Research Proposal # \_\_\_\_\_\_\_\_\_

(board use only)

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 | | |

**Protection of Human Subjects Certification**

1. Have you completed the Protection of Human Subjects training offered by the National Institute of Health (NIH) – Office of Extramural Research?

|  |  |  |  |
| --- | --- | --- | --- |
|  | yes |  | no |

Please include a copy of your Certification of Completion with this IRB proposal.

**Project Information**

|  |  |
| --- | --- |
| **Date of Submission** |  |

|  |  |
| --- | --- |
| **Project Title** |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Project Type** (check one) | Masters  Thesis |  | Dissertation |  | Faculty Research |  | Undergrad Research |  | Grad  Research |  | Staff Research |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **The project will be conducted from** |  | **until** |  |
|  | Start date |  | Ending date |

**Action Classification:** Please select one of the following.

|  |  |
| --- | --- |
|  | **Exemption** |
|  | **Expedited** |
|  | **Full Review** |

**Project Funding Sources (s).** Indicate all that apply:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **External Grant** | | **Agency Name:** | | |  |
|  | **PPU Grant** | **Type:** | |  | | |
|  | **Other (describe)** | |  | | | |
|  | **Non-funded research** | | | |  | |

|  |  |
| --- | --- |
| **If grant funded,** application deadline or date of transmittal  **(Note**: Submit one copy of grant proposal as soon as it is available) |  |

**Collaborating Institutions**

1. Are you collaborating with someone from another institution?

|  |  |  |  |
| --- | --- | --- | --- |
|  | yes |  | no |

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

|  |
| --- |
|  |

1. 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:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | minors |  | fetuses |  | pregnant women |
|  | test subjects for new drugs or clinical devices |  | abortuses |  | persons committing illegal behavior |
|  | educationally or economically disadvantaged persons |  | incarcerated |  | 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 HumanSubjects

|  |
| --- |
|  |

**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 |