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 (http://www.hhs.gov/ohrp/) 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.

1. Research is defined as "a systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge."
2. Research designates "an activity designed to test a 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).
3. 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.*** This means that any data collected for classroom purposes only do not need IRB approval; however, any data collected that will be used outside of class and published or presented in any way will need to seek IRB approval. 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 9 reviewing Members who prescreen all research with Human Participants. The 9 reviewing Members consist of three members from College of Arts and Sciences, one member each from the School of Education, School of Business and Economics, School of Health Sciences, and the School of Psychology, Family and Community. The full IRB board further consists of one University administrator, and one person from outside the University. IRB members are responsible for articulating its policies and procedures and reviewing research that fulfills the criteria articulated above. The chair of the IRB is appointed by the Vice President of Academic Affairs (VPAA) who has ultimate authority regarding the IRB policies and procedures. Other IRB members are recommended to the VPAA by either the IRB Chair or Deans of the Schools from which the members come. You can find the list of IRB members on the SPU IRB web site.

The IRB meets monthly. You can find the meetings on the SPU calendar and on the IRB website.

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 SPU community members (i.e. faculty, students and/or staff). 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 generated by the following people:

1. SPU Faculty or Staff who are PIs.
2. SPU Students who are PIs for the purpose of class assignments, degree completion or professional development. Student PIs must also have faculty or staff sponsorship.
3. 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.
4. PIs who are not faculty, students or staff of SPU and who wish to collect data *specifically* from the SPU community (See special instructions at the end of this document)

[1] Definition from the National Institutes of Health

[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 or the study violates SPU community standards and policies.

IRB Application
The IRB application can be found on 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 measures and procedures
4) Time frame for the proposed study
5) Expected risks and benefits to individual participants
6) Maintenance of confidentiality
7) Consent documentation

It is extremely important that you write succinctly yet provide appropriately detailed answers to each application question so that the IRB can evaluate your project. Please also remember to use common, lay language, easily understandable to an educated person who may not be a specialist in your particular subdiscipline.

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
2) Contain deception
3) Contain sensitive questions
4) When disclosure of participant identity would place them at risk of criminal/civil liability and/or damage to their financial standing, employability, or reputation
5) May lead to physical discomfort or harm greater than ordinarily encountered
6) Gathers data from vulnerable populations such as prisoners or 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, scripts for researchers interactions with participants) to an IRB member from your School or College. Students must obtain their sponsor's review and signature before submitting the application to the IRB Member.

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

PIs who are not members of SPU must have an SPU sponsor who submits the material on the non-member's behalf (see further details below).

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-approved Informed Consent templates on the IRB website. You must follow the wording on the template as closely as possible. For more information and tips regarding writing you informed consent see
http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm

Your application must include a completed Informed Consent Checklist at the end of the Application Form 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 generally do not need documented informed consent (e.g. collect their signature) if your research includes anonymous 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 or other vulnerable populations.

Even if you do not need documented informed consent, you usually 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 involve deception. You may choose to also use a debriefing form for other forms of research that provide some risk to the participants that is much greater than they would experience outside of daily life. 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; if you choose to use a debriefing form or opportunity, you must include a script of this debriefing in your application.

IRB Application Review
The IRB Member associated with your School (e.g. SPFC) or College (i.e. CAS) will review the IRB application to ensure that the study meets principles of Beneficence, Respect and Justice found in the Belmont Report (http://ohsr.od.nih.gov/guidelines/belmont.html). More specifically, the IRB Member will review the application to ensure voluntary consent, participant privacy and confidentiality. The IRB Member will also evaluate the risk involved in the study and weigh it against the benefit to the individual participants. *IRB Members do not review their own IRB applications but pass them on to the IRB Chair for appropriate distribution*.

Review Categories

The IRB Member 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 were gathered.

Category 5: Data collected for organizational Quality Assurance programs.

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

After completing an initial review, the IRB member will then determine if the application is eligible for the expedited review process 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

1) Surveys that may cause discomfort or distress (e.g. detailed personality inventories)
2) Research that deals with sensitive or private aspects of the participants' behavior
3) Activities that involve lab-based exercise
4) Activities that are outside of normal, every day behavior

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.

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. Research that contains deception will be reviewed by the full IRB. Typical full IRB review includes studies with minors, prisoners, and mentally or physically impaired participants. Research with prisoners receives full IRB review that includes the IRB Community Member and Prisoner Advocate. Federal guidelines also indicate that research on pregnant or lactating women also undergoes full review.

If you believe your study will be receiving Full Review, please make sure you check the IRB website and/or the SPU Calendar to make sure you are submitting to your IRB Member by the deadline to make the meeting you hope.

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 IRB Member regarding an initial decision regarding the study status (i.e. exempt, expedited or full review) within two weeks. If the IRB Member determines that the research proposal carries more than minimal risk, the PI should expect up to another two weeks for expedited review. If the IRB Member 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 IRB Member may ask the PI for clarifications or revisions to the application or planned research project. This is especially likely when the initial reviewer(s) deem 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
3) Procedures are proposed that may be or may appear to coerce participation.

The IRB Member will provide the request for revision in writing. If the PI is a student, the IRB Member 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 IRB Member how he or she addressed the requested revisions. Students must receive their Sponsor's signature on the documented revisions before submitting them to the IRB Member. The IRB Member 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 IRB Member 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 IRB Member. If the initial decision was based on an

expedited review, the PI can request a review by the full IRB. Further appeals of an IRB decision will be directed to the Office of Academic Affairs through the Chair of the IRB.

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

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

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 to the IRB Member who reviewed the initial study in writing and include the original study number.

The IRB Member will notify the PI of approved revisions, further clarifications or, if the IRB Member 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 IRB Member to let him or her know that the data collection phase of the study is completed. Study completion can be documented by submitting a Status Report. If the PI believes that the data collection will take more than a year, he or she must contact the IRB Member in writing six weeks before the study expiration date to ask for no more than a one-year extension. This is also done by submitted a Status Report. If an extension is not requested, the IRB approval will expire and the PI must resubmit his or her entire application for a new review. <u>After multiple requests for an extension and/or subsequent revisions, the IRB Member may ask for an entirely new application in order to document the study as it is currently implemented.</u>

Storing Human Subjects Research Data
Records (including signed informed consent documents) and data 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 Academic department, IRB, SPU or external agency or organization supporting or conducting the research during this time period. If storage space is needed to store consent forms, please contact your IRB Member.

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 if the sponsoring institution has a federally registered IRB or have IRB approval from a federally registered IRB organization such as Western IRB. 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 the federally registered IRBs.[2] However, we need to have copies of the original IRB application and 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.

Additionally the Sponsoring IRB number and expiration date must be on the informed consent. Data can not be collected past the expiration date of the IRB approval.

Once the IRB receives this information 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.

Research that is not compliant with IRB Policy and Procedures

PI's may not recruit human subjects or collect data in a manner that was not approved by the IRB. This includes changing protocols, recruitment material or collecting data after the IRB permission has expired or without discussing the changes with the study's IRB Member. Data that are collected outside of the approved IRB may not be used for study purposes (e.g. publication).

[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 or the study violates SPU community standards and policies.