SEATTLE PACIFIC UNIVERSITY
Institutional Review Board (IRB)

Policies and Procedures for Protection of Human Participants in Research

The following policies protect 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.

The policies also protect the University, employees who conduct research, and students who conduct research under the supervision of employees. The policies help protect by providing guidelines of conduct that are based upon vital ethical and legal research principles.

These policies apply to all research activities that involve human participants. The policies apply to any project that includes off-campus participants or on-campus participants.

The definition of research taken from the federal IRB handbook\(^1\) is “A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.” This definition is further informed by comments from the Belmont Report of 1978. 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.” Projects that meet the criteria in Sections 2.1 are conducted through the University by faculty, administration, staff, or students and qualify as research according to the definition above, must be reviewed by a Research Coordinator (RC). These projects may be designated as studies (e.g., master’s theses or a study funded by a Faculty Research Grant) or may be part of a larger undertaking (e.g., students required to conduct a survey as part of a course).

Implementation of the policies is a joint responsibility of the University and its employees. The University is responsible for communicating these principles to employees, monitoring their applications, and enforcing their applications. Employees are responsible for designing and conducting research according to the highest ethical principles of their own professional fields and according to University policies.

Section 1 General Policies

1.1 No researcher shall undertake a project that is covered by this document without following the procedures in Section 2.

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\(^1\) Student assessment within the context of classes is not considered research. Please consult the IRB Guidebook at [http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm](http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm) for further information about the definition of research.
1.2 The University and its employees recognize their responsibility for protecting the rights and welfare of human participants. Researchers document this responsibility through written and oral informed consent with each participant.

1.3 No participants will be exposed to unreasonable risks to health and welfare. Appropriate research procedures and facilities help protect participants’ safety.

1.4 Research that entails risk or substantial mental and/or physical discomfort will be carefully explained to participants. The researcher must document that participants understand the potential risks or discomforts, as well as potential benefits, prior to their participation.

1.5 Research involving legal minors (less than 18 years of age), adult legal dependents, and persons who are unable to give informed consent may be approved if the study involves no risk to welfare or suffering and the study may directly benefit the participants.

1.6 Data gathered in research will be confidential. Confidentiality extends to data collection, interpretation, storage, publication, and disposal.

1.7 Participants may withdraw from any part of or all research activities at any time. A withdrawal will bring no penalty or loss of benefits to which participants are otherwise entitled.

1.8 Researchers are accountable for the accuracy of their written and oral reports.

1.9 All research sponsored by Seattle Pacific University should be clearly labeled as Seattle Pacific University research.

Section 2 Procedure

2.1 The University Institutional Review Board (IRB) has an all-university perspective and responsibility to insure that research projects involving human participants provide appropriate protection to the participants. Any research project involving human participants with Seattle Pacific University faculty, staff, or students serving as principle investigator (PI), must be reviewed by the appropriate Research Coordinator (RC). Researchers who are members of the SPU community and are also involved in research studies reviewed by other IRB’s but are not PI’s need not have the study reviewed by the SPU IRB if the other agency has Federalwide Assurance. Research in the following categories must be submitted to a research coordinator for review:

Categories:
1) Research that is part of a university course or degree requirements;
2) Research that is conducted for or sponsored by a university office;
3) Research that is conducted for or sponsored by a college, school, or university committee;
4) Research that is conducted for or sponsored by a university faculty member as part of his/her professional role or expectations at the university; and
5) Any previously approved study in which data collection tools or processes have been amended.

2.2 All research within the categories listed above will be reviewed. All reviews start with the RC. There are three levels of formal review of research projects:
1. Review by the RC and exempted from further review by the IRB. In certain cases when standard and well known research processes and information gathering techniques are used, the RC can exempt a study from further review. However, no person other than an RC can exempt a study, and no RC can exempt his or her own study or one they direct.
2. Review by the RC and an expedited review by the University IRB Chair. When an RC decides further review is needed, the proposal is forwarded to the chair of the University IRB. That person can either approve the study or forward it for review by the entire IRB.
3. Review by the RC, the University IRB Chair and full review by the IRB. If the chair of the University IRB determines that review by the full IRB is required, he or she will include review in a meeting agenda and forward the proposal on to all members of the University IRB.

2.3 All researchers must formulate a clear study proposal. The proposal must include at least the following written contents:

- In addition to information including the Title of the project, the name, phone number and email address of the principal investigator along with all co-investigator(s) and the signature of the advisor if it is a student study:
  1. Purpose of the study
  2. Sample/population being used including: a description of the population, and a rationale for using this population. Who will recruit the participants and how they will be recruited. Steps taken to avoid coercion and dual relationships.
  3. The methodology used in the study including identification and a brief description of all measures.
  4. Risks including: a description of the risks posed by this method, any other methods that might be used, procedures including confidentiality safeguards, being used to minimize the risk.
  5. Any benefits that may accrue to the participants.
  6. A description of how confidentiality is maintained.
  7. A description of consent procedures including the consent form being used if necessary.
2.4 The researcher, principal researcher of a team, or supervisor of a student researcher delivers the research proposal in approved IRB format as well as copies of any supporting research protocols and/or measurement instruments to the RC of the researcher’s academic unit or office. A school research or thesis committee may review the proposal and give feedback on it before the RC reviews it.

2.5 The RC reviews the proposal and determines the necessary level of review (Section 2.2) for the research. The RC completes the Checklist for Research Proposals and the Essential Information for Consent form and notifies the researcher of the level of review necessary.

2.6 Research sponsored by an RC will be reviewed by another RC or a University IRB member.

2.7 Any research project is subject to continuous review by the IRB and may be investigated by the IRB at any time at the IRB’s sole discretion. The RC and/or the University IRB will monitor the research and decide when and if it needs review.

Section 3  Research Coordinator

3.1 The Research Coordinator (RC) informs faculty or staff about research policies and procedures and monitors research projects in the academic unit or office. The RC is also the school or office liaison with the University Institutional Review Board (IRB).

3.2 The Dean of each academic unit will designate at least one faculty member to be RC for that school. The Vice Presidents will designate one RC for non-academic University offices. The length of appointment will be at least 12 months, so as to provide continuous coverage of the projects.

3.3 The RC should have education in basic research designs he or she is likely to review.

3.4 The RC attends in-service education sponsored by the VPAA’s Office on research, especially sessions on ethics and law.

3.5 The VPAA’s Office will accord special work load consideration for RCs whose schools are particularly active in research. Some schools generate more research than other schools. Special considerations for RC’s in the busiest schools will encourage them to get involved and stay involved in the process.
Section 4  University Institutional Review Board

4.1 The University Institutional Review Board (IRB) is a standing University committee. It reports to the VPAA. The IRB has the following functions:

1. Review policies and procedures for ethical and legal aspects of research that involves human participants and propose revisions as necessary.
2. Evaluate research proposals according to criteria established in this policy document. The committee may approve the proposal or return it with comments to the researcher.
3. Act as a hearing and referral board for complaints about treatment of human participants in research that is conducted through the University.
4. Design and implement faculty in-service sessions on research ethics and law.

4.2 The committee has five members: three of the school or college Research Coordinators (RC’s), one University administrator, and one person from outside of the University. The person from outside the University must not be otherwise affiliated with the University and not be part of the immediate family of a person who is affiliated with the University. At least one RC must be from an academic school. The non-university representative ideally would have education in ethical and/or legal matters. The IRB may not consist entirely of men or entirely of women.

4.3 The VPAA appoints University IRB members for three year terms. Terms should be staggered in order to insure continuity. If an RC resigns from RC status before the end of the three-year term, he or she will be replaced by another RC to fill out the time remaining in the term.

Section 5  Sanctions

5.1 Failure to comply with Institutional Review Board (IRB) policy: Research investigators are the most frequent source of noncompliance with human subjects regulations. The most common lapses in investigator compliance include unreported changes in protocols, misuse or nonuse of the informed consent document, and failure to submit protocols to the IRB in a timely fashion. Problems such as these are often caused by communication difficulties. With investigator goodwill, these cases can be resolved by the Research Coordinator (RC) in consultation with the IRB chair without jeopardizing the welfare of research subjects.

5.2 Occasionally, an investigator will either avoid or ignore an IRB. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the RC
will contact the IRB Chair who will act promptly to halt the research, take appropriate remedial action regarding any breach of regulatory or institutional human subject protection requirements. This action will vary depending upon the nature of the research study. The Chair of the IRB will refer the matter to the VPAA who will address the question of the investigator's fitness to conduct human subject research. In addition, any serious or continuing noncompliance with DHHS human subjects regulations or the determinations of the IRB must be promptly reported to OPRR (or the department or agency head) [Federal Policy §__.103(b)(5)].