**IRB EXEMPT STATUS APPLICATION**

IRBnet No.:       Date Submitted to IRBnet:

**This form is ONLY for minimal risk research where no personally identifiable information/ individual identifiers are known by or collected by researchers.**

**If personally identifiable information is collected or known by the researcher(s), the project will not qualify as exempt, and the researcher should use the Expedited/Full application form.**

**All forms must be submitted via 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 subjects or access identifiable human subject data. **Training certification should be submitted with the application.**

|  |  |  |
| --- | --- | --- |
| **Name and Title(Check one)**  | **Department/Email Address** | **Training Completed** |
|      ( ) Faculty( ) Staff ( ) Student( ) Other, explain:   |       | ( ) CITI Basic, Date:       ( ) NIH, Date:      |
|      ( ) Faculty( ) Staff ( ) Student( ) Other, explain |       | ( ) CITI Basic, Date:       ( ) NIH, Date:      |
|      ( ) Faculty( ) Staff ( ) Student( ) Other, explain |       | ( ) CITI Basic, Date:       ( ) NIH, Date:      |
|      ( ) Faculty( ) Staff ( ) Student( ) Other, explain |       | ( ) CITI Basic, Date:       ( ) NIH, Date:      |

Additional personnel or other information:

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

If yes, ( ) Graduate or ( ) Undergraduate

**B. SCREENING QUESTIONS**

 **1.** Will the research expose participants to discomfort or distress beyond that normally encountered in daily life?

 ( )Yes ( )No

1. Could disclosure of participants’ responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation? ( )Yes ( )No
2. Does any part of the research require deception or incomplete disclosure of information to participants? ( )Yes ( )No
3. Will prisoners (or their data and/or specimens) be participants in the research? ( )Yes ( )No
4. For research proposed under categories 1-5, is the research subject to FDA regulations? ( )Yes ( )No
5. Will the researcher have, or research project gather, any individually identifiable information about participants (e.g., name, email address) at any point? ( )Yes ( )No

Note: a **YES** for **questions 1-6** above indicates your research does NOT meet exempt criteria. Submit an application for Expedited or Full Review.

**C. EXEMPT CATEGORY CLAIMED (check all that apply):**
**( ) 1.** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

If you checked this category, to do the research under this exempt category, it must be conducted in commonly accepted educational settings and not deviate from normal educational practices, and no individual identifiers are collected from participants.

Is this true? ( )Yes ( )No

If no, please submit an application for expedited or full review.

**( ) 2.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, **unless**: Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects.

If you checked this category, the activity may **not** involve any interactions of the researcher with children, if they are participants. Does it involve interactions with children? ( )Yes ( )No

If yes, submit an application for expedited or full review.

**( ) 3.** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) of this section, if: the human subjects are elected or appointed public officials, or candidates for public office; or federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

**( )** **4.** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that **subjects cannot be identified**, directly or through identifiers linked to the subjects.

For research under this category, will any of the data, documents, records, or biological specimens be collected or created **after** the date of this application? ( )Yes ( )No

If yes, submit an application for expedited or full review.

For research under this category, will any of the information obtained from private sources of data, documents, records, or biological specimens be recorded by the investigator in such a manner that subjects could be identified directly or through identifiers linked to the subjects? ( )Yes ( )No

If yes, submit an application for expedited or full review.

( ) **5**. Research and demonstration projects conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those pro­grams; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.

( ) **6**. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

1. **RESEARCH ACTIVITIES - *Check all that apply:***

( ) Internet or email data collection ( ) Observation of participants

( ) Existing data, publicly available ( ) Record review

( ) Existing data, NOT publicly available ( ) Research using existing specimens

( ) Focus groups ( ) Surveys or questionnaires

( ) Audio recordings ( ) Interviews

( ) Other:

**RESEARCH SUMMARY - *Succinctly but thoroughly respond to the following. In addition to narrative,*** ***please provide copies of any research and recruitment materials/communications that will be used.***

* + - 1. Describe the research purpose and objectives:
			2. Describe the research methods:

 **3.** Describe the participant population:

 **4.** Recruitment Information:

 **a.** Describe how the participants will be recruited:

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

 **c.** Will any participants be under 18 years of age? ( )Yes ( )No

 If yes, justify and describe how you will meet the exemption requirements:

**5.** Estimate the duration of the study:

 **6.** Will all of the research activities be conducted at the University of Scranton? ( )Yes ( )No

 a. If no, list the site/collaborator(s):

b.A letter(s) has been submitted to the IRB from the collaborator to document how they intend to support the research. ( )Yes ( )No

 **7.** Describe how participants will provide consent:

 **8.** 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:

**9.** Describe any potential risk to participants from participating in the research:

**10.** Indicate how you intend to minimize any risks to participants:

**11.** Describe procedures to protect participants’ privacy and confidentiality, including who will have access to data and how it will be stored:

 **12.** Describe the potential benefits from the research:

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

( ) Questionnaires, surveys

( ) Standard Research Tools (published testing materials, etc.)

( ) Recruitment Materials

( ) Consent Documents

 ( ) Other, list:

1. **PRINCIPAL INVESTIGATOR (PI) ASSURANCE AND SIGNATURE - *Please check all items and sign.***

( ) I understand that, as the PI, I am ultimately responsibility for the protection of the rights and welfare of human participants and the ethical conduct of research under this protocol. I agree to conduct the study in accordance with the approved protocol and ensure that all personnel involved in the research will do the same.

( ) I agree to follow the University of Scranton IRB Policies.

( ) I certify that the information provided in this application is complete and correct, and believe that my project qualifies as Exempt from the Federal Regulations.

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

( ) I agree to maintain copies of all questionnaires, survey instruments, interview questions, data collection instruments, and information sheets for human participants for three years following termination of the project,

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

( ) I understand it is my responsibility to resubmit an application to the IRB if I need to make any changes that alter the exempt status determination and approval.

( ) I understand this project will be closed by the IRB three years from the date of approval and records will be retained in the IRB office for 3 years after that date.

( ) I understand that IRB exempt determination or 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.

Project Title:

**SIGNATURE:**  **Note: Students are not eligible to sign this page.**

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