

Point Park University Institutional Review Board
for the Protection of Human Subjects

Institutional Review Board Protocol

Investigators

Principal Investigator

_____	_____
Name	Department
_____	_____
Position/Rank	Email address
_____	_____
Daytime phone	Name of Institution

address	

Co-Investigator(s) (e.g. thesis/dissertation committee chair; faculty sponsor, use a second sheet for any additional names)

_____	_____
Name	Department
_____	_____
Position/Rank	Email address
_____	_____
Daytime phone	Name of Institution

address	

Co-Investigator(s) (e.g. thesis/dissertation committee chair; faculty sponsor, use a second sheet for any additional names)

_____	_____
Name	Department
_____	_____
Position/Rank	Email address
_____	_____
Daytime phone	Name of Institution

address	

Collaborating Institutions

2. Are you collaborating with someone from another institution?

yes no

If “Yes”, in what capacity (e.g. CoPI’s, or other ...)

3. Has this project been subjected to IRB review at another Institution?

yes no

If “Yes”, provide a copy of the determination letter from that IRB review.

Project Description

Purpose of the study

Characteristics of the Subject Population

Approximately, how many participants will be enrolled?

Age Range

Gender

Inclusion Criteria / Exclusion Criteria

Protected Populations and Sensitive Subjects

Indicate if any Human Subjects from the following list would be involved in the proposed research:

<input type="checkbox"/>	minors	<input type="checkbox"/>	fetuses	<input type="checkbox"/>	pregnant women
<input type="checkbox"/>	test subjects for new drugs or clinical devices	<input type="checkbox"/>	abortuses	<input type="checkbox"/>	persons committing illegal behavior
<input type="checkbox"/>	educationally or economically disadvantaged persons	<input type="checkbox"/>	incarcerated	<input type="checkbox"/>	mentally disabled

NOTE: The inclusion of vulnerable populations will require a review by the full IRB committee.

If included, please describe any protected populations or special subjects that will be included within the proposed study, and how their rights will be safe guarded.

METHODS AND PROCEDURES

Method of Subject Selection

Study Site(s)

Methods and Procedures Applied to Human Subjects

RISKS/BENEFITS

In your judgment, does your research involve more than minimal risk? Indicate your response with an 'X' in the appropriate box

yes no

Potential Risks

Protection against Risks

Potential Benefits

Economic Consideration

CONFIDENTIALITY

INFORMED CONSENT

CONFLICT OF INTEREST

ENCLOSURES

Document name/description	Number of pages

Certification Page

Primary Investigator

I am aware that additions to or changes in procedures involving human subjects as well as any problems connected with the use of human subjects once the project has begun must be brought to the attention of the IRB.

I agree to provide whatever surveillance is necessary to ensure that the rights and welfare of the human subjects are properly protected. I understand that I cannot initiate any contact with human subjects before I have received approval/or complied with all contingencies made in connection with the approval. I understand that as the principal investigator I am ultimately responsible for the welfare and protection of human subjects and will carry out the project as approved.

Signature, Principal Investigator

date

Approval by Faculty Sponsor, Graduate Program Director or Doctoral Program Director for student research.

I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research and supervision of human subjects as required by law.

Signature and Title

date

Approval by Department Designee

I affirm the accuracy of this application, and it meets the standards required by the Point Park University IRB guidelines.

Signature, Department Designee

date

POINT PARK UNIVERSITY
IRB Committee Decision

Approved **Not Approved** **to proceed**

Approved with
Modifications _____

Signature

Date