SAN JOSÉ STATE UNIVERSITY

Human Subjects - Institutional Review Board Frequently Asked Questions

http://www.sjsu.edu/research/irb

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General Questions about the IRB, Procedures, and Timelines

What is the Institutional Review Board?

The Institutional Review Board (IRB) is a ten to fifteen member committee whose task is to review all research conducted by SJSU students, faculty, and staff that involves the use of human subjects, and to make sure that this research is being done in compliance with SJSU policy S08-7, federal policy 45CFR46, and other applicable regulations.

When is IRB approval required?

Submission of a protocol package for approval by the IRB is required when the following two criteria are met:

1. The activities are considered research. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

2. The activities involve human subjects. Research is considered to involve human subjects if it involves living individuals about whom an investigator obtains data through intervention or interaction with the individual(s), or about whom the investigator obtains identifiable private information. Intervention includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

   There is human subjects involvement when:

   - Human beings are asked to participate physically in an activity or to donate their tissue, organs, fluids, and other bodily material.

   - People are asked to participate through interaction that solicits personal information (e.g., surveys, interviews, observation).

   - Information concerning specific, individually identifiable human beings is asked for from third parties - whether through access to files, databases, or other means - or through direct inquiry of third parties concerning the individuals in question.

Who needs to submit an IRB protocol?

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

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 & Research prior to

collecting data at SJSU by filling out an IRB registration form and submitting a copy of the protocol that was reviewed by their home institution as well as a copy of the IRB approval letter. The IRB registration form is available on the IRB website at: http://www.sjsu.edu/research/docs/irb-registration.pdf

Are there different types of IRB review? What is exemption?

There are three types of IRB review:

1. Expedited Review. Protocol approval is determined by a single reviewer. At SJSU, all protocols that do not qualify for exemption (see below) go through an expedited review.

2. Full Review. Protocol approval is determined by every voting member of the IRB. Individual reviewers have the ability to select a full review if they believe the protocol raises concerns that warrant examination by the entire committee.

3. Exemption. Protocol exempt status is determined by the IRB coordinator and the activities are registered with the Office of Research rather than going through a formal IRB review process.

   Exemption is not the same as exclusion from purview of the SJSU policy for the protection of human subjects in research. Protections for the subjects of the research are still in place. In order for a protocol to qualify for exemption, all of the following criteria must be fulfilled: 1) the research cannot pose greater than minimal risk to participants, 2) the research cannot involve a vulnerable subject population (e.g., children, prisoners, pregnant women), 3) the research must fit into one of the categories of exemption outlined on the second page of the IRB application.

   Exempt status is conferred by the Office Research prior to data collection after the investigator has submitted all of 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.

The type of documents that investigators must submit are the same, regardless of what type of review occurs. The type of review that the protocol will undergo is communicated to investigators by the IRB coordinator once a complete protocol is received and evaluated.

What is IRB registration?

Registration is a means of documenting research activities that do not need to go through a formal IRB review at SJSU, but where protections for participants of the research are still in place. The circumstances that necessitate IRB registration are as follows.

- Protocols that qualify for exempt status. In this case investigators must still submit a complete protocol (see Questions about Documents section below), and must obtain consent from the subjects. However, the protocol does not go through a formal IRB review and it takes less to time to get the registration approved.

- SJSU Investigators who are awaiting approval of a grant or other funding source. Because some funding agencies require that investigators demonstrate awareness of policies for human subject protections in research, a registration indicating intent to conduct human subjects research is issued. In this case, the investigator should email the Intent to Conduct Human Subjects Research Registration Form to the IRB coordinator (see Questions about Submission and Contact Information section below). If funding is approved, the investigator must then follow up with submission of a complete IRB protocol prior to conducting the research.

- SJSU Investigators who have IRB approval from an outside institution to conduct research at that institution. In this case, the investigator should mail the Intent to Conduct Human Subjects Research Registration Form, along with the supporting documents described on the form to the IRB coordinator (see Questions about Submission and Contact Information section below). SJSU investigators must be named as members of the research team in the approval from an external IRB, even if they are not the principal investigators.

- Non-SJSU investigators who have IRB approval from their home institution to conduct research at SJSU. In this case, the investigator should mail the Intent to Conduct Human Subjects Research Registration Form, along with the supporting documents described on the form to the IRB coordinator (see Questions about Submission and Contact Information section below). SJSU must be named as a participating institution on the IRB approval from the home institution, and the activities described should be campus-specific.

How long does it take to get approval?

On average, it can take about a month to get approval for a well-prepared protocol undergoing an expedited review. Registration of a protocol that qualifies for exemption usually takes about 7-10 business days. These timeframes can vary depending on the volume of protocols received at a given time in the semester and the level of preparation of the protocol. During busy times, such as the end of a semester, it can take longer to get approval.

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 following is a more detailed breakdown of the timelines and procedures that investigators can expect:

- The investigator submits two copies of a complete IRB protocol to the IRB Coordinator in the Office of Research. 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 investigator, and sends the protocol to an IRB reviewer (time varies, but typically 1-7 business days after the protocol is received).

  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 business 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 the Office of 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 business days).

Are reviews conducted during the summer?

Yes, but there may be fewer reviewers available over the summer, and applicants may experience delays. If you need to submit a protocol during the summer make sure that you allow ample time for IRB review. Many investigators submit during the summer with the intention of beginning their work in the Fall semester.

How long is the IRB approval valid?

IRB approval is granted for one year from the approval date. The date the protocol expires will be indicated on the approval letter. Investigators are responsible for submitting an Extension Request Form to the IRB coordinator in the Office of Research prior to the expiration date indicated on their IRB approval letter if they wish to continue with data collection beyond the one year approval period. Approval of an extension request usually takes about 7-10 business days, provided there are no major significant changes to the study.

What happens if I need to make changes once I get IRB approval?

Once a research protocol has received final IRB approval, investigators must submit a description of any significant changes to their project to the IRB coordinator along with any documents that have changed. Addendum requests may be made by emailing the information to the IRB coordinator (see section below). Approval of an addendum request usually takes about 7-10 business days, but may vary depending on the extent of the changes and whether or not the protocol would need to undergo additional review as a result.

Questions about Protocol Submission and Contact Information

How do I submit my protocol?

Email or fax submissions of the protocol package are not accepted. Two paper copies of a complete protocol can be mailed to the Office of Research or dropped off in person. The address for submission is

Alena Filip, IRB Coordinator
The Office of Research
San Jose State University
One Washington Square
San Jose, CA 95192-0025

If you prefer to drop off the protocol in person, you may do so during our office hours, posted here: http://www.sjsu.edu/research/contact

The Office of Graduate Studies & Research is located in the Administration Building, Room 223.

If you are submitting an extension request form or wish to request an addendum to the existing protocol, you may email your request to Alena.Filip@sjsu.edu.

Who do I contact if I have any questions about the IRB?

If you have questions about the IRB, please contact the IRB coordinator, Alena Filip.

Phone: 408-924-2479
Email: Alena.Filip@sjsu.edu

Questions about Documents

What is an IRB protocol?

To ensure compliance the IRB requires that all investigators submit a standard set of documents designed to procure all of the essential information about a particular study prior to initiation of the research. All of the documents and materials that are submitted to the IRB are what constitute the IRB protocol.

What kinds of documents need to be submitted to get IRB approval?

All forms and templates are available on the IRB website:
http://www.sjsu.edu/research/irb/irb-forms

The following is a list of documents that make up the IRB protocol:

- **Training Verification**

  San Jose State University has contracted with CITI (Collaborative Institutional Training Initiative) to provide tutorials for investigators on responsible conduct in research.

  Investigators who are staff and faculty must complete a mandatory online training about conducting human subjects research available at:
  https://www.citiprogram.org/Default.asp?
  Investigators may select from any one of the modules available that is most closely applicable to their discipline.

  If the investigator has previously submitted a certificate of completion from the

training to the Office of Research, it is not necessary to include the certificate with every application.

A student training module is also available through CITI. The training for students is recommended but not mandatory, unless it is part of a class assignment or the student is receiving federal funding for the research. Students should be aware that the sponsoring professors that sign off on their protocols must have completed the training requirement. If the professor has previously completed the training, it is not necessary to include the certificate with every student application.

- **IRB Application**

  The IRB application is two pages and includes a Request to Use Human Subjects in Research as well as a Request to Determine Eligibility for Exemption. Exempt status is conferred by the Office of Research once the protocol has been evaluated to ensure that the research entails only minimal risk to participants, does not involve a vulnerable population, and falls into at least one of the six prescribed categories of exemption.

  If the investigator is a student, a sponsoring professor must read and approve the student's IRB protocol and sign the first page of the application where indicated.

  The IRB application is required for all protocol submissions, and the anticipated start date on the application must allow enough time for IRB review.

- **Protocol Narrative**

  An IRB protocol narrative addressing the methods and procedures of the research must be submitted with all IRB paperwork. Investigators must fill out all of the applicable fields on the narrative that is available on the IRB website.

- **Informed Consent Materials**

  Attach to the application the appropriate consent form, letter, or script containing all of the elements of informed consent.

  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 the types of informed consent materials that may need to 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. However, the Office of Research 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 information for your records and do not write any information that could identify you on the survey."

- If the protocol does not qualify for exemption, the investigator must submit a document that solicits the informed consent of participants (e.g., consent form, script). Written consent may be waived under certain circumstances. For example, when participants come from a culture that has an oral rather than written tradition or when the subject population is illiterate, investigators may submit an informed consent script, outlining the manner in which informed consent will be obtained verbally. Investigators must explicitly request that written consent be waived in their protocol narrative, and must document alternative procedures for obtaining informed consent. Requests to waive the need for written consent will be considered on a case by case basis.

- If the research involves minors, the investigator must always submit a consent form that solicits the permission of a parent or guardian, as well as information on how assent will be obtained from the minor (either verbally or in writing depending on the age group).

- If the research involves minors who are wards of the state, the investigator must submit written permission from the judge assigned to the youth for their participation.

- If the research involves the evaluation of student records in which the investigator has access to individually identifying student information, the investigator must submit a consent form that solicits the permission of the student, or a parent/guardian if the student is a minor, to access the records. Permission from a participating institution is also required when applicable.

- If the research involves evaluation of employee records in which the investigator has access to individually identifying employee information, the investigator must submit a consent form that solicits the permission of the employee to access the records. Permission from a participating institution is also required.

- If the research involves evaluation of medical records in which the investigator has access to individually identifying patient information, the investigator may be

required to submit a consent form that solicits the permission of the patient to access the records. Investigators may also provide an unsigned terms and conditions of service from the hospital/clinic that states records may be accessed for research purposes as evidence that the patients had already been informed about the use of their records for research. Permission from a participating institution is also required.

The IRB website provides consent form templates for adults and parents/guardians of minors, cover letters, and instructions for online or anonymous surveys.

- **Data Instruments**

  Attach to the application all data instruments, and other materials to be distributed to participants (e.g., surveys, questionnaires, interview questions, description of physical interventions or tests, data intake sheets).

- **Translations**

  If applicable, provide translations of both the consent documents and all data instruments to be distributed to participants AND provide a Verification of Translation Accuracy Form signed by someone other than yourself who is adept in the language. Investigators may translate documents, but may not verify the accuracy of the translation. The IRB does not require that a certified translator perform the document translation. The verification may, for example, be provided by a member of the Department of World Languages and Literatures or an individual who has the equivalent of bachelor's degree in that language.

- **Permissions from Participating Institutions**

  If applicable, obtain permission from outside institutions or agencies that either serve as a source of subjects, a source of records and information, or on whose facilities your project will be conducted. Participating institutions may include schools, hospitals, government agencies, community organizations, etc.

  Be aware that other institutions may have their own IRBs; if so, you must make your project known to them and go through the proper channels to get permission.

  Permission from participating institutions must be on their letterhead and must include: the title of the study, the inclusive dates for which the permission is granted, and the title and type written name of the individual with the authority to grant such permission, in addition to their signature.

A Summary of the Fundamental Rules When Conducting Human Subjects Research

Federal and California State statutes and University policy require that investigators are knowledgeable about and comply with regulations for the protection of human subjects in research. Investigators conducting research in accordance with SJSU policy must:

- Obtain HS-IRB approval prior to soliciting subjects or collecting data. This includes projects that may qualify for exemption. Exempt status is determined by the Office of Research and not by the researcher. NOTE: Exemptions from HS-IRB review will not be granted for research involving protected classes of subjects (e.g., fetuses, pregnant women, prisoners, children, or those institutionalized as mentally disabled) even though the research may appear to belong to an exempt classification.

- 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 may be collected from the subjects, unless the researcher has provided thorough documentation indicating to participants that they will be identified in publication or dissemination.

- Provide special safety procedures, as needed, to avoid any harm to subjects. Harm includes psychological trauma, physical injury, and the release of potentially damaging personal information.

- Provide additional protection for "at risk" subjects, such as children, pregnant woman, the elderly, the infirm, and any person receiving treatment for a serious psychological or physical problem.

- Provide immediate and follow-up care in case of research-related injury, and report any research-related injuries to the Institutional Officer overseeing the IRB, Dr. Pamela Stacks. To report research-related injuries or any adverse events, please contact our office in writing (email is ok):

  Dr. Pamela Stacks, Associate Vice President of the Office of Research
  c/o Alena Filip, IRB Coordinator

  Alena.Filip@sjsu.edu
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  San Jose, CA 95192-0025