Who Needs to Submit an IRB Protocol

1. SJSU faculty, students, or staff planning to conduct human subjects research.

2. Outside investigators are not required to obtain SJSU IRB approval if they already have approval from their home institution. However, outside investigators must register their protocol with the Office of Graduate Studies and Research prior to collecting data at SJSU by filling out an IRB application and submitting a copy of the protocol that was reviewed by their home institution as well as a copy of the IRB approval letter.

Types of IRB Review

There are three types of IRB review:

1. Expedited Review (protocol approval is determined by a single reviewer).

2. Full Review (protocol approval is determined by every member of the IRB).

3. Exempt Review (protocol approval is determined by the IRB coordinator). Exemption is not the same as exclusion from IRB review. Exempt status is conferred by the Office of Graduate Studies and Research prior to data collection after the investigator has submitted all the required supporting documents. These may include a complete protocol narrative, agreements from participating institutions, data instruments, and information on how informed consent will be obtained, when applicable.

Timeline

Protocols must be submitted and approved prior to data collection or recruitment of human subjects. The stated timelines and dates in the protocol must allow enough time for IRB approval. The IRB can not retroactively approve data collection and protocols with unrealistic timelines will be withdrawn from consideration. Data collected without IRB approval cannot be used in publication or dissemination.

The investigator submits two copies of a complete IRB protocol to the IRB Coordinator. Any subsequent documents or revisions that are submitted must contain the researcher's name and protocol tracking number.

If the protocol qualifies for exemption, the IRB coordinator will email the investigator to indicate that the protocol will be registered under an assigned tracking number. The investigator may begin after receiving a second email indicating the registration has been approved (7-10 business days).

If the protocol does not qualify for exemption, the IRB Coordinator pre-screens all protocols, generates a tracking number, identifies any necessary preliminary revisions or missing documents, emails the researcher, and sends the protocol to an IRB reviewer (time varies, but typically 1-7 days).

The reviewer will be informed of the preliminary revisions that were requested. If the requested revisions are minor, the investigator may wait until the reviewer has made a recommendation before submitting the corrections.

The IRB Reviewer examines the protocol, identifies any required revisions, and returns the protocol to the IRB coordinator (7-25 days). The IRB reviewer can either:

1. Approve the protocol.

2. Provisionally approve the protocol, pending the submission of revisions, additional documents, or information. The revisions are submitted to and reviewed by the IRB coordinator.

3. Request a Full IRB Review. Cases when this may occur:

   * The research involves greater than minimal risk to participants.

   * The subjects are a protected/vulnerable group (e.g., prisoners).

   The IRB meets once a month during the Fall and Spring semesters. Full Reviews are scheduled as needed for the next available monthly meeting. Investigators are notified by the IRB coordinator regarding the date, time, and location of the Full Review.

4. Ask the investigator to re-submit a new protocol. Cases when this may occur:

   * The protocol is poorly written or lacks the information needed to make a recommendation.

Once the protocol is approved by the reviewer, and the investigator has submitted any requested revisions, it is forwarded to the Associate Vice President of Graduate Studies and Research for final approval. The IRB coordinator notifies the researcher of IRB approval via email, followed by an official letter in the mail (1-7 days).

Addendums and Extensions

Once a research protocol has received final IRB approval, investigators may submit a description of any significant changes to their project to the IRB coordinator along with any documents that have changed. Approval is granted for one year. Investigators must submit an Extension Request Form to continue with data collection beyond the one year approval period prior to the expiration date indicated on their IRB approval letter.

2. How the information will be recorded by the investigator (e.g., written notes, photographs, audio/video recording, transcription). If participants will be recorded or photographed, the investigator should describe how these materials will be used and must state this information on the consent form.

   The risks and benefits of the study.

   A clear description of the kinds of identifiers, if any, that will be obtained and reported, or mechanisms for maintaining confidentiality (e.g., how materials will be kept safe, who has access to the data, and measures the investigator will implement in reporting data, such as the use of pseudonyms or other kinds of coding systems).

   How informed consent will be obtained if participants are adults and how assent will be obtained if participants are minors (see Informed Consent Materials section for more information).

Refer to the Protocol Narrative template on the IRB website for details regarding the above points (http://www.sjsu.edu/gradstudies/irb). This template should be used for drafting your protocol.

Informed Consent Materials

Attach to the application the appropriate consent form, letter, or script containing all of the elements of informed consent. If a paper copy is to be distributed to participants, it must be on SJSU departmental letterhead.

The purpose of informed consent procedures is to:

1. Inform participants of the research and what it will entail, including the risks and benefits of the research.

2. Inform participants of their rights (e.g., participation is voluntary).

3. Provide participants with information on who to contact if they have any questions.

The following is an outline of what kind of informed consent materials should be submitted for IRB review:

If the protocol qualifies for exemption and data is being sought directly from participants, the investigator may obtain informed consent either in writing or verbally. Documentation of informed consent is not required; however, GS&R recommends providing participants with information that addresses the above three items in writing whenever applicable. For anonymous surveys, for example, signature lines on the standard consent form are replaced with a statement such as “Your

completion of the survey indicates your willingness to participate. Please keep this

Provide potential subjects with information necessary to make an informed decision regarding participation in the study.

Protect the confidentiality of all subjects participating in research and all data that