CSUP IRB Operational Policy and Procedures

Introduction, Mission, Ethical Principles

1. **Purpose** To describe the mission of the Colorado State University Pueblo (CSUP) Institutional Review Board (IRB), the purpose, the authority under which it operates, and the scope of research conducted at CSUP that is under IRB oversight.
2. **Scope** Activities that meet the regulatory definition of research involving human subjects or clinical investigation involving human subjects and conducted under the auspices of CSUP must be reviewed and approved by the IRB prior to any human research activity. A definition of activities that meet the regulatory definition of human research can be found here: <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html>
3. **References**

**The Belmont Report:** [**http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html**](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html)

1. **Definitions**
   1. **Autonomy**: Independence or freedom, as of the will or one’s actions.
   2. **Confidentiality**: Data are linked to individual participants, but researchers keep the identities of the participants confidential through various means of security and access controls.
   3. **Commission:** National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
   4. **Federalwide Assurance (FWA)**: The only type of assurance currently accepted and approved by Office for Human Research Protections (OHRP). Through the FWA, an institution commits to HHS that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.
   5. **Human Subject**: A living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information
   6. **Institutional Review Board (IRB)**: A faculty led group who reviews and approves research with the primary focus on the rights and welfare of the participants.
   7. **Investigator**: An individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB.
   8. **Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
   9. **Undue Influence**: The interference with the normal functioning and decision-making of an IRB or other RICRO unit, or to influence an IRB or other RICRO faculty or staff member, outside of established processes or through normal and accepted methods, in order to secure a particular determination or outcome.
2. **Authority of the IRB:** 
   1. Institutional Authority

5.1.1. The CSUP IRB, under the supervision of the Provost, serves as the review board for human research and operates in accordance with federal regulations (45 CFR 46; 21 CFR 50; 21 CFR 56; 21 CFR 312; 21 CFR 812); state and local regulation; other federal regulations specific to funding sources related to the protection of participants in human research; and the Belmont Report.

5.1.2. The IRB assists researchers, staff, and faculty with providing oversight in maintaining an ethical environment for human subject’s research activities. CSUP complies with the federal regulations governing review of research that involves human subjects. Accordingly, CSUP applies the same standards for oversight to all research activities involving human subjects, regardless of funding or funding source.

5.1.3. Review of human subject’s research at CSUP is conducted in accordance with our Federalwide Assurance (FWA). This assurance pledges the University to comply with federal regulations for all federally supported research.

5.1.4. The CSUP IRB works to protect the rights and welfare of research participants, to provide guidance on research integrity issues, and to assist the research community in conducting and promoting responsible and ethical research. All personnel using humans for research are required to comply with applicable federal regulations. To operationalize this in practice the CSUP IRB has established operational procedures documented elsewhere in this document. ***The procedures are specific practices that should be adhered to in the use of human participants in research at CSUP.***

* 1. Limitations on Institutional Authority

5.2.1. All human research conducted by the University must be approved by an IRB or granted an exemption by a University IRB (through its members or staff, as specified in the IRB’s standard operating procedures) or the Provost. Research that has been reviewed and approved by a University IRB may be subject to further review and disapproval by other review bodies or officials (including the Provost); however, no person or organization may override an IRB’s disapproval determination.

1. **Ethical Principles Governing the IRB**
   1. In 1974 the passage of the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission was charged with identifying the ethical principles underlying biomedical and behavioral research. In The Belmont Report the Commission specified three principles guiding human research. These three principles are: 1) respect for person; 2) beneficence; and 3) justice.

6.1.1. Respect for Person

6.1.1.1. Human participants are autonomous

6.1.1.2. Individuals with diminished autonomy (e.g., prisoners, children, developmentally disabled) require extra precautions to protect their welfare in research activities.

6.1.1.3. Consequence:

6.1.1.3.1. Individuals are informed about a research project in a comprehensible manner so they can decide whether to participate in it or not.

6.1.1.3.2. Participation in a research project is voluntary.

6.1.1.3.3. The privacy and confidentiality of individuals is honored.

6.1.2. Beneficence

6.1.2.1. The researcher maximizes potential benefits while minimizing potential harm

6.1.2.2. The researcher makes a systematic assessment of the risks and benefits and determines that:

6.1.2.2.1. There is no brutal and inhumane treatment of participants.

6.1.2.2.2. Risks are reduces as much as possible.

6.1.2.2.3. There is a justification of significant risk.

6.1.2.2.4. Risks and benefits are fully disclosed in the informed consent process.

6.1.3. Justice

6.1.3.1. There is equitable selection of participants.

6.1.3.2. There is a fair distribution of risks and benefits across groups.

6.1.3.3. Individuals are not systematically selected because of their convenient availability, their compromised positions, or because of prevalent social, racial, sexual, economic, or cultural biases.

1. Protection for Undue Influence

7.1. CSUP IRB members have numerous interactions with investigators and others in the performance of their assigned roles. The University will investigate and resolve any reported attempt to inappropriately pressure (i.e., to exercise undue influence upon) an IRB member because of that individual’s role.

7.2. Any attempt to exercise undue influence over the IRB should be reported as follows:

7.2.1. An IRB member who experiences undue influence should first report the occurrence to the IRB chair, who will attempt to mediate or resolve the concern, in consultation with the Provost, as necessary or appropriate.

CSUP IRB Regulatory Authority

1. **Purpose** To define the activities that meet the regulatory definition of research involving human subjects or clinical investigation involving human subjects and conducted under the auspices of CSUP that require prospective IRB review and approval prior to any human research activity.
2. **Scope** Colorado State University – Pueblo (CSUP) has one registered Institutional Review Board (IRB) under its Federalwide Assurance (FWA) with the U.S., Department of Health and Human Services (DHHS). This IRB reviews research related to social, behavioral, educational and biomedical research areas and is registered to comply with the Office of Human Research Protections (OHRP) regulations 45CFR46 and FDA regulations 21CFR50 and 21CFR56. This policy establishes role, authority, and independence of the IRB as it applies to the University research community, researchers from other institutions under the oversight of CSUP IRB approval, or sites with an IRB that CSUP IRB relies on as the IRB of record.
3. **References**

DHHS 45 CFR 46

FDA 21 CFR 50

FDA 21 CFR 56

1. **Definitions**
   1. **Clinical Investigation**: Involves a test article and one or more human subjects and either is subject to requirements for prior submission to the Food and Drug Administration (FDA) under section 505(i), 507(d), or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by, the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulations [21CFR50.3(c), 21CFR56.102(c)].
   2. **Clinical Trial [NIH]**: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.
   3. **Human Subject**: a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information (45 CFR 46); an individual who is or becomes a participant in research, either as a recipient of the test article or as a control and/or an individual on whose specimen an investigational device is used. A subject may be either a healthy human or a patient. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.
   4. **Institutional Review Board (IRB)**: A faculty led group who reviews and approves research with the primary focus on the rights and welfare of the participants.
   5. **IRB Authorization Agreement (IAA)**: A formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) review to an IRB of another institution or an independent IRB. IRB Authorization agreement is synonymous to a Memorandum of Understanding (MOU) or Reliance Agreement. The agreement may be based on the nature of the established financial, legal, or collaborative relationships between the entities.
   6. **Research**: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to *generalizable knowledge*. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
   7. **Test Article**: Any drug (including a biological product) for human use, medical device for human use, human food additive, color, adaptive, electronic product, or any other article subject to regulation under the jurisdiction of the FDA.
2. **CSUP IRB Jurisdiction**
   1. The Provost at Colorado State University – Pueblo has established one IRB to review all human subjects’ research conducted at or sponsored by CSUP. The CSUP provost is responsible for institutional oversight of the CSUP IRB. All research activities that meet the federal definition of “research” and “human subject” or meets any definitions above that are regulated by FDA must be reviewed and approved by the CSUP IRB if:

12.1.1. The research is sponsored by CSUP, or

12.1.2. The research is conducted by or under the direction of any employee or agent of CSUP in connection with their institutional responsibilities, or

12.1.3. The research is conducted by or under the direction of any employee or agent of CSUP using any property or facility of this institution, or

12.1.4. The research involves the use of this institution’s non-public information to identify or contact human research participants or prospective participants.

* 1. IRB: All human research conducted by the faculty, staff, students, or other trainees with primary appointment at CSUP.

12.2.1. In those instances in which conflicts of interest preclude a quorum for review, the project may be transferred to another institution’s IRB with appropriate expertise for review and approval.

5.5.2 Should an IRB or faculty member, staff member, student, or other trainee request review by an alternate IRB, the chair will review the request and, if appropriate, consult with the other IRB and decide which IRB shall review and have primary oversight. The Provost may overrule a chair’s refusal to refer an application to another IRB.

* 1. Cooperative Research:

12.3.1. Researchers at Colorado State University - Pueblo frequently interact with entities or individuals outside the University with relation to research activities involving human participants. These interactions can be varied, but the University’s (and its researchers) regulatory obligations and alternatives for addressing them may differ depending on the relationship with the entity or individual outside CSUP in the context of the research.

12.3..1.1. Engagement in Research: A research site becomes “engaged” in research when its employees or agents intervene or interact with living individuals for research purposes, including obtaining informed consent, or obtaining individually identifiable private information for the purposes of non-exempt research activities. A research site is always considered engaged in human research when it receives a direct grant or other award to support research involving human subjects, even if the human subject portion of the research is carried out by another institution. You can find additional guidance at <http://www.hhs.gov/ohrp/policy/engage08.html>

12.3.1.2. University’s Position on Outside Entities Engaged in University Research: CSUP’s default positon on research performed at multiple locations is that each may review and approve its own participation in the research, but when possible, an IRB Authorization Agreement should be used to avoid duplicate review. When the overall Principal Investigator (PI) of research conducted at multiple locations is affiliated with the University, or the University is otherwise involved as a primary or coordinating center, the PI must assure the CSUP IRB reviewing the research that each performance location involved in the research has requested an Authorization Agreement or that the research has been properly approved at that location prior to the human subjects research activity is initiated there and must notify the CSU IRB of any lapse or change in approval status. When CSUP agents are acting as an extension site of multi-site research approved and overseen by another institution’s IRB, then the CSUP IRB will review and approve CSUP participation in that research and act as a secondary form of oversight only for the portion of the research conducted at CSUP.

12.3.1.4. If the outside entity is engaged in federally funded collaborative research activities, the outside entity must obtain a Federalwide Assurance (FWA) with OHRP in either the case of primary oversight or secondary oversight by CSUP.

12.3.1.5 The CSUP IRB will not review or allow for human research to be conducted at CSUP unless an agent of CSUP is directly involved in the research and can submit the project to the CSUP IRB for review.

* 1. The Provost, as the designated Institutional Official has authority to review decisions of the IRB. The Provost can conclude that a research protocol with CSUP IRB approval does not fully comply with the policies or obligations of CSUP and may disapprove, suspend, or terminate a project on behalf of the institution. Should the IRB disapprove, suspend, or terminate a project, no person or entity, including the Provost may reverse that decision.

1. **Purpose** To outline the structure of the CSUP Institutional Review Board and resources.
2. **Scope** This policy applies to the University research community, researchers from other institutions under the oversight of CSUP IRB approval, or sites with an IRB that CSUP IRB relies on as the IRB of record.
3. **References**
   1. 45 CFR 46.107
   2. 21 CFR 56.107
4. **Definitions**
   1. Alternate Member: Alternate Institutional Review Board (IRB) committee members may be designated, as needed, for regular voting members. The appointment of alternate members should be based on expertise similar to that of the regular voting member. An alternate member may vote only when the regular voting member is absent.
   2. Institutional Review Board (IRB): a faculty led group who reviews and approves research with the primary focus on the rights and welfare of the participants.
   3. Regular Member: A member with full voting rights who is listed in the IRB Registration.
5. **CSUP IRB Operational Procedures**
   1. Composition of CSUP IRB: The registered CSUP IRB is in compliance with 45 CFR 46.107 and 21 CFR 56.107 with voting members that include faculty members from various academic disciplines as well as behavioral scientists, physicians, researchers, non-scientific members, and community representative not affiliated with the university.
      * 1. The CSUP IRB has a minimum of five members with diverse representation in regards to race, gender, cultural issues and scientific areas.
        2. There is more than one member from the scientific area.
        3. There is more than one member from a non-scientific area and this member is represented at every convened meeting.
        4. There is more than one member who is not affiliated with the institution and who is not part of an immediate family of a person employed by the institution.
        5. There is at least one member who is knowledgeable about and has experience working with vulnerable populations in regularly reviewed research, such as: children, prisoners, pregnant women, handicapped or mentally disabled persons.
   2. Appointment of IRB Members (Full Voting Members or Alternates to Members):
      * 1. The Provost at CSUP appoints members to the committee in consultation with the IRB Chair and the deans of the CSUP colleges, if applicable.
        2. Names are recommended to the Provost by the IRB and college deans, if applicable, to maintain the federal regulations regarding committee composition.
        3. The appointment of chair is done by the Provost based on the recommendations of the IRB and Office for Research and Sponsored Activities.
   3. Term Limits:
      * 1. Membership on the IRB is for three years or fewer with the possibility of the term being extended in three-year increments or less.
        2. Appointment to the chair is for three years or less with the possibility of the term being extended in three-year increment or less.
   4. IRB Training:

17.4.1. CSUP IRB members who are also faculty members at CSUP must have completed Citi (or equivalent) training in either the behavioral or biomedical components of the Citi training process for IRB members\*.

17.4.2. Current CSUP IRB members are grandfathered on this requirement until completion of their most recent three year term.

1. **Human Research Project Classification for Review**

18. 1. Purpose To define the procedures for human research project review.

18.2. Scope This policy applies to the University research community, researchers from other institutions under the oversight of CSUP IRB approval, or sites with an IRB that CSUP IRB relies on as the IRB of record. All research involving human subjects, regardless of funding, is subject to IRB oversight and must be submitted to the IRB for review and approval.

18.3. References

18.3.1. 45 CFR 46.103 (b) (4)

18.3.2. 21 CFR 56.103 (b) (5)

18.3.3. 45 CFR 46.101. (b)(1-6)

18.3.4. 21 CFR 56.104(c-d)

18. 4. Definitions

18.4.1. **Alternate Member**: Alternate Institutional Review Board (IRB) committee members may be designated, as needed, for regular voting members. The appointment of alternate members should be based on expertise similar to that of the regular voting member. An alternate member may vote only when the regular voting member is absent.

18.4.2. **Institutional Review Board (IRB)**: a faculty led group who reviews and approves research with the primary focus on the rights and welfare of the participants.

18.4.3. **Full Member**: A member of the CSUP IRB appointed by the CSUP Provost for a definite term of service.

18.5. Procedure

18.5.1. **Exempt Studies**: Studies determined to be “exempt” per the federally defined categories are acknowledged rather than approved by the IRB. Before they are acknowledged, exempt studies must be found to be ethical and in compliance with the policies adopted by the CSUP Institutional Policies and IRB Policies. The IRB applies the ethical principles of the Belmont Report to all human subject’s research, including the activities determined to be “exempt.”

18.5.1.1. Exempt determinations are made by the Chair of the CSUP IRB or his/her designee. The designee may be a voting member of the board or a Citi credentialed IRB staff member (regardless of voting status).

18.5.1.2. In order to be deemed exempt, all research activities must fit into one or more of the exempt categories defined by 45 CFR 46 and 21 CFR 56.

18.5.1.3. Limitations of Extending Exemption Status

18.5.1.3.1. Children: Exemption for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed.

18.5.1.3.2. Prisoners: Exemptions do NOT apply. Full Board review is required at initial review. Expedited Categories 8 and 9 may apply to continuing review.

18.5.1.3.3. Risk: If the study presents a risk not articulated in the categories of exemption, such as the risk of causing distress to the subject, the IRB may review the study by an expedited or full board procedure.

18.5.1.4. Categories of Exempt Research: Research activities not regulated by the FDA in which the only involvement of human subjects will be in one or more of the categories defined in 45 CFR 46.101(b)(1-6) are eligible for acknowledgment of exempt review.

18.5.1.5. FDA Exemptions: FDA outlines additional categories of clinical investigations that are exempt from the requirements of IRB review:

18.5.1.6.1. Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the Institution is subject to IRB review. [21 CFR 56.104(c)]

18. 5.1.6.2. Taste and food quality evaluations as outlined in 45 CFR 46.101(6).

18.5.1.6. Procedures for Exemption Determination: Exempt determinations may take place during a meeting between the IRB chair (and designee) and the Principal Investigator, or they can take place via electronic submission. Regardless of the setting for review, the following is necessary to make the determination:

• Appropriate IRB Application.

• All recruitment materials (e.g., letter of invitation, announcement, recruitment flyer, etc.).

• Consent process and documentation, when appropriate.

• All surveys, questionnaires, instruments, interview topics, etc.

• Letter (s) of support from each non-OSU site of performance, when appropriate.

• If sponsored, a copy of the grant application(s) and/or contract.

• Confirmation completion of required Citi training for the Principal Investigator applying to the CSUP IRB.

18.5.1.7. The IRB reviewer reviews all the requests for exemptions and determines whether the request meets the criteria for exempt research.

18.5.1.7.1. The IRB reviewer documents the determination of exempt status with a letter acknowledgement of the status. The IRB reviewer verifies whether the submission meets the definition for both research and human subject. The reviewer indicates whether the project is exempt. If the project is determined to be exempt, the reviewer will also note the rationale for the determination by identifying the category or categories under which this is permitted.

18.5.1.7.2. Any issues or questions related to the project will be communicated to the investigators in writing and maintained in the protocol file.

18.5.1.7.3. Annual renewal applications are required for exempt research at CSUP. The exemption is valid for one year. At any time that the exemption is modified, a new period of one year is issued. If the research extends beyond the one year date, the researcher must submit notification to the IRB Chair to confirm that the activity is ongoing without change.

18.5.1.7.4. The Chair (or designee) will review all new exempt applications and project revisions by the above procedures. Any reportable events, such as deviations and unanticipated events, will be recorded and maintained in the application file.

**18.5.2. Expedited Studies**

18.5.2.1. Expedited determinations are made by the Chair of the CSUP IRB or his/her designee. The designee may be a voting member of the board or a Citi credentialed IRB staff member (regardless of voting status).

18.5.2.2. In order to be deemed expedited, all research activities must fit into one or more of the expedited categories defined by 45 CFR 46 and 21 CFR 56.

18.5.2.3. Limitations of Extending Expedited Status

18.5.2.3.1. Children: Expedited review for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children,

18.5.2.3.2. Prisoners: Expedited review does NOT apply. Full Board review is required at initial review. Expedited Categories 8 and 9 may apply to continuing review.

18.5.2.3.3. Risk: If the study presents a risk not articulated in the expedited categories, such as the risk of causing distress to the subject or placing them at legal jeopardy, the IRB may review the study by full board procedure.

18.5.2.4. Categories of Expedited Research: Research activities defined by OHRP as eligible for expedited review.

18.5.2.5. Procedures for Expedited Review Determination: Expedited review determinations are made by the CSUP IRB Chair and/or designee following electronic submission of a complete application, as previously described.

18.5.2.6. The IRB reviewer reviews all applications and determines whether the request meets the criteria for expedited review.

18.5.2.7. The IRB reviewer documents the determination of expedited status with an email acknowledgement of the status. The IRB reviewer verifies whether the submission meets the definition for both research and human subject. The reviewer indicates whether the project is eligible for expedited review. If the project is determined to be eligible for expedited review, the reviewer will also note the rationale for the determination by identifying the category or categories under which this is permitted and forward the application to one other member of the CSUP IRB for additional review.

18.5.2.7.1. Any issues or questions related to the project will be communicated to the investigators in writing and maintained in the protocol file.

18.5.2.7.2. Annual renewal applications are required for expedited research at CSUP. The exemption is valid for one year. At any time that the project is modified, a new period of one year is issued, following review. If the research extends beyond the one year date, the researcher must submit notification to the IRB Office to confirm that the activity is ongoing without change.

18.5.2.7.3. The Chair (or designee) will review all new applications and project revisions by the above procedures. Any reportable events, such as deviations and unanticipated events, will be recorded and maintained in the application file.

**18.5.3. Full Committee Review Studies**

18.5.3.1. Full Committee Review determinations must be made for all studies that do not meet the requirements for either exempt status or expedited review as defined by 45 CFR 46 and 21 CFR 56.

18.5.3.2. The review must be conducted at a convened meeting of the CSUP IRB at which a quorum or majority of current members are present, not to include members on sabbatical or extended travel in determining the IRB total membership.

18.5.3.3 In order to approve a study, the IRB must determine that all of the requirements specified in 45 CR 46.111 are satisfied by majority vote.

18.5.3.4 IRB members who have a conflict of interest in a research project may provide information to the IRB, but may not participate in the vote; nor do they count toward determination of the quorum.

8.5.3.5. Procedures for Full Committee Review Determination: Full committee review determinations are made by the CSUP IRB Chair and/or designee following electronic submission of a complete application as previously described.

18.5.3.6. The IRB reviewer reviews all applications and determines whether the request meets the criteria for full committee review.

18.5.3.7. The IRB reviewer documents the determination of full committee review status with an email acknowledgement of the status. The IRB reviewer verifies whether the submission meets the definition for both research and human subject.

18.5.3.7.1. Any issues or questions related to the project will be communicated to the investigators in writing and maintained in the protocol file.

18.5.3.7.2. Annual renewal applications are required for full committee review research at CSUP. The exemption is valid for one year. At any time that the project is modified, a new period of one year is issued, following review. If the research extends beyond the one year date, the researcher must submit notification to the IRB Office to confirm that the activity is ongoing without change.

18.5.2.7.3. The Chair (or designee) will review all new applications and project revisions by the above procedures. Any reportable events, such as deviations and unanticipated events, will be recorded and maintained in the application file.

**19. CSUP Principal Investigator Procedures**

19.1. **Operational Definition.**

19.1.1 The CSUP IRB consists of 8-12 members, all of whom are volunteers and are appointed by the provost. For consideration a member should have prior experience conducting and publishing human research, have completed Citi Training or something comparable and have an area of expertise which is in balance with the other current membership (see 17. CSUP IRB Procedures). In addition, the IRB will include at least one community member who does not meet any of the previous requirements.

19.1.2 The CSUP IRB is supported by the CSUP Office of Research and Sponsored Programs administratively and with part-time staff support. The CSUP ORS maintains OHRP authorization and ongoing sanctioning updates.

19.1.3 The CSUP IRB Chair reviews all applications initially and has a teaching load release of 3 credit hours, however all other faculty IRB members provide their assistance as a service activity without academic release .

19.2. **Submissions**

19.2.1. Principal Investigator definition

Principal Investigators applying to the CSUP IRB must be a member of the CSUP faculty or staff. In general students may not apply with the following exceptions: graduate students pursuing a Master’s Degree Thesis requirement or Doctoral Degree dissertation requirement, as well as undergraduate Honors/Leadership students completing final project requirements. All student applications must include a faculty or staff co-investigator who is acting as a mentor to the student.

**19.2.2. Submission Requirements**

19.2.2.1. Submissions to the CSU IRB should be made electronically by the Principal Investigator to the current CSUP IRB Chair to ensure a timely review.

19.2.2.2. All principal investigators or faculty mentors for student principal investigators must have completed Citi training, or an equivalent, and submit documentation of having done so.

19.2.2.3. All submissions should be completed using the CSUP research approval form found here:

[https://www.csupueblo.edu/research-and-sponsored-programs/\_doc/irb-application-for- human-subjects-research.pdf](https://www.csupueblo.edu/research-and-sponsored-programs/_doc/irb-application-for-%20human-subjects-research.pdf)

19.2.2.4. Subject consents should be designed using the applicable CSU templates found here: <https://vpr.colostate.edu/ricro/irb/templates/consent-assent-templates/>

19.2.2.5. Any surveys, recruitment materials, and/or debriefing statements to be used in the project should also be submitted electronically as part of the application process.

**19.2.3. Submission Limitations**

19.2.3.1. The applying principal investigator will act as the first and primary communicator with the CSUP IRB and is ultimately responsible for the conduct of the research project.

19.2.3.2. The CSUP IRB will review no more than two submissions from a single principal investigator within a given semester. All multiple submissions should be made in separate time frames so that no more than a single project from a given principal investigator is under review at any one time.

19.2.3.3. The principal investigator must be a faculty or staff member of CSUP, or in the following cases only a student at CSUP. Student led projects must include a CSUP faculty acting as a mentor and identified in the application as co-principal investigator.

19.2.3.3.1. A graduate student completing thesis or dissertation requirements may apply to the CSUP as a principal investigator for a human research project.

19.2.3.3.2. An undergraduate student completing final project requirements in the honors and/or leadership programs may apply to the CSUP as a principal investigator for a human research project.

**19.3. Research approvals and renewal.**

19.3.1. All classifications of human research approved or identified as exempt by the CSUP IRB receives a one year period of approval.

19.3.2. Research not completed within this period must be extended through a written contact by email with the IRB chair and re-approval for an additional year.

19.3.3. Research is considered complete once presentation and/or publication objectives have been reached and the raw data collected has been discarded.

19.3.4. Any significant modification to the research protocol, procedures, consent process, etc. must be reviewed and approved by the CSUP IRB prior to continuing the research. This process should also be initiated by written contact by email with the IRB chair.

19.3.5. Classroom based research

19.3.5.1. Human data collection projects conducted within the classroom setting using students as subjects, but with no objective to generalize the information obtained beyond that classroom, does not require IRB approval. This is because such a process does not meet the OHRP definition of human research. All responsibility for the safe conduct of such teaching practices lies with the academic department. In such cases where this is common practice (e.g. a research and statistics class) it is recommended that the faculty member teaching the class complete some form of IRB training before proceeding. If subjects are to be obtained from outside the classroom, it is recommended that the department establish an interdepartmental IRB to review such projects, with a make-up similar to the CSUP IRB (see 17. CSUP IRB Procedures). Further, this does not remove the requirement for CSUP IRB review and approval if the project/s are to be generalized. At a minimum, Interdepartmental IRB’s should be approved by the CSUP IRB and chaired by an individual who has received IRB training.

19.3.5.2. Human research conducted within a CSUP class, which will ultimately be generalized, whether by the student or the faculty member, must receive CSUP IRB review and approval prior to the project being conducted. In addition, such projects require that the faculty member act as the principal investigator.