



**Institutional Review Board (IRB)
Policy for Human Subjects Research**

**California State University, Stanislaus
Office of Research and Sponsored Programs**

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1.0 Preamble

California State University, Stanislaus (hereafter, Stanislaus State) safeguards the rights and welfare of human subjects involved in all research projects conducted by an employee, student or agent of this institution in connection with his or her institutional responsibilities. This responsibility is guided by the ethical principles set forth by the national Commission for the Protection of Human Subjects of Biomedical and Behavior Research in its report, Ethical Principles and Guidelines for the Protection of Human Subjects of Biomedical and Behavioral Research (commonly known as the Belmont Report). The Belmont Report sets forth three basic ethical principles for conduct of human subjects research:

- Respect for Persons
 - Respect individual autonomy
 - Protect individuals with reduced autonomy
- Beneficence
 - Maximize benefits and minimize harms
- Justice:
 - Equitable distribution of research burdens and benefits

Stanislaus State has designated the University Institutional Review Board (UIRB) to review proposals for research involving human subjects and to evaluate and mitigate risks to those subjects, researchers, and Stanislaus State. In addition to the UIRB, all University sanctioned Institutional Review Boards (IRBs) at the University will use the following policies and procedures to review and approve human subject research.

Any project involving human subjects research must be approved by the IRB prior to the initiation of research (including selection of subjects, informed consent, and data collection). Research studies or projects that do not involve human subjects do not need to be submitted for IRB review. This applies not only to research conducted on campus, but also to research conducted under the auspices of the University at any off-campus site. Research conducted by faculty, students, or staff members who apply for protocol review after the research has started have violated University and federal policy related to human subject research and such research will not be reviewed nor approved. Instructors and research advisors should contact the IRB Administrator with any questions or concerns.

2.0 Definitions

2.1 Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(1)). 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.

2.2 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 or identifiable biospecimens (45 CFR 46.102(e)(1)).

An intervention includes physical procedures by which data are gathered and manipulations of a living person or person's environment are performed. An interaction includes communication or interpersonal contact between investigator and subject. This includes in-person, 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 associate with the information.

For a study to be considered human subjects research, the data obtained must be about the living individual. If you are conducting research using secondary publicly-available data with no individual identifiers, this does not require IRB approval.

2.3 Generalizable Knowledge

Generalizable knowledge is meant to draw 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) and enhance scientific or academic understanding. Activities that are disseminated with the intent to influence behavior, practice, theory, future research designs, etc. are contributing to generalizable knowledge.

2.4 Minimal Risk

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

3.0 University-Sanctioned Institutional Review Boards

3.1 Composition

The University Institutional Review Board (UIRB) and other University sanctioned IRBs shall have at least five members, of varying backgrounds to facilitate a complete and adequate review of all human subject research activities conducted at Stanislaus State. The members shall possess the requisite experience, expertise, and diversity to promote respect for the Board's advice and counsel in safeguarding the rights and welfare of human subjects. If a substantial portion of the research reviewed by the IRB involves a vulnerable category of human subjects (such as children, prisoners, or mentally disabled persons) or involves discipline specific research that is outside the scope of the current IRB membership, the Chair and Executive Secretary of the IRB (Director of Research and Sponsored Programs) shall consider expanding the committee by one or more individuals who are knowledgeable about and experienced in working with these subjects or areas of research. Such consultants may not vote with the IRB.

3.2 Appointment and Terms

Appointment. Appointment of new members for the UIRB shall be made by the University's Committee on Committees. As detailed above, the UIRB and other University sanctioned IRBs at Stanislaus State shall be comprised of at least five members, and shall include:

- At least one member whose primary field is scientific,
- At least one member whose primary field is nonscientific,
- At least one member who is not otherwise affiliated with the institution, and who is not an immediate family member of a person who is affiliated with the institution.

Terms. Each UIRB member shall serve a three-year term. At the conclusion of the term of service, a member may be re-appointed to an additional three years. No one shall serve on the UIRB for more than six consecutive years.

3.3 Duties

The IRB shall implement this policy in accordance with all relevant laws and regulations. To do so, the IRB shall create procedures, forms and other instruments, as it deems necessary. If provisions in this policy or in IRB procedures, forms, or other instruments (collectively "policy") are construed to conflict with federal law, then the IRB shall bring such possible conflicts promptly to the attention of the Academic Senate and University counsel and, pending amendment of the policy, shall implement the policy in a manner that conforms with the law, as understood by the IRB. The IRB has authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall be reported promptly to the investigator and the Research Integrity Officer. The IRB has purview over informed consent, data maintenance, and security, up to but not including destruction of the data.

3.4 Sponsored Research

Stanislaus State sponsors have primary responsibility to ensure that all research conducted by outside agents under their sponsorship is conducted in accordance with all relevant regulations, laws and Stanislaus State policies.

4.0 Classroom Research Projects

4.1 Classroom Activities Involving Data Collection

Courses sometimes require students to undertake small projects in which other people are interviewed, observed, or otherwise serve as sources of information. The purpose of these course projects is to provide students with a closer view of social, educational, or psychological processes, and/or with an opportunity to practice methods of observation or skills customary to the various disciplines. Although most class assignments of this nature pose little or no risk to students, some may warrant enhanced attention because of the risks or vulnerabilities to the participants. It is incumbent upon the individual faculty member to consider and to mitigate potential risks in such non-research classroom activities. Because such activities are not

undertaken with the goal of developing or contributing to generalizable knowledge, the IRB does not consider them to be research, and activities of this nature are beyond the purview of the IRB.

4.2 Student Research Projects

Any student-initiated and/or student-conducted data collection activities designed to develop or contribute to generalized knowledge, and/or result in a publication or public presentation (outside of the classroom setting) which uses human subjects, requires review and approval by the IRB. This includes graduate theses, dissertation research, and honors theses. Responsibility for obtaining the IRB approval for student research resides equally with the student and the faculty advisor.

Students, instructors, and advisors must comply with University Policy for IRB review *prior to* authorizing student research. Only when the IRB has approved the research may the instructor allow students to collect data. The following guidelines must be followed during data collection:

- The instructor may not **require** students to be a research subject in a study as part of their course grade,
- Whenever possible, there should be no identifying information about the student on the recorded data. Research involving longitudinal studies of identified subjects over time must be kept confidential for proprietary or security reasons and data access and sharing practices may be reviewed by the IRB annually.
- Students must be reasonably informed about the nature of the experiment and any risks prior to their participation.

4.3 Honors or Graduate Thesis or Project Approval

IRB approval for thesis or project research involving human subjects must be secured prior to commencing research and appear in the bound copy of any final research project or thesis. The student will include the following statement in the methodology section of the thesis or project. "The University Institutional Review Board approved project (or thesis) # _____ on _____ (date)."

Upon approval, the IRB Administrator will forward a copy of the student's protocol approval letter to the faculty advisor within five (5) days. Theses and projects without IRB approval will not be approved by the Graduate School.

4.4 Assessment and Evaluation

All academic departments and administrative support units routinely collect data about class or campus program effectiveness. Students, staff, employers, and alumni are often asked to participate in structured interviews, written surveys, or focus groups in order to assess and evaluate academic programs or administrative support services. Since the goal is not to develop or contribute to "generalizable knowledge," faculty and administrators conducting these types

of routine assessment and evaluation activities are not required to take any action with regard to IRB notification or approval.

Assessment and evaluation activities that address a student, staff, employer, or alumni's personal life (e.g., dating behaviors, drug use, social life) and go beyond routine data collection are subject to IRB review. Additionally, when the nature of the inquiry involves a "risk" (physical, psychological, social, economic, or legal) or a "vulnerable population" (children, prisoners, mentally disabled persons, or persons with a medically diagnosed condition that is used as a criterion for the study), these types of assessment and evaluation activities require IRB review.

4.5 Public Use Data Files

Various public agencies and private organizations make available files of data collected from individuals. After stripping them of identifiers, they make these data available to the public or to subscribers. Acquisition and use of such data does not constitute human subject research because there is not interaction with the subject, and the subject is not identifiable to the researcher.

4.6 Oral History Research

Oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings does not constitute "research." Oral history projects are not normally classified as human subjects research and do not require submission to the IRB. However, if the purpose of a project is to develop or test hypotheses or theories about human behavior, if information will be used in a thesis or dissertation, or if the oral history is conducted on subjects that entails risks or involves a vulnerable population, it does require IRB review.

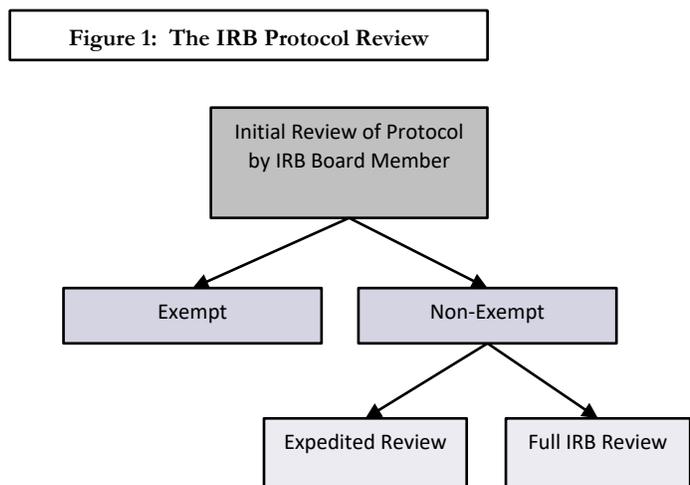
5.0 Protocol Review Procedures

5.1 Initial Review

When a protocol is received by the IRB Administrator and determined to be subject to the IRB policy, it is forwarded to an IRB member for initial review. At that time, the IRB member determines whether the research is exempt or non-exempt.

5.2 Exempt v. Non-Exempt Designation

If the application is declared exempt by the IRB, there is no further review. If the protocol is declared non-exempt, the IRB



determines whether the project is eligible for expedited review or requires full board review.

5.2.1 Conditions of Exempt Research

Exempt research is research with human subjects, but once approved by an IRB reviewer, is “exempt” from ongoing review, unless the research is amended in such a way that it no longer meets the eligibility requirements. A complete list of exempt research categories is listed in the IRB Procedures document (5.2).

5.3 Expedited Review

The IRB is able to review certain applications on an expedited basis if they meet specified criteria. While many of the same activities eligible for exemption are also eligible for expedited review, the primary difference is the level of risk. Exempt research must be inherently risk free. Expedited review is used when the level of risk increases and needs to be managed in some way, such as through the use of confidentiality procedures. If the protocol is designated as eligible for expedited review, one member of the IRB works with the researcher to make any necessary revisions to ensure that risks are minimized, informed consent is documented appropriately, and that the research design meets applicable legal, ethical, and professional standards. Throughout the process, the IRB member keeps faculty advisors and/or relevant researchers informed of progress and related concerns.

Research involving any of the following may present more than minimal risk to participants and may therefore disqualify the project for Expedited Review:

- Use of deception
- Study of vulnerable populations
- Study of illegal activities like drug use
- Study of private activities like sexual behavior.

5.4 Full Board Review

If a project involves more than minimal risk to human subjects, or if the project involves vulnerable populations (defined as groups that may include children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons), then the protocol requires full board review.

In preparation for the full board review, one member of the IRB will review the protocol and will work with the researcher to make any revisions necessary to ensure that risks are minimized, informed consent is documented, and the research design meets applicable legal, ethical, and professional standards. The entire board membership will review the protocol to assure that the design and safeguards of the research meet the requirements. When the IRB is satisfied that the research meets the requirements, the IRB will rule on the protocol through a formal motion/second and vote under the following conditions:

- **Approved.** The project is approved as submitted and the researcher will receive notification.
- **Approved with Conditions.** Conditional approval is defined as approval pending minor clarification and/or modification by the investigator. Projects with conditional approval are not considered active until full approval is secured. 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 chair for verification that the requested changes have been made to secure approval.
- **Revisions Required.** The project has substantive issues or missing information, that will require correction or completion before the IRB can determine if approval will be provided. The researcher will be required to address concerns by submitting a revised protocol to the IRB before a decision will be made regarding approval.
- **Approval Denied.** The IRB determines the criteria for IRB approval of the research is not met and the research cannot be conducted.

5.5 Training Requirements

Stanislaus State requires that all investigators, faculty advisors of student investigators, IRB members, and any other university employees engaged in human subjects research successfully complete a certified human subjects training program. Appropriate training shall be designated by the IRB. Detailed information regarding the training is located in the IRB Procedures (section 4.1).

6.0 IRB Oversight

Stanislaus State IRB-approved research protocols are subject to continuing IRB oversight. Oversight is designated for one year from the date of certification. Consistent with the Common Rule (the principal federal policy for protecting human research subjects), the IRB should conduct continuing reviews of human subjects research at intervals appropriate to the degree of risk, but not less than once per year. If the research will continue beyond the one year anniversary of IRB approval, the researcher must submit a Summary/Continuation Form in a timely fashion prior to that date. The Stanislaus State IRB has the authority to observe, or to ask a third party to observe, the consent process and the research. Oversight by the IRB ensures compliance with University, State, and Federal regulations.

7.0 IRB Non-Compliance

Non-compliance is defined as research not conducted in accordance with institutional policy or federal regulatory requirements for human participant protection. Complaints of non-compliance should be reported to the Research Integrity Officer who will notify the IRB. Non-compliance may constitute research misconduct. Some examples of non-compliance include:

- Falsifying IRB documents
- Conducting human subjects research without IRB approval

- Deviating from the IRB approved protocol or consent process
- Modifying a protocol without prior IRB approval
- Failing to maintain regulatory documents
- Providing inadequate oversight of research
- Causing injury or harm to human subjects or other unanticipated problems involving risks to subjects or others
- Showing a pattern of repeated non-compliance actions or omissions that, if unaddressed, may compromise the integrity of the University's human research protection program. The pattern may reflect a lack of knowledge on the part of the investigator or a lack of commitment by the investigator and/or research team to human subject's protection.