 Institutional Review Board (IRB)

APPLICATION FOR APPROVAL FOR USE OF HUMAN PARTICIPANTS IN RESEARCH

**Instructions:** Please complete this application form if you are planning to conduct research involving human participants. Saint Peter’s University rules and regulations prohibit the start of any research that has not been approved by the SPU Institutional Review Board (IRB). Principal investigators who are SPU students must have a SPU faculty mentor in order to conduct research. Principal investigators who are not affiliated with Saint Peter’s University must have a SPU faculty sponsor in order to do research at SPU.

**I. Principal Investigator**

Name:

Project Title:

Email Address:

Telephone:

School/College: Department:

Type of project:

 New Continuation Renewal Change in procedure in approved project

Estimated timeline for project: Start Date: End Date:

Type of Review Requested Exempt Expedited Full Review

Note: Final Review Status to be determined by IRB.

Research training tutorial: NIH CITI

Date research training completed:

Note: Please attach copy of training certificate.

Funding source/agency (if applicable):

Relationship to Saint Peter’s University: Faculty Student Admin Non-SPU

Note: Project cannot begin before IRB approval is received.

**II. Additional Research Personnel**

Co-Investigator(s):

 Faculty Mentor:

 Required for SPU undergraduate, masters, or doctoral students.

 SPU Sponsor:

 Required for non-SPU affiliated researcher.

Note: SPU Faculty Mentors must submit appropriate dissertation/project approval form. SPU Sponsors must provide SPU site-approval letter. These documents are to be included with the IRB application.

**III. Description of Research**

1. Give a complete description of the nature and purpose of this research.

2. Describe in detail all procedures to which the human participants will be subjected. (Include a specific description of any equipment or instruments to be used and how participants will be involved). In addition, indicate if there are any conflicts of interest and how they will be addressed

3. Check **ALL** the different procedures to be used in this study:

 Questionnaires/surveys

 Interviews

 Audiotaping/videotaping

 Social or behavioral intervention

 Medical or nursing intervention

 Review of records

 Mechanical devices

 Data collection using the internet

 Observation of participants

 Other, please specify:

4. Attach copies of all questionnaires, surveys, interview questions, etc. If the research involves interviews that may evolve as the research progresses, include a list of discussion topics and any starter questions for each topic to be discussed.

5. Will your research involve any of the following?

 a. Deception, incomplete disclosure to participants Yes No

 b. Administration of drugs Yes No

 c. Induction of mental and/or physical stress Yes No

 d. Covert observation Yes No

 e. Information on sexual attitudes, preferences, or practices Yes No

 f. Information on alcohol or drug use Yes No

 g. Information pertaining to illegal behavior Yes No

 h. Genetic information Yes No

 i. Information regarding patient’s medical records Yes No

 j. Information regarding a student’s educational records Yes No

 k. Information pertaining to a person’s psychological health Yes No

 l. Procedures that may be regarded as an invasion of privacy Yes No

 m. Information that could damage an individual’s reputation Yes No

6. If you checked **YES** for any item in question 5 above, provide justification. Describe the precautions that will be used to protect privacy and minimize risks to participants.

**IV. Research Location**

1. Describe the location(s) in which the research will be conducted (e.g., school, clinic, hospital, etc.).

2. List all SPU sites where the research will be conducted. For each site explain how the investigator has access to a population that would allow recruitment of the participants.

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3. List all non-SPU sites where the research will be conducted, including contact information for each site. For each site, explain how the investigator has access to a population that would allow recruitment of participants.

4. If the primary site for the research is **not** Saint Peter’s University (SPU), you must provide site approval letter and IRB approval (if the site has one) before this application can be approved. Conditional approval may be granted in special circumstances pending site approval and/or site IRB approval confirmation.

**V. Participant Population**

1. The research involves the following (check all that apply):

 Adults

 Prisoners

 Pregnant Woman, Fetuses, or Neonates

 Cognitively Impaired

 Children--0-7 years old (parental consent and oral assent, as appropriate)

 Children--8-17 years old (parental and written assent required)

 Students--18 years old and above (consent form required)

 SPU students (consent form and student addendum required)

2. State the total number of participants expected and relevant demographic breakdowns if applicable:

3. Will participants be screened to include or exclude based on:

 Gender Ethnicity Race Other (specify)\_\_\_\_\_\_\_\_

4. If participants will be screened based on gender, ethnicity, race, and/or other, provide justification.

5. Estimate how much time will be required of each participant.

6. State if the participants will be compensated, and if so, how.

**VI. Recruitment of Participants**

1. Describe how participants will be recruited for participation in this research. Specify whether there are conflicts of interest and/or potential for undue pressure to participate and how it will be mitigated.

2. Which of the following recruitment tools will be used?

 Flyers and/or posters

 Letters

 Emails

 Telephone

 Internet

 Newspaper

 In person request

 Other tools

Please explain:

3. Attach copies of all proposed flyers, posters, letters, emails, pamphlets, print advertisements, phone scripts, etc. All recruitment materials must be approved by the IRB prior to use.

**VII. Description of Risks**

1. Describe any physical risks that may be faced by participants, and the measures that will be used to minimize these risks.

2. Describe any psychological risks that may be faced by participants, and the measures that will be used to minimize these risks.

3. Describe any social risks that may be faced by participants, and the measures that will be used to minimize these risks.

4. Do you believe that this research poses only minimal risk to the participant?

Note: According to DHHS Regulations “minimal risk” means: “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.”

Yes No

5. If you answered **NO** to question 4 above, specify the nature of the greater than minimal risk. Describe all possible harms and your plan to mitigate these harms in order to ensure the safety of participants.

6. Explain your plan for dealing with adverse events and unanticipated problems involving greater than minimal risk participants.

**VIII. Description of Benefits**

1. Describe the potential benefits of this study, if any, to the participant, as well as to the class of participants (e.g., computer users), the community, and/or general scientific knowledge.

2. If the risk in this study is greater than minimal risk, explain how the risks are reasonable in relation to the expected benefits either to the participant, to others, or to the scientific community.

**IX. Informed Consent**

Voluntary and informed consent is necessary for all research involving human participants and must be documented in some manner. The investigator may determine which method of documenting consent is in the best interest of the participant population, but the SPU IRB reserves the right to require alternative and/or more stringent means of documenting consent.

1. Which of the following apply to this research?

 Informed consent will be obtained from all participants and documented with a signed, written consent form.

Implied consent will be obtained from participants, but no signed consent form will be used, as in the completing of an on-line survey.

Parental consent will be obtained, along with the appropriate assent for children, as per section V, question 1 above.

Fully informed consent will not be obtained from all participants. Investigator seeks a waiver of consent requirement.

Explain reasons for request of waiver.

2. How will the participant’s informed consent be documented in this study?

3. Describe the circumstances under which consent will be obtained and by whom?

4. Please see the **Informed Consent Guidelines** for the required elements of informed consent that should be included in any consent form. A copy of the appropriate Consent Form(s) must be attached to this application.

**X. Confidentiality**

1. Explain provisions to protect the confidentiality and privacy interests of participants.

2. Describe the procedures you will use to secure and protect your collected data during the course of your research.

3. State whether any data that identifies individual participants will be stored, published, or in any way disclosed to third parties.

4. State how long the collected data will be stored.

5. Explain whether you anticipate using any data from this study for future studies and why. Note: this information must be included in any consent form.

6. Describe your plan for the disposing (or storing) of your data after you have completed your project.

**XI. Adverse Events Reporting**

1. All adverse events and unanticipated events must be reported to the Saint Peter’s University IRB within three business days of the event or problem. To send a report, use Adverse Events Form.

**XII. Certification and Signatures**

**Principal Investigator:**

**I (we) certify that I am (we are) aware of the ethical guidelines set forth by the Department of Health and Human Services, and the policies and principles of Saint Peter’s University with respect to research involving human participants and reaffirm my commitment to the principles and regulations set forth therein. I (we) will conduct the study identified above according to the stated and approved protocols. If I (we) decide to make any changes in the procedures, or if any participant is injured, or if any problems occur which involve risk to participants or others, I (we) will immediately notify and inform the SPU IRB.**

**Print your name: Date:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Co-Investigator:**

**Print your name: Date:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Faculty Mentor** *(If the investigator is a student, faculty mentor must sign below)*:

**I certify that I am aware of the ethical guidelines set forth by the Department of Health and Human Services, and the policies and principles of Saint Peter’s University with respect to research involving human participants and reaffirm my commitment to the principles and regulations set forth therein. I have read and approve of this protocol. I believe that this is appropriate scientific research as defined by the DHHS (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that the student is competent to conduct the research as described herein.**

**Print your name: Date:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Please attach student research approval document. Student research will not be approved without faculty mentor approval.

**Faculty Sponsor** *(If the investigator is not affiliated with SPU, faculty sponsor must sign below)*:

**I certify that I am aware of the ethical guidelines set forth by the Department of Health and Human Services, and the policies and principles of Saint Peter’s University with respect to research involving human participants and reaffirm my commitment to the principles and regulations set forth therein. I believe that this is appropriate scientific research as defined by the DHHS (i.e., a systematic investigation designed to develop or contribute to generalizable knowledge) and that this investigator is competent to conduct the research as described herein.**

**Print your name: Date:**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Please attach sponsor certification and on-site approval document.

**Please save a copy of this form for your records. Submit the completed application form, along with all attachments, by email to jfeinberg@saintpeters.edu and send one printed copy, with all attachments and signatures, to IRB Office, Pope Hall 101. Electronic copy will be considered official submission.**

**If mailing hard copy:**

**Office of IRB Saint Peter’s University**

**Attn: Joshua Feinberg; Psychology Department Pope 101**

**2641 Kennedy Blvd**

**Jersey City, NJ 07306**