support; loss of laptop with private, identifiable information about research participants. Significant adverse events must be reported to the IRB as soon as possible within 5 working days for the protection of the participants.
- **Minor:** Minor adverse events should be reported to the IRB only if they result in a modification of the protocol to mitigate and/or detail this event.

### **Reporting adverse events:**

- **Serious and Significant** adverse events must be reported to the IRB as soon as possible within 5 working days, for the protection of the participant, should be reported through Cayuse on the Incident Report in a timely manner.
- The report must include actions taken to mitigate the current adverse event and to avoid the adverse event in the future. A copy of the current informed consent document and any other supporting documentation must be included for review. Adverse events will usually trigger modification of the protocol and related documents, which must be approved by the IRB.
- **Minor** adverse events that require reporting should be reported through Cayuse on the Incident Report in a timely manner.

### **Review of adverse events:**

The IRB Chair must review Adverse event reports to determine the level and relatedness of the event. Possible consequences are listed below.

- **Serious/significant adverse event:**  
If the IRB Chair determines that the adverse event is related to the research and is serious or significant, the Chair may choose to:
  - suspend or terminate the research immediately,
  - or report their findings to the board for their input;
  - or call an emergency meeting of the board to discuss the matter.

If the IRB Chair/IRB determines that the research participant may be in immediate risk, the board may suspend or terminate approval of a protocol, requiring the immediate cessation of data collection from research participants.

The Adverse Event Report is sent to the Institutional Official (IO) with the board's acceptance or their recommendations for any action needed beyond the mitigation proposed by the researcher.

Serious adverse events may need to be reported to OHRP, sponsors, and/or the FDA, as required. These reports must include the actions the institution is taking or plans to take.

- **Minor adverse event:**  
The IRB reviews Minor adverse event reports to assure protocol modifications are initiated when necessary.

### **Possible outcomes following an adverse event:**

- **Serious/significant adverse event:**

Possible actions that may be taken may include:

- acceptance of the mitigations proposed;
- require revision of the protocol;
- require revision of the informed consent;
- suspend participant enrollment;
- require informing enrolled participants of the adverse event;
- require additional information be provided to past and current participants;
- require that current participants re-consent to participation;
- monitoring of the research by the IRB;
- reduction of approval period to less than one year;
- suspension or termination of the research;
- confiscation of the data.

- **Minor adverse event:**

Continued occurrence of minor adverse events may trigger a report to the IO for further action.

## 7.7 Expedited Review of Research

The CSUEB IRB may use the expedited review procedure [45 CFR 46.110] to review either or both of the following at its discretion:

1. some or all of the research appearing on the list below and found by the reviewer(s) to involve no more than minimal risk,
2. minor changes in previously approved research during the period for which approval is authorized.

45 CFR 46.110(b)(iii) also allows expedited review of research for which limited IRB review is a condition of exemption under §46.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8). The CSUEB IRB will implement limited review for these categories of research rather than expedited review. (The procedure is nearly the same, except limited review may focus more on data security).

A minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in (i) the level of risks to subjects; (ii) the research design or methodology; (iii) the number of subjects enrolled in the research (no greater than 10% of the total requested); (iv) the qualifications of the research team; (v) the facilities available to support safe conduct of the research; or (vi) any other part of the research that would otherwise warrant review of the proposed changes by the convened IRB.

- Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more reviewers (i.e., a subcommittee of the IRB) designated by the Chair or IRB Coordinator from among members of the IRB.
  - For IRB members to serve as designees to the IRB Chair for expedited review, they will be matched as closely as possible with their field of expertise to the study.
  - Alternate members may be designated as expedited reviewers.
- When reviewing research under an expedited review procedure, the IRB Chair, or designated IRB member(s), will receive and review all documentation that would normally be submitted for a full-board review, including the complete protocol, recruitment flyers, survey instruments, etc.
- In reviewing the research, the reviewers may exercise all of the authority of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the non-expedited procedure set forth in 45 CFR 46.108.
- For Human Subjects Research in which the student is acting as a Principal Investigator conducting expedited category research, the student must have a faculty sponsor who will serve as the

responsible investigator (RI) and faculty advisor on the study. The student will list the faculty as the PI on the Protocol submitted using the Cayuse system. The advisor is responsible for overseeing the student's work.

Approval of research approved through Expedited Review does not expire, except in cases where the IRB has specified an approval period and documented the reasons for limiting the approval period as required by 45 CFR 46.110(b)(1)(i).

### **Categories of Research Eligible for Expedited Review**

The activities listed below in (1) - (7) should not be deemed to be of minimal risk [63 FR 60364-60367, November 9, 1998] simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

- The categories in this list apply regardless of the age of subjects, except as noted.
- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- The expedited review procedure may not be used for classified research involving human subjects; and, for fundamental research purposes, CSUEB does not accept classified research.
- The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

### **Research categories 1 through 7 pertain to both initial and continuing IRB review:**

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (NOTE: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week. [Children are defined in the DHHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."][45 CFR 46.402(a)]

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an un-stimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)  
 Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).  
 [Note: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.104(d)(2). This listing refers only to research that is not exempt.]

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. [NOTE: Some research in this category may be exempt from the DHHS regulations for the protection of human subjects. See Exempt Categories and 45 CFR 46.104(d)(2) and (d)(3). This listing refers only to research that is not exempt.]

(8) Continuing review of research previously approved by the convened IRB as follows:  
 (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long- term follow-up of subjects; or  
 (b) where no subjects have been enrolled and no additional risks have been identified; or  
 (c) where the remaining research activities are limited to data analysis.  
 [Of note: Category (8) identifies three situations in which research that is greater than minimal risk and has been initially reviewed by a convened IRB may undergo subsequent continuing review by the expedited review procedure. For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever the conditions of category (8)(a), (b), or (c) are satisfied for that site. However, with respect to category 8(b), while the criterion that "no subjects have been enrolled" is interpreted to mean that no subjects have ever been enrolled at a particular site, the criterion that "no additional risks have been identified" is interpreted to mean that neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.]

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. [Under Category (9), an expedited review procedure may be used for continuing review of research not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.]

All members of the IRB will be apprised of all expedited review approvals by means of an annual report compiled by the IRB Coordinator.

- Copies of the expedited review approvals will be made available for any optional review at the request of any IRB member.

## 7.8 Further Review/approval of IRB Actions by Others within the Institution

Research that has been approved by the IRB is subject to review and disapproval by institutional officials, but those officials may not approve research that has been disapproved by the IRB. [45 CFR 46.112]

- Specifically, the President of California State University, East Bay reserves authority to prohibit or suspend any research, development, or related activity they find 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.

## **7.9 Initiation of Research Projects**

All research involving human subjects must be reviewed and approved by the IRB prior to initiation of the research project.

- Approved research requiring review by the convened IRB is subject to continuing review at intervals appropriate to the degree of risk, not less than once per year IRB [45 CFR 46.109(e)], except as described in 45 CFR 46.109(f).
- The date of continuing review will be based on the date of IRB approval. [See Section 7.4 Continuing Review of Active Protocols for further details.]
- The approval date and the termination (expiration) date are to be clearly noted on all IRB certifications sent to the PI and must be adhered to. The PI must allow sufficient time for development and review of renewal submissions. By federal regulation, no extension to the date can be granted.

## **7.10 Appeal of IRB Decisions**

If a subcommittee of the IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator may appeal, in writing, for review by the convened appropriate IRB.

- If the convened IRB makes a decision that the investigator believes to be unduly restrictive on the proposed research, the investigator should first discuss the matter with the Chair of the IRB or the IRB Coordinator, taking care to explain the reasons for believing that the proposed procedures are in compliance with University policy and with federal regulations.
- If the issue cannot be resolved satisfactorily by negotiation, the investigator may appeal the decision of the IRB, in writing to the Chair and IRB Coordinator.
- The IRB will reconsider the appeal based upon the new information provided and will continue to re-review protocols as long as the investigator wishes to appeal.

## **7.11 Canceling a review**

The IRB reserves the right to cancel a review effort that becomes inactive.

- Circumstances including lack of response by the PI(s) to Board instructions or no reply to emails asking for updates are examples of reasons to do so.
- The IRB Coordinator will inform the PIs of the action and close the file.
- The PI may also indicate that they wish to withdraw their protocol which will result in its cancellation.
- The process of review and approval may be restarted upon the submission of a new, current protocol application.

## 8 Criteria for IRB Approval of Research

In accordance with 45 CFR 46.111, in order to approve research, the IRB must determine that all of the following requirements are satisfied:

- (1) Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- (2) Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
- (3) Selection of subjects is equitable.
  - a) In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
  - b) The issue of coercion is especially important in educational settings. This aspect is emphasized in the review of protocols.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.
- (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by §46.117.
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- (8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards should have been included in the study to protect the rights and welfare of these subjects.

### 8.1 Risk/Benefit Assessment

The goal of the assessment is to ensure that the risks to research subjects posed by participation in the research are justified by the anticipated benefits to the subjects or society. Toward that end, the IRB at CSUEB will:

- o judge whether the anticipated benefit, either of new knowledge or of improved health or welfare of the research subjects, justifies asking any person to undertake the risks;
- o disapprove research in which the risks are judged unreasonable in relation to the anticipated benefits.

The assessment of the risks and benefits of proposed research - one of the major responsibilities of the IRB - involves a series of steps, which will accomplish the following:

- o **identify the risks** associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research;
- o **determine whether the risks will be minimized** to the extent possible;
- o **identify probable benefits** to be derived from the research;
- o **determine whether the risks are reasonable in relation to the benefits** to subjects, if any, and assess the importance of the knowledge to be gained;
- o **ensure that potential subjects will be provided with an accurate and fair description** of the risks or discomforts and the anticipated benefits.

The CSUEB IRB recognizes that risks to subjects are minimized by

- o using procedures which are consistent with sound research design and which do not

- unnecessarily expose subjects to risk; and
- whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

Further, the IRB recognizes that risks to subjects are reasonable in relation to anticipated benefits, if any, and to the importance of the knowledge that may reasonably be expected to result by adhering to the following:

- In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research - as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research; and
- The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

### **8.1.1 Scientific Merit**

In order to assess the risks and benefits of the proposed research, the IRB must determine that:

- the research uses procedures consistent with sound research design;
- the research design is sound enough to reasonably expect the research to answer its proposed question; and
- the knowledge expected to result from this research is sufficiently important to justify the risk.

In making this determination, the CSUEB IRB will draw on its own knowledge and disciplinary expertise, and it may draw on the knowledge and disciplinary expertise of others, such as reviews by a funding agency, or departmental review.

The signature (ink or digital) of a faculty member in 'charge' of a student's project (by mentoring, sponsoring, guiding, serving on a thesis committee, etc.) is required on the protocol application. This is to assure one measure of review of the project for merit and that neither the student nor the subjects are unduly exposed to risk. At CSUEB in the Cayuse Human Ethics (IRB) system, the faculty acting as the Responsible Investigator (RI) is listed as the PI and the student as Co-PI.

## **8.2 Selection of Subjects is Equitable**

The IRB will review the inclusion/exclusion criteria for the research to ensure equitable selection of subjects.

- In making this assessment the IRB will consider the purpose(s) of the research and the setting in which the research will be conducted.
- The IRB is particularly cognizant of the special problems of research involving vulnerable populations, such as children, students, prisoners, fetuses, pregnant women, human *in vitro* fertilization, individuals with impaired decision-making capacity, or persons who are economically or educationally disadvantaged (see Vulnerable Populations).

### **8.2.1 Recruitment of Subjects**

The IRB will ask for and review all recruitment procedures, materials and advertisements to ensure that they are consistent with the protocol, accurate, and non-coercive.

- When subjects are being paid, the IRB will review both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence.
- Payment to subjects should not be considered a benefit to participation.

## **8.3 Informed Consent**

The IRB will ensure that informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

- In addition, the IRB will ensure that informed consent will be appropriately documented in accordance with, and to the extent required by 45 CFR 46.117. See also Section 9 below for detailed policies on informed consent.

## 8.4 Data Safety Monitoring

The IRB will review the data safety monitoring plan for protocols involving more than minimal risk during initial review and at continuing review. If sufficient details have not been provided, the IRB will request additional information to make a better-informed decision.

## 8.5 Privacy and Confidentiality

The IRB will determine whether adequate procedures are in place to protect **the privacy** of subjects and to maintain **the confidentiality of the data**.

### Definitions

- Privacy - having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- Confidentiality - methods used to ensure that information obtained by researchers about their subjects is not improperly divulged.

### Regulations

46.102(e) includes the following in its definition of human subjects:

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

### Confidentiality

- Confidentiality and anonymity are not the same. “Anonymous” research is research conducted in such a way that it is not possible to trace any data or information gathered back to the subjects from whom it was obtained. All other research is such that the data gathered are “confidential.”
- Names are not the only identifiers. NetIDs and social security numbers are other possibilities on campus, but their use must be justified due to the potential loss of personal identity.
- Subjects’ participation in the research may need to be kept confidential as well as their data.
- See Section 14.1 for detailed information regarding certificates of confidentiality.

## 8.6 Vulnerable Populations

The IRB will determine if appropriate **additional safeguards** are in place to protect the rights and welfare of subjects if they are likely to be members of a vulnerable population (e.g., persons with diminished autonomy). See Section 10 below for detailed policies on vulnerable populations.

## 9. Informed Consent

### 9.1. Informed Consent Process

No investigator may involve a human being as a subject in research without obtaining the legally effective informed consent of the subject or the subject's legally authorized representative, unless a waiver of consent has been approved by the IRB in accordance with Section 9.3 of this policy.

- Investigators must obtain consent prior to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB.

Consent must always be sought under circumstances that:

- provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate; and
- minimize the possibility of coercion or undue influence.

The IRB will consider where the consent process will take place and the individual who will be obtaining consent (e.g., the investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process.

- When the potential participant's understanding of the research may be impaired because of the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process.
- The information that is given to the subject or the representative must be in language understandable to the subject or the representative.
- No informed consent, whether oral or written, may 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.
- A person knowledgeable about the consenting process and the research (i.e., a member of the project's research team) to be conducted must obtain the informed consent.
- If someone other than the investigator conducts the interview and obtains consent, the investigator needs to formally delegate this responsibility and the person so delegated must have received appropriate training to perform this activity.

### 9.2. Basic Elements of Informed Consent

Informed consent must be sought from each potential subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.

The basic elements of informed consent are:

1. 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;
2. a description of any reasonably foreseeable **risks** or discomforts to the subject;
3. a description of **benefits** to the subject or to others which may reasonably be expected from the research;
4. a disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject;
5. a statement describing the extent to which **confidentiality** of records identifying the subject must be maintained;
6. for research involving more than minimal risk, an explanation as to the availability of medical treatment in the case of **research-related injury**, including who will pay for the treatment and whether other financial compensation is available;

**Additional elements of informed consent to be applied, as appropriate, include:**

1. 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;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation must be provided to the subject;
6. The approximate number of subjects involved in the study;
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and
9. for research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

### **9.3. Waiver of Informed Consent**

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

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**
5. Whenever appropriate, the subjects must be provided with additional pertinent information after participation;

or

1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - o public benefit or service programs;
  - o procedures for obtaining benefits or services under those programs;
  - o possible changes in or alternatives to those programs or procedures; or
  - o possible changes in methods or levels of payment for benefits or services under those programs;and
  - o the research could not practically be carried out without the waiver or alteration.

### **9.4. Documentation of Informed Consent (Signed Consent)**

Informed consent must be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.

1. Informed consent is documented by the use of a written consent form (**hardcopy or digitally secured**) approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent.
2. A copy of the consent form must be given to the person signing the form.
3. The consent form may be either of the following:
  - a. **written consent document** (preferred by federal regulations and the IRB) that embodies the

elements of informed consent; it may be read to the subject or the subject's legally authorized representative, but the subject or representative must be given adequate opportunity to read it before it is signed; or

b. **short form written consent document** (with justification to the IRB for its use) stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, 1) there must be a witness to the oral presentation; 2) the IRB must approve a written summary of what is presented to be signed by the subject or representative; 3) the witness must sign both the short form and a copy of the summary; 4) the person actually obtaining consent must sign a copy of the summary; 5) a copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

## **9.5. Waiver of Documentation of Informed Consent (Waiver of Signed Consent)**

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that the:

1. only record linking the subject and the research would be the informed consent document and the principal risk would be potential harm resulting from a breach of confidentiality (**NOTE:** Subjects must be asked whether they want documentation linking them with the research, and their wishes must govern.).
2. the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

## **9.6. Review and Approval of the Informed Consent Form**

The IRB is responsible for the review and approval of the informed consent form prepared by the investigator.

- The wording on the informed consent form must contain all of the required elements and meet all other requirements as described in this section.
- The IRB needs to ensure that the required language for a valid authorization to release health information is included in separate HIPAA (Health Insurance Portability and Accountability Act) Authorization form.
  - The IRB may waive the requirement for an authorization or may alter the form or content of the authorization only in accordance with and as permitted by the HIPAA Privacy Rule (45 CFR 164.508). Such actions and the justification for them must be fully documented in the minutes of the IRB meeting where the action was taken or reported (if approved by expedited review).

## **9.7. Parental Permission and Assent**

See Section 10.1.1 for policies on parental permission and assent in research involving children.

## **9.8. Surrogate Consent**

Policies and procedures governing human subjects research are designed to protect human subjects from exploitation and harm and, at the same time, make it possible to conduct essential research on problems that are unique to persons who are incompetent, or who have an impaired decision-making capacity.

The regulations generally require that the investigator obtain informed consent from subjects. Under

appropriate conditions, investigators also may obtain informed consent from a *legally authorized representative* of a subject (surrogate consent).

- **Definition:** **Legally authorized representative** means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
  - If there is no applicable law addressing this issue, **legally authorized representative** means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. [45 CFR 46.102(i)].

Surrogate consent may be obtained from a court appointed guardian of the person **or** a health care agent appointed by the person in a Durable Power of Attorney for Health Care (DPAHC).

- For example, a subject might have designated an individual to provide consent with regard to health care decisions through a durable power of attorney and have specified that the individual also has the power to make decisions on entry into research.
- Such surrogate consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements:
  1. The practitioner may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
  2. Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.

The IRB may require investigators to conduct a **competency assessment** whenever there is a possibility of either impaired mental status or decision-making capacity in prospective subjects.

If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

## **9.9. Consent and Language Barriers**

Researchers should prepare both English language and translated consent forms for studies that include non-English-speaking subjects.

- An explanation of the translations and evidence of the comparability of the English and non-English consent forms may be requested by the IRB.
- The IRB may consult with language experts or require a "back-translation" into English.
- The protocol should include documentation that verifies the accuracy of the translation and back-translation.
- The IRB may request additional protections in the description of methods for non-English-speaking subjects, including but not limited to, evidence that the translation took place, identification of the translator, and documentation of the translator's belief that the subject understood the study and the consent process.

## 10 Vulnerable Populations

### 10.1 Research Involving Children

Research involving children is governed by 45 CFR 46, Subpart D.

#### 10.1.1 Definitions

**Children** –individuals who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Residents under 18 years of age are considered minors in California, unless they are "emancipated" by court order. For research with children in other jurisdictions the investigators must know the age considered 'adult'.

**Assent** - a child's affirmative agreement to participate in research. Mere failure to object, absent affirmative agreement, should not be construed as assent.

**Permission** - the agreement of parent(s) or legal guardian to the participation of their child or ward in research.

**Parent** - a child's biological or adoptive parent.

**Legal guardian** - an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

#### 10.1.2 Allowable Categories

The IRB will look at the extent of risk to the child based upon their age, maturity, and psychological state, and will categorize research with minor children into one of the following four groups.

- **46.404 Research not involving greater than minimal risk.**
- **46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.**
- **46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.**
- **46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**

Consent by one or both parents (or legal guardians) and assent by the child are dependent upon the category and numerous factors that the IRB will consider and evaluate on a protocol by protocol basis. Stipulations in federal regulations apply, but they also allow for determinations by the CSUEB IRB.

1. Research not involving physical or emotional risk greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests, thus minimal risk. [45 CFR 46.404]
  - Only one parent or legal guardian needs to give permission
  - Assent by the child is required
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subject. [45 CFR 46.405]
  - The risk is justified by the anticipated benefit to the subjects
  - Only one parent or legal guardian needs to give permission
  - Assent by the child is required
3. Research involving greater than minimal risk and no reasonable prospect of direct benefit to the individual subject, but likely to yield generalizable knowledge about the subject's disorder or condition. [45 CFR 46.406]

- The risk represents a minor increase over minimal risk;
- The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations
- The permission of both parents, or legal guardian, is required (unless one parent is deceased, unknown, incompetent, or not reasonably available or only one parent has legal responsibility for the care and custody of the child)
- Assent by the child is required

4. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children. [45 CFR 46.407]

- Research in this category must be considered carefully, and if federally funded by PHS, must be approved by the Secretary of Health and Human Services, and requires consent of either both parents, or legal guardian, and assent by the child.

### **10.1.3 Parental Permission and Assent**

#### **10.1.3.1 Parental Permission**

In accordance with 45 CFR 46.408(b), the IRB must determine that adequate provisions have been made for soliciting the permission of each minor's parent(s) or guardian.

- Parents or guardians must be provided with the basic elements of consent as stated in 45 CFR 46.116(a)(1-8) and any additional elements the IRB deems necessary.
- The IRB may find that the permission of one parent is sufficient for research to be conducted under 45 CFR 46.404 or 45 CFR 46.405. The IRB's determination of whether consent must be obtained from one or both parents will be documented in the meeting minutes.

Consent from both parents is required for research to be conducted under 45 CFR 46.406 and 45 CFR 46.407 unless

- One parent is deceased, unknown, incompetent, or not reasonably available; or
- When only one parent has legal responsibility for the care and custody of the child

The IRB may waive the requirement for obtaining consent from a parent or legal guardian if:

- The research meets the provisions for waiver in 45 CFR 46.116(d)(1-4) and if the IRB determines that the research protocol is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children)
- An appropriate mechanism for protecting the minors who will participate as subjects in the research is substituted, and that the waiver is not inconsistent with Federal, State, or local law.
  - The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Permission from parents or legal guardians must be documented in accordance with and to the extent required by 45 CFR 46.117.

#### **10.1.3.2 Assent from Children**

The assent process should be tailored to the age, maturity, and psychological state of the children involved and should be easy for the children to understand. The CSUEB IRB recommends the following to obtain assent, but may require other means such as all noted below and in certain circumstances:

- verbal script (ages 7 to 11),
- written assent document (ages 12 to 15), and
- a written assent matching the detail of an adult consent document (ages 16 to 17).

Minor subjects 12 years of age or older must sign assent after the parent or legal guardian has given consent unless [45 CFR 46.404]:

- The research holds out the prospect of direct benefit to the subject and which is available only in the context of the research (e.g., new therapy when none is available)
- The subject is incapable, mentally or emotionally, of being reasonably consulted
- The IRB specifically waives the requirement.

Except when the above exclusions are present, children between the ages of 7 and 17 must give positive assent directly to participation in the research.

At times there may be inconsistency between parental permission and child assent.

- A "no" from the child should be regarded as the desire of the child and seen to override a "yes" from a parent.
- Conversely, a child typically cannot decide to participate in a study over the objections of a parent.
- There are individual exceptions to these guidelines (such as when the use of an experimental treatment for a life threatening disease is being considered). The underlying principle is that children should not be forced to be research subjects, even when their parents give permission and consent.

### **The Assent Form**

Researchers must draft a form that is age appropriate and study specific, considering the typical child's experience and level of understanding, and composing a document that treats the child respectfully and conveys the essential information about the study. The assent form should do the following:

1. Tell why the research is being conducted, in simple, age-appropriate language.
2. Describe what will happen and for how long or how often.
3. Say it is up to the child to participate and that it is okay to say no.
4. Explain if any aspect of involvement in the research will hurt and if so for how long and how often.
5. Say what the child's other choices are, including withdrawing from participation.
6. Describe any good things (benefits) that might happen.
7. Say whether there is any compensation for participating.
8. Encourage the asking of questions.

- For younger children, the assent document should be limited to one page if possible.
- Illustrations might be helpful and large type makes a form easier for young children to read.
- Studies involving older children or adolescents should include more information and may use more complex language.

**In determining whether children are capable of assenting**, the CSUEB IRB will consider the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.

- If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research.

Even when the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances detailed in the Waiver of Informed Consent section of this manual.

In addition, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legal guardian permission is not a reasonable requirement to protect the subjects (e.g., neglected or abused children), it may waive consent requirements of parents or legal guardians, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided that the waiver is not inconsistent with Federal, State, or local law.

- The choice of an appropriate mechanism would depend upon the nature and purpose of the

research activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

When parental or legal guardian permission is obtained, and child assent is required it must be documented in accordance with and to the extent described in the federal regulations and Informed Consent and Assent sections of this manual.

#### **10.1.3.3 Children Who are Wards**

Children who are wards of the State or any other agency, institution, or entity can be included in research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition, **only if such research is:**

- related to their status as wards; or
- conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research meets the condition(s) above, an advocate must be appointed for each child who is a ward (one individual may serve as advocate for more than one child), in addition to any other individual acting on behalf of the child as legal guardian or in *locum parentis*.

- The advocate must be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

### **10.2 Research Involving Pregnant Women, Human Fetuses and Neonates**

Research involving Pregnant Women, Human Fetuses and Neonates is governed by 45 CFR 46, Subpart B.

#### **Definitions**

**Dead fetus** - A fetus that exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord.

**Delivery** - Complete separation of the fetus from the woman by expulsion or extraction or any other means.

**Fetus** - The product of conception from implantation until delivery.

**Neonate** - A newborn.

**Nonviable neonate** - A neonate after delivery that, although living, is not viable.

**Pregnancy** -- The period of time from implantation until delivery. A woman is assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

**Viable** - As it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

#### **Research Involving Pregnant Women or Fetuses**

Pregnant women or fetuses may be involved in research if all of the following conditions are met [45 CFR 46.204]:

- Where scientifically appropriate, pre-clinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;
- The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the

fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

- Any risk is the least possible for achieving the objectives of the research;
- If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the provisions for informed consent;
- If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the provisions for informed consent, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
- Each individual providing consent under paragraph 4. or 5. of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
- For children who are pregnant, assent and permission are obtained in accord with the provisions of permission and assent;
- No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
- Individuals engaged in the research will have no part in determining the viability of a neonate.

## **Research Involving Neonates**

Neonates of uncertain viability and nonviable neonates may be involved in research if all of the following conditions are met [45 CFR 46.205]:

- Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.
- Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.
- Individuals engaged in the research will have no part in determining the viability of a neonate.
- The requirements of Neonates of Uncertain Viability or Nonviable Neonates (see below in this section) have been met as applicable.

**Neonates of Uncertain Viability.** Until it has been ascertained whether or not a neonate is viable, a neonate may not be involved in research covered by this subpart unless the following additional conditions have been met:

The IRB determines the following:

- The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective, or
- The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; **and**
- The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained in accord with the provisions of permission and assent, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

**Nonviable Neonates.** After delivery, nonviable neonates may not be involved in research covered by this subpart unless all of the following additional conditions are met:

- Vital functions of the neonate will not be artificially maintained;
- The research will not terminate the heartbeat or respiration of the neonate;
- There will be no added risk to the neonate resulting from the research;
- The purpose of the research is the development of important biomedical knowledge that cannot

- be obtained by other means; and
- The legally effective informed consent of both parents of the neonate is obtained in accord with the provisions of permission and assent, except that the waiver and alteration of the provisions of permission and assent do not apply.
- However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice to meet the requirements of this paragraph, except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph.

**Viable Neonates.** A neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of IRB Review Process and Research Involving Children.

#### **Research Involving, after Delivery, the Placenta, the Dead Fetus or Fetal Material**

- Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, must be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.
- If information associated with material described above in this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent sections of this manual are applicable. [45 CFR 46.206]

#### **Research Not Otherwise Approvable**

The Secretary of the Department of Health and Human Services (DHHS) will fund research that the IRB does not believe meets the requirements of **Research Involving Pregnant Women or Fetuses** or **Research Involving Neonates** only if [45 CFR 46.207]:

- The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and
- The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:
  - a. That the research in fact satisfies the conditions of **Research Involving Pregnant Women or Fetuses**, as applicable; or
  - b. The following:
    - 1) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates;
    - 2) The research will be conducted in accord with sound ethical principles; and
    - 3) Informed consent will be obtained in accord with the provisions for informed consent and other applicable sections of this manual.

### **10.3 Research Involving Prisoners**

Research involving prisoners is governed by 45 CFR 46, Subpart C.

#### **Applicability**

This policy applies to all biomedical and behavioral research conducted under the auspices of CSUEB involving prisoners as subjects. Even though the IRB may approve a research protocol involving prisoners as subjects according to this policy, investigators are still subject to the administrative regulations of the California State Department of Corrections and Rehabilitation and any other applicable state or local law. [45 CFR 46.301]

#### **Purpose**

Whereas prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this policy to provide additional safeguards for the protection of prisoners involved in research activities to which this subpart is applicable. [45 CFR 46.302]

## Definitions

[According to 45 CFR 46.303]

**Prisoner** – any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

**Minimal Risk** – the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

## Composition of the IRB

In addition to satisfying the general requirements detailed in the IRB section of these procedures, **when reviewing research involving prisoners, the IRB must also meet the following requirements [45 CFR 46.304]:**

- A majority of the IRB (exclusive of prisoner members) must have no association with the prison(s) involved, apart from their membership on the IRB.
- At least one member of the IRB must be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

## Additional Duties of the IRB

In addition to all other responsibilities prescribed for the review process sections of this set of procedures, the CSUEB IRB will review research involving prisoners and approve such research only if it finds that [45 CFR 46.305]:

1. The research falls into one of the following **permitted categories** [45 CFR 46.306]:
  - a. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - b. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;
  - c. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research; or
  - d. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology medicine and ethics, and published notice, in the Federal Register, of his intent to approve such research.
2. any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the

prison is impaired;

3. the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;
4. procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. the information is presented in language which is understandable to the subject population;
6. adequate assurance exists that parole Board will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. where the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, considering the varying lengths of individual prisoners' sentences, and for informing subjects of this fact.

In addition to the federal regulations given above, CSUEB IRB policy allows for review of prisoner research only if it is initiated by:

- A faculty or staff member with documented experience conducting research with prisoners, or who has included in their research team an individual with documented experience conducting research with prisoners; or
- An unaffiliated investigator with documented experience conducting research with prisoners who has included CSUEB faculty, staff or students in their research team.

**Please note that CSUEB does not allow for review of student-initiated research that includes research with prisoners.**

### **Waiver for Epidemiology Research**

The Secretary of DHHS has waived the applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain research conducted or supported by DHHS that involves epidemiologic studies that meet the following criteria:

- (1) In which the sole purposes are
  - (i) To describe the prevalence or incidence of a disease by identifying all cases, or
  - (ii) To study potential risk factor associations for a disease, and
- (2) Where IRB has approved the research and fulfilled its duties under 45 CFR 46.305(a)(2)–(7) and determined and documented that
  - (i) The research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and
  - (ii) Prisoners are not a particular focus of the research.

- The specific type of epidemiological research subject to the waiver involves no more than minimal risk and no more than inconvenience to the human subject participants. The waiver would allow the conduct of minimal risk research that does not now fall within the categories set out in 45 CFR 46.306(a)(2).
- The range of studies to which the waiver would apply includes epidemiological research related to chronic diseases, injuries, and environmental health. This type of research uses epidemiologic methods (such as interviews and collection of biologic specimens) that generally entail no more than minimal risk to the subjects.
- In order for a study to be approved under this waiver, the IRB would need to ensure that, among other things, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

### **10.4 Persons with Mental Disabilities or Persons with Impaired Decision-Making Capacity**

Research involving subjects who are mentally ill or subjects with impaired decision-making capacity warrants special attention. This section does not particularly address scope of practice concerns or ethical issues surrounding the same.

- Research involving these populations may present greater than minimal risk;
- may not offer direct medical benefit to the subject;
- and may include a research design that calls for washout, placebo, or symptom provocation.
- In addition, these populations are considered to be vulnerable to coercion.

### **IRB composition**

The IRB membership must include at least one member who is an expert in this area of research.

- Consideration may be given to adding another member who is a member of the population, a family member of such a person or a representative of an advocacy group for that population.
- The IRB may utilize *ad hoc* members as necessary to ensure appropriate expertise.

### **Approval Criteria**

Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:

1. Only incompetent persons or persons with impaired-decision making capacity are suitable as research subjects for the particular study.
  - Competent persons are not suitable for the proposed research.
  - The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects.
  - Incompetent persons or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.
2. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant.
  - Incompetent people or persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.
3. Procedures have been devised to ensure that participant's representatives are well-informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision-making capacity.
  - Health care agents [appointed under Durable Power of Attorney for Health Care (DPAHC)] and next-of-kin, or guardians, must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

### **Additional Concerns**

Both investigators and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate.

- For subjects with fluctuating decision-making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.
- **It is the responsibility of investigators to monitor the decision-making capacity of subjects enrolled in research studies and to determine if surrogate consent must be re-obtained. Note, however, that having worked or currently working with people with impaired decision-making, does not qualify one outright for determining competency. Competency must be judged by one qualified to make such determination.**
- The IRB may require investigators to obtain a competency assessment whenever there is a

possibility of either impaired mental status or decision-making capacity in prospective subjects.

Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

## **11 Complaints, Non-Compliance, and Suspension or Termination of IRB Approval of Research**

### **11.1 Complaints**

The Chair of the IRB and the IRB Coordinator at CSUEB will promptly handle (or delegate staff to handle), and, if necessary, investigate all complaints, concerns, and appeals received by the IRB. This includes complaints, concerns, reports of deviation from protocols, and appeals from investigators, research participants, and others.

### **11.2 Expressions of Concern and General Information**

The IRB Chair and the IO shall receive and consider expressions of concern from any source regarding adequacy of protection for human subjects involved in research or related activities conducted at or sponsored by CSUEB.

The IRB Chair and IRB Coordinator, through the university web, shall also provide investigators with information regarding all regulations and procedures affecting protection of human subjects in research and related activities.

### **11.3 Non-Compliance**

All members of the CSUEB community involved in human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with federal and state regulations and institutional and IRB policies governing the conduct of research involving human subjects.

- **“Non-compliance”** is defined as failure to comply with any of the regulations and policies described in the Assurance or these procedures. Non-compliance may be minor or sporadic or it may be serious or continuing. Non-compliance often stems from deviating from an approved protocol or conducting a human subject activity without an approved protocol.
- **“Minor or sporadic non-compliance”** is defined as failure to comply with IRB policies, which in the opinion of the IRB Chair and IRB Coordinator are administrative in nature. Examples of minor or sporadic non-compliance could include turning in a report of an unanticipated problem a day late or failure to date a consent form.
- **“Serious non-compliance”** is defined as failure to follow any of the regulations and policies described in this document and which, in the judgment of either the IRB Chair or the convened IRB, increases risks to participants, decreases potential benefits, or compromises the integrity of the human research protection program. Research being conducted by any investigator (student, responsible investigator, etc.) without prior IRB approval is considered serious non-compliance.
- **“Continuing non-compliance”** is defined as a pattern of non-compliance that, in the judgment of the IRB Chair or convened IRB, suggests a likelihood that instances of non-compliance will continue without intervention. Continuing non-compliance also includes failure to respond to a request to resolve an episode of non-compliance.
- If in the judgment of the IRB Chair and IO, the reported non-compliance is not serious, not continuing, and the proposed corrective action plan seems adequate, no further action is required.

### **11.4 Inquiry Procedures**

In the event of a reported instance of non-compliance by an Investigator as stated herein, the CSUEB IRB will make a good-faith effort to work with the Investigator to gather relevant information on a ‘Deviation Report,’ and to clarify any misunderstandings that may have resulted in a concern over non-compliance.

If after seeking information from the Investigator, the IRB determines that there may be grounds for the

report of non-compliance, the IRB will conduct a thorough inquiry. A determination may be made that an inquiry is necessary by the IRB based on several issues that may include but are not limited to the following:

- Subjects' complaint(s) that rights were violated.
- Report(s) that the investigator is not following the protocol as approved by the IRB.
- Evidence of failure to submit a human subject research protocol to the CSUEB IRB for review for research being conducted with human subjects at or by CSUEB as described.
- Unusual and/or unexplained adverse events in a study.
- An external (e.g., sponsor) audit.
- Repeated failure of investigator to report required information to the IRB.

If in the judgment of the IRB Chair and IO, the reported non-compliance is serious, but not continuing, and the proposed corrective action plan seems adequate, the non-compliance event will be recorded and the corrective actions will be verified. If the corrective actions are completed as specified and no additional non-compliance is determined to have taken place, no further action is required.

If in the judgment of the IRB Chair and IO, the non-compliance is serious and continuing, a formal inquiry (described below) may be held.

If in the judgment of the IRB Chair and IO, any report or allegation of non-compliance warrants suspension or termination of the research before completion of any review or investigation to ensure protection of the rights and welfare of participants, the IRB Chair may terminate or suspend the research as described in below with subsequent review by the IRB.

If appropriate given a serious or continuing non-compliance, the IO and IRB chair will appoint a subcommittee consisting of IRB members, and non-members if appropriate, to ensure fairness and expertise. The subcommittee is to be given a charge by the IRB, which can include any or all of the following:

- Review of the protocol(s) in question.
- Review of federal audit report of the investigator, if applicable and appropriate.
- Review of any relevant documentation, including consent documents, case report forms, subject's investigational and/or medical files etc., as they relate to the investigator's execution of her/his study involving human subjects.
- Interview of appropriate personnel if necessary.
- Preparation of either a written or oral report of the findings, which is presented to the full IRB at its next meeting.
- Recommended actions, if appropriate.

  

- The IRB determines the appropriate action based on its own knowledge and the facts gathered by the IRB Chair, IRB, or appointed subcommittee investigation.
- The IRB keeps the investigator informed about the subcommittee and IRB's final determination in writing.
- The IRB Chair ensures documentation in the form of a "Deviation Report Management Memo" that describes the report received, review conducted, determinations, action plan, and final actions taken.
- The IRB Coordinator attaches the completed Deviation Report and Deviation Report Management Memo to the protocol in question in the Cayuse Human Ethics module. If no protocol existed, the investigators in question may be required to complete a protocol in the Cayuse module for documentation purposes, even though protocols cannot be approved in arrears.

## **11.5 Unreviewed Research**

In the event that the IRB determines that research with human subjects was or is being conducted at

CSUEB or by a CSUEB Investigator without a protocol having been submitted for review and approval by the CSUEB IRB, the IRB will immediately inform the Institutional Official of the non-compliance.

The Institutional Official will then report such non-compliance to those who, in the judgment of the IO, need to be informed, who would include, but are not limited to: the Investigator, the appropriate Faculty Advisor or Mentor, the Department Chair, College Dean, and/or School Director. The research must be stopped, a deviation report created and reviewed as described in 11.4.

## **11.6 Suspension or Termination**

In the event of non-compliance, and pursuant to the procedures specified herein, the CSUEB IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects.

- Any suspension or termination of approval must include a statement of the reasons for the IRB's action in writing and must be reported promptly to the investigator;
- and, if appropriate, the sponsor, appropriate institutional officials, and the Department of Health and Human Services or Agency head (when funded by PHS).

**When study approval is terminated by the IRB**, in addition to stopping all research activities, any subjects currently participating will be notified that the study has been terminated.

- Procedures for withdrawal of enrolled subjects should consider the rights and welfare of subjects.
- If follow-up of subjects for safety reasons is permitted and/or required by the IRB, the subjects will be informed and any adverse events/outcomes will be reported to the IRB and the sponsor.

Failure to abide by the Assurance and these CSUEB **Procedures for the Protection of Human Subjects** and federal regulations may result in the following sanctions, among others:

- Suspension or termination of IRB approval of specific research protocols or of all research involving human subjects in which the investigator participates. Repeated circumstances could result in the loss of privilege to conduct human subject research within the department or college.
- DHHS action. In making decisions about supporting or approving applications or proposals covered by this policy the Department of Health and Human Services or Agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension as described above, and whether the applicant or the person or persons who would direct or has directed the scientific and technical aspects of an activity has, in the judgment of the Department of Health and Human Services or Agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects.
- Institutional or individual action by the federal OHRP and/or the FDA, when applicable. The federal OHRP and/or the FDA may
  - withhold approval of all new CSUEB studies by the IRB;
  - direct that no new subjects be added to any ongoing studies;
  - terminate all ongoing studies, except when doing so would endanger the subjects; and/or
  - notify relevant state, federal and other interested parties of the violations.
- In the event of non-compliance, the IRB will notify all relevant officials, administrators, or faculty of the event, as appropriate. The IRB will refer for **disciplinary action** the investigator or other personnel involved in a study pursuant to CSUEB policies and procedures, up to and including revoking confirmation of a degree, retraction of a published paper, and dismissal.

Failure to secure necessary CSUEB IRB approval before commencing human subject research must be reported to the Institutional Official responsible for the IRB. In addition to the determination and action made through the deviation report review, the IO may refer the matter to the appropriate Dean and Provost for possible disciplinary action.

Investigators should also be aware that, in general, CSUEB **indemnifies** them from liability for adverse

events that may occur in CSUEB studies that are approved by the CSUEB IRB.

- Failure to follow approved procedures may compromise this indemnification and make the investigator **personally liable** in such cases.

## **11.7 Reporting**

Unanticipated problems involving risks to subjects or others, serious or continuing noncompliance with regulations or the requirements or determinations of the IRB, and suspensions or terminations of IRB approval must be promptly reported by the IRB and the IRB Coordinator as appropriate to the:

1. Institutional Official (IO)
2. Investigator's department chair and dean as appropriate, and
3. The federal Office for Human Research Protections and any sponsoring department or agency head (if externally funded).

If the determination includes suspension of a federally-funded investigator, the federal OHRP, Division of Compliance Oversight (DCO) must be notified by the IRB Coordinator. Reports to OHRP will be submitted in accordance with federal requirements and directed to the OHRP Division of Compliance Oversight (DCO), as applicable.

All appropriate institutional officials must be informed of the IRB's decision.

## 12 Investigator Responsibilities

**Principal investigators (PIs) are ultimately responsible for the conduct of research.** PIs may delegate research responsibility; however, they must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility. The CSUEB Assurance and these procedures apply to employees, including faculty members, staff, and student investigators.

In order to satisfy federal regulations and protect human subjects, PIs who conduct research involving human subjects must:

- develop and conduct research that is in accordance with the ethical principles in the Belmont Report;
- develop a research plan that is scientifically sound and minimizes risk to the subjects;
- have sufficient resources necessary to protect human subjects, including: supervision, a sufficient number of appropriately trained staff, and appropriate support services;
- protect the rights and welfare of prospective subjects;
- have plans to monitor the data collected for the safety of research subjects;
- have a procedure to receive complaints or requests for additional information from subjects and respond appropriately;
- ensure that pertinent laws, regulations, and institution procedures and guidelines are observed by participating faculty and research staff;
- obtain and document informed consent as required by the IRB and ensuring that no human subject is involved in the research prior to obtaining their consent;
- ensure that all research involving human subjects receives IRB review and approval in writing before commencement of the research;
- comply with all IRB decisions, conditions, and requirements;
- ensure that protocols receive timely continuing IRB review and approval by submitting timely requests;
- report unexpected or serious adverse events to the IRB;
- obtain IRB review and approval in writing before changes are made to approved protocols or consent forms; and
- seek IRB assistance when in doubt about whether proposed research requires IRB review.

### 12.1 Investigators

#### Principal Investigators

At CSUEB **faculty or staff members** may serve as the Principal Investigator or as the faculty sponsor for students on a research project involving human subjects.

Emeriti and adjunct faculty of the University may also serve as the PI or as the faculty sponsor for students on a research project involving human subjects.

The IRB recognizes one responsible PI (Responsible Investigator or RI) for each study, who has ultimate responsibility for the research activities. For faculty and staff submitting protocols, the PI is equivalent to the RI. Protocols that require skills beyond those held by the PI must be modified to meet the investigator's skills or have one or more additional qualified faculty as co-investigator(s). In the case of a student submitting a protocol, a faculty or staff advisor must act as the Responsible Investigator (RI).

#### Student Investigators

Students may serve as Co-PIs. They must have a faculty sponsor who fulfills the Responsible Investigator (RI) eligibility criteria and who will serve as faculty advisor on the study. At CSUEB the Cayuse Human Ethics (IRB) system is used for submission of protocols. When submitting the protocol the research team lists the faculty advisor as Principal Investigator and the student as Co-PI.

## **Research Team**

The PI and other individuals, also known as co-investigators, who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the protocol, constitute the “research team.”

## **12.2 Protocol Development**

Using the Cayuse Human Ethics (IRB) system, the investigators must carefully and fully develop the protocol, including a detailed description of the research project, and required attachments, including consent/assent form(s), making sure that consent information is aligned with the research plan.

The protocol application must include or address:

- Title of the study
- Purpose of the study
- Sponsor of the study
- Results of previous related research as appropriate
- Subject inclusion/exclusion criteria
- Recruitment procedures
- Justification for use of any special/vulnerable subject populations
- Study design (including, as needed, a discussion of the appropriateness of research methods)
- Description of procedures to be performed
- The possible/potential risks to the subjects
- Provisions for minimizing risks/managing adverse reactions
- The anticipated benefits of the research
- An assessment of the risk/benefit ratio
- Circumstances surrounding the consent procedure
  - Setting
  - Subject autonomy concerns
  - Language difficulties
  - Vulnerable populations
  - Procedures for documenting informed consent
  - Obtaining assent from minors
  - Using witnesses and/or translators
- Document and data storage
- Compensation to subjects for their participation, if any (rare)
- Compensation for injuries to research subjects (high risk studies)
- Costs to subjects for their participation in the study, if any
- Costs to third-party payers because of subject's participation
- Provisions for protection of subject's privacy
- Description of the resources available to protect research subjects, including: supervision, number and training of staff, appropriate support services
- Training and experience with human subjects and conduct of research with human subjects.

Proposed consent/assent form (as applicable) must include or address:

1. The general principles and basic elements of informed consent
2. Translated consent documents, as necessary, considering likely subject population(s)
3. Approved formats for consent or waiver of consent conditions.

Prior to final approval of the protocol by the IRB the investigator must receive all other approvals that may be needed and provide evidence of the approval as attachments to the protocol, (e.g., CSUEB's Environmental Health and Safety certification of specific equipment requiring such).

If the researcher is submitting a proposal for or has received an award of federally-sponsored funding, a copy of the proposal or scope of work and human subject-related details must be included as an attachment with the protocol.

- If there is a significant variation between the proposal to the federal agency and the IRB protocol, the

- investigator must identify and justify the discordance.
- Members of the ORSP may review IRB applications against funding and contract requirements, guidelines, and approved documents.
- It is the PIs responsibility to ensure that the ORSP post-award staff receives a copy of the Human Subject Research Approval Letter prior to expending sponsored-funds (e.g., grant funding) for human subject research.

### **12.3 Modifications to Approved Research**

Investigators must seek IRB approval before making changes in approved research, unless the change is necessary to eliminate an immediate hazard to the subject (in which case the IRB must then be notified at once).

- Minor changes (i.e., changes that do not involve increased risk or discomfort) may be approved by the IRB Chair.
- The PI must submit requests for approval of modifications through the Cayuse Human Ethics (IRB) system by accessing the original approved protocol in the system, clicking on 'New Submission', and then choosing "Modification." See section 7.5 Modification of an Approved Protocol for more information.
- **NOTE:** IRB approved modifications to ongoing research do NOT extend the original approval expiration date unless continuing review is also conducted.

### **12.4 Continuing Review after Protocol Approval**

Ongoing research studies approved with a full-board review must be reviewed by the IRB at least annually for research, or more often if the IRB finds that the degree of risk to subjects warrants more frequent review.

- **This renewal must take place prior to the approval expiration date noted on the approved protocol;** otherwise, subject recruitment/enrollment must be suspended and, if the research is DHHS-sponsored, the Agency must be notified.
- **It is the responsibility of the investigators to know when their protocol expires and submit a timely continuing review application.**
- The investigator should allow sufficient time for development and review of renewal submissions.

**NOTE:** The "approval date" and the "approval expiration date" are listed on all IRB approval letters..

In addition to the usual protocol submissions to the IRB, a progress report must be included with the request for continuation including information since the last protocol review. See section 7.4 Continuing Review of Active protocols for more information.

### **12.5 Required Reports to the IRB**

Prompt reporting, within 10 working days, to the IRB Chairperson and IRB Coordinator at [irb@csueastbay.edu](mailto:irb@csueastbay.edu) is required when any unanticipated problem involving risks to subjects or others occurs. In addition the following reports are required.

- Investigators must promptly report any unexpected or serious adverse event. This includes study-related injuries or events, including those which are previously unknown reactions that are more severe than mild, as well as expected or well-described reactions that are either life-threatening or fatal.
- Investigators must report the progress of the research to the IRB in the manner and frequency prescribed by the IRB, but no less than once a year for research approved with full board review.
- When a research project approved with full board review is completed, the investigator must promptly notify the IRB and file a final progress report, (including the information listed above for continuing review of protocols), for the last research project period.

Once data collection has been completed and the research is closed at the University, the PI is not required to submit any further reports of the research to the IRB, but should submit notification of closure of the protocol using the Cayuse Human Ethics (IRB) system.

## 12.6 Investigator-Required Record Keeping

Investigators must retain copies of approved IRB documents. Investigators must implement a system to comply with retention and approval expiration dates.

- In addition to providing a copy of the signed and dated consent form to each subject,
  - a copy must be stored securely by the PI and placed in the subject's file (or medical record if the subject is a patient and this requirement has not been waived by the IRB),
  - and a copy must be retained by the PI for a minimum of three years after completion of the research.

## 12.7 Conflict of Interest – Investigators

All investigators must follow the CSUEB [Conflict of Interest Policy](#).

- Investigators must identify for resolution under that policy's specific procedures any conflict of interest associated with a study, including but not limited to their personal investment in or other financial relationship with a company that might profit from the study.
- As part of the protocol submittal process for IRB approval, all investigators must disclose any potential or real financial conflict of interest they may have as a result of the sponsorship for the study.
- If the Investigator is permitted to proceed with the study following review under the Conflict of Interest and IRB policies and processes, the research consent form provided to subjects must include an appropriate description of any relationship that might be received as a potential conflict of interest. **Such disclosure must be also reflected in the consent form.**
- If the Conflict of Interest status of an investigator changes during the course of a study, the individual is required to declare this to the IRB Coordinator and ORSP for externally funded research.

## 12.8 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 and complete core training requirements.
- 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.
- To satisfy the initial education requirement, investigators conducting non-exempt category research must complete the required modules with an overall competency level at 80%.

New research protocols and applications for continuing review of non-exempt research will not be approved from investigators (and applicable members of their team) who have not completed their required 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 CSUEB 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, or CITI IRB Members training** 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 study.

**Continuing Education and Recertification** – All PIs, staff, students and research personnel who conduct non-exempt category 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.

- Recertification of training must be accomplished by taking the online “refresher course” offered by CITI through CSUEB.
- While the CITI training system and the Cayuse Human Ethics training are collaborative systems, upon request PIs must submit documentation of the successful completion of the refresher course by all personnel involved in human subject research to the ORSP, to the IRB, or to other institutional officials.
- Investigators who are also IRB Chair, IRB members, or part of the IRB staff will need to satisfy specific training requirements, e.g., the IRB Member training.

## **Additional Resources**

- Human research protection information is available on the [IRB web page](#) on an ongoing basis to ensure that the University research community is apprised of current regulatory and policy requirements and training opportunities.
- System training job aids are available on the CSU East Bay website and additional systems training is available upon request. Please direct any requests for Human Subject-related training to [irb@csueastbay.edu](mailto:irb@csueastbay.edu).
- The federal Office of Human Research Protections (OHRP) also offers free training. Their website is <http://www.hhs.gov/ohrp/>.

## **12.9 Subject Recruitment**

Investigators are responsible for recruiting research subjects in a manner that is justifiable, fair, ethical and equitable. IRB approval is required for all recruitment procedures and materials.

- Recruitment materials must be consistent with the approved IRB protocol, accurate, and not coercive.
- Recruitment of subjects from other institutions (places of work, schools, public venues, etc.) may require a form of authorization or permission to recruit there, which is the obligation of the investigator. If the other institution will be performing recruitment or data collection, then they are an institution involved in the research of the study and would need IRB protocol approval.

## **12.10 Payment to Subjects**

Plans to pay participants must be justifiable and equitable. The researchers must carefully consider the feasible, appropriateness, level of involvement and potential participant out of pocket expenses, and the ramifications or impact of the payment on the participant. The CSUEB IRB will review both the proposed amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence or other negative impact to the participant.

- Payment to research subjects may be an incentive for participation or a way to reimburse a subject for travel and other expenses incurred due to participation. However, payment for participation is not considered a research benefit and must not be used to coerce subjects to participate in the research.
- Payments should reflect the degree of risk, inconvenience, expense, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study.
- The consent form must describe the terms of payment and the conditions under which subjects

would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

Payment or compensation is the responsibility of the investigator, not the IRB, and must follow state, federal, and local regulations and policies. Payments are subject to IRS regulations and may impact financial aid and taxes

- For example, concerns of identifying information to issue checks, cash, or gift certificates to payees, use of social security number, verification of U.S. citizenship or permanent resident status, etc., to receive payment are all the responsibility of the investigator.
- In particular, payments to CSUEB students may only be made through their BayCards and have an impact on financial aid.
- See [the FAQs Research Participant Incentives Payments](#) for more information.

## **12.11 Investigator Concerns**

Investigators who have concerns or suggestions regarding CSUEB's human research protection program should convey them to the IRB chair and IRB Coordinator at [irb@csueastbay.edu](mailto:irb@csueastbay.edu), or through direct email or to the institutional official (IO), as appropriate.

- The appropriate entity will research the issue, and when deemed necessary, convene the parties involved to form a response for the investigator or make necessary procedural or policy modifications, as warranted.

## **13 Health Insurance Portability and Accountability Act (HIPAA)**

HIPAA regulations apply to 'covered entities'. At CSUEB only Health Care Providers under the auspices of or within CSUEB are considered covered entities. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the creation of a Privacy Rule for identifiable health information.

**The objective of the rule is to protect the privacy of an individual's health care information.** It creates a federal "floor" of protection so that every person in this country has at least the same basic rights and protections, though some may have additional rights depending on state law.

### **13.1 Effects of HIPAA on Research**

Effective April 14, 2003, the Health Information Portability and Accountability Act (HIPAA) became law. Any research that is derived from a "[covered entity](#)" (Health Care Provider under the Auspices of or within CSUEB) must comply with this law.

#### **Research under HIPAA**

HIPAA defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."

- This definition is identical with the one used in the Common Rule as given in 45 CFR 46.102.
- HIPAA describes privacy standards for protecting PHI (protected health information), and so only applies to research that involves humans' (not animals') health information. (see [NIH - HIPAA Privacy Rule, Information for Researchers](#) for further information)

#### **HIPAA and New Documentation Requirements**

When private health information is involved, then study documents submitted must include a HIPAA authorization form, a waiver of authorization form, and a de- identification form.

#### **Patient Rights and Research**

Under HIPAA, patients have certain rights.

- Those that may affect research include the right to receive a Notice of Privacy Practices,
- the right to access, inspect, and receive a copy of one's own PHI (protected health information),
- the right to request an amendment to one's own PHI,
- and the right to an accounting of certain disclosures of PHI that occur outside the scope of treatment, payment and health care operations that have not been authorized.

## 14 Special Topics

### 14.1 Certificate of Confidentiality

#### Statutory Basis for Protection

Protection against compelled disclosure of identifying information about subjects of biomedical, behavioral, clinical, and other research is provided by the Public Health Service Act §301(d), 42 U.S.C. §241(d):

"The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

- Certificates of Confidentiality constitute an important tool to protect the privacy of research study subjects. Certificates are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.
- Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to subjects. For more information, the OHRP can be consulted.
- Certificates are granted sparingly. The study's funding source, if any, is not relevant to the decision.
- The certificate goes beyond the consent form in ensuring confidentiality and anonymity. Without the certificate, researchers can be required by a court-ordered subpoena to disclose research results (usually as part of a criminal investigation of the subjects).

Any investigator engaged in research in which sensitive information is gathered from human subjects (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality. Research can be considered "sensitive" if it involves the collection of:

- information about sexual attitudes, preferences, practices;
- information about personal use of alcohol, drugs, or other addictive products;
- information about illegal conduct;
- information that could damage an individual's financial standing, employability, or reputation within the community;
- information in a subject's medical record that could lead to social stigmatization or discrimination; or
- information about a subject's psychological well-being or mental health.

This list is not exhaustive. Researchers contemplating research on a topic that might qualify as sensitive should contact the IRB Coordinator within the ORSP for help in applying for a certificate.

The IRB may require investigators to apply for a Certificate of Confidentiality.

#### Limitations

The protection offered by a Certificate of Confidentiality is not absolute. A Certificate protects research subjects only from legally compelled disclosure of their identity. It does **not** restrict voluntary disclosures.

- For example, a Certificate does not prevent researchers from voluntarily disclosing to appropriate

authorities such matters as child abuse, a subject's threatened violence to self or others, or from reporting a communicable disease.

- However, if researchers intend to make such disclosures, this should be clearly stated in the informed consent form which research subjects are asked to sign.

In addition, a Certificate of Confidentiality does **not** authorize the person to whom it is issued to refuse to reveal the name or other identifying characteristics of a research subject if

- the subject (or, if he or she is legally incompetent, his or her legal guardian) consents, in writing, to the disclosure of such information;
- authorized personnel of the Department of Health and Human Services (DHHS) request such information for audit or program evaluation, or for investigation of DHHS grantees or contractors and their employees; or
- release of such information is required by the Federal Food, Drug, and Cosmetic Act or regulations implementing that Act.

## 14.2 Mandatory Reporting

While preparing a research protocol, investigators must keep in mind that the State of California mandates reporting to designated officials and/or agencies for the following:

- Child Abuse - California Child Abuse and Neglect Reporting Act (CANRA) - California Penal Code Section 11164-11174.3
  - [CSU Mandatory Reporting of Child Abuse and Neglect Policy](#)
- Title X - Title IX of the Education Amendments of 1972, Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance (34 C.F.R. 106).
  - [Title IX](#) is a federal law that protects students, educators and school employees against all forms of sex or gender discrimination, including: sexual harassment, sexual misconduct, sexual exploitation, dating and domestic violence, stalking, and retaliation.
- Elder Abuse - California Penal Code section 368
  - [Adult Protective Services](#)
- Communicable Disease - There are requirements that public health professionals must report about 85 communicable diseases to local health departments. See Title 17 CCR section 2500 et seq; Title 16 CCR section 1364.10 (failure to report communicable disease is a misdemeanor).
  - [Alameda County Disease Control](#) or inquire at the CSUEB Student Health Center.

Investigators should consult these sources to determine if potential subjects should be advised of mandatory reporting requirements during the informed consent process.

## 14.3 Cal State East Bay Students and Employees as Subjects

As it is part of the culture at CSUEB to encourage learning-by-doing and to be involved in community-based projects, activities that involve research with human volunteers are likely to occur.

- Members of the CSUEB community themselves might then be the subjects of a research project.
- It is important to distinguish whether the project constitutes research as defined in federal regulation and review of the project would be necessary by the IRB.
- When CSUEB students and/or employees are recruited as potential subjects, researchers must ensure that there are additional safeguards for these subjects.
  - The voluntary nature of their participation must be of primary concern and without undue influence on their decision.
  - Researchers must emphasize to subjects that neither their academic status or grades, or their employment, will be affected by their participation decision.
- To minimize coercion, investigators should avoid, whenever possible, the use of their students and

employees in their research.

- This statement is not made to preclude their use.
- Investigators should solicit subjects through means such as bulletin board notices, flyers, advertisements in newspapers, and announcements in classes other than their own.
- However, when a faculty member's own students are the subjects of the research, such as in evaluating a teaching method, then, as the PI, the above concerns must be addressed in the protocol application submitted to the IRB.
- Having availability of student grades or personal student information as faculty, staff, or students does not mean the information at hand may be used for research. FERPA regulations govern what may or may not be used and what consent must be obtained before use of existing student data. Researchers planning to use CSU East Bay students as participants in their research projects should review FERPA regulations, consult with their department chair in advance, and provide a complete description of intended data collection and use in their IRB protocol. See also section 14.15 Access to CSUEB Email addresses and Student Data.

#### 14.4 Student Research

Students who are learning scientific methods in the classroom by conducting human subjects research projects for pedagogical reasons and who do not intend to publish or otherwise disseminate their results do not meet the federal definition of research and thus these projects do not need to be reviewed by the IRB. Because such activities occur within the context of a course, they are *de facto* educational and, thus, do not need to be deemed educational by any additional review.

- The concept of ethical review of research is an important aspect of education in research methods.
- The CITI training program and its incorporation into classroom work is highly recommended.
- One objective of an overall human subjects protection program is to ensure that class assignments include appropriate precautions. The CSUEB IRB is available to advise on the scope and nature of assignments, as they pertain to the regulations, to ensure minimization of risk.

#### 14.5 Master's Theses, Master's Projects, Dissertations, or Other Research to be Disseminated

Master's theses, Master's projects, dissertations, or other student research to be disseminated outside the university (such as through publication or presentation at an academic conference) are activities considered to meet the federal definition of human subject research and must be independently submitted to the IRB by the student-researcher, who is deemed the primary investigator.

- When students conduct research as part of a course of study, **a faculty member ultimately is responsible for the protection of the subjects**, becoming the responsible investigator (RI)/faculty advisor, even if the student is the primary researcher and actually directs the project.
- These provisions of oversight by a faculty as Responsible Investigator (RI) also apply when students are not formally enrolled in coursework for credit, but are engaged in research to gain experience as preparation for application to graduate study.
- The provisions also apply to former students and volunteers who are not currently enrolled as students, working under the supervision of a faculty member.
- **Advisors** assume the responsibility for students engaged in independent research.
- **Instructors** are responsible for research that is conducted as part of a course.
- Master's Theses, Master's projects, dissertations, or other research to be disseminated outside the

university which form part of a class are expected to fall within the exempt or expedited categories of minimal risk research. If the research is designed as such, there is a higher likelihood that the review can be completed in time for the students to complete their projects within a given semester.

- In situations where students conduct more than minimal risk research as part of a course, requiring full IRB review, approval in sufficient time cannot be guaranteed.
- For Master's theses, Master's projects, dissertations, or other research to be disseminated outside the university approved under these procedures, **the advisor/instructor assumes responsibility for the conduct of the student research and is responsible for ensuring that projects are conducted in accordance with the IRB's requirements.**
  - **Faculty advisors/instructors must educate students on the ethical conduct of research and help them prepare applications for IRB approval.**
  - **Use of the CITI training program is recommended for this training purpose.**

Training in the concepts of human subjects protections is a requirement of those involved in conducting non-exempt category research activities.

While training in the concepts of human subjects protections is not a federal requirement for those involved in conducting Exempt category research activities, such training enhances the research experience and is highly recommended.

## 14.6 Oral History Research

Included herein are references from the American Historical Association and the Oral History Association, as CSUEB acknowledges their collaborative work with OHRP to obtain exclusion of oral history projects from IRB review<sup>(1)</sup>.

The CSUEB IRB recognizes that this discipline of research, where there is significant interaction with human subjects in the conduct of recording their oral history, has unique components. The discipline

- utilizes unique methodologies,
- is practiced guided by a disciplinary code of ethics<sup>(1)</sup>,
- and is built on a relationship of trust between the interviewer/investigator and narrator/subject.
- "oral history involves interviews for the record, explicitly for preservation as a historical document."

<sup>(1)</sup>.

*"The U.S. Department of Health and Human Services' Office for Human Research Protection has now agreed that oral history as the practice has been professionally defined does not meet the regulatory definition of "research" and therefore is excluded entirely from IRB review, without seeking formal exemption. If oral historians deem that their oral history projects do not meet the regulatory definition of research, they can proceed without consultation with an IRB. If a project does meet the regulatory definition of research, it could still be "exempted" by an IRB, but that must be determined by the IRB. [For the regulatory definitions, see: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm>]<sup>(1)</sup>*

The CSUEB IRB confirms that the principles behind human subject protection must be addressed in oral history, and other forms of qualitative research methodologies.

- In order to fulfill its responsibility, the CSUEB IRB has determined that all instances of oral history data collection using open-ended, qualitative interviews of a nonrandom sample of individuals should receive at least an Exempt review by the IRB.

In determining whether the proposed data collection constitutes "research" under the federal guidelines, the IRB will be guided by these principles:

- A. Oral history activities *the sole purpose of which* is to document a specific historical event or the experiences of individuals without an intent to draw conclusions or generalize findings would generally not constitute "research" as defined in federal regulations.

- Examples might be oral histories taken exclusively for the intent to archive the experiences documented with a local historical society or museum.
- B. Oral history activities undertaken for the purpose of archiving data to be used in the preparation of work to be published or presented in a scholarly forum, or for the purpose of developing or contributing to generalizable knowledge **would** constitute research.
  - Examples might be oral history data collection for the purpose of informing public policy debate with generalized findings, or for the purpose of providing a repository of information for other investigators to conduct research as defined by 45 CFR 46.

**Thus, the CSUEB IRB, in consultation with the IO, has established the following process regarding oral history projects.**

- A protocol describing the study must be submitted to the IRB for review.
  - Protocols that, in the judgment of the IRB, constitute “research” under the federal regulations and which satisfy the criteria given below will be granted approval under “exempt” status by the IRB administrator with the chair’s oversight.
  - Any aspect of the protocol not including or falling outside of these specific criteria will be referred to the chair for a more detailed review:
    - evidence of appropriate training, specifically the CITI human subject program
    - a statement of the topic of the interview
    - a broad description of the questions that could potentially be asked, acknowledging that an oral history interview is by definition open-ended
    - a written evaluation of the risks
    - an informed consent form indicating the topic of the interview, the estimated duration of the person’s participation, and the question or questions that might be used to begin the interview.
    - The consent form should also contain the following:
      - a statement that participation is voluntary,
      - that it is possible the subject matter might be difficult in some way for the person to speak about, and that therefore, the participant can stop at any time.
      - the researcher’s name and contact information,
      - and the assurance that minors will not be involved.

Citations:

- 1) <https://www.historians.org/about-aha-and-membership/aha-history-and-archives/historical-archives/questions-regarding-the-policy-statement-on-institutional-review-boards>

## 14.7 Research Involving Coded Private Information

For purposes of IRB procedures, *coded* means that:

- (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and
- (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information.

- Under the definition of human subject in Section 2 of this policy, *obtaining* identifiable private information for research purposes constitutes human subjects research. *Obtaining* means receiving or accessing identifiable private information for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information already in the possession of the investigator.
- In general, private information is considered to be individually identifiable when they can be linked to

specific individuals by the investigator(s) either directly or indirectly through coding systems.

- Private information is not considered to be individually identifiable when they cannot be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.

Research involving **only** coded private information does **not** involve human subjects if the following conditions are both met:

- (1) the private information was not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
- (2) the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information pertain because, for example:
  - (a) the key to decipher the code is destroyed before the research begins;
  - (b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);
  - (c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
  - (d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

In some cases, an investigator who obtains coded private information about living individuals under one of the conditions cited in 2 (a)-(d) above may

- (1) unexpectedly learn the identity of one or more living individuals, or
- (2) for previously unforeseen reasons now believe that it is important to identify the individual(s).

**If, as a result, the investigator knows, or may be able to readily ascertain, the identity of the individuals to whom the previously obtained private information pertains, then the research activity now would involve human subjects.**

Unless such human subjects research is determined to be exempt (See Section 7.2), IRB review of the research would be required. Informed consent of the subjects also would be required unless the IRB approved a waiver of informed consent (See Section 9.3).

### **Who Should Determine Whether Coded Private Information Constitutes Human Subjects Research**

The investigator in consultation with the IRB Chair or designee will determine whether the research involving coded information requires IRB review.

- If the request is verbal (by phone or in person) or by email, it is the investigator's responsibility to maintain documentation of such a decision.
- If the investigator submits a formal submission, the request must be submitted using the Cayuse Human Ethics (IRB) system and must include sufficient documentation of the activity to support the determination. F
- Formal submissions will be responded to in writing and a copy of the submitted materials and determination letter/email will be kept on file.

### **14.8 Research with Minors in an Educational Setting**

The CSUEB IRB has established procedures regarding research activities dealing with minors in an educational setting because of its potential prominence at CSUEB.

- CSUEB is acknowledged to have considerable investment in training teachers and conducting pedagogical research.
- By federal regulation, CSUEB Assurance, and IRB procedures, the participation of any students, staff, or faculty in a research project either as investigators or as subjects must involve the IRB to evaluate the potential risks to the persons enrolled in such projects.
- Consideration under the Common Rule applies to all human subjects in research, regardless of age or circumstance, including public school students.

- The Common Rule identifies children as vulnerable subjects (e.g., 46.111).

The following summarize the procedures applying to the conduct of research with minors in education.

- The submitted protocol must include the advertising mechanism (paper flyers, email communication, etc.) so that the IRB can review the text.
- The submitted protocol must describe the means of obtaining informed consent as it typically applies to adults (permitting the child's involvement) and/or assent as it typically applies to minors.
  - Requests for waivers of parental permission must be justified against regulations.
  - Consents need to be written at appropriate comprehension levels and translated into other languages as appropriate.
- Investigators conducting the research project must show evidence of training in the protection of human subjects.
  - CITI, [www.citiprogram.org](http://www.citiprogram.org), is the default training mechanism at CSUEB.
  - The training must include modules pertaining to "minors as vulnerable subjects."
- Coercion is a very real possibility in educational circumstances. A teacher studying her/his own students could exert undue influence without being aware of it.
  - The teacher as investigator must address this risk and how it will be minimized in the protocol.
  - Whether extra credit is to be granted for participation (i.e., compensation) in the project must be explained.
  - Parents may need to be assured that their children will not be harmed (physically, emotionally, or intellectually) by participating (or not).
  - These same factors need to be addressed in the informed consent forms.
- While typically an educational project has minimal risk associated with it, there is still the possibility that during its conduct child abuse and/or neglect could be revealed. Policies regarding "mandatory reporting" would then need to be considered.
- Provisions of FERPA (The Family Educational Rights and Privacy Act) allow researchers to access educational records belonging to students that contain names, addresses, phone numbers, etc., but not data like attendance, ethnicity, test scores, etc. without consent. Before such data is released or used, the school must have told parents that such 'directory' type information can be released and that the parents can choose not to allow disclosure.
- Provisions of PPRA (The Protection of Pupil Rights Amendment) as amended by the "No Child Left Behind Act" of 2001 include the right of parents/guardians to inspect surveys and questionnaires used in a school and require their permission when the surveys collect sensitive information.
- Circumstances of review, as adopted by the IRB (these are typical and the IRB may apply a different review):
  - Limited Review
    - by regulation, "research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (1) research on regular and special education instructional strategies or (2) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods" constitutes exempt category research. This does not mean that it is exempt from review; rather, an application must still be submitted and the IRB will conduct an Exempt or Limited Review of the protocol;
    - observations of children in public settings when the researchers do not interact with the subjects;
    - studies using existing data about children, (a) if it is publicly available, or (b) if it is recorded in such a way by the investigator that the identity of the children cannot be determined either directly or indirectly;
    - studies conducted by federal departments or agencies about government programs, such as welfare programs.
  - Expedited Review

- educational research conducted in other countries;
- research involving interviews, surveys, or observation in which the researcher participates in the activities observed;
- taste and food quality evaluations and consumer acceptance studies conducted at a school
- Full Review
  - projects involving a medical procedure
  - projects involving more than minimal risk

While educational research in private schools is not subject to the same federal regulations as in public schools, unless conducted under an applicable program of the US Dept. of Education, the CSUEB IRB will still generally apply these policies and procedures in its review.

#### **14.9 Internet Research**

Conducting research using information available on the Internet poses a number of questions for an IRB, including the CSUEB IRB, in terms of the IRB principles: respect for persons, beneficence, and justice.

For example, persons participate in chat rooms not expecting that they are being studied. On the other hand, posting to the Internet is an open public forum and the loss of privacy is implied. Thus, the CSUEB IRB will review applications on a case-by-case basis and establish policy and procedures progressively.

- YouTube: Research with this web site has been determined to be exempt from review by the IRB based upon the YouTube stated policies, and in consultation with other IRBs.
- The YouTube Privacy Policy states: *Any personal information or video content that you voluntarily disclose online (on discussion boards, in messages and chat areas, within your playback or profile pages, etc.) becomes publicly available and can be collected and used by others.... Any videos that you submit to the YouTube Sites may be redistributed through the internet and other media channels, and may be viewed by the general public (<http://www.youtube.com/t/privacy>).*

**Please note that investigators are responsible for ensuring that any research conducted on a social media site complies with the Terms and Conditions of the site.**

#### **14.10 Research in International Settings**

The CSUEB IRB reviews studies involving human subjects conducted abroad by CSUEB investigators and in conjunction with international colleagues.

Additionally, the US Code of Federal Regulations (CFR) Basic HHS Policy for Protection of Human Research Subjects addresses international research as follows:

46.101

(g) “[U.S.] policy does not affect any foreign laws or regulations which may otherwise be applicable and that provide additional protections to human subjects of research” and (h) “When research ... takes place in foreign countries, procedures normally followed in the foreign countries to protect may differ from those set forth in this policy.”

- There are cultural norms to consider and differences in local legislation abroad and responsibilities of investigators.
- When there are international IRBs involved we will be aware of *cultural imperialism* and try to accommodate local rulings, particularly around areas of informed consent/parental permission/assent of minors, documentation, and determining when subjects are children as defined by the regulations.

The IRB requires, however, that all studies comply with U.S. standards *to the extent possible* when

conducting research abroad.

**It is the responsibility of the researcher to (a) comply with IRB regulations, (b) inform the IRB of the need to vary IRB regulations due to the international context, and (c) indicate to the IRB how adjustments to your protocol will comply with the regulations or, at a minimum, preserve the spirit of the regulations.**

Consequently, investigators should consider the following for inclusion in the submitted Protocol:

- o Determine the Principal Investigator: CSUEB investigators or colleagues abroad? If the PI is abroad, pre-eminence may be extended to the colleague and its IRB (or equivalent).
- o Describe the training that international colleagues will receive in human subject protections (e.g., will the CSUEB principal investigator (PI) be the mentor and have oversight? Is training with the CITI program practicable?).
- o Assess U.S. regulations (CFR) and their impact. Would they be directive, with a sense of obligation to comply?
- o Determine what an American journal, where the PI intends to publish, expects in terms of IRB review and approval for such research.
- o Determine whether the local population used as human subjects might be construed as vulnerable under U.S. standards. Provide clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.
- o Evaluate the liabilities that could affect the University and the participants, *especially when the study originates at CSUEB.*

**The CSU International Agreement Policy requires that ALL agreements with an international component be reviewed and approved by the university president and the Chancellor's Office prior to signing. International agreements committing university resources or that involve student travel related to a study must be reviewed under the CSU International Agreement Policy.**

#### **14.11 Engagement of CSUEB in Research**

Review by an institutional review board (IRB) is required whenever the institution is engaged in human subject research.

Researchers may either seek review by the CSUEB IRB or request that the CSUEB IRB rely on the review of another institution's IRB.

The Office for Human Research Protections (OHRP) considers an institution “engaged” in non-exempt human subject research when its employees or agents, for the purposes of a research project, obtain:

- a. Data about the subjects of the research through intervention or interaction with them;
- b. Identifiable private information about the subjects of the research;
- c. The informed consent of human subjects; or
- d. Study, interpret, or analyze identifiable private information or data for research purposes.

- o The CSUEB IRB bases its determination of engagement on the [OHRP Guidance on Engagement of Institutions in Human Subjects Research](#).
- o The CSUEB IRB considers CSUEB to be engaged in human subjects research when a CSUEB researcher initiates a human subjects research study or CSUEB receives a grant, contract, or cooperative agreement from a funding agency (e.g., National Institutes of Health, National Science Foundation, Department of Defense) to conduct human subjects research.
- o CSUEB will still be considered engaged in human subject research whenever a CSUEB researcher

- initiates a human subjects research study, even if all activities involving human subjects are carried out by another entity (e.g., contractors, enumerators, collaborators) and that entity only provides de-identified data to the CSUEB researchers.
- CSUEB is engaged in research if any CSUEB faculty, staff member, or student engages in the activities listed above in the OHRP definition of engagement.

In addition, CSUEB **is** engaged in research when:

- CSUEB faculty, staff, or students are listed as research personnel on a research study initiated by a non-CSUEB investigator;
- Non-CSUEB researchers are using CSUEB resources or facilities (e.g., computers or labs) to conduct human subjects research; or
- CSUEB faculty, staff members, or students are representing the research/researchers (e.g., CSUEB personnel are actively identifying/approaching potential subjects and encouraging them to participate in a research project). This representation might include actively recruiting subjects, or obtaining the consent of subjects.

CSUEB is **not** engaged in research if none of the above apply, and if its faculty or staff members or students:

- Inform prospective subjects about the availability of research;
- Provide prospective subjects with written information about research, which may include a copy of the relevant informed consent document, and other IRB-approved materials) but do not obtain subjects' consent or act as authoritative representatives of the investigators;
- Provide prospective subjects with information about contacting investigators for information or enrollment;
- Obtain and appropriately document prospective subjects' permission for investigators to contact them;
- Provide email contacts for potential CSUEB subjects; or
- Participate as subjects in a research study initiated by a non-CSUEB investigator.

**If a CSUB faculty or staff member, or student is involved in a research project in a role which constitutes engagement in research, then CSUB IRB review and approval is required.**

If a CSUB faculty or staff member, or student are involved in a role which does not constitute engagement in research, then the CSUEB IRB must be provided with a description of the research to be completed, and the approval of the IRB which is overseeing the project.

- The CSUEB IRB may require a formal review of the project, or may accept the external IRB's approval without review as determined by the CSUEB IRB chair.
- The CSUEB IRB reserves the right to reject projects in which CSUEB is not engaged in research.

#### **14.12 Research at Cal State East Bay by Unaffiliated Investigators**

The IRB is supportive of research by others who want to collect data from human subjects at CSUEB, while at the same time being mindful of the impact on resources and implications for the campus.

Individuals may of course collaborate with members of the CSUEB faculty and staff to conduct investigations of mutual interest; this section is not meant to address or restrict such collaborations. However, there may be persons without direct or formal association to CSUEB who request authorization to use CSUEB facilities or the campus population in order to conduct a study involving human participants. Here, this would be regarded as research – by the OHRP definition - conducted by an “unaffiliated investigator.”

- An “unaffiliated investigator,” as used in this policy, is any researcher who is not either (1) a student, (2) a faculty member, or (3) a staff member at CSUEB.
- The unaffiliated investigator must be affiliated with another *bona fide* research organization, termed here as the “home institution.” It may be the academic institution or a research agency (contract, governmental, or not-for-profit) with which the investigator is currently affiliated or the degree-granting

institution in which the investigator is enrolled as a student.

**Conduct of research.** An unaffiliated investigator may conduct research at CSUEB **only with the prior approval of the CSUEB IRB.**

- Responsibility for the actual conduct of the research remains solely with the unaffiliated investigator. It is understood that approval to conduct human subjects research at CSUEB in no way implies that either the CSUEB IRB, the Office of Research, or any official of CSUEB assumes responsibility for the conduct of research on campus by unaffiliated investigators.
- The unaffiliated investigator may independently want to enlist the aid of someone on campus (a "facilitator") to assist with logistical matters, such as providing access to records, making available research facilities or space, obtaining contact information for faculty, staff, or students of CSUEB, or distributing materials with which to recruit participants.
- Alternatively, the CSUEB IRB can require a facilitator as a condition of approval. Depending upon the extent of the involvement (e.g., actual data collection), the IRB may place obligations on the facilitator (e.g., requiring training in human subjects research).
- Depending upon the level of involvement of CSUEB faculty, staff, or students, CSUEB may be considered to be engaged in research or not, as given in section 14.12.

The unaffiliated investigator should give a rationale for wanting to use – specifically - the CSUEB campus population. This should be in the hypothesis or subject description sections of the protocol (of the home institution, CSUEB, or both) and in the request of the IRB to be authorized to conduct research at Cal State East Bay.

**Requirement to comply with all CSUEB IRB policies and procedures.** As described in Sections 1 and 3 of these policies, the CSUEB IRB retains oversight of human research conducted on campus by unaffiliated investigators and such investigators will be expected to comply with all CSUEB IRB policies.

- The CSUEB IRB reserves the right to ask for and obtain other evidence from the unaffiliated investigator to authenticate the proposed research to be conducted at CSUEB. This could include, in addition to training records, authorizations for the use of survey instruments and data collecting equipment and financial information for when participants are to be monetarily compensated.

**Training in human subject research.** Unaffiliated investigators must demonstrate their training in human subject research equivalent to what the CSUEB IRB would demand of a CSUEB investigator to possess in a similar research study.

- The CSUEB IRB expects at minimum the training equivalent to the group of modules labeled "Basic Human Subjects", either "Social and Behavioral Focus" or "Biomedical Focus" depending upon the research focus. Training may be obtained through CITI ([www.citiprogram.org](http://www.citiprogram.org)).

**IRB protocol reviews.** Prior to seeking approval at CSUEB, the unaffiliated investigator is obligated to obtain approval from the Institutional Review Board (IRB) or other human subjects protections committee at the unaffiliated investigator's home institution.

- It is recognized that there may be instances where there is no such committee, in which case the CSUEB IRB may be used to conduct the review. This decision to oblige rests with the IRB chair.
- The unaffiliated investigator must provide to the CSUEB IRB the final protocol (including surveys, consents, etc.) with the approval memo from the home institution.
- If the CSUEB IRB finds that CSUEB is engaged in research, then a standard (Limited, Expedited, or Full Board as appropriate) review of the protocol will be done or a reliance agreement with the investigator's IRB may be pursued.
- If the CSUEB IRB finds that CSUEB is not engaged in research, then the protocol may be reviewed by the IRB chair and accepted as presented.

The unaffiliated investigator is responsible for ensuring that all matters of concern to CSUEB (contained in CSUEB's protocol application) specified during this review are addressed in the protocol of the home institution as well.

**Indicating affiliations in documents.** Documents such as recruitment flyers and email messages, consent

forms, surveys, etc., must include the investigators' names, home institution affiliation, and contact information for the unaffiliated investigator(s).

- Documents listed above must indicate that IRB approval has been obtained from the home institution (as appropriate). For example, this sentence could be used in the documents:
  - This research study was originally approved by the IRB at 'XYZ University' under protocol number '12345'. It was subsequently approved for conduct at CSUEB by its IRB under protocol CSUEB-IRB-YYYY### (as assigned by CSUEB, where YYYY is code for the year and ### for the sequence).
- Additionally, documents must be clear and unambiguous in respect to the various phone numbers, institutional affiliations, research offices, committees, psychological services, medical centers, etc. **The subjects must be able to discern the appropriate institutions.**

## 14.13 The IRB and Studies of Assessment and Evaluation (SAE)

Many human studies at CSUEB are engagements or investigations in which individuals (human subjects) are asked to assess and/or evaluate something. They provide input about products, programs, services, and/or policies using a variety of constructs, for example, attitudes, opinions, values, needs, expectations, preferences, and/or satisfaction. The CSUEB IRB has labeled such studies as SAE. Typically, they are low risk and do **not** require IRB oversight because they do not fulfill the criteria to be considered research:

1) a systematic investigation of 2) human subjects that will 3) contribute to generalizable knowledge (DHHS 45.CFR 46.102 (l)).

- Within the context of this guideline, the term evaluation is defined as: "the systematic determination of the quality or value of something".

Examples of SAE protocols include, but are not limited to:

- a College of Business and Economics (CBE) assessment of persons' shopping habits to establish a business;
- a CBE evaluation of a product by asking the opinions of people using the item;
- a survey of patrons at a park by landscape architecture faculty or students regarding their satisfaction with the park;
- an evaluation of a process or activity at a work-site where opinions of employees or clients are collected for a Master's in Public Administration degree;
- an investigation by a student of social behavior of the means and effectiveness of specific advertising, and,
- generally, any evaluation of consumer satisfaction with a program, product or policy to determine its merit, worth, and/or value.

**Note:** See also guidance for IRB protocols that involve assessment or evaluation in classroom activities, demonstrations, and assignments appearing in Section 14.5 (Student Research), Section 14.6 (Master's Theses, Master's Projects, Dissertations, and Other Research to be Disseminated) of these *Procedures of the IRB*. It may be more appropriate to consult these sections for IRB protocols of this nature.

Typical SAE Research Methodology. SAE protocols may utilize various data collection methods, such as:

- questionnaires (both paper and electronic surveys),
- interviews (face-to-face and by phone),
- focus groups,
- and observation.

  

- Besides the attitudes, opinions, and other constructs (as listed above) of individuals, personal data such as gender, age, race/ethnicity (see note 2 below), zip code of residency, income, etc. are also often obtained from the subjects, some of which could be used to identify individual respondents even though personal identifying information such as names, telephone numbers, and email addresses are not obtained.

- These data described above are recognized as important in such research and IRB policy does not preclude or prohibit the collection of such information. However, the concerns for the IRB are: the level of risk for participants, that the data collected from them are stored securely and protected, and whether the participants/data are anonymous or confidential.
- While typically there is little risk ("the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life") associated with SAE protocols, research has shown that as few as three variables can readily re-identify persons in anonymous data sets (see note 3 below). **Thus, the IRB must be assured that the researcher has procedures in place to protect against the release of the data (inadvertent or otherwise) and, in the event of an inadvertent or accidental release of data, that participants cannot be readily identified from the records; this is accomplished through review of the protocol when it is submitted to the CSUEB IRB.**

To elaborate for the purpose of SAE protocols, this distinction is made.

- **Confidential** means that the researcher knows who the respondent is, but is keeping such information concealed.
- **Anonymous** can involve interviewing without ever collecting identifying information.
  - Thus, face-to- face interviews cannot be anonymous, but asking random people "off the street" questions about something (like a park or a piece of art) - without collecting their names - is a kind of anonymity as long as subjects are not recorded in any way.
  - Online surveys may be anonymous if there is no link between the survey result and the email address or IP address of the subject.

These are the criteria by which the IRB will conduct an initial review for SAE protocols:

- Verifies that all required components (e.g., means of recruitment, consent form, methods, survey instrument, appropriate training, etc.) are included in the protocol.
- Assures that the protocol satisfies the conditions of category 2 of exempt review as defined in the DHHS CFR (following) pertaining to human subjects research.

Research involving the use of ... survey procedures, interview procedures or observation of public behavior, if at least one of the following criteria is met:(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

- Determines if minors will be recruited as subjects. Federal protections for minors do not allow Limited Review for projects using survey activities where minors are included as subjects. Please see section 7.2 Exempt Research for more information.
- Assesses further the appropriate understanding and usage of the terms anonymity and confidentiality in the protocol, the informed consent form, and the survey instruments.
- Examines surveys to be used, evaluating the level of risk and the logistics of e-surveys (implied consent, skipping vs. required questions, etc.).

Additionally, the IRB will consider the following during the review and approval process for SAE protocols:

- Location of the Research and the Potential for Coercion. Does the PI work at the proposed location? Is the PI in a position of some power or authority over others who may be recruited to participate? Could the survey or study be seen as coercive if an employee doesn't want to participate? And, if so, what are the ways in which the PI plans to ameliorate these concerns?
- Adequate Descriptions of Anonymity and Confidentiality. Either circumstance can apply in SAE protocols. The protocol must clearly distinguish between confidential and anonymous data collection and use. Confidential data may be rendered anonymous through either the aggregation of individual responses during the data analysis and reporting processes or by some other means of de-identification. The PI should explain how anonymity is ensured in the reporting of results. In the case

where the SAE protocol is determined to be confidential, the review will be done by an IRB member.

- The Need for Permissions or Authorizations. As applicable, PIs must document that they have permission and/or authorization to use a site for research purposes (e.g., to conduct a survey at a commercial establishment like a restaurant) and/or recruit/engage individuals at a site for the research (e.g., to allow employees to use their time at work for the research study). In other words, are decision-makers and administrators within the company or institution aware that their employees or other resources are being used as ‘subjects’ for research purposes? The potential for liability does exist and the IRB requires securing these permissions as necessary.
- The Sampling Plan and Inclusion of Under-represented Groups. Are under-represented groups adequately included? This fulfills the IRB principle of justice. Is the sample representative of a specific population or one of convenience? Is the stated number of subjects meant to be those recruited or actually sampled, in other words what is the anticipated return or response rate? Is oversampling under consideration (collecting data from more than the estimated sample size in order to account for low response rates)?
- Data Security. Once the data are collected, how will the security of the material be ensured, that is protected against inadvertent release? Who will have access to the data? How long will the PI retain the data and the completed data collection tools (e.g., completed surveys, interview transcripts, audio or video records).
- Participant Benefit/Risk Analysis. What statements has the PI made in the protocol and the informed consent form to justify the “use” of human participants in this research?

The IRB will complete a review based on the above information. Usually, SAE protocols will be reviewed through Exempt or Limited Review.

#### Guidance and Advisory Notes

- 1) Scriven, M. (1991). Evaluation thesaurus. 4th ed. Newbury Park, CA: Sage Publications.
- 2) In 2008, the US Census Bureau adopted the following changes in its procedures for asking race/ethnicity demographic questions. (Refinement of race/ethnic classifications continues at the federal level; see for example [http://arksped.k12.ar.us/documents/data\\_in\\_research/DDS\\_FAQ\\_NEW\\_FEDERAL\\_RACE\\_and\\_ETHNICITY.pdf](http://arksped.k12.ar.us/documents/data_in_research/DDS_FAQ_NEW_FEDERAL_RACE_and_ETHNICITY.pdf)). It is recommended that PIs use the following conventions in consumer survey type protocols.
  - It is more appropriate to use the term “Latino/a/x” rather than “Hispanic.” There are some Latinos who are not Hispanic, e.g., Portuguese and Brazilians.
  - Asian/Pacific Islander is often split as separate categories: (1) Asians and (2) Pacific Islanders. Asians normally refer to East Asians (e.g., Japanese, Koreans, Chinese), while Pacific Islanders include Australasians, etc.
  - Use “Caucasian” or “Anglo-American,” not “Caucasian American.”
  - Bi-racial or multi-racial -- rather than multicultural – may be the more appropriate term. Someone could be of Asian descent but identify with Chinese and American cultures, and consider him/herself to be multicultural.
- 3) L. Sweeney. Weaving Technology and Policy Together to Maintain Confidentiality. *Journal of Law, Medicine & Ethics*, 25, nos. 2&3 (1997): 98-110  
[<http://dataprivacylab.org/dataprivacy/projects/law/jlme.pdf>].

#### **14.15 Access to CSUEB Email addresses and Student Data**

- Please note that IRB approval does not automatically grant the right to distribute surveys on campus.
- Investigators who require email addresses for random samples of specified populations of CSUEB student, faculty, or staff should contact the Office of Institutional Research, Analysis and Decision Support.
- Complete lists of student email addresses are seldom provided except for institutional research.
- If CSUEB student record data is desired, again, contact the Office of Institutional Effectiveness and Research (IER). These types of requests may only be granted if there is an operational need for the data by the organizational entity being studied.
- Investigators should **not** submit a research protocol to the IRB prior to contacting IER.

## **15 (Forthcoming)**

This document is meant to be a living document, and will be updated with new policies as needed.

## **APPENDICES**

- 1) **NIH Exempt Human Subjects Research Infographics**
- 2) [OHRP Human Subject Regulations Decision Charts: 2018 Requirements](#)
- 3) [IRB Helpful Tips Brochure](#)