|  |  |
| --- | --- |
|  | **APPLICATION FORM – INITIAL REVIEW**INSTITUTIONAL REVIEW BOARD/HUMAN SUBJECTS COMMITTEEOffice of Research and Sponsored Projects/IRB5500 N. St. Louis Ave., Lech Walesa Hall, Room 0042Phone: 773/442-4675 www.neiu.edu/~sprogram |

**DIRECTIONS FOR COMPLETING THE APPLICATION FORM**

**1.             Investigator Education:**

All investigators must complete initial and continuing education requirements in human subject protections. Otherwise, the submission will not be accepted. Follow [CITI Instructions](file:///P%3A%5CAAA%20GRANTS%20and%20HUMAN%20SUBJECTS%5CHUMANSUBJECTS%5CIRB%20CITI%20TRAINING) to access the training.

**2.             Submission Procedure:**

One (1) electronic copy of all materials, (with the application and informed consent form in Word format), should be emailed to irb@neiu.edu.

The application cannot be distributed for IRB review until electronic copy of the application and all supporting materials are received. Where applicable, these may include surveys, interview questions, permission letters, recruitment materials, any translations, collaborative institution IRB approval, and/or informed consent forms that follow the NEIU template.

**3.** **Use this checklist to ensure your submission is complete:**

☐ Completed and signed Application form

☐ Copy of the recruitment documents that will be used

☐ Copy of the informed consent/assent/parental permission document(s) that will be used

☐ Research instruments (e.g., survey questionnaires, interview guides, observation guides, etc.)

☐ Research protocol (e.g., thesis proposal)

☐ Copy of IRB approvals from partner institutions, e.g., CPS RRB

☐ Support letters from performance sites

☐ Other relevant documents (e.g., information sheets, debriefing scripts, etc.)

 **4. Level of Review:**

 Use **Exempt Categories Checklist** to determine if your research may qualify for exemption. **Include the exempt checklist with your application.** Use **Expedited Categories Checklist** to determine if your research may qualify for expedited review. **Include the expedited checklist with your application.**

 Studies that **do not qualify** for Exemption or Expedited review must be reviewed by the IRB at a convened meeting (**Full Board level review**). Studies requiring Full Board review present more than minimal risk to subjects, and/or involve populations, such as children, prisoners, and/or other groups with diminished capacity to consent (e.g., Alzheimer patients) or vulnerable to coercion or undue influence. **Only the IRB can make a final determination concerning the level of review required for a given study.**

|  |  |
| --- | --- |
|  | **APPLICATION FORM – INITIAL REVIEW**INSTITUTIONAL REVIEW BOARD/HUMAN SUBJECTS COMMITTEEOffice of Research and Sponsored Projects/IRB5500 N. St. Louis Ave., Lech Walesa Hall, Room 0042Phone: 773/442-4675 www.neiu.edu/~sprogram / |

|  |
| --- |
| **NEIU IRB Protocol No.:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date of IRB Review:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_For office use only |

**DATE APPLICATION COMPLETED:**

|  |
| --- |
| **PROJECT TITLE** |
| **PRINCIPAL INVESTIGATOR**Name (Last, First) Degree(s) University Status Campus Phone Number      |
| Department Campus Mailing Address Mail Code E-mail Address |
| **List all co-investigators below, including those from other institutions** |
| **CO-INVESTIGATOR ☐*****or* FACULTY SPONSOR ☐**Name (Last, First) Degree(s) University Status Campus Phone Number |
| Department Campus Mailing Address Mail Code E-mail Address |
| **CO-INVESTIGATOR**Name (Last, First) Degree(s) University Status Campus Phone Number |
| Department Campus Mailing Address Mail Code E-mail Address |
| **CO-INVESTIGATOR**Name (Last, First) Degree(s) University Status Campus Phone Number |
| Department Campus Mailing Address Mail Code E-mail Address |
| **CO-INVESTIGATOR**Name (Last, First) Degree(s) University Status Campus Phone Number |
| Department Campus Mailing Address Mail Code E-mail Address |

**FUNDING SOURCES**

Check all of the appropriate boxes for funding sources for this research. Include pending funding source(s). **NOTE: Any subsequent addition of funding must be reported to the IRB via an amendment.**

|  |  |
| --- | --- |
| ☐ **Federal**☐ **Extramural - other****Department**☐ **Gift**☐ **Commercial - company name**:       ☐ **Other**:        | **If federally funded, provide name and address of individual to whom certification of IRB approval should be sent:**      Name      Address line 1      Address line 2      City, State, Zip |

**P.I. of Grant or Contract**:

**Name of Funding Source**:

**Grant/Contract No. (if available)**:

**Grant/Contract or Project Title**:

**PERFORMANCE SITES**

|  |  |  |
| --- | --- | --- |
| **List all collaborating and performance sites*****(i.e. pre-k-12 schools, international sites)*** | **Provide certification or letter of IRB approval** | **Provide letters of cooperation or support (as appropriate)** |
|  |  |  |
| 1.
 | **☐ Attached****☐ Will follow****☐ N/A** | **☐ Attached****☐ Will follow****☐ N/A** |
| 1.
 | **☐ Attached****☐ Will follow****☐ N/A** | **☐ Attached****☐ Will follow****☐ N/A** |
| 1.
 | **☐ Attached****☐ Will follow****☐ N/A** | **☐ Attached****☐ Will follow****☐ N/A** |

**I. PROJECT DESCRIPTION**

1. **Purpose, goals, and methods.** Include background, relevant literature, research questions, and hypotheses. Describe methods of data gathering and analysis that will be used.

|  |
| --- |
|  |

1. **Research activities.** Describe in detail what subjects will be asked to do, what information will be collected about them, and when or how often research activities will be conducted. For complex or multi-phase studies, a separate attachment describing the methods may be included which contains graphics, tables, timelines or schedule of events.

|  |
| --- |
|  |

1. **Classroom setting.** Will any aspect of the research be conducted in a classroom setting during class time?

☐ No

☐ Yes - describe what those who choose not to participate will be doing, and provide justification for use of class time for research.

|  |
| --- |
|       |

***Please submit Appendix A “Use of School Classrooms”***

1. **Compensation/Incentives**. Will participants or others be offered incentives for the research (e.g., gifts, payment, extra credit, reimbursement, services, or other incentives for participation)?

☐ No

☐ Yes - describe the amount of compensation and when and how compensation/incentives will be awarded.

|  |
| --- |
|       |

1. **International research.** If research will be conducted at an international site, indicate the investigator’s familiarity with the culture and cultural norms, and how the research may affect an individual’s standing in their community. ☐ N/A

|  |
| --- |
|  |

***Please submit Appendix E “International Research”***

1. **Project Dates.** Indicate the expected start date and end dates for the research activities

|  |
| --- |
| **Antici Start date:        or after IRB Approval****Antici End date:** |

**II. PROCEDURES**

1. **Recruitment procedures**

1a. Describe the proposed participants (number, age range, demographic information, the population from which the participants will be recruited, eligibility criteria, other relevant details).

|  |
| --- |
|       |

1b. Describe recruitment procedures. Include how participants will be initially identified, approached, or contacted regarding the research and in what setting.

|  |
| --- |
|       |

***Please provide a copy of any recruitment materials, advertisements, flyers, text of emails, verbal invitation script, etc. that will be used.***

1. **Consent procedures**

2a.Describe the process proposed to seek and obtain informed consent and/or assent. Include step- by-step descriptions of how participants will be informed about the research, and how the PI will gauge participants’ understanding of the research and obtain their agreement to participate in the research. ***If requesting a waiver of documentation of consent or assent, provide justification.***

|  |
| --- |
|       |

***Please provide a copy of the consent form, verbal consent script, information sheet, etc. that will be used to obtain the participants’ consent.***

2b.Does the investigator, co-investigator, any member of the research team, or anyone else assisting with the research have an authority relationship (e.g., instructor/student, employer or supervisor/employee, physician/patient, etc.) with potential participants?

☐ No

☐ Yes\* - describe the relationship, and indicate how the research and consent process will be conducted to avoid undue influence on participants.

|  |
| --- |
|  |

2c. Will all participants, their parents/guardians, and/or their legally authorized representative (as applicable) be fluent in English?

☐ Yes

☐ No - explain how informed consent will be obtained, and provide a copy of the translated documents to be used.

|  |
| --- |
|  |

**III. PRIVACY AND CONFIDENTIALITY**

1. Describe the conditions under which interaction with the subjects will occur (e.g., consent discussion occurs in a private room). Explain how these conditions adequately address the privacy interests of subjects.

|  |
| --- |
|  |

2. Will the researchers obtain any **personally identifiable information (PII)** from or about participants (e.g. names, addresses, telephone numbers, etc.)?

☐ No (Proceed to question 3).

☐ Yes:

2a. Identify which of the direct identifiers below will be obtained:

|  |  |  |
| --- | --- | --- |
| ☐ Full Names | ☐ Initials | ☐ Photographs of participant in which s/he is identifiable |
| ☐ Telephone numbers | ☐ Email Address | ☐ Video(s) of participant |
| ☐ Birthdate | ☐ Postal Address | ☐ Audio Recording |
| ☐ Any ID# (e.g. Student ID, etc.)       |
| ☐ Other:       |

2b. How long will the PII be maintained?

|  |
| --- |
|       |

2c. Why is it necessary to maintain direct identifiers?

|  |
| --- |
|   |

2d. Describe the coding system that will be used to protect against disclosure of these identifiers.

|  |
| --- |
|   |

2e. How long will the link between identifiers and code be maintained?

|  |
| --- |
|       |

2g. Could identification of participants or their responses place them at risk of: ☐ criminal liability, ☐ civil liability, or be damaging to their: ☐ financial standing, ☐ employability, ☐ insurability, ☐ reputation, or be ☐ stigmatizing? ☐ N/A

2h. Explain how the researcher will mitigate these risks (e.g. limiting access to identifiers, obtaining a Certificate of Confidentiality from NIH, etc.). If a Certificate of Confidentiality is obtained, provide a copy to the IRB once available.

3. Will any demographic information be collected which could lead to a deductive disclosure of participant(s) identities? If so, how will participant privacy be addressed?

|  |
| --- |
|       |

4. In what format(s) will the data originate (e.g. paper, digital, electronic media, video, audio, or photographic)?

|  |
| --- |
|  |

5. Describe how data will be shared among research team members, collaborators at external institutions, etc.

|  |
| --- |
|       |

6. In what format(s) will data be maintained during the life of the study (e.g. paper, digital, electronic media, video, audio, or photographic)?

|  |
| --- |
|       |

7. Where will data be stored (include both paper/hardcopy records and digital/electronic files)?

|  |
| --- |
|       |

8. What security provisions will be made to protect the data (e.g. password protection, encryption, etc.)?

|  |
| --- |
|       |

9. Are there potential ethical or legal circumstances that would make it necessary to break confidentiality (e.g., requirements for mandated reporting or other professional obligations to report)?

☐ No

☐ \*Yes – Describe these circumstances.

|  |
| --- |
|  |

\* This must be disclosed in the consent document(s).

10. **Final disposition.** Please describe when PII and deductive identifiers will be removed from the dataset and/or the records retention plan for the research records.

|  |
| --- |
|       |

**IV. OTHER INFORMATION:**

1. **External Interests.** Does any investigator responsible for the design, conduct, or reporting of the project (including their immediate family members) have a financial, personal, or political interest that may conflict with their responsibility for protecting human participants in NEIU research?

Financial, personal, or political interests related to the research (the sponsor, product or service being tested, or a competing product or service) may include:

* compensation (e.g., salary, payment for services, consulting fees)
* intellectual property rights or equity interests
* board memberships or executive positions
* enrollment or recruitment bonus payments

.

☐ No – As PI, I attest that I have conferred with my co-investigators and key personnel and confirmed that no financial, personal or political interests currently exist related to this research.

☐ Yes – Describe the related financial, personal or political interests, and **attach a COI disclosure and management plan.**

|  |
| --- |
|  |

**INVESTIGATOR’S ASSURANCE**

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study, and the ethical performance of the project.

I agree to comply with all NEIU policies and procedures, as well as with all applicable federal, state and local laws regarding the protection of human subjects in research, including, but not limited to, the following:

* The project will be performed by qualified personnel according to the NEIU IRB certified protocol,
* No changes will be made in the protocol or consent form until approved by the NEIU IRB,
* Legally effective informed consent will be obtained from human subjects if applicable, and
* Adverse events will be reported to the NEIU IRB in a timely manner.

I will complete the required educational program on ethical principles and regulatory requirements in a timely manner.

I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Date

**FACULTY SPONSOR’S ASSURANCE**

By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol.

In addition,

* I agree to meet with the investigator on a regular basis to monitor study progress,
* Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them,
* I insure that the investigator will promptly report significant or untoward adverse effects to the NEIU IRB in a timely manner,
* If I will be unavailable, as when on sabbatical leave or vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence and I will advise the NEIU IRB by letter of such arrangements, and
* I insure that the investigator will complete the required educational program on ethical principles and regulatory requirements in a timely manner.

I further certify that the proposed research is not currently underway, and will not begin until approval has been obtained.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Faculty Sponsor\* (if PI is a student or a fellow) Date

\*The faculty sponsor must be a member of the NEIU faculty. The faculty member is considered the responsible party for legal and ethical performance of the project.

**DEPARTMENT HEAD SIGNATURE**

As department head, I acknowledge that this research is in keeping with the standards set by our department and I insure that the Principal Investigator has met all departmental requirements for review and approval of this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department Head Date

Type name of Department Head: