**IRB EXPEDITED OR FULL REVIEW APPLICATION**

IRB No.:       Date Submitted to IRBnet:

**A. GENERAL INFORMATION**

|  |
| --- |
| Project Title:       |
| PI:       | Email:      |
| Department:       | Work Address (Bldg and No.):       |
| Phone:       | Emergency Phone:       |
| Co-PI(s):       | Co-PI(s) Contact Info:       |
| Student Researcher: | Student Researcher Contact info: |

**1. Sponsor Information-Check One**

( ) Not funded.

( ) Internal funding. Type:

( ) External funding. List agency name:

**2. Project Personnel:** Include the PI and all personnel who may interact with participants or access identifiable human participant data. Submit copies of the training certifications with the application.

|  |  |  |
| --- | --- | --- |
| **Name and Title(Check one)** | **Email Address** | **Training Completed** |
|      ( ) Tenure Track Faculty( ) Non-Tenure Track Faculty/Clinical Faculty( ) Staff ( ) Student( ) Other, explain:   |       |  ( )CITI Basic, Date:        ( ) NIH, Date:       |
|      ( ) Tenure Track Faculty( ) Non-Tenure Track Faculty/Clinical Faculty( ) Staff ( ) Student( ) Other, explain:   |       |  ( )CITI Basic, Date: enter date  ( ) NIH, Date: enter date |
|      ( ) Tenure Track Faculty( ) Non-Tenure Track Faculty/Clinical Faculty( ) Staff ( ) Student( ) Other, explain:   |       |  ( )CITI Basic, Date: enter date  ( ) NIH, Date: enter date |
|      ( ) Tenure Track Faculty( ) Non-Tenure Track Faculty/Clinical Faculty( ) Staff ( ) Student( ) Other, explain:    |       |  ( )CITI Basic, Date: enter date  ( ) NIH, Date: enter date |

Additional personnel or other information:

**a.** Is this a student research project? ( )Yes ( ) No

If yes, ( ) Graduate or ( ) Undergraduate

**B. CATEGORY CLAIMED**

( ) Request for Full IRB review

OR

( ) Request for Expedited Review-Research reviewed under this category must involve no more than minimal risk and be described by one or more of the allowed [categories](http://www.hhs.gov/ohrp/policy/expedited98.html) (see <http://www.hhs.gov/ohrp/policy/expedited98.html>). 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 Code of Federal Regulations (CFR) 46.102(i)].

**C. OTHER REQUIRED INFORMATION**

 **1.** Is an investigational drug, biologic, or device proposed for use with participants in this study? ( ) Yes ( ) No

**a.** If **yes**, an application must be submitted to the U.S. Food and Drug Administration for an Investigational Device Exemption (IDE) or Investigational New Drug (IND) authorization. Provide a copy of these materials to the IRB for review.

 **2.** Does the research require any other committee review? ( )Yes ( ) No

 ( ) IBC for use of biohazardous materials (blood, tissue, serum, etc.)

Indicate status: ( ) Registration Approved, IBC No.       or ( )Registration Pending

 ( ) IACUC for using Animal Models

Indicate status: ( ) Protocol Approved, IACUC No.       or ( )Protocol Pending

(  ) Radiation Safety Committee for use of **ANY** radiation emitting devices and radioactive materials.  This includes, but is not limited to: ALL devices, machines, and materials emitting x-rays (including DEXA, DXA), gamma rays, protons, neutrons, and any radioactive substance (regardless of chemical form).  Use of lasers and microwaves also requires review and approval by the RSC.

 **3.** Are you working with a researcher from an institution with their own IRB? ( ) Yes ( ) No

 i. If yes, do you intend for the University of Scranton to serve as the IRB of record?

( ) Yes ( ) No

 If yes, you must submit an IRB of Record form for each researcher from each institution.

**4**. Will the research be conducted with a non-University of Scranton collaborator(s) from outside the organization? Collaborators may include agencies, entities, institutions, or individuals who are serving as a study site/host, providing support to the research process (such as facilitating recruitment or testing). Collaborative studies often include activities where each of the institutions involved are significantly engaged in the research, usually by means of local investigators carrying out research activities at each study site.

 ( )Yes ( )No

 **a.** If yes, describe how the collaborator will be involved in the research:

  **b.** If yes, provide letters of support from each collaborator and list the names and addresses of each here:

 **c**. If yes, will any of the collaborating entities/ individuals from outside organizations be involved in interventions or interactions with the participants? ( ) Yes ( ) No

 If yes, do they have a current professional license for the activity? ( ) Yes ( ) No

 If no, or not applicable, explain:

**D. RESEARCH ACTIVITIES**

**1.** Check all that will apply to your participants for this research:

( ) Analyze data previously recorded ( ) Test or record physiological measures

( ) Contact by mail, email, or telephone ( ) Observe or record spontaneous behavior

( ) In person interview ( ) Manipulate participants

( ) Internet survey ( ) Collecting tissues or fluids

( ) Medical Record Review ( ) Questionnaires/survey

( ) Photographs ( ) Audiotapes/Videotapes/Recordings

( ) Incentives ( ) Using control group and study group

( ) Transcription Services (interview, focus group) ( ) Other, explain:

**2.** Do you intend to recruit from any of the following special populations? ( ) Yes ( ) No

If yes, **c**heck the type of participants and be aware that Full IRB Review may be required if greater than minimal risk:

( ) Minors under the age of 18 ( ) Pregnant Women

( ) Fetus/Fetal Tissue ( ) Prisoners

( ) Economically/Educationally Disadvantaged ( ) Cognitively Impaired.

( ) Non-English Speaking Participants ( ) Other:

**3.** Categorize the risk of the research:

( ) No more than minimal risk. ( ) Greater than minimal risk.

**E. RESEARCH SUMMARY (*Complete all sections on this form. Please attach copies of all research/recruitment materials that will be used. Although attachments may also include/describe content listed below, the information must be described in this section of the form. Do NOT say ‘See Attached’.***

***Please provide sufficient detail in each section to enable the IRB to understand the research project and its parts and make appropriate determinations.***

* + - 1. Describe the research purpose and objectives:
			2. Describe the research methods:
			3. Describe the participant population:
			4. Recruitment Information

 **a.** Describe how you will recruit the participants:

 **b.** Indicate the anticipated number of participants:

 **c.** Are enough participants being recruited to achieve the objectives of the research (e.g., to provide for statistical analysis or to achieve saturation of a topic)?

 Explain:

**5.** Estimate the anticipated Start Date:

 Estimate the anticipated End Date:

**6.** Does research involve the use of publicly available or currently existing data?

 ( ) Yes ( ) No

  **a.** If yes, list source of the data or specimens:

1. Indicate whether the data is currently de-identified or how it will be de-identified:

**7.** Will you be providing any incentives to the participants? ( )Yes ( ) No

 **a.** If yes, check the type: ( ) Cash ( ) Gift Card, to where:

 ( ) Other, list:

 **b.** Specify the amount provided:

 **c.** Provide justification for why the incentive is necessary:

 **d.** Indicate when the incentive will be issued and how you will handle payment if the participant withdraws part way through the study:

**8.** Check all of the supporting materials submitted with this application:

 ( ) Questionnaires, Surveys ( ) Screening Criteria

 ( ) Standard Research Tools ( ) Letters of Support

 ( ) Recruitment Materials ( ) Training Certificates

 ( ) Consent Forms ( ) Assent Forms

 ( ) Photo/Video Release Form ( ) Confidentiality Agreement for

( ) Other, list:       ( ) Transcription Services (this form must be signed by the transcriptionist)

**9.** Check all of the materials that will be submitted at a later date:

 ( ) Translated Document ( ) Certification of Translation

( ) Final Survey/Interview Tools ( ) Letters of Support

 ( ) Recruitment Materials ( ) Collaborative Agreement

 ( ) Other, list:

**F. INFORMATION FOR RESEARCH WITH SPECIAL POPULATIONS (Check all that apply.)**

( ) For research with participants under the age of 18, complete F.1.

( ) For research with participants with English as a SECOND language, complete F.2.

( ) For research with all other protected categories, complete F.3.

( ) If no special categories apply to your research, check this box and skip to section G.

**1.** Participants under 18 years of age.

1. Informed consent will be obtained from at least one parent or guardian.

( )Yes ( ) No

1. Describe the process for how parental informed consent will be obtained:
2. Will you also obtain assent from the participants? ( )Yes ( ) No

 If yes, describe the process to obtain assent from the participants:

1. Justify why you must use this group of participants for the research:

**2.** Participants with English as a Second Language:

 **a.** List the languages that materials will be translated to:

**b.** List the titles of all materials that will be translated (Do not translate materials until you have approval for the English version.):

1. List the individual/entity that will be completing the translation, and a brief description of their qualifications to do so:
2. I will submit an IRB Amendment Form with the translated and back translated materials in addition to a Translation Certification Form for each language.

 ( )Yes ( ) No

**3.** Other Protected Categories of Participants

**a.** Are any participants members of other protected populations? ( )Yes ( ) No

* 1. Describe the protected population category:

* 1. Justify why you must use this group of participants for the research:
	2. Describe how this group of participants will be protected to meet all regulatory requirements:
	3. Additional information:

**G. PRIVACY AND CONFIDENTIALITY INFORMATION**

**1.** Will you be in possession of or collect any information that identifies the participants, including any combination of indirect identifiers that could potentially identify participants? ( ) Yes ( ) No

**2.** If yes, indicate the type of identifying information ~~to be collected~~:

**3.** Describe how this information will be protected and kept confidential:

**4.** Describe where the information will be stored, and who will have access to it:

**H. RISK INFORMATION**

**1**. What is your assessment of the level of risk? Federal guidelines state that risk "is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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." **There is never no risk to research; however, risk may be either of the following:**(Greater than minimal risk requires Full Review).

( ) No more than minimal risk.

( ) Greater than minimal risk

 ( ) **a.** Potential for direct benefit to participant.

 ( ) **b.** No potential for direct benefit to participants.

1. Describe all potential risks to participants in the research and why you believe it to be of minimal risk:

 **a.** If risk may appear be greater than minimal but you believe it should be considered within minimal risk parameters for this population, please explain:

**3**. Indicate how you will minimize risks outlined above to participants:

**4.** Are there alternative methods to acquire the information that could avoid the risks?

 ( )Yes ( )No

 If yes, explain:

 **5.** Do you plan to record or test physical responses as part of the research?

 ( )Yes ( )No

1. If yes, I, and my co-investigators, understand how to activate the emergency response procedure for the University or site at which the study will be conducted.

 ( ) Yes ( )No

**I. BENEFITS INFORMATION (**Compensation or incentives are not a benefit.)

**1**. Describe the direct or potential benefit of this research to the participants involved:

1. Explain the risk vs. benefit and how the risk is justified by the benefit for the participants in this study. (If using both a study group and a control group, more than one level of risk may be involved.):
2. Describe the potential benefits of the research to society as a whole. Include only those benefits that may result from the research (as distinguished from benefits of therapies participants would receive even if not participating in the research):

**4**. Indicate what, if any, benefits may accrue to individuals who are not participants, but who are similar to the participants in terms of social characteristics (e.g. those who are the same socioeconomic status, gender, race/ethnicity, age, immigration status, disability status or medical status):

**J. INFORMED CONSENT INFORMATION**

**1.** Are you submitting an informed consent document? ( )Yes ( )No

1. List the title of each consent form submitted (ex. ‘Focus Group Consent’, ‘Interview Consent):
2. Check one:

 ( ) Consent will be done in a group setting

 ( ) Consent will be done individually

 ( ) Consent will be embedded in a survey document or questionnaire.

1. Describe who will be obtaining consent for this study:
2. Where will this process and discussion take place:

**e.** Will any audio recordings, video recordings, or photographs be used?

 ( )Yes ( )No

Note: Make sure the Informed Consent document includes which of these will be used and the date the material(s) will be destroyed or erased (not to exceed three years from the completion of the research).

If yes, complete the following:

1. Describe the purpose for collecting these materials:

**ii.** Indicate the date the materials will be destroyed:

**iii.** Will any of these materials be used for publication? ( )Yes ( ) No

 If yes, also submit an IRB Video/Photo Release Form for approval.

2. Are you applying for any type of Waiver of the Informed Consent Requirement?

 ( )Yes ( ) No

 If yes, complete the rest of this section.

  **a.** ( )Request to Waive Consent Entirely or Allow Alteration for Consent.

* + - 1. Explain why this research involves no more than minimal risk to the participants or their privacy:
			2. Explain why the waiver will not adversely affect the rights and welfare of the participants:
			3. Explain why the research could not be carried out without the waiver or alteration:
			4. Explain how the participants will be provided with additional pertinent information after participation (For example, in deception studies).
1. ( )Request to Waive Documentation of Consent (The consent process will be completed with an IRB approved form, but no signed forms will be collected.)

Check the option below and justify the waiver request that best meets the purpose of the request.

( )The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality or discovery that they had participated in such research. Each participant will be offered a copy of the informed consent form but may refuse it. Explain:

**OR**

( )The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. Explain:

**K. PRINCIPAL INVESTIGATOR ASSURANCE AND SIGNATURE PAGE**

*Check each box to verify you understand and agree to the following:*

( ) I agree to follow all University of Scranton IRB Policies and Procedures.

( ) I agree to conduct the study in accordance with the approved protocol and will not modify or revise a protocol until an IRB Amendment Form is submitted and approval is received from the IRB and/or sponsor, except when necessary to protect the safety, rights, or welfare of participants.

( ) I agree to personally conduct or supervise the described investigation(s).

( ) I agree to inform all research participants of the investigational nature of this project as required in 21CFR56 and 45CFR46.

( ) I will ensure that the requirements for obtaining informed consent are met per the regulations found at 21CFR56 and 45 and 45CFR46.

( ) I agree to immediately report any unanticipated events or adverse experiences that occur during the course of this research to the IRB Administrator.

( ) I agree to ensure that all investigators, collaborators, associates, colleagues, and employees assisting in the conduct of the study(s) are informed about their obligations to follow University of Scranton IRB Policies and Procedures and all confidentiality requirements.

( ) I agree to maintain adequate and accurate records, including copies of all consent documents, and to make those records available for inspection in accordance with the regulations. (Records must be kept on file 3 years from the project completion date.)

( ) I understand I must submit an IRB Annual/Continuing Review Form at a minimum of once per year.

( ) I understand that any medical procedures or treatments of human participants will be performed by or under the supervision of a person who is licensed or certified to perform that particular procedure.

 ( ) Check here if N/A.

( ) I understand that IRB approval for research does not constitute approval to use University facilities or resources, and that other University or site policies and procedures may apply. It is my responsibility to seek and obtain other approvals as may be required.

( ) I understand all investigators associated with this research must renew their human participant research training every 3 years.

( ) I understand that the research may not begin until I have received the official notice of approval from the IRB.

Project Title:

***The entire application MUST be submitted to the IRB via IRBnet.***

SIGNATURE:

|  |  |
| --- | --- |
| PI Signature: | Date:       |
| Printed Name:       |