California State University
San Bernardino
Institutional Review Board
Standard Operating Procedures
-Investigator Version-

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I. IRB Initial and Continuing Review of Research

All activities that fit OHRP's definition for *research* and *human subjects* or the FDA definition of *clinical investigation* and *human subjects* must be reviewed by the IRB to assure that the protocol meets with federal, state and institutional regulations. See OHRP Decision Charts.

A. Level of Review

There are three levels of review: exempt, expedited, and full board reviews. The appropriate review procedure is determined by federal regulations and applied based on how human participants are involved in the research. For details, please see: https://www.csusb.edu/institutional-review-board/categories-review

1. Exempt Review

a. **Description:** Research can be approved as "exempt" if it is no more than "minimal risk" and fits one of the exempt review categories as defined by federal regulation 45 CFR 46. Studies that may qualify for "Exempt" must be submitted to the IRB for review. Exempt determinations are made by IRB members, not by investigators, and do not require a convened committee meeting.
b. **Incomplete Disclosure and/or Deception:** The 2018 Revised Common Rule allows for incomplete disclosure to be approved as Exempt if authorized by participants through a prospective agreement in which they are informed that they will be unaware of or misled regarding the nature or purpose of the research and the research falls into one or more Exempt research categories. Click here for more information on Incomplete Disclosure and Deception.

2. Expedited Review

a. **Description:** The IRB may use an expedited procedure to conduct initial review of research provided that research activities do not fall under any of the general restrictions, present "no more than minimal risk" to participants, and fits in one of the federally designated expedited review categories.
b. **Summary of Expedited Categories:**
Click here for more information about Expedited Categories
c. **Incomplete Disclosure and/or Deception:** The IRB will consider research that involves incomplete disclosure or misleading/false information for Expedited review if the risk associated with either is necessary, entails only minor or moderate risk to participants and falls into at least one Expedited category.

3. Full Board Review

a. **Description:** Research that does not qualify for expedited or exempt review (presents more than minimal risks to subjects and/or participants considered to be vulnerable [children, prisoners, cognitively impaired) must be reviewed at a convened IRB committee meeting at the scheduled date as posted on the IRB website.

b. **Incomplete Disclosure and/or Deception:** Any research involving incomplete disclosure or misleading or false information that does not fall into an Exempt or Expedited category and/or entails more than moderate risk to participants' well-being requires a Full Board review.
c. **Vulnerable Populations:** Considering whether the study involves participants that are likely to be vulnerable to coercion or undue influence, and, if so, whether additional safeguards have been included to protect the rights and welfare of these participants. Special populations or vulnerable participants include children, pregnant women, prisoners, physically or cognitively challenged, economic or socially disadvantaged, subordinate individuals (e.g. students and employees), and fetuses. Additional safeguards for all participants that are likely to be vulnerable to coercion or undue influence must be included in the study to protect the rights and welfare of these participants (45 CFR 46.111(7)(b)).
d. **Range of Actions for Full Board Reviews:** Following the presentation of the study and discussion of the study by the Board, any voting member may make a recommendation for one of the following motions:

- **Approval:** For studies which meet Federal and Institutional criteria for approval as laid out in 45 CFR 46.111 , including:
    - Risks to subjects are minimized
    - There is an appropriate risk-to-benefit ratio
    - The selection of subjects is equitable
    - Appropriate procedures are followed for obtaining and documenting informed consent, or waiving or altering informed consent documentation or procedures
    - The research plan has adequate provisions for monitoring the data collected in order to ensure participants' wellbeing
    - Additional safeguards are included to protect the rights and welfare of any vulnerable populations involved in the research
- **Approval Pending:** For studies which otherwise meet the above criteria for approval, but for which minor changes are required before approval may be granted.
- **Deferred:** For research proposals which require substantive or complex changes, or additional information, before they meet approval criteria. The Board may vote to defer a final decision of approval or disapproval until the investigators adequately responds to the Board's concerns.
- **Disapproval:** If a study does not meet approval criteria, and the Board cannot see that a deferral would change the situation, the Board may vote to disapprove a proposed study. If disapproved, no proposed study procedures may take place, and the study may not be re-submitted for review.
- **Tabled:** If, due to a loss of quorum, or lack of time or expertise, the Board is unable to provide adequate review of a study, then the review may be postponed until another meeting.

For the IRB to consider any of these motions, it must be seconded by another voting member. For a motion to pass, the majority of present voting members must agree.

B. Criteria for IRB Approval of Research (across levels)

1. Materials

IRB reviewers must have access to all necessary application components and materials, including:

- List of investigators and research personnel
- CITI certificates for all investigators and research personnel
- Conflict of interest statement
- Recruitment materials and advertising intended to be seen or heard by potential participants, including email solicitations
- Project description
- Surveys, questionnaires, interview scripts, videos or other instruments
- Confidentiality plan
- Description of risks and benefits
- Letters of assurance or cooperation with research sites
- Proposed consent forms, information sheet(s) and/or scripts as appropriate
  - Informed Consent
  - Waived informed Consent
- Assent forms/scripts when appropriate
- Debriefing statement when deception used

For a detailed description of each application component/material, refer to the IRB Application Template.

2. Primary Requirements

In order to approve research, federal regulations at 45 CFR 46.111 require that the IRB (reviewer or Full Board) determine that all of the following requirements are satisfied:

- Risks to participants are minimized
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable.
- Informed consent will be sought from each prospective participant or the participant's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116.
- Informed consent will be appropriately documented, in accordance with, and to the extent required by 45 CFR 46.117.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- When some or all of the participants are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB will ensure additional

safeguards have been included in the study to protect the rights and welfare of these participants. Refer to Vulnerable Participant Populations.

3. Additional Requirements Specific to Informed Consent

Informed consents may be written, oral or electronic in nature. The IRB will review consent forms to ensure they are on the PI's office letterhead (preferred not required), are written at the 6th to 8th-grade reading level (or lower if needed) and include the following information: include:

- A statement that the research has been approved by the Institutional Review Board of California State University, San Bernardino (should be in the first paragraph)
- Identification of the researcher(s)
- The nature and purpose of the study
- Expected duration of participant involvement
- How confidentiality or anonymity will be maintained
- The voluntary nature of participation
- Compensation/Incentives (if applicable)
- Participants right to withdraw at any time (without penalty if applicable)
- Information about foreseeable risks and benefits
- Contact information for questions or additional information

Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective participants during the consent process. If a study exceeds minimal risk, the consent form should specify how costs pertaining to any injury incurred due to study participation will be covered and by whom.

a. Informed Consent Form for Non-English-Speaking Participants: If non-English speaking persons will be recruited, the IRB will review a description of the qualifications of the person who will conduct the translated consent process (verbal and written). The IRB must review the English version of the consent document first before approving the translated version. After the English version has been approved by the IRB, the investigator will be required to submit a copy of the translated document to the online system for approval.

Alternatively, 46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally.

A witness to the oral presentation is required, and the participant must be given copies of the short form document and the summary. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

b. Waiver of Required Informed Consent Form: Waivers of informed consent may be granted under certain limited conditions, and any request for such should include an explicit justification. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants, if it finds either:

i That the only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of

confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; or

ii That the research presents no more than minimal risk of harm to participants, and involves no procedures, for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

c. **IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent:** 45 CFR 46.116 An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

The research or demonstration project is to be conducted by, or participant to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine : (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and requirements to obtain informed consent, provided the IRB finds and documents that:

- The research could not practicably be carried out without the waiver or alteration.
- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the participants will be provided with additional pertinent information after participation.

4. Additional Requirements Specific to Recruitment and Compensation or Incentives

a. **Recruitment Procedures:** The IRB is required to evaluate whether participation selection procedures for a given research study are fair to ensure that for the particular purpose of the research the burdens of research participation are distributed equitably across groups of people.

i **Women and Minorities:** The IRB must estimate the degree to which underrepresented groups, such as women and minorities are being used in research studies

- If the research is NIH-funded, investigators must comply with the agency's guidelines. For more information on this topic, go to Inclusion of Women and Minorities as research participants.

ii **College Students:** The IRB must estimate the degree of situational coercion and, through guidelines, assist researchers to reduce the pressure that a student may experience when recruited to participate in research. The IRB encourages

investigators to follow recruitment procedures intended to create the opportunity for students to participate in research while reducing the possibility of unintended coercion. For example, avoid one-on-one solicitations of students by faculty, graduate assistants or other students. If research participation is a course requirement, offer an equitable alternative to participation in a study as a method of obtaining course credit (e.g., summarize a journal article, attend a research lecture, and assist with data collection) and conduct data collection outside of the scheduled class time.

iii **Employees:** The IRB must consider the potential for coercion or undue influence and breeches of confidentiality when employees are recruited as research participants.

b. Recruitment Materials: The following information should be included in recruitment materials:

- Name and contact information of the principal investigator and/or research facility;
- Concise description of the purpose of the research;
- Eligibility criteria for participant participation;
- Time or other commitment required of the participants;
- Location of the research and person to contact for further information; and
- Statement saying, "This study has been approved by the CSUSB IRB" (including the IRB # is recommended).

c. Legitimate Access to Records: Recruitment procedures in which names of individuals are released from private sources to an investigator are generally not endorsed by the IRB. Recruitment procedures should allow for the individual to consent to the release of information in advance of being contacted directly by an investigator.

d. Established Legal/Ethical Protections: The IRB advises against the release of identifiable private information from a source to an unaffiliated researcher without the permission of the potential participant where legal and ethical guidelines prohibit the source from doing so.

e. No Established Legal/Ethical Protections: The IRB advises against procedures that involve a person or organization providing information about another individual/potential participant without their permission for the purpose of recruitment. The IRB recommends procedures that allow for an organization or an enrolled participant to provide information about the study to a prospective participant (flyer, postcard or other announcement) that allows for the prospective participant to initiate contact if they would like additional information about the study.

f. Compensation/Incentives: Other than reimbursement for reasonable travel and lodging expenses, the IRB should be sensitive to whether other aspects of proposed payment or course extra credit for participation could present an undue influence, thus interfering with the potential participants' ability to give voluntary informed consent. The IRB does not permit practices that involve remuneration of any kind to a provider for patient referrals or bonus payments to members of the research team for purposes of participant recruitment. Any remuneration (in cash or any kind) for patient referral is considered unethical because it may compromise the provider-patient relationship and, bonus payments to the investigator, study coordinator or provider for the purpose of encouraging recruitment of participants to the study may compromise the judgment of the research team and therefore is not acceptable. Referral incentives may include, but are not limited to monetary compensation, stock options, material goods or other

incentives such as food or entertainment. In addition, bonus payments to the investigator, study See OHRP's guidelines on participant compensation.

5. **Additional Requirements Specific to Privacy/Confidentiality**
   As a condition of protocol approval, the IRB must determine that there are adequate provisions to protect confidentiality of information related to potential or current participants, throughout the study, including preliminary to the research, recruitment and enrollment, research participation and after conclusion of the research.

6. **Other Additional Requirements**

   In addition to the above regulations, the IRB must also consider the following.

   a. **Adequacy of research description:** Sufficient information must be provided for IRB to effectively assess the risk to participants versus the benefits of the research.
   b. **Certification that all study personnel have completed required training:** The IRB must confirm that all investigators and key personnel have provided valid CITI training (or equivalent) certificates.
   c. **Conflict of Interest (PI and study staff):** Federal regulations require investigators to disclose any conflicts of interests (COI) in research they may have related to the IRB application. The term "conflict of interest in research" refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising a researcher's professional judgment in conducting or reporting research. COIs must be disclosed to participants in the informed consent. For more information, refer to OHRP's guidance on COIs.
   d. **Expertise of research team:** The ability of the research team to minimize risk must be taken into consideration when vulnerable populations are involved, or the research is deemed as involving high risk to participants.
   e. **HIPAA applicability and waivers:** IRB and the HIPAA Privacy Rule ensures that privacy and confidentiality is maintained when private information is given. The Privacy Rule, at 45 CFR parts 160 and 164, establishes a category of health information, defined as protected health information (PHI), which a covered entity may only use or disclose to others in certain circumstances and under certain conditions. In general, the Privacy Rule requires an individual to provide signed permission, known as an Authorization under section 164.508 of the Privacy Rule, before a covered entity can use or disclose the individual's PHI for research purposes. Under certain circumstances, however, the Privacy Rule permits a covered entity to use or disclose PHI for research without an individual's Authorization.
   f. **Scientific merit:** The IRB must review all studies to ensure that:
      - The research uses procedures consistent with sound research design to produce anticipated benefits and reduce risk
      - The purpose and specific aims are clear and feasible, and the research will contribute to generalizable knowledge
   g. **California laws and university policies:** The IRB evaluates the responses provided in all corresponding sections of the submission application to determine that the study will be conducted in accordance with applicable regulations and requirements.

7. **Modifications to Approved Research:**

Federal regulations require that any revision to previously approved research involving human subjects receive IRB approval in advance of implementation except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103 (b)(4)(iii)). A modification is defined by the IRB as a change that does not alter the overall character or purpose of the original project. Minor changes that do not adversely alter the overall risk-benefit profile of the study may receive an expedited review. For full board reviews, the convened committee reviews proposed changes that may affect the willingness of enrolled subjects to continue participation and/or increase the risk to research subjects.

8. Continuing of Review

In accordance with federal regulations, the IRB requires that ongoing research protocols undergo continuing review at intervals appropriate to the degree of risk, but not less than once per year. The frequency and extent of continuing review for each study is based upon the nature of the study, the degree of risk involved, the novelty of the research procedures, the experience of the clinical investigator in conducting clinical research, the IRB's previous experience with the investigator and/or sponsor, the projected rate of enrollment and the vulnerability of the study subject population.
Continuation of the research after the date of expiration of IRB approval is a violation of federal regulations. To assist investigators in fulfilling the requirement for continuing review, the IRB's online submission system sends expiration notices at 90, 60, and 30 days prior to expiration to the investigator, faculty advisor, and study coordinator. If investigators do not submit a completed application for continuing review at least 30 days before the protocol expiration date, the IRB cannot guarantee that the application will be reviewed before the date of expiration. It is the investigator's responsibility to ensure that approval for an active protocol remains current. The IRB expiration date can be found on the main study page in the online submission system, in the IRB approval letter, and in the expiration notices.

9. Duration of Project Approval

Federal regulations require that every approved study receive continuing review "not less than once per year." Accordingly, an approval period cannot exceed 365 days. The procedure for setting the effective approval date and the duration of protocol approval are based on harmonized guidance from the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA).

10. Communicating the IRB's findings and Actions to Investigator

Once the protocol has been adequately reviewed, the investigator will receive notification of the review outcome via email through the online system. Once the investigator has received notification that the protocol is approved, research may begin. If revisions are required for approval the email correspondence will instruct the investigator to use the online system to make changes and/or comments on the topics that require a response. Upon IRB review and approval of the response, the investigator will receive correspondence indicating IRB approval.

11. Closures of IRB Protocols

A closure of full board and expedited IRB applications need to be submitted if all procedures are completed that involve human participants (e.g., recruitment, data collection and identifiable data analysis). A final report should be submitted via the online system.

12. Keeping a Written Record of IRB Decisions

The meeting agenda, reports and the meeting minutes as approved by the IRB will be maintained electronically on the computer and/or shared drive in the Office of Academic Research by the Research Compliance Officer and/or support staff. The Psychology and Social Work IRB Designated Reviewers will maintain their records electronically through the online IRB System.

C. Non-Human Subjects Research (NHSR) Submissions

Studies are considered "NHSR" when they do not meet the 45 CFR 46 definitions of human subjects research. Investigators who believe their project qualifies as NHSR can review the NHSR guide on the IRB website. If the investigator determines their project is considered NHSR and they don't need a determination letter, they can start their project. If the investigator determines their research is NHSR and does need a determination letter, they can make an NHSR request through the IRB online application system. The IRB must make this determination if the PI or student researcher requires a determination letter from the IRB stating the study does not require IRB review.

All projects that involve FDA-regulated products are required to be submitted as an IRB application. If a project involving FDA-regulated products is submitted through the NHSR information request it will be returned with instructions to submit a regular IRB application.

D. Other Types of Research

1. International Research

CSUSB faculty or students who intend to conduct human participant research abroad must obtain CSUSB IRB approval prior to commencing research activities. Research conducted outside the U.S. must respect applicable national laws.

If a study involves more than minimal risk, investigators will be required to obtain approval from a Research Ethics Board, an IRB equivalent, or a ministry of health. Local collaborators and local IRBs can provide insight on local laws, such as privacy or other laws that may restrict the export from other countries of personally identifiable data. As determined by the IRB, an expert in the culture of the other country may be used in lieu of the IRB equivalent.

CSUSB IRB has no oversight responsibility when research with human participants is performed at another site by CSUSB faculty members who are on an unpaid leave of absence, or are otherwise not conducting research in connection with their CSUSB responsibilities. If the faculty member brings back identifiable private or intends to continue the research at CSUSB, a new CSUSB IRB application must be submitted.

Many international universities have Ethics Committees that can review and approve research. HHS provides a resource to identify federally assured sites that are updated annually. If a study involves minimal risk, the IRB equivalent to an approval letter or permission letter from the research site may be acceptable. The CSUSB IRB will review these on a case-by-case basis. Investigators are encouraged to contact the Chair CSUSB IRB to discuss issues related to International Research.

All international research studies must adhere to recognized Ethics Codes such as 45 CFR 46, the Declaration of Helsinki, the Nuremberg Code, or the Belmont Report. Consent and recruitment documents must be in the language that is readable and understandable by the subjects or the short form and translator method may be used.

2. IRB External Investigator Agreement

The External Investigator Agreement is to be used if an investigator that is not affiliated with CSUSB (student, staff, faculty, or administrator) and CSUSB is not engaged (participant recruitment, data collection, communication with participants, analysis with identifiable data) in research. The non-affiliated investigator(s) must have an approved protocol or exemption determination from their home IRB proposing to conduct research at CSUSB, with CSUSB research participants or utilizing human participants' data maintained by CSUSB. The External Investigator Agreement form can be found on our website.

3. IRB Cooperative Research Agreement

The Cooperative Research Agreement is to be used when CSUSB has investigators engaged (participant recruitment, data collection, communication with participants, analysis with identifiable data) in research with another institution (within the US) through collaborative research. If CSUSB IRB is relying on another institution's approval, the following documents must be obtained: an IRB approval letter from another institution, approved protocol, certification of training in human participant research protections for all personnel involved. These documents and the "Cooperative Research Agreement for Human Subjects Research" form can be found on our website.

E. Appeals Process

When an investigator disagrees with a request or determination about their study, the following steps need to be followed to consider the investigator's perspective.

1. Respond to the reviewer in Cayuse. If an investigator feels that a requested change to their study protocol or materials is unduly burdensome without a clear benefit to participant wellbeing and rights, the first step is always for the investigator to engage the reviewer in conversation. This step can help resolve any investigator-reviewer disagreements that are due to miscommunications between the two parties because fundamentally irreconcilable views on the ethical acceptability of the research are quite rare. To initiate conversation, the investigator should first use the "Add Comment" feature within Cayuse to provide a clear justification of both the burden presented by the requested change and why participant rights and wellbeing are potentially unaffected. There may be some dialogue on these points, and it is important all communication exchange is preserved in the context of the original IRB application.

The IRB will not consider further appeals and/or escalation until there is evidence of a conversation between the reviewer and the investigator in Cayuse. Investigators will be redirected to Step 1 until complete.

2. If the conversation is truly at an impasse, the investigator will be directed to email a request for ad-hoc committee review to irb@csusb.edu within 30 days with the following information:
   - Study protocol number (e.g., IRB-FY##-###)
   - Request for "subcommittee review" of a reviewer's determination, stipulation, or required change
   - The specific item number(s) of the disputed change (e.g., "F3a")

   The IRB Research Compliance Officer will respond within two business days confirming receipt of an ad-hoc committee review request.

3. If the ad-hoc committee finds in favor of the initial reviewer and the investigator still wishes to pursue appeal, the investigator will be advised to reply directly to the determination email (from irb@csusb.edu) requesting full board review. The appeal will then be brought to the full committee at the next convened IRB meeting, and the full committee will vote.

4. The vote of the full IRB committee is considered final and cannot be overruled by administrative action following the steps outlined above. The determination of the committee will be communicated to the investigator via email within five business days of the IRB meeting at which the issue was discussed.

II. Reporting of Unanticipated Problems, Serious or Continuing Noncompliance, and Any Suspension or Termination of IRB Approval

The California State University, San Bernardino Institutional Review Board has the authority to terminate or suspend research currently being undertaken with human participants that has not been conducted in an ethical manner.

A. Reporting Procedures

1. By Investigators

Investigators must report all unanticipated problems or adverse events to the IRB in writing within 5 business days and no further data collection can be continued until further notice from IRB. Should an unanticipated adverse event occur during the course of data collection, the investigator must immediately stop the research being conducted and report the occurrence to the IRB. Should a participant require medical attention or counseling, the investigator will provide appropriate contact information. The IRB can serve as a resource to the investigator for that information. The investigator can initiate changes to the research protocol prior to obtaining IRB approval to eliminate apparent immediate hazards to participants, but must report all changes promptly to the IRB. The criteria to determine whether an event meets the criteria for unanticipated problems and/or adverse events are described in detail below.

2. By the IRB

When the IRB becomes aware of problems involving human participant research, it is required by federal regulations to investigate and under certain conditions report those problems to the appropriate institutional official. Problems are reported to the AVP for Research at CSUSB and/or the Federal Office for Human Research Protections (OHRP), depending upon the severity of the problem and whether or not it was anticipated. Subsection 1.2 describes the information the IRB will use to determine whether or not an incident is reported to OHRP.

B. Unanticipated Problems and Adverse Events with Human participants

1. Circumstances involving unanticipated problems

a. Unanticipated problems: in general, include any incident, experience, or outcome that meets all of the below three criteria:

- unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied; and
- related or possibly related to participation in the research (*possibly related* means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

All three of these criteria need to be met for an incident to be classified as an unanticipated problem. For example, a breach of confidentiality that occurs during the research process and places participants at risk, is only an unanticipated problem if it was not described as a risk in the consent form. All unanticipated events must be reported to the IRB by the investigator and to the AVP of Research and OHRP by the IRB.

b. Adverse events: include any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, that possibly could be related to participation in the research. Adverse events encompass both physical and psychological harms. They occur most commonly in the context of biomedical research, although on occasion, they can occur in the context of social and behavioral research.

Adverse events may be caused by one or more of the following:

- the procedures involved in the research;
- an underlying disease, disorder, or condition of the participant; or
- other circumstances unrelated to either the research or any underlying disease, disorder, or condition of the participant.

In general, adverse events that are determined to be at least partially caused by (1) would be considered related to participation in the research, whereas adverse events

determined to be solely caused by (2) or (3) would be considered unrelated to participation in the research. If there is any reasonable possibility that the adverse event might have been caused by the procedures involved in the research *and* the event is unexpected, then it must be reported to the IRB by the investigator(s) and the IRB must report the event to the AVP of research and the OHRP.

2. Documentation Required for unanticipated problems

The investigator must submit an incident report to the IRB via Cayuse Online System within 5 business days. Reporting such events which occur in research is required by the Office of Human Research Protections. When an unanticipated problem and/or adverse event occurs no further data collection should be continued until further notice from IRB.

3. Communicating Unanticipated Problems

Communication for unanticipated problems steps should consist of:

a. Investigators report unanticipated problem(s) to CSUSB IRB via Cayuse Online System
b. CSUSB IRB determines the severity of the unanticipated problems
c. CSUSB IRB communicates actions to the investigator
d. CSUSB IRB reports unanticipated problems to OHRP (if applicable)

C. Serious or Continuing Noncompliance

1. Circumstances involving Serious or Continuing Noncompliance

a. Noncompliance: Includes the failure to comply with OHRP regulations or CSUSB IRB Policies and Procedures and failure to follow the requirements or determinations of the IRB.

b. Serious Noncompliance refers to any form of noncompliance that significantly increases risk to participants, significantly decreases potential benefits, failing to receive IRB approval for human participants research, inconsistencies with consent form, failure to remove a participant's information when requested by the participant, and, failure to respond to a request from the IRB to resolve an episode of non-compliance, and intentional deviations from the approved protocol by investigators, research staff or other party involved in the conduct of research. Protocol deviations are acceptable, however, if they received prior approval from the IRB or are performed to eliminate apparent immediate hazards to the participant. Multiple instances of non-serious noncompliance may also constitute serious noncompliance when considered collectively.

c. Continuing Noncompliance refers to a pattern of any form of noncompliance, including minor forms, that indicate a lack of understanding or disregard for OHRP regulations or CSUSB IRB requirements that protect the rights and welfare of participants. OHRP considers noncompliance to be continuing if it persists after the investigator knew or should have known about it.

Examples of serious or continuing noncompliance include, but are not limited to, failing to apply for IRB exempt determination or approval, failing to protect participant

confidentiality, violating informed consent and/or voluntary participation, continuing recruitment following a protocol suspension, collecting data under an expired protocol, using unapproved materials, putting participants at additional or unnecessary risk and not reporting unanticipated problems and/or adverse events.

D. Suspending or Terminating of IRB Approvals

1. Circumstances for Suspending or Terminating

The 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 is associated with unexpected serious harm to participants (45 CFR 46.113). A suspension or termination of IRB approval of research may occur at any time during the period for which IRB approval has already been given. Such suspension or termination would apply to research that has not been reviewed or approved.

For a multicenter research project for which many or all institutions engaged in the research project choose to rely upon their local IRBs for review of the project, a local IRB's decision at one institution to suspend or terminate its approval of the research only applies to the conduct of the research project at that institution. On the other hand, if all institutions engaged in a multicenter research project rely upon a central IRB for review of the project, the central IRB could suspend or terminate its approval of the research either at one institution because of a unique problem regarding the conduct of the research at that institution or at all institutions because of a study-wide problem.

Suspension of IRB approval may be appropriate when a significant issue is first identified and while the IRB investigates the matter. For example, if there is an allegation of serious noncompliance by an investigator or a human participant safety issue that needs further investigation and evaluation, the IRB may decide to suspend its approval of the research project while the allegation or issue is undergoing evaluation.

2. Circumstances Related to Human Participants Research Conducted without IRB Approval

If an investigator conducts any form of human participant [subject] research, as defined by OHRP without IRB approval may be grounds for suspension or termination.

3. Considerations of Participants

The IRB may consider whether it is appropriate to notify participants about the suspension and the reasons for it, and if so, when the participants should be notified when it could affect health and wellbeing, given that complete information may not be available.

E. Reporting to OHRP for Unanticipated Problems Involving Risks to Participants, Serious or Continuing Noncompliance, Suspending or Termination of IRB Approval

Upon becoming aware of any incident, experience, or outcome (not related to an adverse event) that may represent an unanticipated problem, the investigator should assess whether the incident, experience, or outcome represents an unanticipated problem by applying the criteria

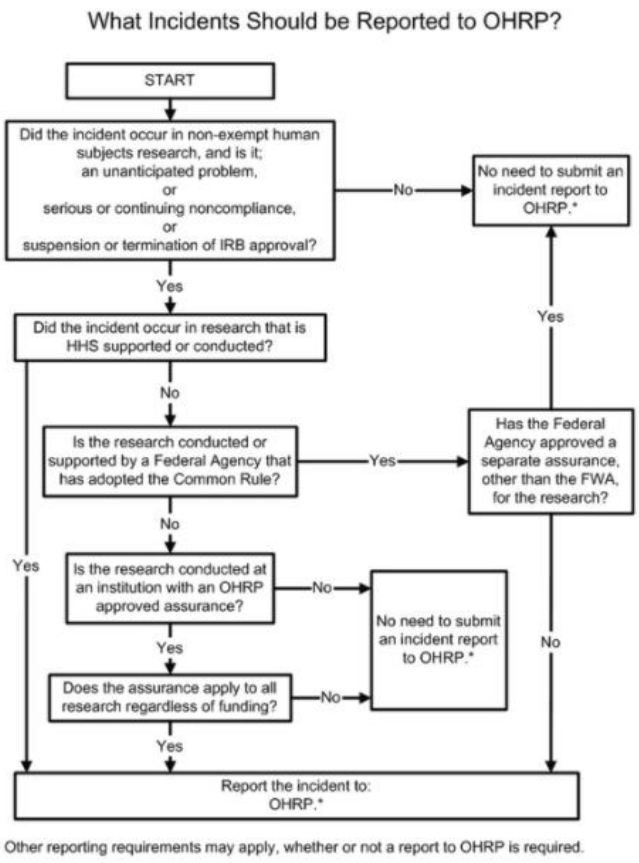
described above. If the investigator determines that the incident, experience, or outcome represents an unanticipated problem, the investigator must report it within 5 business days to the IRB.

1. **IRB procedures for reporting incidents from the investigator to CSUSB IRB**

    a. **The type of information that is to be included in reports of unanticipated problems.** The investigator will report unanticipated problem(s) to the CSUSB IRB on the Cayuse Online System within 5 business days and no further data collection should be continued until further notice from IRB. Investigators need to document the specific day and time of event, all associated additional risks to participants, and actions that were taken from the investigator during and after the event.
    b. **A description of which office(s) or individual(s) is responsible for promptly reporting unanticipated problems to the IRB, appropriate institutional officials, any supporting department or agency heads (or designees), and OHRP.** Once the IRB receives the incident report, the IRB Compliance Officer and IRB Chair will determine the severity of the unanticipated problem and determine actions based on risk to participants and severity of the unanticipated problem. These actions are listed below under "Range of Actions for Unanticipated Problems".
    c. **A description of the required time frame for accomplishing the reporting requirements for reportable events.** Following review from the CSUSB IRB Compliance Officer and IRB Chair, they will submit a report promptly to OHRP.
    d. **The actions the IRB decides to take will be communicated to the PI.** The IRB will communicate promptly with the PI regarding any action taken.

2. **Information to be included in incident reports from CSUSB IRB to OHRP**

    To fulfill the regulatory requirements for reporting incidents, OHRP would consider it acceptable for an institution to comply with written procedures specifying that the following information be included in an incident report submitted to OHRP:



a. For unanticipated problems involving risks to participants or others:

- Name of the institution (e.g., university, hospital, foundation, school) conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem; and
- Actions the IRB is taking or plans to take to address the problem (e.g., revise the protocol, suspend participant enrollment, terminate the research, revise the informed consent document, inform enrolled participants, increase monitoring of participants).
- Actions taken, if any, by investigators after the incident to address the problem.

b. For serious or continuing noncompliance:

- Name of the institution (e.g., university, hospital, foundation, school) conducting the research;
- Title of the research project and/or grant proposal in which the noncompliance occurred, or, for IRB or institutional noncompliance, the IRB or institution involved;
- Name of the principal investigator on the protocol, if applicable;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the noncompliance; and

- Actions the IRB is taking or plans to take to address the noncompliance (e.g., educate the investigator, educate all research staff, educate the IRB or institutional official, develop or revise IRB written procedures, suspend the protocol, suspend the investigator, conduct random audits of the investigator or all investigators).

c. For suspension or termination:

- Name of the institution (e.g., university, hospital, foundation, school) conducting the research;
- Title of the research project and/or grant proposal that was suspended or terminated;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB that was suspended or terminated and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the reason for the suspension or termination; and
- The actions the IRB is taking or plans to take to address the suspension or termination (e.g., investigate alleged noncompliance, educate the investigator, educate all research staff, require monitoring of the investigator or the research project).

F. Range of Actions by the IRB to Investigator for Unanticipated Problems, Adverse Events or, Serious or Continuing Noncompliance

There are a range of actions that may occur from CSUSB IRB following awareness of an unanticipated problem, adverse event, or serious or continuing noncompliance. Actions will be decided by the CSUSB IRB Compliance Officer, IRB Chair, and IRB Vice-Chair (if appointed), often in consultation with the full board. Actions will be dictated by specific events and severity of each situation. Possible actions are listed below:

- The IRB or investigator can request modification of inclusion or exclusion criteria to mitigate newly identified risks.
- The IRB or investigator can request implementation of additional procedures for monitoring participants.
- The IRB can require suspension of enrollment of new participants, suspension of research procedures in currently enrolled participants, modification of informed consent documents to include a description of newly recognized risks, and provision of additional information about newly recognized risks to previously enrolled participants.
- Actions may be reported to the AVP for Research, who will follow university guidelines for reporting.
- The IRB can suspend or terminate approval of research that, among other things, has been associated with unexpected serious harm to participants (45 CFR 46.113).
- The IRB can require investigator(s) to retake the CITI human participants training.
- The IRB can suspend investigator(s) from conducting human participants research for an IRB determined period of time depending on the severity of the non-compliance incident.
- The IRB can require investigator(s) to have future applications to be reviewed as full board for a specified period of time.

In addition to potential ethics concerns, the IRB will report all potential incidents of research misconduct and/or questionable research practices to the AVP for Research.

III. Scope and Authority

A. IRB Independence and Institutional Authority

The CSUSB IRB functions independently. The IRB maintains a current Federal Wide Assurance (FWA) and follows the regulations and guidance of the Office for Human Research Protections (OHRP) for all studies conducted under that assurance. Research that is not federally funded and that is outside of the FWA is subject to the same scrutiny.

1. Institutional Responsibility

The Federal wide Assurance filing requires CSUSB to adhere to the following:

- apply the Belmont Report principles of respect, justice, and beneficence to all human participants research regardless of funding;
- apply federal rules whenever CSUSB becomes engaged in human participants research or the IRB provides review and oversight of federally funded research;
- comply with Title 45 Code of Federal Regulations Part 46 (45 CFR 46) and Subparts B, C, and D (pregnant women, fetuses or embryos; prisoners; and children);
- require written informed consent for all research, unless informed consent is waived;
- require training and certification in human research protection of all university officials and researchers, and
- the university will provide adequate space and staff to support the IRB's review and record keeping duties.

2. Enabling Policy and Regulation

The Common Rule (45 CFR part 46) and its implementation by the Office of Human Research Protection defines policies and procedures to be undertaken by the CSUSB IRB for federally funded human participant's research.

3. IRB Authority

The IRB has the authority to "to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities, including exempt research activities under §46.104 for which limited IRB review is a condition of exemption" (45 CFR 46.109a).

4. IRB Responsibility

The CSUSB Institutional Review Board (IRB) implements a review process established within the Code of Federal Regulations (45 CFR 46) to ensure that human participants research complies with federal regulations, institutional policies and ethical standards.

5. IRB Jurisdiction

The IRB reviews research when procedures are proposed to obtain information about a living individual through the use of a survey, interview, observation, experiment, focus group, or the analysis of human tissues, records, samples, or other identifiable private information previously

collected from human participants. All research involving human participants must be reviewed and approved by the Institutional Review Board (IRB) in advance of study initiation.

B. Ethical principles that govern the IRB in assuring that the rights and welfare of human participants are protected.

Professional Codes of Ethics

Each researcher should be familiar with the professional code of ethics pertinent to their respective disciplinary associations and professional associations. For general principles pertaining to ethical practice of human participants research refer to the links below.

- Code of Federal Regulations
- Belmont Report

C. Federal and State Regulations for Human Participant Research

1. **Federal Regulations**
   a. **Code of Federal Regulations – Revised Common Rule, 2018 Requirements (45 CFR 46):** The revised Common Rule under 2018 requirements can be found at the following website.
   b. **Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II):** HHS modified a Privacy Rule in August 2002 (see the summary of the HIPPA Privacy Rule). This Rule set national standards for the protection of individually identifiable health information by three types of covered entities: health plans, health care clearinghouses, and health care providers who conduct the standard health care transactions electronically.
   c. **Family Educational Rights & Privacy Act (FERPA) (34 CFR Part 99:** Data collected by educational institutions are subject to regulation under the Family Education Rights and Privacy Act (FERPA). The CSUSB IRB is not the university's FERPA authority. The IRB may require evidence of FERPA compliance by the university FERPA official from whom data is being obtained.
   d. **Protection of Pupil Rights Amendment (PPRA) (20 U.S.C. § 1232h; 34 CFR Part 98):** Personal data on students obtained from educational records are also protected by the Protection of Pupil Rights Amendment (PPRA). (See 34 CFR Part 98; 20 U.S.C. § 1232h).
   e. **Other Statutes and Regulations:** In addition to the Common Rules, HIPPA, and FERPA, researchers should be familiar with federal statutes and regulations that may have implications on the collection and protection of private information.
   f. **California Health and Safety Code:** The California Health and Safety Code does contain specific regulations on the use of human participants in medical experimentation.
   g. **Health and Safety Code Section 24170-24179.5:** Protection of Human Subjects in Medical Experimentation Act.
   h. **Experimental Subject's Bill of Rights in Biomedical Research:** California Assembly Bill 1752: Human Experimentation, which became effective January 1, 1979, provides that all investigators doing a "medical experiment" must offer their participants a copy of the "Experimental Subject's Bill of Rights" in addition to the Informed Consent. Failure to do so may result in civil or criminal penalties.

i. **Subjects' Bill of Rights in Medical Research: All research participants must be informed of their rights when they're enrolled in a research study.**
j. **California State Penal Code; Research Involving Prisoners**
k. **Civil Code Section 1798 et. seq., the Information Practices Act of 1977 (IPA):** The Information Practices Act of California defines the steps and procedures California agencies must take to ensure privacy and protected information for state citizens.'
l. **Government Code Section 6250 et seq., the California Public Records Act (PRA):** The California Public Records Act defines what constitutes public record information versus private information in the conduct of trade and activities in California.