Steps for Submitting Your Research to the UIRB

1. Submit your Research Protocol

- Cover Page Application
- Research Protocol (see Protocol Instructions)
- Copy of research instruments to be used, e.g., surveys, interview guides, self-report scales, etc.
- Informed Consent Form (see Sample Informed Consent)
- Letters of support from connected agencies, if necessary

2. Obtain Approval For the Research

Following the review, the UIRB will either issue an approval letter (one of the four types listed below), or will ask for modifications and edits that need to be made and re-submitted before final approval can be determined. Full board protocols will receive approval after issues discussed at the full board meeting are addressed.

- ✦ Full Board: The research requires a full board review before approval can be given.
- ✦ Expedited: The research is approved and is authorized to proceed for one year.
- ✦ Exempt: The research is exempt from *further review* and is authorized to proceed for one year.
- ✦ Beyond the Purview of the UIRB: The research does not require IRB review and is authorized to proceed.

3. An approval letter will be sent to you. This letter will include the UIRB-assigned protocol number. Once you are in possession of this letter, you may start your data collection.

Graduate students: UIRB approval must appear in the bound copy of your final research project or thesis. Include the following sentence in your methodology section:

The University Institutional Review Board approved project (or thesis) # _____ on _____ (date).

UIRB Protocol Instructions

The investigator(s) shall provide the following information to the UIRB *using the headings shown*. An overall research proposal *may* be attached, but the researcher must explicitly address each of the points listed in the Research Protocol outline. **For graduate students**: if your methodology section contains all of the required information, you may simply attach that to the application. If your methodology section only contains part of the required information, attach it along with an addendum providing the additional required information.

Research Protocol Content:

- **Title** of the Research Proposal
- **Hypothesis** statement (research question to be explored)
- **Purpose** of Research (in the context of a summary of previous research, with an explicit statement of what is and is not known about the topic. Indicate what the proposed research could add, stated as *benefits to be gained by the discipline* and *by the subjects)*.
- **Methods** of the Research Activity (include the *appropriateness* of the design).
- **Procedures** to be used, focusing on the experiences of the subjects in the research.
- **Subjects** of the research to include:
    - Selection criteria
    - Exclusion criteria
    - Projected number of subjects?
    - Demographic characteristics
    - Vulnerable Populations: justify use of subjects such as *children, pregnant women, ethnic minorities, prisoners, mentally disabled persons, economically or educationally disadvantaged persons, students in the classroom, or employees in their workplace*.
    - Risks to Subjects and precautions taken to minimize risks
    - Managing Adverse Reactions, physical or emotional, of subjects due to participation.

- **Copy of research instruments** to be used, e.g., surveys, interview guides, self-report scales, etc.
- **Informed Consent** (see Sample Informed Consent)
- **Letters of support** from connected agencies, if necessary

Levels of UIRB Review

The four levels of UIRB review are as follows:

Full Board: This applies to any activity qualifying as human subjects research that does not meet the criteria for Exempt or Expedited Review. Often such research protocols involve "vulnerable participants" such as minors and/or persons at risk of psychological harm, including harm if confidentiality were violated or deception involved. The research involves more than minimal risk to the subject(s).

Expedited: This applies to standard non-invasive physical recordings, use of existing documents or records where the subject can be identified, standard laboratory procedures or perception or cognition, and certain projects disqualified from Exempt review conditions. The research involves minimal risk to the subject(s).

Exempt: This applies to normal educational practices, standard surveys, interviews, observations of public behavior (unless participants can be identified, disclosures could place participants at risk, participants are considered "vulnerable," or the research involves deceiving the participants). It also includes the collection or study of existing data, documents, or records where the subject cannot be identified. The Exempt Category means that the research does not need **further review** beyond the initial UIRB board member's review. *This is not to be confused with the research being exempt from any review at all.*

Beyond the Purview: This applies to research that does not involve human subjects, but for procedural reasons requires UIRB approval.

Human Subjects Research Definitions and Guidelines

The CSU Stanislaus' policy of research with human subjects is derived from *Code of Federal Regulations Title 45 Public Welfare, Part 46 Protection of Human Subjects.*

Research

The ED Regulations for the Protection of Human Subjects, Title 34, Code of Federal Regulations, Part 97, define research as "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

The regulations define human subject as "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. [Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a school health record).]

(1) 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.

(2) 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.

Making behavioral observations of humans in a natural setting, having persons fill out surveys, collecting data to compare effectiveness of several teaching methods, or studying patient records qualify as research *if* the activities are designed to lead to "generalizable knowledge." It does not matter whether the investigators are faculty or students. The UIRB assumes that the intent is to contribute to "generalizable knowledge" if the results may be presented in any forum, including meetings or publications, *external* to this institution. All Master's Theses and Projects involving human subjects are considered contributions to generalizable knowledge and therefore must be submitted for UIRB review. In summary, the criteria used to determine if an activity is research involve both the *nature* of that activity and the *use* of the data gathered.