Institutional Review Board

Policies and Procedures
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Institutional Review Board

I. Introduction

Point Park University is committed to the pursuit, acquisition and teaching of new knowledge, and does so through the support of research conducted by faculty and students. It is the policy of Point Park University that research that involves human and non-human subjects, must be conducted in accordance with established ethical and professional standards, and that all such research must be approved by the University’s Institutional Review Board (IRB). Point Park University’s policies and procedures for its IRB were developed in accordance with the United States Department of Health and Human Services Institutional Review Board Guidebook, retrieved from: http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

A. Jurisdiction

Under the authority delegated by the Point Park University administration the IRB has the authority and responsibility to review research proposals involving human and non-human subjects and to render decisions that approve, or not approve any such research, conducted under the auspices of Point Park University.

Because the Point Park University Institutional Review Board is created by and ultimately a responsibility of the Office of Academic and Student Affairs, the final review and approval of all research proposals resides with the Chief Academic Officer. The Chief Academic Officer’s signature on approved proposals will constitute the final step in granting approval to all research proposals.

1. Purpose

The primary purpose of the Point Park University IRB is to protect the rights, welfare and dignity of all human and non-human subjects recruited to participate in research conducted under the auspices of the University.
2. **Relationship to other faculty committees**

The Point Park University IRB functions independently of but in coordination with other University faculty committees. For example, each school within the University may, but is not required to have its own research committee which reviews protocols before they are submitted to the IRB. The Point Park University IRB and the Chief Academic Officer, however, will render a final decision whether to approve, or disapprove the research proposal based upon the strict protection of the human and non-human subjects recruited to participate in the research.

3. **Scope**

The Point Park University IRB will first determine if the proposal is an actual research study, and secondly, it will determine if such research involves human and non-human subjects. Approval by the IRB of a faculty member’s degree-granting institution shall not be seen as a substitute for the need for approval by the Point Park University IRB where such faculty member is proposing to use the University’s students or staff as research subjects. **Research** is defined by the regulations as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” [Federal Policy § 46.102 (d)]. **Human subjects** are defined by the regulations as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [Federal Policy § 46.102 (f)]. (Section 102(f) goes on to define the meaning of such terms as “intervention” and “private information.”) http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.102.
B. Administration of the Institutional Review Board

1. **Membership** – the following was sourced from United States Department of Health and Human Services Institutional Review Board Guidebook, retrieved from http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

   **Federal Policy Requirements**

   - The Federal Policy [§ 46.107] provides that the IRB must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB must be sufficiently qualified through the experience and expertise of its members and the diversity of their backgrounds, including considerations of their racial and cultural heritage and their sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare to human and non-human subjects.

   - If the IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, the IRB must consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. Department of Education (ED) regulations require, in addition, that when an IRB reviews research for one of its programs that purposefully requires inclusion of handicapped children or mentally disabled persons as research subjects, the IRB must include at least one person primarily concerned with the welfare of these subjects [34 CFR 350.3(d)(2); 34 CFR 356.3(c)(2)].
• The IRB must make every nondiscriminatory effort to ensure that it does not consist entirely of men or entirely of women. Selections must not, however, be made on the basis of gender.

• The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote.

• No IRB member may participate in the review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. Such member may not participate in the discussions, deliberations or voting on any such project.

2. Point Park University IRB Membership

a. IRB Committee Members

The members of the IRB will review research proposals, attend the IRB meetings to discuss whether the proposals meet the necessary requirements and make decisions to approve or not approve the proposals. The Point Park University IRB will be comprised of eleven (11) members:

Eight (8) faculty standing members – two (2) members will be from each of the University’s four schools, and the length of term will be two years. One (1) staff standing member whose area of expertise is research and/or statistical analysis, and his/her length of term will be one year. One (1) at large rotating member will be from the investigator’s content area, per each IRB request.
b. **IRB Staff**

The IRB meeting will be staffed by an individual assigned by the Office of Academic and Student Affairs who will prepare the minutes of the meeting for revision or approval by the IRB Chair. The IRB staff member will oversee the execution of the Committee’s written decisions, including obtaining signatures and sending the written decisions to the investigator.

c. **IRB Chair**

The IRB Chair will oversee the functions of the Committee and provide timely reports to the Point Park University Chief Academic Officer. The Point Park University IRB Chair will be elected by the Committee for a term of two years.

4. **Record Keeping** – in accordance with Federal Policies § 46.115; 46.103; 46.116 (b) (5).

   a. The Point Park University IRB will prepare and maintain timely and accurate documentation of all its activities. Such documentation must include copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects, if any.

   b. The IRB staff member will retain written copies of minutes of the IRB meetings, and an electronic copy will be retained on the University server. All IRB documentation (hard copy and electronic) will be retained for a minimum of seven (7) years.
C. Institutional Responsibilities

1. Communication

a. The Chair of the Point Park University IRB will provide summary reports as agenda items for the Point Park University Faculty Assembly. These reports shall not include details as to the name of the investigator or any other information concerning the nature of the research project or the voting by the members.

b. Written summaries of all research proposals reviewed each academic year will be prepared annually and submitted to the Point Park University Chief Academic Officer.

c. The Point Park University IRB Policies and Procedures will be disseminated to faculty on an annual basis, including forms for submission of research proposals. Also, the Point Park University IRB Policies and Procedures will be accessible on the University’s web page.

d. All matters related to the IRB’s work will be kept confidential and will not be discussed outside officially convened meetings of the IRB.

D. Institutional Procedures and Guidelines

1. Authorized Institutional Official

The Chief Academic Officer of Point Park University or their designee will have the responsibility of providing oversight of the functions of the IRB. Any such designee shall hold the title of the Authorized Institutional Official (AIO) and said person will have the ultimate authority over the functions of the IRB and will work to insure that it functions effectively and protects the rights and welfare of the participants of research conducted at the University. The Chair of the IRB will report directly to the Authorized Institutional Official and provide timely and accurate reports to the AIO on all meetings and
decisions of the IRB.

2. **Required Signatures on the IRB Proposal**
   
a. The department chairperson’s signature or the signature of a tenured faculty member designated by the school’s Dean, on IRB proposals involving students who are conducting research involving human and non-human subjects (students at Point Park University) will be required prior to review of such proposal by the IRB.

b. All faculty and staff members submitting proposals to the IRB who are conducting research involving human or non-human subjects (students at Point Park University) as part of their doctoral degree requirements must obtain the signature of their dissertation chairperson. The dissertation committee chairperson’s signature on the IRB proposal will be obtained before the proposal is submitted to the IRB.

c. All faculty and staff members who are conducting research involving human and non-human subjects (students at Point Park University) as a part of their ongoing professional research endeavors and such research is not being conducted as a component of their doctoral dissertation requirements may submit research proposals directly to the IRB.

3. **Guidelines for the Initial IRB Research Review**
   
a. Upon receipt of fully completed IRB proposals to conduct research, the chairperson of the IRB shall convene a meeting of the IRB Committee to review the proposal. Five of the eleven members of the IRB will constitute a quorum at meetings of the IRB to review research proposals. The IRB chairperson will receive proposals and convene the Committee within thirty (30) days.
b. The IRB chairperson will identify one ad hoc member of the Committee with competencies in the areas of research contained in the proposal to fill the rotating position on the Committee. This ad hoc member may come from either within or outside of Point Park University.

c. A majority vote of those present at a duly convened meeting is required for an official decision of the IRB. The Committee may vote to either:
   i. **Approve as is** the research proposal without any required modifications or changes to the proposal;
   ii. **Approve with modifications** specified by the IRB. A second meeting will be conducted by the IRB after the researcher has made the specified changes to the proposal;
   iii. **Not approved.** The research proposal is rejected as is for reasons that are indicated in the Committee’s written report.

d. The Point Park University IRB will consider the following criteria in reviewing IRB applications:
   i. Real and potential *risks* to the physical, emotional, and/or psychological safety of human and non-human subjects;
   ii. *Respect for the personal dignity* and autonomy of individuals including special protection of those persons with diminished capacities;
   iii. *Beneficence* for human and non-human subjects which is achieved by maximizing the anticipated benefits and minimizing potential risks of harm;
iv. *Informed active consent* from all human subjects. Consent forms that require potential human subjects to sign off if they do not wish to participate in a research study shall not constitute informed active consent;

v. *Feedback* on the findings and significance of the study to all research participants upon completion of the study. Such feedback may be provided in written form, through face-to-face feedback or both;

e. In addition to submitting eleven (11) completed copies of the Point Park University IRB Review Form, the researcher will also provide, where applicable, the following documentation to the IRB:

   i. complete copies of all research instruments;
   ii. consent forms; grant applications;
   iii. recruitment brochures or announcements;
   iv. advertisements that are intended to be seen or heard by potential research participants;
   v. scoring rubrics.

4. **Guidelines for the Continuing IRB Research Review**

   a. Research involving human and non-human subjects that spans more than one academic year shall be required to submit a continuation application to the Point Park University IRB. Such continuation applications are required for each academic year that a research program operates continuously;
b. The IRB chairperson may designate a primary IRB reviewer for all continuation applications. When used, the primary reviewer will conduct an in-depth analysis of the operations of the research program over the past year. The primary reviewer will play a lead role in reviewing the continuation application by the full IRB;

c. Continuing research reviews will include:
   i. a status update on the operation of the research proposal;
   ii. the number of human and non-human research participants to date;
   iii. a description of any modifications to the original proposal;
   iv. a summary of any problems encountered;
   v. a summary of the number of research participants who discontinued their involvement or failed to participate to completion;
   vi. the projected completion date.

II. Attachments

Attachments are intended to be incorporated into this document in entirety.

A. Request for Determination of Non-Human Subject or Non-Research
B. Action Classifications
Request for Determination of Non-Human Subject or Non-Research
(Adapted from University of Maryland, College Park)

1. Principal Investigator’s Name, Email Address, Telephone Number and Mailing Address (Please note that a student cannot serve as a Principal Investigator)

2. Co-Investigator’s Name, Email Address, Telephone Number and Mailing Address

3. Student Investigator’s Name, Email Address, Telephone Number and Mailing Address

4. Department Name

5. Project Title

6. Point Park Proposal Number

7. Study Information
   A. Give a brief description of the project. (Describe the specific objectives, including background information and rationale for the proposed project. This summary should be written in a way that will be intelligible to non-specialists in your specific area).
   B. Describe the subject population/type of data specimens to be studied. (Identify who your subjects will be and indicate the type of data of specimens you will collect. Describe the methods in which the data or specimens will be collected, stored, and how confidentiality will be maintained).

8. Determination of “Research.”

   Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.
A. For existing specimens, was the data/specimen obtained in a systematic manner?
   No ___  Yes ___  NA ___

B. For future data collection, will the data/specimen be obtained in a systematic manner?
   No ___  Yes ___  NA ___

C. Is the project designed to develop or contribute to generalizable knowledge?
   No ___  Yes ___  NA ___

D. Is the intent of the project to create an archive for the purpose of providing a resource for others to do research?
   No ___  Yes ___  NA ___

E. For research involving coded private information or specimens, was the private information or specimens collected specifically for the currently proposed research project through an interaction or intervention with living individuals?
   No ___  Yes ___  NA ___

9. Determination of a “Human Subject”

   Human Subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) 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.

   Interaction includes communication or interpersonal contact between investigator and subject.

   Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order to obtaining the information to constitute research involving human subjects.
A. Does the study involve intervention or interaction with a “human subject?”
   No___  Yes___

B. Does the study involve access to identifiable private information?
   No___  Yes___

C. Are data/specimens received by the investigator with identifiable private information?
   No___  Yes___

D. Are the data/specimens coded such that a link exists that could allow the data/specimen to be re-identified?
   No___  Yes___

10. Signatures

________________________________________  _________________
Principal Investigator     Date

________________________________________  _________________
Student Investigator     Date
Action Classifications

Full Committee meetings are held on a monthly basis to review anything that a primary investigator has to bring before the board. Any research proposal that is brought in front of the IRB will be discussed and classified into one of the following forms of action.

- **Exemption** occurs when the IRB has reviewed the proposal and has concluded that the human and/or non-human subjects are subjected to “minimal risk” and the research being presented is valid. No further investigation is necessary.

- **Expedited** review approval occurs when the board decides that only one IRB member, appointed by Chair, needs to investigate and review the proposal because it proves to have “minimal risk.”

- **Full Review** occurs when the review board feels as though any subjects may be considered at more than minimal risk and the proposal warrants a full and thorough review by the entire board.

Upon review of the research proposal, the Institutional Review Board will respond by

- Approve as is
- Approve with modifications
- Not approved

The decision of the Institutional Review board will stand until the project is changed and reviewed again at a future meeting.