**Table of Contents**


Mission 5Introduction 6

Ethical Principles: The Belmont Report 7

Definitions (as used for the purposes of these procedures) 9Institutional Authority 13**Assurance of Compliance 13**

**Cal State East Bay IRB Office 13**

**State Law 13**

**University Responsibility 13**

**Ethical Principles 13**

Cal State East Bay IRB 15Authority of the IRB 15

Jurisdiction of the IRB 15

IRB Relationships and Reliance Agreements 16

Roles and Responsibilities 18

Resources for IRB 19

Reporting & Conduct of Quality Assurance/Quality Improvement Activities for IRB Operation 20

IRB Membership 21Composition of the IRB 21

Appointment of Members to the IRB 22

Use of Consultants (Outside Reviewers) 22

Conflict of Interest – IRB Members 23

Duties of IRB Members 23

Attendance Requirements 23

Training and Ongoing Education of Chair & IRB Members in Regulations and Procedures 24

Liability Coverage for IRB Members 24

Review of IRB Member Performance 25

IRB Records 25**Minutes of an IRB Meeting 26**

Membership Rosters 27

Records Retention Requirements 27

Written Procedures and Guidelines 27

Review Process 28Human Subjects Research Determination 29

Exempt Research 29

Categories of Research Permissible for Exemption 30
Additional protections 32
IRB Meetings 32
Schedule of IRB Meetings 32
Quorum 32
New Protocol Applications 33
Pre-Meeting Distribution of Documents 34
Consultants 35
Conflicts of Interest 35
Possible IRB Actions Taken by Vote 35
Determination of Risk 36
Period of Approval 37
Independent Verification Regarding Material Changes 37
Consent Monitoring 38
Reporting IRB Actions 38
Continuing Review of Active Protocols (Renewals) 38
Continuing Review Process 39
Expedited Review of Continuing Review 40
How is the Continuing Review Date Determined? 40
What occurs if there is a Lapse in Continuing Review? 41
Studies that are Approved but Never Started 42
Modification of an Approved Protocol 42
Adverse Events and Unanticipated Problems 43
Expedited Review of Research 45
Further Review/approval of IRB Actions by Others within the Institution 47
Initiation of Research Projects 48
Appeal of IRB Decisions 48
Canceling a review 48
Criteria for IRB Approval of Research 48Risk/Benefit Assessment 49
Scientific Merit 50
Selection of Subjects is Equitable 50

76
Mandatory Reporting 77
Cal State East Bay Students and Employees as Subjects 77
Student Research 78
Master's Theses, Master's Projects, Dissertations, or Other Research to be Disseminated 78
Oral History Research 79
Research Involving Coded Private Information 80

**Research with Minors in an Educational Setting 81**
Internet Research 83
Research in International Settings 83
Engagement of CSUEB in Research 84
Research at Cal State East Bay by Unaffiliated Investigators 85

**The IRB and Studies of Assessment and Evaluation (SAE) 87**
14.15 Access to CSUEB Email addresses and Student Data 89
15 (Forthcoming) 88

**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 poew or 2.1 (by)-8 ( (c)-8 (es)-8.1 (per)

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 9 (i)3.1 (c)(i)-8.9 (as)-8 (u)-12.3kFs r tRirT5 (E)2..2.2 (R)-2. 238 (u)-

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,

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

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[a] or interaction[b] with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information[c] or identifiable biospecimens.

[[a] 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.

[b] 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.

[c] 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

of that term by grant and contract agencies. The status of persons having a role

## 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

## 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.

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institutions allow. If so, then each PI should notify their home institution of their intent to request

- 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.

## 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

## 5.7. Training and Ongoing Education of Chair & IRB Members in Regulations and Procedures

**5.9.**

    - 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

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

All research using human subjects must be approved by the institution, and per federal regulations is determined to be Exempt, Limited, or Non-Exempt. “Exempt” and “Limited Review” protocols may also be deemed eligible for Expedited review, meaning they do not need Full Board review and may be instead approved by the IRB Chair or their designee-usually one or more IRB members.

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.

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

(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 contrac-6.3 6.

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 review-1.1 (R)-2.9 (B(E[(quor)-(h /P /MCID8 ( t) (ng t)-1ha-9

- In some circumstances, a shorter review interval (e.g., biannually, quarterly, or after accrual of a

associated with a particular investigator or a research project.

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

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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 on the Minor Adverse Event Report Form to the IRB 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.

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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 limipe ev

**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

(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 procedu (oc)-8-12.3 (g)-1--12.3 (d)

### 7.10 Appeal of IRB Decisions

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:

- 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;
- 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:

- **identify the risks** associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research;
- **determine whether the risks will be minimized** to the extent possible;
- **identify probable benefits** to be derived from the research;
- **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;
- **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

- 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:

-

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 tr (e t)-1n.a(ay)-8 ( t)-l r t it poonday

# 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.

-

**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. 2 (e r)-63.1 (c)-20 (iA)2.4 (nt)-13.1 (i)3.1 2-63.1 (c)-20 (iA)2.3 (at)-1.1 u0.976 0 Td[(A 3 (es)-8 eh )-12.1 (av6.4 (t)-1.1

before it is signed; or

b.

- **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 obta1 (i)3.1 (t)<Tw (-)Tj-0.002 Tter maye.tme.08

## 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(di)3.2 (v)-8 (i)3.1 (TT0 )-8 (t)af.

- 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.

### 10.1.3.3 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 *loco 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.

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 Viabi**

or both of the

### IRB composition

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

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The Chair of the IRB and the IRB Coordinator at CSUEB will promptly handle (or delegate staff to

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

- 

**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 so 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 approva

- 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 3.1 (t)--8 (es)-8 (t)-1.1 (i)-9 (gat)12.3 (en s)-8 ()-9 (gat)(t)-1.1 (y)-8 rve as--8 (es)(m)-4.43 (gat)(t).9 (

- **This renewal must take place prior to the approval expiration date noted on the approved protocol**

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

- 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 expensesincurred 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.

## 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 adg.2 (nd )]dtentiord12.3 (n i)-8 (ghg.4 (U)-14.9 (t)-1.1 6(ent)-1ac 0.21)36(ent)-1e-1 (r)-6

regulations govern what may

- **Faculty advisors/instructors must educate students on the ethical conduct of research and help them prepare applications for IRB approval.**
-

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’ 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)

    - 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

**related**

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.

a similar research study.
    o

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

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).

- o 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.
- o Assesses further the appropriate understanding and usage of the terms anonymity and confidentiality in the protocol, the informed consent form, and the survey instruments.
- o Examines surveys to be used, evaluating the level of risk and the logistics of e-surveys (implied

- Bi-racial or multi-racial -- rather than multicultural – may be the more appropriate term.  Someone