Project Title:

Initial  Revised  Revision Date, if applicable:

1. **Name of Principal Investigator (PI)**

Email:       @shu.edu **or**        @student.shu.edu Phone Number:

Primary/preferred mailing address:     

1. **Academic Degree(s) of PI**:

**List any applicable certifications, licenses and credentials**:

1. **Name of PI’s academic department:**
2. **The PI is a**:  Faculty  Doctoral Student Graduate Student
3. **The study is**:  Master’s Thesis  Doctoral Dissertation  Faculty Research  Other Research
4. **If the PI is a doctoral/graduate student, list the name of the primary faculty mentor**:

Name:       Department:       Email:       Office Phone:

*Note: This faculty member will be copied on all official correspondence from the Seton Hall University*

*Institutional Review Board*

1. **Is/Are there Co-PI (s)?**

Yes  No

If yes, please list:  Name:       Department:

1. **Is this study funded? If so, by whom:**

This study is not funded.

Private Nonprofit, please specify:

An Industry Sponsor, please specify:

State or Local Government Entity, please specify:

Federal Agency, please specify:

A Seton Hall University program/initiative, please specify:

1. **Where will the research study be performed?**

Seton Hall University- South Orange campus

Seton Hall University- Interprofessional Health Sciences campus

Off-site venue(s). Please provide the name(s) and location of the site. A copy of the form(s) authorizing

work to be performed at the site(s), must be included at the time of IRB submission. Your application

will be returned without review if it is submitted without this form.

**List the PI and study personnel who will be assisting in the performance of the research.**

|  |  |  |  |
| --- | --- | --- | --- |
| Study Team Members | Degree(s) and credential(s) | Project Role (Co-Inv., Research Coordinator, Research Assistant, Student Researcher, Faculty Member, Dissertation/Thesis Advisor/Committee Member) | Date of Latest CITI Training (mm/yy) |
| **PI**: |  | **PI** |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Financial Conflict of Interest (COI) disclosures**

*Note: Each person listed in the table above must complete and submit a financial conflict of interest form and be summarized below*.

|  |  |  |
| --- | --- | --- |
| Study Team Members | Does the member possess a financial conflict of interest as outlined in the associated documents with the proposed work to be performed? | |
| **PI**: | Yes | No |
|  | Yes | No |
|  | Yes | No |
|  | Yes | No |
|  | Yes | No |

**Project Overview**

1. **What are the anticipated start and end dates of the study?**       to
2. **Provide a brief justification for any study with a proposed duration less than 1 year and more than 3 years.**
3. **What is the purpose of the study?**

1. **What are the research questions/aims?**

1. **What are the study hypotheses (for quantitative or mixed quantitative and qualitative study designs)?**

1. **What is the study rationale?** *(Note: this is different from the study purpose and review of literature. Why does the study have to be performed? What gaps of knowledge exist? What knowledge may be gained?)*

1. **Using no more than 250 words, provide a brief abstract about the study in non-technical terms; include the number of visits and expected length of the participant’s engagement with the study procedures.**

1. **How do you anticipate the study results to be used?** *(Check all that can conceivably apply)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Petersheim Academic Exposition |  | Scientific conference |  | Manuscript submission to a peer-reviewed journal |
|  | Dr. George Perez Research Colloquium |  | Academic conference |  | Thesis/Dissertation document to be stored in a digital repository |
|  | On-campus oral defense |  | Other *(Specify):* | | |

1. **What methods will be used in the project?** *(Check all that apply)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Audio Recording |  | Behavioral Observations |  | Chart Reviews |
|  | Control Group |  | Double-Blind |  | Evaluation |
|  | Focus Groups |  | Intervention |  | Interview |
|  | Non-invasive |  | Placebo |  | Randomization |
|  | Specimen Collection |  | Surveys/Questionnaires |  | Video Recording |
|  | Other *(Specify):* |  | | | |

1. **Provide a detailed description of the study design and procedures that will be used.**

1. **For the procedures just listed, indicate which study team member will perform them.**

|  |  |  |
| --- | --- | --- |
| Procedure: | Performed by which study team member: | # of times it is performed within a visit during the study |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

1. **For each study team member listed, provide a brief description of the training received/skills necessary to perform each procedure.**

1. **Will biological specimens be used/collected in this protocol?**

No  Yes

If yes, please describe what is being collected, how and where they will be stored, and when/where they will be processed:

1. **Provide a detailed explanation for how the data will be processed after collection and the measures taken to ensure anonymity of the participants.** *Consider the following: Are audio/video recordings from interviews transcribed? What will the rater review these records for to aid in answering the research question? Will digital data be entered and processed using a specific software? If a survey creates composite scores, how will this be done? Are the data coded? Databases created in aggregate?*

1. **Describe the statistical analysis.**

1. **Will deception be used?**

No  Yes

If yes, please provide the rationale for this approach:

1. Will debriefing procedures be used in this study?

No  Yes

If yes, please describe the procedures:

1. **Is follow-up with participants anticipated?**

No  Yes

If yes, please describe the reason(s):

1. **Describe from where and how potential study participants will be identified?**

1. **How do you have access to this population?** [*Please reference any professional or research arrangements that permit your access. If you belong to a professional organization and are accessing a non-public directory with names and email addresses of members for an e-mail-based survey, indicate whether or not you require advance approval to use the directory for the purposes of recruitment (include proof of authorization). If you are using a social media platform and are part of a special board or group, the respective site will have terms of use; you must indicate that you’ve reviewed these terms and will comply with the stipulations*]*.*

1. Describe the recruitment strategy for the just, fair, and equitable recruitment and selection of participants:

1. **Do you have an existing relationship with the potential participants that may subject them to risk of undue influence, coercion or reprisal for not volunteering to participate? This includes relationships such as infaculty-student, faculty-advisee, or supervisor-subordinate.**

No  Yes

If yes, please explain the steps and measures in the recruitment and/or enrollment process that will be used to minimize this risk and ensure that question 10 above is reflective of these approaches.

1. **Will participants receive compensation in this study**?

No  Yes

If yes, describe the form of payment (e.g., check request, gift card, other), schedule of payments (e.g., after each visit, or one lump payment):

1. Describe how the amount of compensation was determined.
2. Where are the funds coming from for this payment?
3. What is your expected study enrollment?

1. **How did you arrive at this number?** This may include a sample size estimation from empirically-derived data, or an approach to reach saturation.

1. **What is the age range of participants?** *(Check all that apply.)*

|  |  |
| --- | --- |
| Children Under 18 years old |  |
| Young Adults (18-21) |  |
| Adults (22-65) |  |
| Seniors (Over 65) |  |

1. List the study inclusion criteria.

1. List the study exclusion criteria. *(Note: If you are excluding women or minorities from your subject pool, you must include a scientific or methodological justification for such exclusions).*

1. Does this project target enrollment to a specific race, gender or ethnic group as participants*? (Note: this question assists in the determination of whether or not the study may contribute to generalizable knowledge in the respective field).*

No Yes

If yes, indicate which group and the rationale for why this group is being targeted as the primary study population*:*

1. Will the project enroll participants from any of the following populations? *Note: These populations must be checked “Yes” if they are not being excluded from the research. If they are being excluded, then they must appear in the study exclusion criteria.*

Yes No

|  |  |  |
| --- | --- | --- |
| a. Employees |  |  |
| b. Students |  |  |
| c Individuals with impaired decision-making capacity *(See below)* |  |  |
| d. Pregnant women |  |  |
| e. Economically and/or educationally disadvantaged persons |  |  |
| f. Prisoners |  |  |
| g. Illiterate, limited, or no English language proficiency |  |  |
| h. Children <18 years *(See below)* |  |  |

*Additional Form Requirement:* If individuals with impaired decision-making capacity are being enrolled, please include Legally Authorized Representative signature page in consent. If children <18 years of age are being enrolled, you will need to include an oral assent script and a parental permission/consent form with child assent form.

1. **What type of data will be received/used by the Principal Investigator/ study team?**

*Check all that apply:*

**De-identified** – Data does not contain any identifiers that could link the data to a specific

participant. *Data must be de-identified in accordance with HIPAA and Common Rule criteria. Scrambling of names and social security numbers is not considered de-identified information.*

**Identified** – Data contains direct identifiers sufficient to identify participants.  *If this box is selected,*

*you must include a HIPAA Authorization Form.*

**Coded** – Data linked to a specific subject by a code rather than a direct identifier. While the data may

contain some protected health information only someone possessing the code can link the

data to a particular participant. If this is selected, specify how the linking document between the participant and code, or the code will be maintained, and list each member of the study team who will have access to the link or code:

1. Describe any equipment items that will come into contact with participants. Include the manufacturer name and model, as well as a description of its general function and your proposed use.

1. **Describe any software programs that will be used in the collection of data or analyses of results and outcomes.**

1. **Will any web-based applications be used during the recruitment of participants, in the collection of data, or analyses of results and outcomes?**

No Yes

If yes, name the applications.

1. **Will mobile devices be used during the study to collect data (e.g., laptops, smart phones, tablet, video/audio recorders)?**

No Yes

If yes, indicate if there are sign-on procedures to access the device or encryption and how data will be labeled for temporary storage (e.g., must be in compliance with question #31).

1. **Please describe how electronic data (e.g., raw, processes, databases), and paper and source documents will be stored. If data are being stored electronically, are they encrypted?**

1. **If you are a student and this project is part of a degree requirement, describe the process for how the data will be stored upon graduation.**

1. **Will data be retained for use in future studies?**

No Yes

If yes, indicate how data will be stored, who will store them and how long they will be retained for this purpose.

**Review of Literature**

Using citations from the professional/scientific literature, provide an appropriate review of contemporary knowledge related to your proposal. This should not exceed 2 pages. If the PI is a student researcher, you should not cut and paste chapters from your dissertation documents into this section. Non-compliance with this request may result in your application being returned without review.

**References/Bibliography**

**Potential Study Risks and Risks/Benefit Analysis**

1. **Indicate the potential risk level of the project:** *(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.” [45.CFR.46.102(j)]. The IRB will make the final determination on the study’s risk level.*  Minimal Risk  Greater than Minimal Risk

1. **Based on this definition, please define the potential sources of risk that participants in your project will be exposed to.** *(Note: risks can be physical, psychological, financial, social or legal. They may also involve breaches of confidentiality and privacy).*

*List in bullet or number format.*

1. **What are the anticipated benefits, if any, to participants or to society from this project?**

*List in bullet or number format.*

1. **Provide a brief explanation describing the process and criterion to withdraw or terminate participants from the study by investigators, or, why there is no need for this type of procedure.**

**Informed Consent Process**

1. **Will written informed consent be obtained directly from all participants?**

Yes  No

If **no*,*** will there be the use of surrogate consent (e.g., legally-authorized representative, parental consent/permission, child assent)? Yes  No , please describe the process to obtain consent

1. **Will the project involve requesting any waiver or alteration of the consent process or a waiver of documentation of consent for any part of the project?** *(Note: the standard process for consent in human subjects research is through written informed consent. If your study includes any mode of consent outside of that process, a waiver or alteration of the consent process is required).*

Yes  *(If both options in question #1 are selected No)*  No  *Skip to question 3.*

**If yes, check one or more of the following boxes and submit the applicable waiver request(s)*.***

|  |  |
| --- | --- |
|  | Waiver of informed consent for the entire study. |
|  | An alteration of the informed consent process. *Note: If deception is involved this box should be checked.* |
|  | Waiver of documentation of informed consent (in the case of electronic surveys, or implied consent where data are anonymous). |

The Code of Federal Regulations Title 45, Part 46.116 (d) ONLY permits an IRB to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent if four very specific criteria are met. Your request will be considered on a case-by-case basis. If any of the boxes in the previous table were checked yes, please answer the following questions:

1. Does the research present **more** than minimal risk of harm to the subject? Yes  No
2. Will the waiver adversely affect the rights and welfare of the subjects? Yes  No
3. Can the research be practicably carried out without the waiver? Yes  No
4. Will the subjects be provided with additional pertinent information after participation, whenever appropriate? Yes  No
5. Indicate why the research could not be practicably carried out without the waiver (*Example: if anonymous data are being collected via an electronic survey, then the proposed research cannot be completed without a waiver of informed consent or a waiver of documentation of informed consent. As an alternative to obtaining informed consent, the submission of the electronic survey implies that the anonymous participant agrees to participate in the study.*):

1. **Does the project propose the use of assent for participants unable to give informed consent?**

Yes  *See below*  No

If yes, describe the process for obtaining assent**:**

**Use of Protected Health Information and HIPAA Requirements**

1. **Check which of the following HIPAA identifiers will be collected and recorded during the course of the study:**

|  |  |  |
| --- | --- | --- |
| Names | Social security numbers or scrambled SSNs | Device identifiers and serial numbers |
| Geographic information including city, state and zip | Medical record numbers | Web URLs (Universal Resource Locator) |
| Elements of dates | Health plan beneficiary numbers | IP Addresses (Internet Protocol |
| Telephone numbers | Account numbers | Biometric Identifiers (finger and voice print) |
| Fax numbers | Certificate or license numbers | Full face and comparable photo images |
| E-mail addresses | Vehicle ID and serial numbers including license plate numbers | Other unique identifying number, characteristic, or code |

* If **ANY** boxes above are checked and you are obtaining written informed consent from each participant, please include a HIPAA authorization form with the application.
* If **ANY** boxes above are checked and you are requesting a waiver or alteration of the consent process or a waiver of documentation of consent for any part of the project, please complete the questions for a HIPAA Waiver of Authorization in the next section.
* If **NO** boxes above are checked, No HIPAA form is needed.

**Request for a HIPAA Waiver of Authorization**

1. This is a request to use identifiable information in the conduct of this research study under a waiver of authorization. The identifiable information being requested is: (*list with specificity*)
2. The identifiable information will be used or disclosed only by members of the research team and the following persons *(identify with specificity the information to be disclosed from question #1 and justify the need to disclose the information to anyone not on the study team).*
3. The proposed study poses minimal risk to the privacy of the subjects because:
4. The identifiable information will be protected from improper use or disclosure by: *(detail how this will be accomplished including limitations of physical or electronic access to the information and other protections)*
5. The identifiers will be destroyed at the earliest opportunity consistent with the research *(discuss the timeframe or the reasons the identifiers must be retained, including health or research justifications or any legal requirement to retain them)*
6. The identifiable information will not be reused or disclosed to any other person or entity other than those identified in the protocol, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB.
7. The proposed study cannot be practicably conducted without a waiver of authorization because: *(discuss reasons why it would not be possible to obtain authorization from individual subjects)*
8. The proposed study cannot be done without the specified identifiable information because: *(discuss reasons why it would not be possible to conduct the research without the identifiable information being requested)*

**Seton Hall University Institutional Review Board Submission Checklist**

The following items must be included in the application and appear IN THE FOLLOWING ORDER:

A fully completed Pre-IRB form

A fully completed Request for Approval form

A fully complete Institutional Review Board Application for a New Human Subjects Research Investigation

Informed Consent Form/Assent Form/Verbal Assent Procedure or Script (if not requesting a Waiver or Alteration of the Informed Consent process). You must use one at least one of the informed consent form templates that are available. In you are using a non-English translation, you must include an official certificate of accuracy for translations into non-English languages, etc.

A HIPAA Authorization form (if not requesting a waiver of HIPAA Authorization in this application)

If applicable, solicitation/recruitment letter, flyers, advertisements, verbal script

Financial Conflict of Interest Form from each member of the study team

Certificate of completion from CITI training with Seton Hall University as the primary affiliation (cannot be more than 3 years old).

“Approval of Doctoral Dissertation Proposal” form signed by all members of the dissertation committee

A copy of any tables or figures that could not be pasted in the application form can be included as a separate document with appropriate referencing

A copy of any surveys, questionnaires, or interview questions/scripts that will be used

One of the following forms must be included if the study is being performed at an off-site, non-Seton Hall University location:

Authorization/approval to conduct research at other location(s)

Or,

Evidence of IRB Approval of the principal investigator is employed full-time at the institution where the research is being conducted

**Principal Investigator Attestation**

By signing this document, I confirm that all of the required information listed on the submission checklist is complete and included in the submission. I understand there are two options for sending electronic copies of the compiled application packet to the Seton Hall University Institutional Review Board on or before the posted deadline (no late applications will be accepted). These include the use of the Teaching, Learning and Technology Center who will scan the entire document at no charge, or I can create my own PDF file and submit through the Institutional Review Board website. I also understand that I am required to submit a hard-copy of the compiled application packet to the Seton Hall University Institutional Review Board Office within 2 business days of the electronic submission; I can hand deliver a copy, send it through inter-office mail, or the United States Postal Service. I understand that failing to submit the hard copy will result in a delay of its review or the submission of an incomplete file will be returned to me and will have to be resubmitted at the next submission deadline.

Click or tap here to enter text.

Print Name



Signature

Click or tap to enter a date.

Date