

Seattle Pacific University Institutional Review Board -- User's Guide

Overview

Researchers who study social, behavioral and physiological attributes of Human Beings are responsible for careful research design that not only incorporates the best of theory, research and analysis but recognizes the humanity and value of their research participants.

The purpose of the SPU Institutional Review Board (IRB) is to ensure the protection of the rights, health, and privacy of individuals who participate in **research** that is conducted through the University. Protection of human participants is the primary goal of these policies. SPU follows [federal research guidelines](#) from the Office of Human Research Protections (OHRP) which is part of the Department of Health and Human Services. SPU IRB is federally registered with OHRP.

The policies of the SPU IRB are also designed to protect University Faculty and Staff members who conduct research, and students who conduct research under their supervision. These policies apply to all research activities that involve human participants at SPU or SPU community members who conduct research within or outside of the University.

This document provides an overview of SPU research with human participants guidelines. In addition to the more exhaustive federal guidelines list above, more information and forms can be found on the SPU IRB website <http://www.spu.edu/orgs/irb/>

Definition of Research

The definition of Research used by the SPU IRB comes from the Office of Human Research Protections (OHRP), the federal agency within the Department of Health and Human Services that oversees IRB's. Research is defined as "a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge." Research designates "an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective."

More simply put, The IRB is responsible to review and approve any proposed research with human participants that occurs ***outside of established or commonly accepted educational settings involving normal educational practices such as regular course evaluations or student assessment***. OHRP refers to this as the "common rule" when ascertaining the need for IRB review.

Any project outside of the common rule that meets ***all*** of the following criteria needs to submit an IRB application for data collection approval.

1. Systematically collects data from multiple human participants ***and*** . . .
2. Stores the data for analysis, ***and*** . . .
3. Publicly presents or archives in printed / electronic form a summary of the results that will be available to others outside of normal classroom activities.

IRB at SPU

SPU's IRB consists of eight Research Coordinators (RCs) who prescreen all research with Human Participants. Several RCs are also IRB members who are responsible for articulating its policies and procedures and reviewing research that carries more than minimal risk to

participants. The chair of the IRB is appointed by the Vice President of Academic Affairs who has ultimate authority regarding the IRB policies and procedures. Other IRB members and RCs are appointed by their Deans. You can find the list of RCs on the SPU IRB web site.

The IRB meets monthly. You can find the meetings on the SPU calendar. The IRB meetings are open to the Public.

Review of Research at SPU

Because SPU IRB's goals include protecting participants as well as researchers, it is chartered to review all research that specifically targets the SPU community as part of its population of study. It is also chartered to review all research performed by members of the SPU community who serve as Principal Investigator (PIs). We define the Principal Investigator as a qualified person who directs or conducts a research project. He/She oversees the scientific and technical aspects as well as the day-to-day management of a research project.¹

Subsequently, the SPU IRB is responsible to review the research from the following people:

1. SPU Faculty or Staff who are PIs.
2. SPU Students who are PIs in their role as students here at SPU. Student PIs must also have faculty or staff sponsorship.
 - a. SPU Faculty, Staff or Student PIs must receive IRB approval before they collect data regardless of the source of data. If PIs collect data outside of SPU, they still need SPU IRB approval.
3. PIs who are not members of SPU and who wish to collect data specifically from the SPU community (See special instructions below)

IRB Application

The IRB application can be found at the SPU IRB website. The IRB application is periodically updated so it is important that you download the latest version from the web site each time you plan to apply. In the IRB application you will be asked to include information on, 1) the purpose of the study, 2) the proposed research sample, 3) research procedure, 4) time frame for the proposed study, 5) expected risks and benefits to individual participants, 7) maintenance of confidentiality, 8) and consent documentation. It is extremely important that you write succinctly yet provide appropriately detailed answers so that the IRB can evaluate your project.

Risks and Benefits

Before applying for IRB approval, PIs should determine the risks and benefits of their proposed study for individual participants. According to the Federal Regulations all research carries with it minimal risk. "*Minimal risk* means that 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 or during the performance of routine physical or psychological examinations or tests."

Research that includes more than minimal risk includes studies that 1) may make participants psychologically uncomfortable, contain deception, contain sensitive questions or disclosure of participant identity would place them at risk of criminal/civil liability or damage to their financial standing, employability, or reputation; 2) may lead to physical discomfort or harm greater than ordinarily encountered and 3) gathers data from vulnerable populations such as prisoners or in some cases minors.

Submitting Your IRB Application

Submit **two hard copies** of the IRB application with any documented protocol (such as the questionnaires or assessment instruments that you propose to use, all correspondence and recruitment material) to an RC in your School or Unit. You can find the list of IRB RCs on the SPU

¹ Definition from the National Institutes of Health

IRB website. Students must obtain their sponsor's review and signature before submitting the application to the RC.

DO NOT submit your IRB application or protocol information via e-mail.

PIs who are not members of SPU can submit their approved IRB material to the SPU sponsor who will then pass it on to the appropriate RC.

Documenting Informed Consent:

You need to secure the signature of non-minor participants documenting that they have given their voluntary informed consent whenever you ask them to do anything different from their everyday lives. You can find the SPU Informed Consent template on the IRB website. You must follow the wording on the template as closely as possible. For more information and tips regarding writing your informed consent see <http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm>

To expedite your application include the Informed Consent Checklist at the end of this document.

All informed consent documents that originate from SPU PIs must clearly label that the research is part of SPU (e.g. use the SPU logo). Once approved, the IRB study # and expiration date must also be included on the Informed consent document.

Non-Documented Informed Consent

You do not need documented informed consent (e.g. collect their signature) if your research includes anonymous, mailed surveys on innocuous subjects or anonymous, noninteractive observation of public behavior (such as shoppers at a mall) of people over 18 years of age and those who are not incarcerated.

Even if you do not need documented informed consent, you need to provide participants an introductory statement that follows the informed consent template including the purpose of the study and their rights as research participants. This can take the form of a letter signed by the PI. Please see the sample undocumented informed consent on the IRB web site.

Debriefing

You need to provide a debriefing form whenever you collect data in research processes that create more than minimal risk and which was reviewed by expedited or full IRB review. For example if you are running an experiment in a laboratory setting, you need to provide a debriefing at the end of the study as an educational tool and to answer any questions that participants might have regarding their participation. Even when no debriefing is necessary, you need to provide an opportunity for people to request a summary of the results.

IRB Application Review

The RC will review the IRB application to ensure that the study meets principles of Beneficence, Respect and Justice found in the [Belmont Report](#). More specifically, the RC will review the application to ensure voluntary consent, participant privacy and confidentiality. The RC will also evaluate the risk involved in the study and weigh it against the benefit to the individual participants. RCs do not review their own IRB applications but pass them on to the IRB Chair for appropriate distribution.

Review Categories

The RC will review the IRB application and categorize the type of review based on its risk to participants. Under federal regulations there are three types of review; exempt, expedited and full review.

Exempt Review

Research which carries no more than minimal risk is exempt from further review by the full IRB. There are several categories of research that is exempt from full IRB review.

Category 1: Research conducted in established or commonly accepted educational settings, involving normal educational practices.

Category 2: Research that involves the exclusive use of **anonymous** surveys, educational tests, interviews, and/or observations of public behavior.

Category 3: Public data, records or documents that “reasonable persons” would not want disclosed.

Category 4: Private archival data, records or documents for which permission was granted for future research at the time the data was gathered.

Category 5: Data collected for organizational Quality Assurance programs.

Other, less common exemptions to IRB review can be found at <http://condor.depaul.edu/~irb/exempt.html>

It is important to note that the RC will review the application to decide the review status of an IRB application. The PI may not assume that his/her research is exempt.

Most research conducted at SPU has minimal risk involved and so most IRB applications reviewed by the local RC are exempt from full IRB review. Research that has more than minimal risk is passed on to a member of the IRB by the RC. The IRB member will then determine if he or she are eligible to review the application under expedited review or if the application should be reviewed by the full IRB committee.

Expedited Review

Research that carries no more than minimal psychological or physical risk but falls outside of the above exempt categories will be considered for expedited review. Typical research that falls under expedited review includes

- Survey/interview research with children;
- Observations of children, if the researcher is also involved in the observed activity;
- Research that deals with sensitive or private aspects of the participants’ behavior or surveys that may cause discomfort or distress (e.g. detailed personality inventories).

For further information on levels of risk associated with research that includes exercise. See the SPU Risk Guidelines for Exercise and Testing Prescription found at the SPU IRB web site.

Further details on acceptable research for expedited review can be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

An expedited review procedure consists of a review of research involving human participants by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in the federal regulations. After reviewing an IRB application under expedited review, the reviewer(s) may choose to forward the application to full review.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Full Review

Research that carries significant risk or includes participants for whom voluntary consent is more likely to be coerced will be reviewed by the full IRB. Typical full IRB review includes studies with

prisoners, and mentally or physically impaired participants. Research with prisoners receives full IRB review that includes the IRB Community Member and Prisoner Advocate.

If a study is to be reviewed by the full IRB the PI will be invited to the IRB meeting. The IRB recommends that the PI attend to clarify any questions or concerns that the IRB may have regarding the study.

The majority of SPU research that carries more than minimal risk receives expedited review. The SPU IRB reserves the right to not approve research that it considers to carry undue risk to participants. Research that exposes participants to toxins, experimental drug trials or experimental interventions that may lead to questionable psychological or physical harm are likely to be not approved by the IRB.

Time Associated With the IRB Review.

The PI may expect to hear from the RC regarding an initial decision regarding the study status within two weeks. If the RC determines that the research proposal carries more than minimal risk, the PI should expect up to another two weeks for expedited review. If the RC determines that the research proposal should be reviewed by the full IRB, the initial review may be extended by four to six weeks.

Revisions to IRB Application

The RC or IRB may ask the PI for clarifications or revisions to the application or planned research project. This is especially likely when the initial reviewer(s) deemed that 1) the risk involved in the study is not in proportion to the benefit to the individual participant; 2) protection of the participants' confidentiality is at risk and / or 3) procedures are proposed that may be or may appear to coerce participation. The RC will provide the request for revision in writing. If the PI is a student, the RC will provide the request to the sponsor as well as the PI. In addition to submitting new material, the PI must respond in writing to the RC how he or she addressed the requested revisions. Students must receive their Sponsor's signature on the documented revisions before submitting them to the RC. The RC or IRB will not approve a study until all revisions are submitted. The SPU IRB does not grant contingent approvals.

Appealing an IRB Decision

PI's may appeal an RC decision. The appeals process depends on the review status. If the initial decision was based on an exempt review, the PI can request a review by an expedited committee through the RC. If the initial decision was based on an expedited review, the PI can request a review by the full IRB through the members of the expedited review. Further appeals of an IRB decision will be directed to the Office of Academic Affairs through the Chair of the IRB.

An RC may also request the IRB to continue with a review of an application if the RC wishes for additional consultation.

Notification of IRB Approval

When a study is approved, the RC logs the study in the IRB tracking data base and assigns the study a number. The RC then contacts the PI in writing (letter or e-mail) with the approval status, the IRB tracking number and the expiration date (e.g. one year) of the IRB approval. The RC will also provide written documentation of the review process.

IRB Study Number

An IRB number is only assigned to approved studies. A PI can not begin to collect data without a study number.

The IRB number and expiration date must be listed on all informed consent documents and all recruitment material or other correspondence regarding the study.

Revisions to an Approved Study

A PI may ask for approval of minor revisions to his or her study. Minor revisions include changes in sampling, recruitment and minor changes in protocol. The request for revision should be made in writing and include the original study number.

The RC will notify the PI of approved revisions, further clarifications or, if the RC ascertains that the changes substantially alter the study, request a new IRB application. If the IRB approves the revision, the PI should continue to use the same IRB number and expiration date of the study regardless of the date of the revision.

Study Completion

After completing working with Human Participants for the study, the PI must contact the RC to let him or her know that the data collection phase of the study is completed. If the PI believes that the data collection will take more than a year, he or she must contact the RC in writing six weeks before the study expiration date to ask for no more than a one-year extension. Additional extensions require that a new application be submitted to the RC. If an extension is not requested, the IRB approval will expire and the PI must resubmit his or her application for a new review.

Storing Human Subjects Research Data

Records pertaining to research that is conducted using human subjects must be retained by the PI for three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department, agency or organization supporting or conducting the research.

PIs Who are Not Members of SPU

PIs who are not members of SPU and who wish to collect data specifically from the SPU community must first receive IRB approval from their own sponsoring institution. They must also have an SPU Faculty or Staff member who will sponsor the research on the SPU campus, serving as a contact person if participants have any questions or concerns. We generally accept reciprocity from IRBs with Federal-Wide Assurance.² However, we need to have copies of the original IRB approval letter. The sponsor needs to attach a memo saying that they are the on-campus sponsor of the research. The PI will also need to create an amended informed consent for use at SPU which has the sponsor's phone number and e-mail address if SPU participants have any questions. A copy of the amended informed consent should be submitted with the material. If the originating institution does not hold federal-wide assurance, the PI should complete the SPU IRB application, have their sponsor sign it and the sponsor should pass it on to the appropriate RC for review.

Once the IRB receives the appropriate information and approves the study it will be entered into the SPU research data base and be cross-listed as a SPU study. The PIs are welcome to collect data once the sponsor receives the cross-referenced SPU number. Additionally the IRB number and expiration date must be on the informed consent³. Data can not be collected past the expiration date of the IRB approval.

² However the SPU IRB reserves the right to not approve the collection of data at SPU from a previously approved IRB if the IRB deems that the risk associated with the study outweighs the individual benefit to SPU participants.

³ If the originating organization has federal-wide assurance then the IRB number should be from the originating organization. If the originating organization does not have federal wide assurance, the PI should use the SPU IRB number and expiration date.

Basic Elements of Informed Consent (Not all items are applicable to every project.)

In language understandable to the participant...

Investigators

- Consent forms must state **who is conducting the research** and clearly labeled that the research is sponsored by SPU. The IRB encourages the use of SPU logo or letterhead.

Purpose

- Use of word "study," "research," or "investigation" to describe activity
- An informed explanation of the **purpose** of the research

Procedures

- A description of the **procedures** to be followed
- Identification of any **experimental treatments, procedures, or devices**
- A disclosure of any appropriate **alternative procedures** or courses of treatment
- The **location(s)** where the procedures will be done
- The expected total **duration** of participation and that of each phase of multi-phase protocols

Risks

- A description of the reasonably foreseeable **risks** and discomforts, or a statement that the research does not involve risks beyond those encountered in everyday life, as appropriate.

Emergency Medical / Psychological Treatment

- Studies involving exercise testing or supervised physical activity include emergency policies and procedures.
- An explanation of any **costs** to the subject for research-related procedures, hospital stays, use of equipment, lost compensation or insurance, or extraordinary transportation requirements
- As appropriate, an explanation as to whether any **compensation** or **medical treatment** is available if injury occurs, what it would consist of (if any), or where further information may be obtained.

Benefits

- A description of possible direct **benefits** to each subject, which may reasonably be expected from the research, or a statement that individual subjects may not directly benefit from participation though there may be benefits to general knowledge or to society.

Confidentiality

- A statement describing the extent to which **confidentiality** of records identifying subjects will be maintained, including who will have access to and the methods for securing such records.

Compensation

- An explanation of any **gratuities** for participation and, if appropriate, procedures to **prorate** amounts for subjects who withdraw before completing the research protocol

Who to Contact

- The name(s), title(s), local toll-free telephone number(s), and e-mail addresses of the **person(s) to contact for answers to questions about the research**, including those for the responsible project investigator, if different
- An invitation to contact the **IRB Office** (IRB@SPU.edu) for **information about the rights of human subjects** in SPU-approved research.
- As appropriate, the name(s), title(s), and daytime and evening telephone number(s) of the **person(s) to contact in the event of a research-related injury, adverse effect, or complaint**

Participation and Alternatives to Participation

- A statement that participation is **voluntary**
- A statement that **subjects may refuse to participate or may discontinue participation** at any time during the project without penalty or loss of benefits to which they are otherwise entitled
- For surveys and interviews, a statement that subjects may **skip any questions** they don't wish to answer
- No language through which subjects are made to **waive any legal rights**, including any release of the university or its agents from liability or negligence

Near the Signature Line

- A statement that **participants will be given a copy** of the consent form

After IRB Approval

- SPU IRB number and expiration date are placed on informed consent and any other recruitment material.