SACRAMENTO STATE

Institutional Review Board (IRB) Procedures

Office of Research, Innovation, and Economic Development

Research Integrity and Compliance

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I. APPLICABILITY OF THE COMMON RULE

The California State University, Sacramento (CSUS) Institutional Review Board (IRB) upholds 45 CFR 46, otherwise known as the Common Rule. The Common Rule is only applicable to research that is funded by an entity that has adopted the Common Rule. It is campus procedure to apply the Common Rule to all research on campus, with few deviations from the Common Rule for non-funded research or research funded by an entity that has not adopted the Common Rule. Deviations from the Common Rule will be identified in this document with an explanation for not applying the Common Rule and the campus' procedure for ensuring the protection of human subjects in accordance with the Belmont Principles of autonomy, beneficence, and justice.

A. Pre-and-Post Final Rule Procedures

1. Non-federally Funded and Exempt Research

After January 19, 2018, initial submissions of human subjects research that is not funded, or that is not funded by an agency that has adopted the Common Rule (45 CFR 46) will be reviewed according to the Final Rule, which was published on January 19, 2017.

Studies approved prior to January 19, 2018 will follow the pre-Final Rule regulations until its expiration or closure, unless the study is 1) not funded by an agency that has adopted the Common Rule and, 2) qualifies for closure under the Final Rule 45 CFR 46.109(f)(1)(iii)(A), or 3) qualifies as Not Research under the Final Rule 45 CFR 46.102(l). Studies will be reviewed for Final Rule qualifications outlined in this paragraph upon an investigator's modification request, annual report submission, or planned re-review by the Research Integrity and Compliance Officer. If a study qualifies for closure under the Final Rule, the investigator will be notified of the study closure due to adherence to the Final Rule.

2. Federally Funded Research (not including Exemptions)

Human subjects research that proposes to be funded by, or is funded by, a federal or other agency that has adopted the Common Rule will be reviewed according to the Final Rule, effective January 19, 2019. Studies submitted under the pre-2018 rule will continue to be reviewed under those regulations until the study is closed.

II. DEFINITIONS

A. Research

The Department of Health and Human Services (DHHS) Code of Federal Regulations (45 CFR 46.102(l)) has defined research as, "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." As described in the Belmont Report, "...the term 'research' designates an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

3. Pilot Studies

As defined by Federal Regulation, research is a "systematic investigation, *including research development, testing and evaluation,* designed to develop or contribute to generalizable knowledge"

(emphasis added). Pilot studies are an integral part of the broader research study and begins the path to hypothesis testing. In other words, there is intent to eventually develop or contribute to generalizable knowledge. These studies must adhere to the same review IRB requirements to protect human subjects, regardless of the number of subjects involved.

If the pilot study does not involve human subjects, the activity does not require IRB review.

4. International Research

IRB determinations and approvals of research applies to the investigator and follows the investigator to their study location and participant population. An activity conducted by a U.S. investigator that occurs outside of the United States is still subject to U.S. regulations and may also be subject to international regulations. CSUS investigators planning to conduct research outside of the country must receive IRB approval prior to conducting the study.

B. Human Subject

A human subject is defined as "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" (45 CFR 46.102(e)(1)).

An *intervention* includes physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes. An *interaction* includes communication or interpersonal contact between investigator and subject. This includes in-person, by phone, email, text, social media, etc.

Identifiable private information means private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

For a study to be considered human subjects research, the data obtained must be **about** the living individual. In some cases, an investigator may interact or intervene with a living individual, but the purpose is to obtain data about a topic other than the individual (i.e. office procedures). These studies may not be considered human subjects research.

C. Generalizable Knowledge

The IRB considers generalizable knowledge to mean drawing conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding.

The majority of scholarly work in academia is intended to be shared, published, presented to colleagues, and is intended to have an impact (theoretical or practical) on others within one's discipline. Activities that are disseminated with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.

D. Minimal Risk

Minimal risk "means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.102(j)).

1. Vulnerable subjects and protected populations

The IRB will follow the federal policy of assessing the purposes of the research and the setting in which the research will be conducted when it involves a populations from subparts to the Common Rule, or a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantages persons.

E. Not Human Subjects Research

The definition of research specifically excludes the following activities:

(1) Scholarly and journalistic activities
   a. Oral history
   b. Journalism
   c. Biography
   d. Literary criticism
   e. Legal research
   f. Historical scholarship
   g. Public health surveillance activities by a public health authority
   h. Research activities authorized by law or court order solely for criminal justice/investigative purposes

This does not excuse the listed activities from following discipline specific ethical guidelines.

F. Additional Situations when IRB Review May Not be Necessary

1. Assisting an Investigator

If a CSUS affiliate is asked to help an investigator for recruitment or space to conduct a study, they may not be engaged in the research or require IRB review. To see a full list of activities, derived from OHRP guidance, that engage and do not engage an individual in research, please view the Cooperative Research and External Investigator Guide:
http://www.csus.edu/research/irb/Cooperative__External_Research_v.3.pdf

2. Program Evaluation, Needs Assessment and Quality Control

Studies conducted for program evaluation, needs assessment, or quality control in which findings are solely intended for use in internal program planning and development and are not designed to contribute to generalizable knowledge are not subject to IRB review.

When the evaluation is undertaken to test a new, modified, or previously untested intervention, service, or program to determine whether it is effective *and will be shared as a program that can be used elsewhere (i.e. generalizing the outcomes for broader implementation)*, the activity is research.

When the purpose of an activity is to assess the success of an established program in achieving its objectives and the information will be used to improve that program, the activity is not human subjects

research. Data may be used for research purposes in the future and will be the responsibility of the person intending to use the data for research to obtain IRB approval, *if data are identifiable*.

3. External Investigator

Persons not affiliated with CSUS who plan to conduct research that involves the use of CSUS facilities or affiliates should provide a copy of their IRB approval letter to whomever they are contacting to gain access to the campus. Documentation can be sent to the Research Integrity and Compliance Officer for official verification, although this verification may be completed by other campus personnel. The CSUS IRB may choose to review the study to ensure ethical practices are implemented when conducting the research. Please view the Cooperative Research and External Investigator Guide: http://www.csus.edu/research/irb/Cooperative__External_Research_v.3.pdf.

4. Classroom Research

Classroom research, or research practice, is an activity required for a course grade with no intent of publishing or presenting results at an off-campus conference or symposium. The IRB does not require the review of student classroom research. Please see Post IRB Approval

Annual Reports or study Closure Reports are not required of exempt research. However, investigators conducting exempt research must follow procedures for Modification Requests and Review and Adverse Event and Unanticipated Problems Reporting. Investigators conducting exempt research are also subject to Noncompliance procedures.

Department/College Research Review Committee for more information.

5. Research Not Involving Human Subjects

Although an activity may be considered research, it may not involve human subjects. Persons involved in a research activity are not considered to be human subjects when the following apply:

- The information collected is not *about* the individual. That is, the person interviewed/surveyed is asked to provide information specific to his/her expertise or profession as opposed to personal information about him/herself (opinions, thoughts, or perceptions). For example, a welder asked to describe the composite of shielding gas, shielding gas flow rate, and formation of the weld bead is not disclosing information about him/herself and, as such, is not a research subject. Likewise, an entomologist who describes the varieties of pesticide used to control a specific pest and to identify the types of pesticides that are used most frequently is contributing his/her expertise rather than information about him/herself.

- The person is asked to wear a device to measure something external to the person (air quality, environmental toxins). No data are collected about the person.

- The information must be about a living individual to qualify as a human subject. Review of death records does not involve human subjects.

III. INSTITUTIONAL AUTHORITY

A. IRB Authority

The Institutional Review Board (IRB) reviews research when campus faculty, students, or staff propose to conduct human subjects research according to the federal definitions of research and human subject. All research involving human subjects must be reviewed by the IRB in advance of study initiation. In some circumstances, IRB review will be a collaborative process if more than one institution is engaged in research.

The IRB serves to protect the rights and ensure the safety of people involved as participants in research. The IRB also provides assistance to the investigator in complying with federal and state regulations and institutional standards for human subjects research. The IRB is guided by the ethical principles as set forth in the *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* also known as the Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html.

B. Shared Authority of the IRB and Institution

Per 45 CFR 46.109, the IRB may approve research reviewed or may require that modifications to the protocol be made to secure approval to conduct the research. The IRB may also disapprove research. IRB decisions are communicated in writing to the investigator. The IRB may also suspend or terminate approval of research that is not conducted in accordance with the approved protocol or that has been associated with unexpected and/or serious harm to subjects (45 CFR 46.113). Actions taken by the IRB to suspend or terminate approval will be documented electronically and reported to the investigator and institutional official(s). If the research is funded by a Common Rule entity, the Office for Human Research Protections (OHRP) will also be notified.

Research approved by the IRB may be subject to additional review by the officials of the institution. Authorized institutional officials may approve or disapprove research planned by an employee, student or agent of the University. The institutional officials may not approve research involving human subjects that has not been approved by the IRB (45 CFR 46.112).

C. University Administrative Support

Administrative support for the IRB is provided through the Office of Research, Innovation, and Economic Development (ORIED). This is accomplished through initial and ongoing review of human subjects research, ongoing education and training, and periodic assessment of resources dedicated in support of these activities by the Research Integrity and Compliance Officer. The Officer serves as first contact for campus IRB inquiries.

The Research Integrity and Compliance Officer receives all IRB applications, reviews them for completeness and accurate review categorization, and routes them appropriately. The Officer will conduct exempt reviews, limited IRB reviews, expedited post-approval reports, and modification review of minor revisions as a voting member designated by the Chair for such reviews.

The Officer will also administer Cooperative Research Agreements, and recommend entering or not entering the agreement to the Chair or Institutional Official. External Investigator inquiries will undergo a verification of external IRB approval as an ORIED matter by the Officer.

The Officer provides a comprehensive educational curriculum for the campus, including IRB members, Sponsored Program staff, student research reviewers, investigators, etc. This includes both online training and in-person workshops.

IRB meeting minutes will be handled by the Officer, as will the administrative tasks leading up to, and following the meeting, such as disseminating protocols for review, the agenda, and previous meeting's minutes, and other items up for discussion.

Reviewers will be assigned by the Officer according to the exempt, limited, expedited, and full board review procedures. Requested revisions and reviewer comments will be mediated by the Officer as liaison for the IRB.

IV. IRB MEMBERSHIP

A. IRB Composition

The IRB is composed of at least five members representing the University faculty, staff and local community. Membership includes at least one individual whose primary concerns are in nonscientific areas and at least one member not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution. The members represent a variety of disciplines of the research reviewed.

B. Selection/Appointments

The Research Integrity and Compliance Officer will confirm that IRB membership follows the requirements set forth in 45 CFR 46.107. New members are appointed through a call for nominations announced through Faculty Senate. Self-nominees submit their CV and other required information to the Faculty Senate. The Senate then confirms the list of nominees and supplies the list to the Office of Research, Innovation, and Economic Development (ORIED). The Associate Vice President of ORIED will forward recommendations to the Provost for appointment. IRB members are appointed for a three-year term. Reappointment may occur for another three-year term provided the member demonstrates knowledge of regulations, an understanding of the application of ethical principles, and has available time to devote to associated responsibilities.

C. IRB Chair

This Chair works closely with the AVP for ORIED and the Research Integrity and Compliance Officer on all IRB matters through frequent meetings or communication. The IRB Chair has a comprehensive understanding of the Belmont Principles, the Common Rule and its subparts, the campus Human Research Protection Policy, and research integrity.

The Chair and Vice-Chair are responsible for cultivating a campus culture consistent with the objectives of the IRB, with an emphasis on the protection of individuals participating in CSUS research. The Chair's role includes an expectation that he/she will:

- Stay current with required certifications,
- Conduct monthly IRB meetings,
- Serve as a first contact for IRB matters, in coordination with the Officer, for matters such as:
    - Determining the necessity for review,
    - Assisting in proposal development,

    - Facilitating compliance with applicable policies and procedures.
    - Contact investigators regarding non-compliance,
    - Assist recruitment efforts and training of new members,
    - Conduct expedited reviews as assigned in the member rotation,
    - Assist with exempt reviews as needed by the Officer,
    - Review Cooperative Agreements or Off-site Investigators, when appropriate,
    - Provide input on policy and procedural changes,
- Work with ORIED to inform the campus community of:
    - Policies & procedures effecting human subject research [HSR]
    - Training requirements for investigators doing HSR
    - Changes in any of the IRB processes that might impact HSR
- Engage in other duties as needed to advance the needs of the IRB and campus regarding human research protections.

This is a three-year position that receives 3 units of course release time per semester from ORIED.

D. IRB Vice-Chair

The IRB Vice-Chair works closely with the Chair and serves in a reserved capacity to ensure continuity within the IRB and its deliberations. The Vice-Chair has a comprehensive understanding of the Belmont Principles, the Common Rule and its subparts, the campus Human Research Protection Policy, and research integrity. As with the Chair, the Vice-Chair is considered responsible for cultivating a campus culture consistent with the objectives of the IRB, with an emphasis on the protection of individuals participating in CSUS research.

The Vice-Chair works closely with the AVP for ORIED and the Research Integrity and Compliance Officer on all IRB matters through frequent meetings or communication. The Vice-Chair's assignment includes an expectation that he/she will:

- Stay current with required certifications,
- Conduct monthly IRB meetings in Chair's absence,
- Serve as general back-up for the Chair with campus communication, training, non-compliance, and protocol reviews,
- Assist recruitment efforts and training of new members,
- Conduct expedited reviews as assigned in the member rotation,
- Provide second opinions on policy and procedural changes,
- Engage in other duties or special IRB projects as needed or requested by the Chair, AVP of ORIED or Research Integrity and Compliance Officer to advance the needs of the IRB and campus with regard to human research protections.

This is a three-year position that receives 1.5 units of course release time per semester, or 3.0 units per year from ORIED.

E. Alternate Member

Alternate members may be appointed to the IRB to serve in the absence of a member in an equivalent discipline. The alternate is selected based on the expertise and perspective he/she can bring to the review process and the discipline for which they are an alternate. The diversity in an individual's academic and/or professional training as well as experience will contribute to selection of an appropriate alternate member.

F. Consultants

The IRB membership includes those familiar with the types of research routinely conducted at CSUS. The IRB recognizes that additional expertise may be necessary when reviewing a protocol (45 CFR 46.107(e)). The IRB may request consultation from a subject matter expert when issues relevant to a protocol require outside expertise. Subject matter experts are not IRB members and may not vote on a motion.

G. IRB Member Conflict of Interest

Regulations stipulate that an IRB member may not participate in the initial or continuing review of a project in which the member has a conflicting interest, except in response to information requested by the committee (45 CFR 46.107(d)). If a member has a conflict of interest (personal, professional or financial), he/she may need to leave the meeting room while voting occurs. Attendance during the meeting is documented in the meeting minutes. If the quorum should fail due to the absence of the member in conflict, the IRB cannot vote and the item will be tabled until the next scheduled meeting. The IRB Chair may determine in rare circumstances whether the member may remain present and abstain from the vote to retain the quorum.

H. Member Training

IRB members must attend new member orientation prior to beginning their service on the IRB and complete the CITI (Collaborative Institutional Training Initiative) course and elective IRB member modules. They will also participate in initial and continuing education by reviewing relevant materials on issues, regulations, and guidance concerning human subjects protections, to be disseminated by the Research Integrity and Compliance Officer. IRB members will be familiar with the Code of Federal Regulations (45 CFR 46) (http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html), the Belmont Report (http://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html) and with this IRB Procedures document. IRB members are also periodically notified of events such as lectures, workshops and conferences related to human research protections occurring nationally and locally.

V. RECORD KEEPING AND DOCUMENTATION

A. IRB Membership Roster

The Office of Research, Innovation, and Economic Development (ORIED) maintains the current IRB membership roster. The IRB roster contains, at a minimum, the following information:

1. Name
2. Title
3. Department
4. Earned degrees
5. Indications of experience for IRB deliberations
6. Employment status or relationship with the university (i.e. full-time employee, stockholder, paid or unpaid consultant)
7. Contact information
8. Representative capacity (scientist/non-scientist)
9. Voting status
10. Appointment Date

11. Term expiration date

B. Documentation of Reviews

The outcome of reviews will be documented in correspondence to the Investigator, in application comments or decisions, and in IRB meeting agendas.

C. IRB Minutes

IRB minutes are taken by the Research Integrity and Compliance Officer and will include the following:

1. Attendance by name, documenting that the required quorum was present, including a scientific member, and a non-scientific member
2. Approval of prior IRB meeting minutes
3. Business items
4. Actions taken by the IRB for initial and continuing review of greater than minimal risk research including the vote, which may result in the following actions:
    i. Approval; date of approval and expiration
    ii. Minor stipulations that require final approval by the IRB Chair or other appointed IRB members
    iii. Return to PI
5. The basis for requiring changes in or disapproving research
6. A summary of any controverted issues and their resolution
7. The determination of the frequency of continuing review based upon degree of risk, if that frequency is to be more often than annually.

D. Quorum and Voting Requirements

To convene a meeting of the IRB, a majority of the voting members of the IRB must be present (one more than half). The committee may not convene without a member whose primary concerns are nonscientific. If the quorum fails during the meeting (early departures, loss of nonscientist, excused for conflict) the meeting will only cover items on the agenda that do not require a vote. Voting items will be tabled until the next scheduled meeting. Any action taken without a quorum present that requires a vote is considered invalid (45 CFR 46.108(b)).

An alternate member may be assigned to replace a member who is not able to attend the convened meeting. The alternate may vote only when in attendance to replace a voting member. Individuals designated as non-voting members may contribute to discussion, however, they may not serve as a primary reviewer, propose a motion, or vote on a motion. In order for a motion to pass, it must receive the approval of a majority of voting members present at the meeting (45 CFR 46.108(b)).

Votes and deliberations on each action reviewed by a convened IRB, include the number of members voting “for”, “against”, and the names and number of those who are abstaining or recusing themselves from the vote are documented in the IRB minutes.

E. IRB Correspondence

Accurate records are maintained of all communications to investigators and from the IRB within Cayuse IRB. Administrative access may be needed to view meeting minutes or other correspondence. The investigator is notified in writing of all IRB decision regarding each protocol and the regulatory criteria

upon which IRB decisions are based. The investigator is responsible for storing IRB correspondence with their research files.

F. Record Retention

Paper and electronic records required by 45 CFR 46 are fully accessible to the Research Integrity and Compliance Officer and are stored for at least 3 years or 3 years after the completion of the research.

VI. EDUCATION REQUIREMENT

CSUS requires that all investigators, faculty advisors of students conducting human subject research, and any other CSUS or auxiliary employees engaged in or reviewing human subjects research successfully complete the appropriate training for their status. This will be the Collaborative Institutional Training Initiative (CITI) Human Subjects course or, for undergraduate and master's students, the NIH tutorial as an alternative to the CITI course. Learner group information is available at http://www.csus.edu/research/irb/training.html.

This requirement is designed to encourage understanding of values toward responsible conduct in research involving human subjects. The tutorial covers basic ethical principles and practices that should be applied whenever human subjects are involved in research studies. The content is based on the Code of Federal Regulations that pertain to human subjects (45 CFR 46), and *Ethical Principles and Guidelines for the Protection of Human Subjects* - known as The Belmont Report. By successfully completing the tutorial, the investigator demonstrates the knowledge of human subject protections necessary to satisfy this requirement, which must be completed prior to review of an IRB application.

VII. FULL BOARD REVIEW AND CONVENED IRB MEETINGS

Human subjects research that does not meet the definition of "minimal risk" must be reviewed by the full board at a convened IRB meeting as described below.

A. IRB Meeting Schedule

A current IRB meeting schedule, including the deadlines for submission may be found at: http://www.csus.edu/research/irb/reviewcatagories.html. The IRB agenda, minutes, and all applicable review materials are sent to the IRB members approximately one (1) week prior to convened meetings to allow sufficient time for review of agenda items.

B. IRB Meeting Procedures

The IRB Chairperson will call the meeting to order once a quorum is established. The IRB will review and discuss the minutes from the prior IRB meeting, if available, and determine if any changes to the minutes are necessary. The IRB Chairperson will call for a vote for the approval of minutes.

The IRB will review and discuss each agenda item requiring action by the IRB. For each agenda item requiring a vote, the Chair will make a recommendation to approve, conditionally approve pending minor modification or clarification, table or disapprove. An IRB member will second the motion and the IRB Chairperson will call for a vote. Review and determination of approval for a protocol may be deferred when necessary if, for example, representational expertise is absent or if quorum is lost.

If the IRB is unable to review all the agenda items within the time allotted for the meeting, or if quorum is lost, the meeting will be reconvened as soon as possible. If it is not possible to reconvene the meeting prior to the next regularly scheduled IRB meeting, the agenda items will be added to the next regularly scheduled meeting.

For new agenda items, if an investigator is available or has supplied their telephone contact information, and they are available during the meeting time, the investigator may attend the meeting in person or via teleconference during the meeting to answer any of the IRB's questions regarding their research study. Investigators may not be present in person or via teleconference for any of the IRB deliberations or vote for their research study. The Research Integrity and Compliance Officer will take minutes at each IRB meeting.

C. Actions Taken by the Convened IRB

The minutes will include all applicable actions listed below and the votes by the convened IRB.

1. Approved: Approved is defined that the study submission is approved as presented and requires no clarification or modification to reach approval.
2. Conditional approval (Minor Stipulations): Conditional approval is defined as approval pending minor clarification and/or modification by the investigator within the study documentation. Once the clarification and/or modification is complete, the revised submission will be sent to the primary reviewer(s), or a reviewer designated by the IRB Chairperson for verification that the requested changes have been made to secure approval.
3. Revisions Required (Return to PI): A review of a study submission will be tabled if the IRB finds that the submission lacks sufficient information to proceed with its review or that substantive clarification and/or modification is needed before a determination can be made. When an investigator responds to the IRB regarding a tabled study review, the response must be reviewed at a fully convened IRB meeting.
4. Disapproved: The IRB determines the criteria for IRB approval of the research is not met and the research cannot be conducted.

D. Materials for Convened IRB Initial Review

All IRB members and consultants, when applicable, will be provided with sufficient information to ensure thorough review of each research proposal or modification to an existing, previously approved proposal. All IRB members will be given the opportunity to discuss each research proposal reviewed during a convened meeting. Consultants may not vote on the review of an item as they are not IRB members.

1. The Initial Review Application
2. Consent form(s)
3. Assent form(s), as applicable
4. Any recruitment materials/fliers
5. Any questionnaire(s)/survey(-ies)/Data collection sheet(s)
6. Any Eligibility screening checklist(s)

E. Expiration of IRB Approval

The initial IRB approval expires one year following its award, unless otherwise stipulated by the committee. Research projects reviewed by the Full Board must be reviewed at least annually (45 CFR 46.109(e)) and will be reviewed using the same procedure during initial review.

F. Criteria for Requiring Review More Often than Annually

Determination for more frequent review is based on the degree of risk associated with participation and/or the involvement of subjects that require additional protections as defined by the Department of Health and Human Services (45 CFR 46.108(a)(3)(ii)).

G. Continuing Review

A continuation of approval is needed if subject recruitment and/or data collection is continuing and will be conducted at least annually unless a determination for more frequent review is made according to Section VII. F. of this procedure. A final report is necessary if all recruitment and data collection procedures are completed. To apply for continuation of approval or to submit a final report, the investigator completes a Closure or Renewal Report via Cayuse IRB. Research that was initially reviewed by the convened committee will receive continuing review by the convened committee unless identified as not exceeding a minimal level of risk at the time of its initial review. Request for continued approval should be submitted in accordance with the appropriate deadline dates posted on the IRB schedule. If a Continuation of approval is not received before the expiration of the study, the investigator must halt research until approval to continue the study is received.

In conducting continuing review of research, the IRB will review:

- The number of subjects accrued;
- A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review, if applicable;
- Any relevant multi-center trial reports;
- Any other relevant information, especially information about risks associated with the research; and;
- A copy of the current informed consent document and any newly proposed consent document.

VIII. EXPEDITED AND EXEMPT IRB REVIEW

Human subjects research that meets the federal definition of “minimal risk” may be reviewed using the expedited or exempt procedure.

A. Expedited Review

Research that meets the federal definition of “minimal risk” and one of the expedited categories must be federally regulated and meet the federal approval criteria. This type of research will be reviewed using the expedited procedure rather than at a convened full board IRB meeting. A list of expedited research categories are listed on the OHRP website here: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html.

The IRB Chair, or one or more experienced IRB members designated by the Chair, may review research that qualifies for an expedited review. When conducting an expedited review, the designated reviewer(s) has the authority to act on behalf of the IRB, except for disapproving the research. During the initial review process, questions may arise that require the investigator to provide additional information or

clarification about the protocol. Questions developed during the initial review are communicated to the investigator via Cayuse IRB within two weeks of application submission. Designated reviewer(s) may return comments with a request to conduct the review after resubmission, or they may designate the Research Integrity and Compliance Officer to conduct the review after resubmission when minor changes are requested. Upon receipt and acceptance of the investigator's response by the IRB designated reviewer(s), approval to conduct the research is communicated to the investigator in writing. IRB members are informed of initial review and protocol modifications reviewed using expedited procedures at the appropriate convened board meeting.

In some cases, one or more designated reviewer will determine that the study does not pose minimal risk and cannot be approved using the expedited procedure. The reviewer(s) determining that the study poses more than minimal risk must document their decision during the review process. This is accomplished through the comment capabilities within the Cayuse IRB form, and/or in the Decision task in Cayuse IRB, and/or in the reviewer checklist in Cayuse IRB.

1. *Post IRB Approval*

Annual Reports or study Closure Reports are not required for research approved under the expedited procedure, although investigators will receive annual notifications of federal requirements. If the IRB provides justification for conducting continuing review, the study will be approved with an annual expiration date and will be subject to Continuing Review (46.109(f)(1)).

Investigators must follow procedures for Modification Requests and Review and Adverse Event and Unanticipated Problems Reporting. Investigators are also subject to Noncompliance procedures and Suspension or Termination when appropriate.

B. Exempt Determinations

Research that meets the federal definition of "minimal risk" and falls under one of the exempt categories will be reviewed by the Research Integrity and Compliance Officer, an IRB member designated by the Officer, or a departmental or college level research review committee for undergraduate and Master's student investigators. Investigators cannot self-determine an exemption. A list of exempt research categories is listed on the OHRP website: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/#46.101.

Exempt research is not required to meet the federal review and approval criteria, unless it meets requirements for Limited IRB Review. However, the IRB may impose certain criteria for exempt research, such as informed consent.

During the initial review process, questions may arise that require the investigator to provide additional information or clarification about the protocol to ensure the exemption determination is correct and to secure approval. Questions developed during the initial review are communicated to the investigator via Cayuse IRB. Upon receipt and acceptance of the investigator's response, approval to conduct the research is communicated to the investigator in writing. IRB members are informed of initial exempt review and exempt review of modifications at the appropriate convened board meeting.

1. *Limited IRB Review*

Research that qualifies for exemption except that it poses risks to privacy and confidentiality of participants and their data will be reviewed under 45 CFR 46.111(a)(7), known as limited IRB review. Exemptions that must be reviewed using the limited IRB procedure are identified in 45 CFR 46.104 (d).

An IRB member must be the reviewer for this type of research. Department/College Research Review Committees cannot make exempt determinations if that exemption meets limited IRB review criteria. The Research Integrity and Compliance Officer, who is also an IRB member, may conduct the review or assign the review to another qualified IRB member. The same procedure for communication, determination, and other reporting for exempt research also apply to exempt limited IRB determinations.

2. Post IRB Approval

Annual Reports or study Closure Reports are not required of exempt research. However, investigators conducting exempt research must follow procedures for Modification Requests and Review and Adverse Event and Unanticipated Problems Reporting. Investigators conducting exempt research are also subject to Noncompliance procedures.

3. Department/College Research Review Committee

There are several committees at CSUS designated as third-party reviewers by the IRB Chair that have received specialized training from the IRB and Research Integrity and Compliance Officer to make exempt determinations of undergraduate or master's student research within the department or college. These committee must report exemption determinations to ORIED. Student exempt research that meets limited IRB review criteria cannot be determined at the department/college level. All Department/College Research Review Committee members are required to complete the CITI training. At least two members per committee must complete a 1.5-hour training in determining non-research, exempt research, and non-exempt research. This training also includes a short tutorial on the use of Cayuse IRB software in the review and routing of applications. These committees provide great support to the IRB in reducing exempt student research traffic. Any department or college that reviews exempt student research without the appropriate training is not in compliance with campus policy.

The following departments/college have committees that review exempt student research:

- College of Education
- Psychology
- Sociology
- Nursing
- Social Work
- Communication
- Criminal Justice

IX. MODIFICATION REQUESTS AND REVIEW

In accordance with 45 CFR 46.108(a)(3)(iii), an investigator cannot modify an originally approved protocol until IRB approval for modifications are provided. This requirement applies to all research due to possible changes of the initial risk evaluation. The only exception to prior modification approval is for eliminating apparent immediate hazards to the subject.

Investigators must certify in the modification request form that no changes have been implemented, and will not be implemented until IRB approval is received. Studies may continue under its initial approval

until the modification approval is received. The IRB may initiate the Criteria for Study Conduct Verification procedure as a measure of ensuring terms of IRB approval.

If changes are minimal, or if the study was originally approved as "minimal risk" and the changes do not affect the initial risk assessment, the review will be conducted by the Research Integrity and Compliance Officer. If the modification increases the risk, the study will be reviewed according to the initial submission procedures in the appropriate review category. If the study was originally approved by the Full Board, significant modifications will be reviewed by the Board at the next convened meeting. Modification reviews may require additional information or documentation from the investigator, and will be communicated to the investigator in writing. Decisions of modifications will be communicated to the investigator in writing. The IRB is informed of modification approvals at the next convened board meeting.

X. CRITERIA FOR STUDY CONDUCT VERIFICATION

Verification from sources other than the investigators that no material changes have occurred since previous IRB review will be determined by the IRB when noncompliance of the campus policy, procedure, or the spirit of the Belmont Principals is suspected (45 CFR 46.108(a)(3)(ii)). This verification is intended to ensure modifications to the study are not implemented without prior IRB approval as stipulated in the regulations and outlined in Section IX. Verification may be accomplished through observation(s) by the IRB or a third part of the consent process and the research (45 CFR 46.109(g)).

XI. COOPERATIVE RESEARCH

Research conducted in collaboration with other universities, research institutions, hospitals, etc. can be reviewed and approved by one OHRP registered IRB to avoid duplicate reviews. A Collaborative Research Agreement or Institutional Authorization Agreement must be utilized to properly document the circumstances of the IRB to be reviewing and the IRB to be relying on review and approval. This agreement must be completed and signed by both/all IRBs prior to commencing research. Please view our Cooperative Research and External Investigator Guide: http://www.csus.edu/research/irb/Cooperative__External_Research_v.3.pdf.

A. Dual Relationships: Student and Employee of Institutions with IRBs

Many students want to conduct research at their place of employment to fulfill education requirements. If the investigator's place of employment also has an IRB, the responsibility of review and approval will lie with the institution that is initiating the research activity. For example, a CSUS student must complete a thesis for an MA program and they propose to conduct research at their place of employment. Since the research is being initiated due to their role as a CSUS student, the research should be reviewed by the CSUS IRB. Most often, the place of employment will not view the activity as research. The employee's supervisor should provide the investigator with a letter of support of the activities to take place to properly document these decisions.

In the reverse scenario, an employee of CSUS may also be a student at another institution. If the research is initiated for degree completion for the other institution, that institution shall be the reviewing IRB. The CSUS IRB will then verify prior IRB approval from that institution by asking for a copy of the IRB approval letter.

XII. ADVERSE EVENT AND UNANTICIPATED PROBLEMS REPORTING

The CSUS IRB requires investigators to report any problems that arise during the course of an IRB-approved research study. *Serious* adverse events or unanticipated problems that are life-threatening or have resulted in serious injury or death must be reported to the police **immediately** whenever possible and the IRB within **at least 48 hours** from the onset of the incident. All other problems must be reported to the CSUS IRB **within 5 days** through Cayuse IRB using the adverse event report form.

The IRB will determine whether the investigator has developed appropriate measures to remedy the problem and to avoid the occurrence of a similar problem in the future. If the IRB determines that the adverse event is related to the research and that the problem was unanticipated, the investigator will be asked *at a minimum* to modify informed consent procedures so that current participants are notified of the event so that they may determine if they wish to continue their participation. The investigator may also be required to revise the informed consent process for use with future participants so that all foreseeable risks that are involved in the study are described. In addition, the IRB will determine on a case-by-case basis whether additional substantive changes such as major revisions to the protocol are required.

Minor adverse events will result in involving the following personnel in an adverse event report, action plan, and IRB verification of action plan implementation: the faculty advisor (if the investigator is a student), and the department chair. The IRB may decide to involve other personnel in these communications at their discretion.

Major adverse events that are also considered unanticipated problems according to OHRP (see below) will result in involving the following personnel in an adverse event report, action plan, and IRB verification of action plan implementation: the faculty advisor (if the investigator is a student), the department chair, the college dean, and potentially the Provost or President.

All adverse events, action plans, and IRB verification of action plan implementation will be reported to the Institutional Official.

Federal law may also require the IRB to report the incident to the Office of Human Research Protections (OHRP) (45 CFR 46.108(a)(4)). The IRB will report the incident to OHRP when it has been determined that the adverse event is also considered an unanticipated problem and therefore meets all of the following criteria:

- The adverse event is unexpected in nature, severity and frequency;
- The adverse event is related or possibly related to participation in the research; **and**
- The adverse event suggests that the research places subjects or others at greater risk of physical or psychological harm than was previously known or recognized.

(Modified from OHRP's "Algorithm for Determining Whether an Adverse Event is an Unanticipated Problem" p. 10).

A. Suspension or Termination

The IRB maintains the authority, under 45 CFR 46.108(a)(4)(ii) and 46.113, to require protocol revisions or suspend or terminate any protocol that is not being conducted in accordance with the CSUS IRB requirements for approved research or that has been associated with unexpected serious harm to subjects.

The IRB will promptly notify, in writing, the research team and the department chair or office head in the event of suspended or terminated IRB approval. When necessary or appropriate, the college dean, Provost or President may also be notified. The Institutional Official will be notified in all instances of suspension or termination of IRB approval.

If the project is funded by a Common Rule agency, federal law may also require the IRB to report the suspension or termination to the Office of Human Research Protections (OHRP) (45 CFR 46.108(a)(4)).

XIII. APPEAL OF IRB DECISION

An investigator may request an appeal of an IRB decision in the following circumstances:

1. A suspension or termination of a previously approved protocol;
2. The investigator believes the IRB's decision was based on inadequate or inaccurate information or is out of compliance with University policy, state law, or federal regulations;
3. Sanctions are imposed by the IRB;
4. The investigator disagrees with the process by which a decision was rendered.

Investigators should send their written appeal directly to the IRB, describing the specific reasons for their request. The Research Integrity and Compliance Officer will arrange a meeting between the investigator and a sub-committee of the IRB that includes the original reviewers, Chair, and Research Integrity and Compliance Officer to discuss the issues and to attempt to come to a satisfactory resolution.

If this process does not resolve the problem, the appeal may be forwarded to the Associate Vice President for Research, Innovation, and Economic Development (AVP) or designee. The AVP may, upon review of the appeal, initiate an inquiry into the process and/or data used by the IRB to arrive at its decision, and issue an opinion on the appropriateness of that process and/or data. The AVP may opt to convene an ad hoc committee to facilitate this review.

The AVP may override an IRB decision to impose sanctions or to suspend/terminate a previously approved protocol. However, according to 45 CFR 46.112*, the decision by an IRB to disapprove a research project cannot be reversed by other officials at the institution; there is no appeal to a 'higher authority'. It should be noted, however, that disapproval is almost always based on specific shortcomings which, if remediated, may result in approval upon subsequent submission.

***§46.112 Review by institution.** Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.

XIV. NONCOMPLIANCE

Noncompliance is the failure to comply with or a deviation from an approved IRB protocol or other approved IRB protocols and federal regulations, or the failure to submit a protocol for review and approval when human subjects research is conducted.

Noncompliance issues can be minor, which would be considered to pose little risk to subjects, or major (serious), such as modifying an IRB protocol without IRB approval that initially went through a full IRB review, activities that impact the risk to subjects, or a history of continual noncompliance.

A. Responses to Noncompliance

It is expected that any noncompliance issues will be promptly reported to the IRB by investigators. Investigators who discover issues of noncompliance should fill out an Incident Report via Cayuse IRB. Information regarding noncompliance may also come from subjects, other investigators, staff and faculty, or the general public.

The Research Integrity and Compliance Officer will receive and route the incident form, originally approved protocol, and other supporting material to a subcommittee who will investigate and make a decision as to whether the issue of noncompliance is justified (based in fact) or not and, if justified, whether it is minor or major. This subcommittee will be composed of the IRB Chair, the Institutional Official, the Research Integrity and Compliance Officer and potentially one or two IRB members. During this time, investigators will be asked to suspend data collection until the non-compliance issue is resolved, per section XII. A. of this procedure.

Minor issues of noncompliance will be handled by the IRB Chair in conjunction with the Research Integrity and Compliance Officer. Examples of responses to minor issues of noncompliance might include, but are not limited to, the following:

- Retaking the Collaborative Institutional Training Initiative (CITI) Human Subjects tutorial.
- Early renewal of an IRB protocol, per section VII. F. of this procedure.
- Notification of noncompliance to the department chair, college dean, Provost, and/or President.

Major issues of noncompliance will be discussed at a full IRB committee meeting and responses will be determined by the committee members with adequate justification. Additionally, major issues of noncompliance will be revealed to the appropriate institutional officials and/or the Office of Human Research Protections (OHRP) of the federal Department of Health and Human Services (DHHS) if appropriate. Examples of responses to major issues of noncompliance might include but are not limited to the following:

- Retaking the CITI Human Subjects tutorial.
- Early renewal of an IRB protocol per section VII. F. of this procedure.
- IRB auditing of research protocol/data collection.
- Notification to past/current subjects or re-consent of current subjects.
- Modification to Human Subjects Research Application.
- Suspension or termination of research per section XII. A. of this procedure.
- Study conduct verification per section X.