POINT PARK
UNIVERSITY

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.

The Point Park University Institutional Review Board is created by and ultimately a responsibility of the Office of Academic and Student Affairs, **therefore** final review and approval of all research proposals resides with the Provost. The Provost's signature, or that of the Authorized Institutional Official as described in Section D.1, 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 department within the University with a graduate program(s) must designate one or more individual(s) to review protocols before they are submitted to the IRB, but is not required to have its own research committee. The Point Park University IRB and the Provost, 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. A proposal approved by another institution's IRB will not automatically be accepted or approved by the Point Park University IRB. ***Research*** is defined by federal regulations as "a systematic investigation, including research development, testingand 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#46.10 2.

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 members must be sufficiently qualified through experience, expertise, and the diversity of their scholarly 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.
- All members of the IRB must annually complete the Protection of Human Subjects training developed by the National Institute of Health (NIH) Office of Extramural Research. This requirement includes the department designee responsible for signing off on proposals prior to submission to the IRB Board. (https://phrp.nihtraining.com/users/login.php)
- 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, in its discretion, **may** 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.

- Definition of a Conflict of Interest

  A conflict of interest involves the abuse – actual, apparent, or potential – of the trust that people have in professionals. The simplest working definition states: A conflict of interest is a situation in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity. An apparent conflict of interest is one in which a reasonable person would think that the professional's judgment is likely to be compromised. A potential conflict of interest involves a situation that may develop into an actual conflict of interest. It is important to note that a conflict of interest exists whether or not decisions are affected

by a personal interest; a conflict of interest implies only the potential for bias, not a likelihood. It is also important to note that a conflict of interest is not considered misconduct in research, since the definition for misconduct is current limited to fabrication, falsification, and plagiarism.

There are many varieties of conflicts of interest, and they appear in different settings and across all disciplines. While conflicts of interest apply to a "wide range of behaviors and circumstances", they all involve the use of a person's authority for personal and/or financial gain. Conflicts of interest may involve individuals as well as institutions. Furthermore, individuals, in certain circumstances, may have conflicts occurring on both an individual and an institutional level, as may be seen among members of an Institutional Review Board (IRB).

Conflicts of interest are broadly divided into two categories: intangible, i.e., those involving academic activities and scholarship; and tangible, i.e., those involving financial relationships.

Further information can be found at: http://ori.hhs.gov/education/products/columbia_wbt/rcr_conflicts/foundation/

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 comprise ten (10) members:

One (1) Faculty Chair of the IRB Board.

Eight (8) faculty standing members – each member must have taught at the master's level for at least two years, must have a terminal degree and be qualified to teach doctoral classes and must come from those academic departments that have graduate program(s).

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) invited guest without voting privileges may be invited from the investigators content area to support the proposal per the IRB request.

b. **IRB Support Staff Role**

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 principal investigator and in the case of student researchers, the advising faculty member. Additionally, they will maintain all records and generate reports as required with the assistance of the IRB Chair.

c. **IRB Faculty Chair Role**

The IRB Chair will oversee the functions of the Committee and provide timely reports to the Point Park University Provost. The Point Park University IRB Chair will be appointed by the Provost. This role has a term limit 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 Provost.

c. The Chair of the IRB will communicate to the primary investigator the results of a proposal if a full committee review is required. If an expedited proposal, the committee member who conducted the review will communicate to the primary investigator the results of the proposal. This review will include the specific details of modifications or changes if they are being requested.

d. 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.

e. 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 Provost of Point Park University or his/her designee, the Chair of the IRB Committee, will have the responsibility of providing oversight of the functions of the IRB. The IRB Chair 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 Provost and provide timely and accurate reports on all meetings and decisions of the IRB.

2. Required Signatures on the IRB Proposal

a. The signature of the faculty sponsor, the graduate program director or the doctoral program director and the department's IRB designee is required for all IRB proposals involving students who are conducting research involving human and non-human subjects at Point Park University. These signatures are required prior to review of such proposal by the IRB.

b. All students, faculty and staff members submitting proposals to the IRB who are conducting research involving human or non-human subjects 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 students, 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. For staff members, the signatures of the individual overseeing the academic/administrative department and the standing staff member of the IRB are required.

d. The primary investigator must attach a copy of the certificate received at the completion of the NIH Human Subjects training to the proposal.

e. Chairs of dissertation and thesis committee heads must attach their own certification of completion of the NIH training to the investigators proposal. These will be retained on file by the IRB Support Staff so that Chair copies are not required for future submissions.

3. Guidelines for the Initial IRB Research Review

a. Upon receipt of IRB proposals requiring the IRB committee to hold a full review, the chairperson of the IRB shall convene a meeting of the IRB Committee to review the proposal. Four of the ten members of the IRB will constitute a quorum at meetings of the IRB to review research proposals requiring full review. The IRB chairperson will receive proposals and convene the Committee within thirty (30) days. Roberts Rules of Order will provide the structure to the board meetings.

b. The IRB chairperson **may** identify one ad hoc member of the Committee with competencies in the areas of research.

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 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.

Attachment A: 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)

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

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

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4. **Department Name**

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5. **Project Title**

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6. **Point Park Proposal Number**

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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).

Attachment A: Request for Determination of Non-Human Subject or Non-Research
(Continued)

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___

Attachment A: Request for Determination of Non-Human Subject or Non-Research
(Continued)

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 obtain 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___

Attachment A: Request for Determination of Non-Human Subject or Non-Research
(Continued)

10. Signatures

Principal Investigator	**Date**
Student Investigator	**Date**

Attachment B: 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.

Attachment B: Action Classifications (Continued)

Exempt Review

Exempt review means that the review can be completed by the IRB Chair or assigned member of the committee rather than a full board. To be eligible for an Exempt Review, the research must meet two established criteria as defined by Federal Regulations [45CFR 46.101(b)(1-6)]. 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.

First, the research may not involve more than "minimal risk". "Minimal risk" is defined as "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.

Second, the research must reside within one or more of the six established categories of human subjects research that are exempt from other provisions of the federal regulations. Specific conditions related to these categories can be found at: *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101*

1. Research will be conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, **unless** the subjects can be identified directly or through identifiers linked to the subjects **and** disclosure of responses could reasonably place the subjects at risk or criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.

3. Research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under item (2) above, **if** (a) the subjects are elected or appointed public officials or candidates for public office; **or** (b) Federal statute(s) require(s) that the confidentiality or other personally identifiable information will be maintained throughout the research and thereafter.

4. Research will involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

Attachment B: Action Classifications (Continued)

5. Research and demonstration projects which are conducted by or subject to the approval of federal agency sponsoring the research, and which are designed to study, evaluate or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under those programs, (c) possible changes in or alternatives to those programs or procedures, or (d) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, if (a) wholesome foods without additives are consumed, or if (b) a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

It is important to note that current federal regulations state that any study approved under Exempt procedures does not have an expiration date, however, Point Park University requires ongoing research to obtain a new approval letter annually.

Expedited Review

An Expedited review allows the review of a research proposal to be completed by the IRB Chair or assigned member of the committee rather than a full board. To be eligible for an Expedited Review, the research must meet two established criteria as defined by Federal Regulations [45 CFR 46.110] and [21 CFR 56.110]. 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.

First, the research may not involve more than "minimal risk". "Minimal risk" is defined as "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.

Second, the research must reside within one or more of the nine established categories that IRBs may use to invoke the expedited review process. Please review the specific conditions related to these categories at: *http://www.hhs.gov/ohrp/policy/expedited98.html*

Attachment B: Action Classifications (Continued)

1. Continuing review of research previously approved by a convened IRB under certain conditions. 2. Clinical Studies of Drugs / Medical Devices under certain conditions. 3. Collection of Blood Samples by finger stick, ear stick, venipuncture within certain segments of population. 4. Prospective collection of Biological specimens by noninvasive means 5. Collection of data through noninvasive procedures routinely employed in clinical practice.	6. Research involving materials that have been collected, or will be collected solely for non-research purpose. 7. Collection of data from voice, video, digital, or image recordings for research. 8. Research on individual or group behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the above categories do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than a minimal risk and no additional risks have been identified.	

Attachment B: Action Classifications (Continued)

Full Board Review

Full Board review is required of all studies that are not eligible for either an Expedited or Exempt review. Generally, these studies involve greater than minimal risk to participants or include one or more category of vulnerable populations as defined by Federal regulations. More specifically, the IRB is particularly concerned with research involving the following:

1. Subjects under the age of 18;
2. Pregnant subjects;
3. Elderly subjects;
4. Socially / Economically deprived populations;
5. Incarcerated subjects or persons under a correctional sentence (parolees);
6. Mentally impaired subjects;
7. False or misleading information to subjects;
8. Withholding information such that subjects' consent is in question;
9. Procedures for debriefing subjects;
10. Biomedical procedures;
11. Procedures that are novel or not accepted practice;
12. Risky procedures or harmful effects, including discomfort, risk of injury, invasive procedures, vulnerability to harassment, invasion of privacy, controversial information, or information creating legal vulnerability