



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

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

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1.0 Introduction

The purpose of the Stanislaus State *Procedures for Human Subjects Research* is to provide guidance on the Stanislaus State *Human Subjects Research Policy*.

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.

Activities deemed not to be research include: (1) scholarly and journalistic activities that focus on a specific individual; (2) public health surveillance; (3) collection and analysis of information, biospecimens, or records by or for a criminal justice agency; or (4) authorized operational activities for national security purposes.

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 or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(j)).

2.5 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 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 disadvantaged persons.

3.0 Not Human Subjects Research

The following comprise situations where IRB review may not be necessary.

3.1 Assessment and Evaluation

For studies conducted for the purpose of **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. If these assessment and evaluation activities address a subject's personal life (e.g. dating behaviors, drug use, social life) and go beyond routine data collection, the study would be subject to IRB review. Additionally, when the nature of the inquiry involves a "risk" (physical, psychological, social, economic or legal) or a "vulnerable population" (defined above), these types of activities require IRB review.

3.2 Classroom Activities Involving Data Collection

For **classroom activities, demonstrations, and assignments** (including projects where other people are interviewed, observed, or otherwise serve as sources of information) unless the data will be collected and used in a systematic investigation that contributes to generalizable knowledge. It is incumbent upon the individual faculty member to consider and to mitigate potential risks in such non-research classroom activities.

3.3 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.

3.4 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.

4.0 Protocol Submission

4.1 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 the appropriate Collaborative Institutional Training Initiative (CITI) Human Subjects course. The nature of the training and access to it is provided on the IRB website.

This requirement is designed to encourage understanding of values toward responsible conduct of research involving human subjects. The CITI course 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). By successfully completing the tutorial, the investigator demonstrates the knowledge of human subjects protections necessary to satisfy this requirement, which must be completed prior to review of an IRB application.

4.2 Required Protocol Documents

Submissions for new protocols will require:

- a. IRB application form. This form is available on the UIRB website, and should include detailed information related to the description of research, methods and procedures, risks, benefits, and confidentiality measures, and informed consent procedures.
- b. Informed Consent. The principal investigator must provide copies of all informed consent documents to be used in the research. Sample informed consent templates may be accessed on the UIRB website.
- c. Study Instruments. These may include surveys, interview guides, recruitment materials, questionnaires, etc.

4.3 Other supporting documentation as appropriate

Other supporting documentation may include letters of support. Research that is conducted at an outside agency (school, hospital, business, etc.) may be required to include a letter of support from that agency.

5.0 IRB Review Process and Levels of IRB Review

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.

5.1 IRB Review Considerations

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:

5.1.1 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 include children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

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” (45 CFR 46.102(j)). 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.

5.1.2 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.

5.1.3 Subject Selection is Equitable

The Stanislaus State 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.

5.1.4 Informed Consent

Informed Consent is Obtained from Each Prospective Subject or the Subject's Legally Authorized Representative. The informed consent must provide the information that a reasonable person would want to have in order to make an informed decision about whether to participate (45 CFR 46.116).

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

- A concise description of the purpose of the research study
- A description of the procedures to be used, the expected duration of the procedures for participants, and identification of any procedures which are experimental
- A description of any reasonably foreseeable risks, discomforts, or benefits to be expected from the research
- A statement describing the safeguards used to prevent inappropriate disclosures of the information collected
- A description of any compensation offered for participation, including whether a commercial profit will be made from the research, and whether the participant will share in that profit
- 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*, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs, and if so, what they consist of, or where further information may be obtained.

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.

5.2 Exempt Determinations

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 six (6) categories of activity, defined in the federal regulations (45 CFR 46.104), that are often risk free and eligible for exemption.

5.2.1 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.

These normal educational practices must not be likely to adversely impact (i) students' opportunity to learn required educational conduct, or (ii) the assessment of educators who provide instruction.

5.2.2 Exemption #2

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey or interview procedures, or observation of public behavior, provided:

- (i) information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects;
- (ii) any disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7).

Research involving educational tests, survey or interview procedures, or observation of public behavior may be considered exempt even if the provisions (i) and (ii) listed above have not both been met if the subjects are elected or appointed public officials or candidates for public office, or if federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

5.2.3 Exemption #3

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

- (a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained, directly or through identifiers linked to subjects;
- (b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers

linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § .111(a)(7).

For the purpose of this provision, **benign behavioral interventions** are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

5.2.4 Exemption #4

Secondary research use of identifiable private information or identifiable biospecimens if at least one of the following criteria is met:

- (i) identifiable materials are publically available; or
- (ii) information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects or re-identify subjects.

5.2.5 Exemption #5

Research designed to study, evaluate, improve or otherwise examine public benefit and service programs.

5.2.6 Exemption #6

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.

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, 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 Appeal of IRB Decision

Once the IRB disapproves, suspends, terminates, or stipulates modifications to submitted documentation, IRB staff will notify the investigator of the action and rationale of the decision

by written correspondence. If clarification of the written notice is needed, the investigator will contact the IRB staff for further clarification. Investigators who disagree with the decision of the IRB will be informed about the IRB appeal process and available options for further consideration.

Submission of Appeal: Once the investigator has decided to enter into an appeal process, the IRB staff will instruct the investigator to provide the rationale and supporting information/material that will aid the IRB in the review of the appeal.

Review Process:

- The IRB staff will forward the response submitted by the investigator to the UIRB Chairperson. ·
- The Chairperson will request the Director of Research & Sponsored Programs to assemble an Ad Hoc Committee composed of IRB and non-IRB members (with at least one member from the same discipline as the investigator) to review the project in question. ·
- The composition of the Ad Hoc Committee should number no less than three (3) and no more than five (5). Membership may include current or former IRB members, IRB administrator, individuals who possess discipline specific knowledge, or others whose perspective may provide invaluable insight.
- The Ad Hoc Committee will review the project and send a written report to the IRB with their recommendation. ·
- The IRB will again review the project and deliver its decision, considering the report of the Ad Hoc Committee, but is in no way bound by its recommendation. If the IRB chooses to act in opposition to the report of the Ad Hoc Committee, it should offer a compelling reason for such a decision. A special meeting of the IRB may be called if the next scheduled meeting is not within 14 days of receipt of the report. ·
- The IRB Staff will notify the investigator in writing of the final decision regarding the current appeal. · The investigator will be informed that they can direct additional unresolved questions, express concerns, and convey suggestions to the Institutional Official. **Note:** the decision of the IRB to disapprove, suspend, terminate, or modify submitted materials cannot be overruled by the Institutional Official.

There are no limitations placed on the appeal process, allowing investigators to appeal decisions and resubmit information as frequently as warranted.

6.0 IRB Maintenance and Meetings

6.1 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.

6.2 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.

6.3 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 until the quorum can be restored. Note: The Executive Secretary is ex-officio (Director of Research and Sponsored Programs) 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.

6.4 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 the policy or in the 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.

7.0 Approved Research Compliance

7.1 Modifications

Investigators with approved protocols must promptly report any proposed modifications to the approved protocol. These modifications may include, but are not limited, to changes to the research methods, design, type or number of subjects, recruitment of participants, or location. Modifications cannot be implemented until they have been reviewed and approved by the IRB.

7.1.1 Modification Review Process

Modifications to approved protocol must be submitted to the IRB for review and approval. Investigators should send a revised version of the approved protocol, with all proposed modifications highlighted, to the IRB administrator. An IRB member will be designated to review the proposed modifications, and the investigator will be notified of the IRB decision.

7.2 Continuing Review Process

The initial IRB approval for research expires one year following its award. A continuation of IRB approval is required to extend the approval period. Continuing IRB review is not required for the following:

- Research that has been determined to be exempt;

- Expedited research conducted by student investigators;
- Research that has completed interventions and only involves one or both of the following:
 - data analysis, including analysis of identifiable private information or identifiable biospecimens
 - accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

A continuing review is required annually for research that has been categorized as expedited and is conducted by a faculty or staff investigator. 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.

To apply for continuation of approval, the investigator must complete a Continuation Form; request for continued approval should be submitted prior to the expiration date of the approved study. If a Continuation Form is not received prior to the expiration date of the approved study, the investigator must halt research until approval to continue the study is received.

The IRB administrator will issue renewal notices by email in advance of the expiration date; however, it is always the Principal Investigator's responsibility to ensure that the extension is approved prior to the expiration date.

7.3 Unanticipated Problems, Adverse Events, and Complaints

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.

7.3.1 Reporting Process

If an adverse event occurs during the course of the research, the researcher must stop the research and immediately report the event to the IRB (via telephone or email).

8.0 Vulnerable Populations

Vulnerable populations, consistent with federal definitions, are deemed vulnerable with regard to informed consent or medical vulnerability. Additional safeguards to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence must be considered and included within the protocol, when necessary.

Consistent with federal regulations, these groups may include children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

8.1 Research Involving Children

A child is defined by the state of California as a person who is under the age of 18 and is not legally emancipated. When reviewing research with children as subjects, the IRB must consider

the potential benefits, risks, and discomforts of the research to children and assess the justification for their inclusion in the research. To approve research involving children, the IRB must ensure that the conditions of 45 CFR 46.401 Subpart D are satisfied as follows:

The research does not involve greater than minimal risk. Adequate provisions are made for soliciting the assent of the child and the permission of at least one parent or legal guardian.

The research involves greater than minimal risk; however, the individual child may receive direct benefit from participating in the research. Adequate provisions are made for soliciting the assent of the child and the permission of at least one parent or legal guardian.

The research involves greater than minimal risk and no prospect of direct benefit to the participant; however, the results of the research will contribute to generalizable knowledge about the subject's disorder or condition. The permission of both parents or legal guardians is required, and assent from the subject must be obtained.

8.2 Research Involving Prisoners

Prisoners have constraints due to their incarceration that affects their ability to make a truly voluntary and uncoerced decision about whether to participate as research subjects.

Investigators should ensure that the advantages of participating in the research are not of such a magnitude that a prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

8.3 Research Involving Persons Economically and Educationally Disadvantaged

Economically or educationally disadvantaged persons are those persons placed at special risk by socioeconomic and educational background. Economically disadvantaged persons include those persons who struggle to provide basic necessities for themselves and their families or communities. Therefore, the use of financial incentives for research participation is a special issue with economically disadvantaged persons. Medical care, remedial education, and financial remuneration are common incentives in research. To a person who is economically disadvantaged, seemingly nominal inducements may be powerfully coercive. Incentives cannot be so strong that they take away a person's voluntary choice to participate in research. Educationally disadvantaged persons may have educational deficits, learning disabilities, or cultural backgrounds that limit communication with a researcher. It is the responsibility of the researcher to ensure that a subject is fully informed. This includes presenting material at an appropriate level, in an appropriate language, and via an appropriate medium (e.g., verbal or visual).

The IRB will review the protocol to determine if the information presented in the informed consent process is appropriate for the education level of the potential subjects; and/or not exploit the subjects' potential vulnerabilities to coercion.

9.0 International Research

When conducting international research, additional review and documentation is required from both the international site and the UIRB. All human subjects research conducted by a Stan State employee, regardless of funding or the study site, require submission to the UIRB.

9.1 Stan State Investigator Collaborating with an International Co-Investigator

The UIRB will require either IRB approval from the international collaborator's home institution, or a letter attesting that local IRB approval is not required.

9.2 Stan State Investigator Not Collaborating with anyone in the host country

The Investigator must identify in the protocol whether there is a local IRB, ethics committee, or government entity that must be consulted or that will perform a review within the host country. A copy of the approval notice or supporting documents for the local review should be included in the UIRB application.

If there is no local IRB, or the research does not rise to the level of review (i.e. social behavioral studies vs. clinical research), the Investigator should note that in the protocol.

The US Office of Human Research Protections compiles a [listing of research standards](#) in 130+ countries. This document enumerates country-level laws, regulations, and guidelines that govern human subject protections. Investigators should use this as a resource to determine if host country IRB approval is required.

All Investigators are required to include letters of support if recruitment will be conducted at certain sites, including but not limited to: schools, hospitals, businesses, etc.

10.0 Confidentiality

The investigator is responsible for protecting information obtained from subjects to avoid unintentional access by others. The informed consent should provide subjects with information related to how their information will be treated confidentially by the investigator.

10.1 Methods to Protect Confidentiality

Appropriate measures to ensure confidentiality include: limiting the personal information recorded to that which is essential to the research; substituting code numbers for names or other identifiers; limiting the number of individuals with access to data containing identifiers; and storing data in locked cabinets, or if stored electronically, on computers which are encrypted and password-protected.

11.0 Compensation and Incentives

The protocol and informed consent form should include relevant information on any compensation or incentives subjects will receive for their participation.

To assist with subject recruitment, incentives may be offered. The IRB will consider the appropriateness of the incentive level/amount, making sure it is reasonable compared to the burden or inconvenience incurred by participants. The amount and type of the incentive should not coerce or unduly influence the prospective subject into participating. The protocol and informed consent should clearly state what incentives are being offered, under what terms the incentive will be provided, the method of providing incentives, and if receipt of the incentive is contingent upon completion of the study.

12.0 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 IRB Administrator. Non-compliance may constitute research misconduct. Some examples of non-compliance include:

- 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
- Falsifying IRB documents
- Providing inadequate oversight of research
- Causing injury or harm to human subjects or other unanticipated problems involving risks to subjects or others