

I. Preamble

California State University, Stanislaus 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

Application of the general ethical principles to the conduct of human subjects research leads to the following requirements:

- Respect for Persons
 - Informed consent
 - Protecting privacy and maintaining confidentiality
 - Additional safeguards for protection of subjects likely to be vulnerable to coercion or undue influence
- Beneficence
 - IRB assessment of risk/benefit analysis including study design
 - Ensure that risks to subjects are minimized
 - Risk justified by benefits of the research
- Justice
 - Ensure that selection of subjects is equitable

At California State University, Stanislaus, **Research** and **Human Subject** are defined as follows:

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.

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. If you are conducting research using secondary publicly-available data with no individual identifiers, this does not require IRB approval.

If an activity involves obtaining information about a living person by manipulating that person or that person's environment, as might occur when a new instructional technique is tested, or by

communicating or interacting with the individual, as occurs with surveys and interviews, the definition of human subject is met.

If an activity involves obtaining private information about a living person in such a way that the information can be linked to that individual (the identity of the subject is or may be readily determined by the investigator or associated with the information), the definition of human subject is met.

Research conducted at CSU Stanislaus and research conducted by faculty, students, or staff of the University must be approved in compliance with the policies and procedures detailed in this manual and in the accompanying attachments. The Office of Research and Sponsored Programs has vested responsibility for oversight of the policy for research with human subjects. The IRB Administrator has responsibility for the procedures implementing the policy, and serves as executive secretary of the University Institutional Review Board (UIRB).

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. For the purposes of Human Subjects Research set forth in this policy, the term "research" refers only to studies that are conducted using human subject participants. This policy does not cover research involving animals, research that does not involve human subject participants (such as archival research), and/or hazardous materials research. These are separate policies that have a different set of professional standards.

Any research project involving human subjects must be approved by the IRB prior to the initiation of research (including selection of subjects, informed consent, and data collection). 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.

II. University-Sanctioned Institutional Review Boards

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 CSU Stanislaus. 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, the Chair and Executive Secretary of the IRB shall consider expanding the committee by one or more individuals who are knowledgeable about and experienced in working with these subjects.

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 CSU Stanislaus 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.

IRB Chair and Vice Chair

At the final regularly scheduled meeting of the academic year, the UIRB members shall elect a Chair. At the first regularly scheduled meeting of the academic year, the UIRB members shall elect a Vice Chair. The Chair shall preside over IRB meetings and shall serve as a signature authority for the approval of research protocols. The Chair shall serve from June 1 of one calendar year through May 31 of the following calendar year. If the Chair is not available, the Vice Chair shall preside over IRB meetings, and serve as the signature authority for approving research protocols.

Quorum and Voting Requirements

To convene a meeting of the IRB, a majority of the voting members (fifty percent plus one) must be present, including at least one member whose primary concerns are nonscientific. The Chair is to be included as a member of the quorum but votes only to break a tie. Protocol approval requires the approval of a majority of the IRB's quorum. If the quorum is lost during the meeting for any reason (early departures, loss of a nonscientist, excused for conflict), no votes may be taken and the meeting will be terminated until the quorum can be restored. Note: The Executive Secretary is ex-officio and is to be included in the quorum or voting process only when he/she is serving as an alternate for a regular voting member who is unable to attend a convened meeting. If a regular voting member cannot attend a meeting, they may designate the Executive Secretary to attend as an alternate, and participate and vote in substitute of the member. To designate the Executive Secretary as an alternate, the member must submit an electronic request to the chair of the IRB in advance of the meeting. 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. An IRB member may not participate in review or approval of research in which he/she has a conflict of interest.

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.

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The IRB has purview over informed consent, data maintenance, and security, up to but not including destruction of the data.

III. Responsibilities of Researchers, Faculty Advisors, Instructors, and Research Sponsors

Investigators have the primary responsibility for protecting the rights and welfare of human research subjects and are responsible for complying with all applicable provisions of their institution's assurance. The Director of Research and Sponsored Programs files a Federal-wide Assurance (FWA) for the Protection of Human Subjects to the Office for Human Research Protections (OHRP). Investigators are expected to be knowledgeable about:

- Conducting their research according to the IRB-approved protocol and complying with all IRB determinations.
- Providing a copy of the IRB-approved informed consent document to each subject or the subject's legally authorized representative at the time of consent, unless the IRB has specifically waived this requirement. In cases where informed consent documents require the participant's signature, all signed consent documents are to be retained for at least three (3) years after completion of the research and according to institutional policy.
- Individuals conducting research are responsible for the security and confidentiality of all data.
- Ensuring that each potential subject understands the risks of the research and participation.
- Obtaining and documenting the informed consent of each subject or each subject's legally authorized representative unless the IRB has waived these requirements.
- Research integrity requires meticulous attention to the acquisition and maintenance of research data since questions about the integrity of the research are often answered by inspecting and reanalyzing the primary data. The researcher should follow professional standards in maintaining original data records. Federally funded data should be maintained by the PI for at least 7 years beyond completion of the funded project.

Additionally, investigators are responsible for reporting promptly to the relevant IRB any unanticipated problems involving risks to subjects or others or any serious or continuing non-compliance. If an adverse event occurs during the course of the research, the researcher must stop the research and immediately report the event to the Research Integrity Officer who will notify the IRB.

The researcher should refer to information on *Applying for IRB Approval* and *IRB Review* to determine how to apply for and receive approval for research. If the research (data collection) 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.

Classroom Research Projects

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

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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.

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 from each other. 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 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.

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 his/her 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.

Sponsored Research

CSU Stanislaus 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 CSU Stanislaus policies.

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, pregnant women, 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.

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.

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.

Applying for UIRB Approval

1. Obtain an IRB research protocol application form (the UIRB application is available from the UIRB website).
2. Complete the IRB research protocol application form by providing all requested information and attaching all supporting documentation.
3. Return the protocol to the office designated on the application form.

IV. IRB Review Criteria

The IRB is responsible for reviewing all proposals that involve human subjects research. All submissions will first be reviewed for exceptions to the IRB policy (e.g., research that falls outside of the definition of "human subjects research" as defined by this policy) by the IRB Administrator; submissions that are determined to be subject to the policy will be forwarded to the IRB for review. The IRB Chair or a designated IRB member determines the status of review required for each research protocol.

Each protocol shall be designated as:

- Beyond the purview of the IRB
- Exempt from further IRB review and oversight,
- Subject to IRB review and expedited, or
- Subject to IRB full board review and oversight.

Once a determination of the review status has been made, and the appropriate level of review has been completed, the IRB Administrator will notify the researcher within five working days.

If the IRB member determines that a research protocol is subject to further IRB review and oversight, it will be reviewed to ensure the following:

Risks to Subjects are Minimized

Risks include physical harm, or pose psychological, social, economic, or legal harm, especially when data are collected related to sexual activity, use of alcohol or illegal drugs, or involvement in illegal activities.

Vulnerable populations, consistent with federal definitions, are deemed vulnerable with regard to informed consent or medical vulnerability. These groups may include children, pregnant women, prisoners, mentally disabled persons, or persons with a medically diagnosed condition that is used as a criterion for the study.

Minimal risk is defined as: "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 during the performance of routine physical or psychological examination or tests." The IRB ensures that each research protocol implements procedures which are consistent with sound research design, does not unnecessarily expose subjects to risk, and whenever appropriate, utilizes procedures already being performed on the subjects for diagnostic or treatment purposes.

Risks to Subjects are Reasonable in Relation to Anticipated Benefits

The IRB evaluates the importance of the knowledge that may reasonably be expected to result from the proposed research in relation to the potential risks to human subjects. The IRB does not consider "the completion of master's degree requirements" as a benefit of the proposed research.

Subject Selection is Equitable

The CSU Stanislaus IRB reviews subject selection procedures for equity in light of the purpose of the research and the setting in which the research will be conducted.

Informed Consent is Obtained from Each Prospective Subject or the Subject's Legally Authorized Representative

The IRB ensures that the informed consent procedures for each study include:

- A statement that the study involves research, an explanation of the purpose(s) of the research, and the expected duration of the subject's participation.

- A description of the procedures to be used and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that could be advantageous to the subject.
- A statement describing the safeguards used to prevent inappropriate disclosure of the information collected.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- *For research involving more than minimal risk*, a description of any compensation and/or medical treatment that will be made available to the subject if injury occurs, as well as where to obtain further information.
- Informed consent must be documented. When appropriate, the research plan must make adequate provision for monitoring the data collected to ensure the safety of subjects. In addition, there must be adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

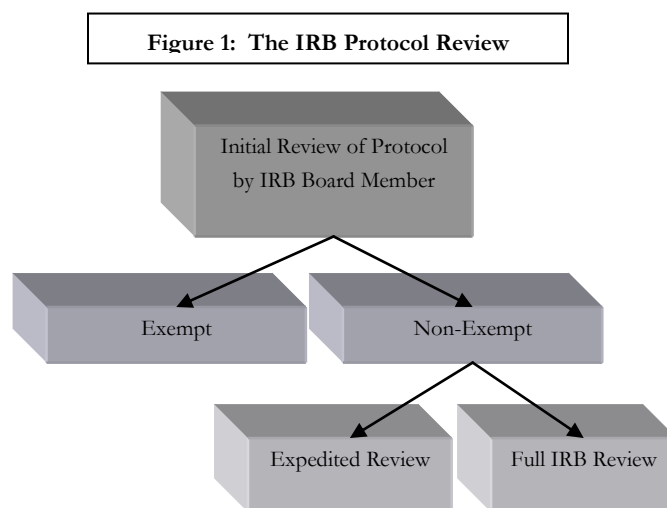
V. Protocol Review Procedures

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.

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.



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. There are five categories of activity, defined in the federal regulations, that are often risk free and eligible for exemption.

Exemption #1

Research conducted in established or commonly accepted educational settings involving normal educational practices such as (i) research on regular and special education strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, classroom management methods.

Exemption #2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures, or observation of public behavior unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

Exemption #3

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Exemption #4

Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Exemption #5

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

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.

Full Board Review

If a project involves more than minimal risk to human subjects, 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. In the event that the regularly scheduled IRB meetings are not adequate to provide timely review for the protocols received, the IRB Administrator will schedule additional meetings as needed. 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:

- If only minor revisions are necessary, the IRB may move to approve, contingent on revisions to be approved by the Chair (or designated official);
- If the board determines that significant revisions are required, the researcher is asked to re-submit a revised protocol to the IRB for reconsideration.

IRB Oversight

CSU Stanislaus 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 CSU Stanislaus 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.

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.

VI. Individual/Institutional Record Keeping and Quality Assurance Audits

The IRB shall prepare and maintain adequate documentation of IRB activities.

1. Copies of all research protocols reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects. All files are to be kept in a designated area and should have the following information, including:
 - a. The approval letter for the amended protocol
 - b. Consent form
 - c. IRB protocol statement
 - d. The abstract, consent forms / cover letters / recruitment ads / discussion / attachments such as letters / questionnaires
 - e. The original IRB approval letter
 - f. Continuing review forms and IRB approvals (if necessary)
 - g. Adverse event reports (if any) and approvals for adverse event reports.

2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.

The above information is maintained for a period of five (5) years beyond the completion of the research / funded project. The IRB Administrator will keep all archival protocols for a period not to exceed 20 years.