

FORM – Claim of Exemption Application

Office of Sponsored Programs (OSP)

Northeastern Illinois University

5500 N. St. Louis Avenue

Chicago, IL 60625-4699

Phone: 773-442-4670 Fax: 773-442-4673

<http://www.neiu.edu/~sprogram/>

Exemption Screening Questions

If you answer 'Yes' to any of the questions A through D below, then **STOP** and use the application form for initial IRB review.

If you answer 'No' to all questions A-D below, continue to complete this claim of exemption application.

Important: Please include a completed screening form with your application

A. For research involving special populations, interventions or manipulations

1. Does your research involve pregnant women, fetuses, or prisoners? Yes No
2. Does your research involve using survey or interview procedures with children? Yes No
3. Does your research involve the observation of children in settings where the investigator(s) will participate in the activities being observed? Yes No

B. For research using survey procedures, interview procedures, observational procedures and questionnaires

1. If data are to be recorded by audiotape or videotape is there potential harm¹ to subjects if the information is revealed or disclosed? Yes No
2. If the subjects are to be identifiable either by name or through demographic data, is there potential harm to participants if the information is revealed? Yes No
3. Will data collection include sensitive information (e.g. illegal activities, or sensitive themes such as sexual orientation, sexual behavior, undesirable work behavior, or other data that may be painful or very embarrassing to reveal, such as death of a family member, memories of physical abuse?) Yes No

C. For research using existing² or archived data, documents, records, or specimens only

1. Will any data, documents, records or specimens be collected from subjects after the submission of this application? Yes No
2. If the data, documents, records, or specimens are originally labeled in such a manner that subjects can be identified, directly or indirectly through identifying links, is the investigator recording the data for the purposes of this research in such a manner that subjects can be identified, directly or indirectly through identifying links (i.e., demographic information that might reasonably lead to the identification of individual subjects – name, phone number; or any code number that can be used to link the investigator's data to the source record – medical record number or hospital admission number)? Yes No

D. For research using protected health information

1. Will the research involve the use or disclosure of individually identifiable health information including: names, dates (other than years), telephone numbers, fax numbers, electronic e-mail addresses, social security numbers, medical records numbers, health plan beneficiary numbers, account numbers, certificate/license numbers, device identifiers and serial numbers, web URLs, internet addresses, biometric identifiers, full face or comparable images, or any unique identifying number, characteristic, or code? Yes No

¹Harm to subjects means that any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or can be damaging to the subjects' financial standing, employability, or reputation.

²Existing means the items exist before the research was proposed or was collected prior to the research for a purpose other than the proposed research.

To Be Completed By The Investigator	
Date Application Completed:	
Application Document Version #:	

For NEIU OSP Only	
NEIU IRB #:	
Assigned IRB:	

I. Project Title:		
II. Principal Investigator:		
Name (Last, First)	Degree(s)	University Status/Title
Date of Investigator Training	Department	College
Campus Mailing Address		
Campus Phone Number	Campus Fax Number	E-mail Address

III. Co-Investigators: List all, including those from other institutions. If you require space for additional co-investigators please use Appendix P.		
Co-Investigator or Faculty Sponsor Name (Last, First)	Degree(s)	University Status/Title
Date of Investigator Training	Department	College
Campus Mailing Address		
Campus Phone Number	Campus Fax Number	E-mail Address
Co-Investigator or Key Research Personnel – Role: Name (Last, First)	Degree(s)	University Status/Title
Date of Investigator Training	Department	College
Campus Mailing Address		
Campus Phone Number	Campus Fax Number	E-mail Address
Co-Investigator or Key Research Personnel – Role: Name (Last, First)	Degree(s)	University Status/Title
Date of Investigator Training	Department	College
Campus Mailing Address		
Campus Phone Number	Campus Fax Number	E-mail Address

IV. Funding Sources

A. Check all of the appropriate boxes for funding sources (including pending sources) for this research.

- | | | | |
|---|--|---------------------------------------|---------------------------------|
| <input type="checkbox"/> Extramural Federal | <input type="checkbox"/> Extramural Non-Federal | <input type="checkbox"/> Intramural | <input type="checkbox"/> Other: |
| <input type="checkbox"/> HHS | <input type="checkbox"/> Industry- PI initiated | <input type="checkbox"/> Departmental | <input type="checkbox"/> None |
| <input type="checkbox"/> NIH | <input type="checkbox"/> Industry- Sponsor initiated | | |
| <input type="checkbox"/> Other | <input type="checkbox"/> State | | |
| | <input type="checkbox"/> Foundation | | |

B. You must complete the following information, when applicable. *Note: If the funding is pending at the time of submission, you must notify the IRB via an amendment when there is a subsequent change of funding status (e.g., change from “pending” to “funded,” or if there is a change in the funding source).*

1. NEIU OSP number:

Please provide this number for all research applications that are supported by a grant or contract, and indicate whether the funding is approved or pending at the time of application. Please note the PAF Number is assigned by the Office of Research Services in the Office of the Vice Chancellor for Research.

2. P.I. of Grant(s) or Contract(s):

For Federally funded research: If the PI of the grant is not the PI. for this research application or is a non-NEIU investigator, he/she must be listed on Page 1 (or Appendix P) and her/his affiliation must be listed below under performance sites.

3. Name of Funding Source(s):

4. Grant/Contract No(s). (if available):

5. Grant/Contract or Project Title(s):

6. If the PI of the grant is a non-NEIU investigator, please explain the type of funding relationship or agreement that exists between the grant PI and the NEIU PI (i.e. performance site, subcontract, consultant).

If federally funded, submit one copy of the complete initial funding application for review and provide the name and address of the individual to whom certification of IRB approval should be sent:

Name (Last, First)

Address line 1

Address line 2

City

State

Zip

V. Performance Sites¹		
List all collaborating and performance sites. Final approval of a performance site may be withheld until documentation of IRB approval or exemption is obtained for that site.		
	<i>Provide certification or letter of IRB approval or exemption and a copy of the approved consent document</i>	<i>Provide letters of cooperation or support (as appropriate)</i>
1. Is NEIU a performance site? <input type="checkbox"/> Yes <input type="checkbox"/> No	N/A	N/A
2. Other:	Attached Will Follow	Attached Will Follow
3. Other:	Attached Will Follow	Attached Will Follow
4. Other:	Attached Will Follow	Attached Will Follow
¹ A performance site is a site that conducts the research using a NEIU initiated research protocol or grant, or under a sub-contract to NEIU, with NEIU as the lead research site. If NEIU is conducting the research as a site for a grant that originates elsewhere, the lead site must be listed as a performance site for NEIU.		

VI. Additional Reviews Required		
Depending upon the research design, review by other NEIU committees or other committees outside of NEIU may be required before submission is made to OSP. Please indicate if review and approval by any of these committees is necessary for this research, and provide the date of approval. Please attach copies of any preliminary approval documents to this application.		
	<i>Review Required?</i>	<i>Date of Approval</i>
Departmental Review	Yes No N/A	
School Classroom -performance sites - please name: _____ _____ _____ <i>Provide documentation of the approval of the relevant IRB, and FWA # for each site, if available. If not, provide written approval of the school principal or school district on school letterhead. Also, complete Appendix A if research is conducted during classroom time.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	
Other- International performance sites Provide documentation of the approval of the relevant IRB (or equivalent), and FWA # for each site, if available.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No	

VII. Exemption Category Claimed

Please identify all that apply to your research (check applicable boxes). If your research involves only procedures included in the list below, it may be reviewed for exemption. If there are research procedures outside of this list, then please STOP and use the application form for initial IRB review.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This category may include children.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior for which subjects can not be identified directly or through coded identifiers, or, if they can be identified, release of the information would not be harmful to the subject. (If this option is selected, check at least one of the choices below)
 - a. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) for which subjects cannot be identified, or release of the information would not be harmful to the subject. This category may include children.
 - b. Research involving the use of survey procedures or interview procedures or observation of public behavior for which subjects cannot be identified, or when they can be identified, the release of the information would not be harmful to the subject(s). This category may not include children, unless the research involves observations of public behavior when the investigator(s) does not participate in the activities being observed.
3. Research involving the use of educational tests, survey or interview procedures, or observations of public behavior involving elected or appointed public officials (or candidates for public office).
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. The "Standards for Privacy of Individually Identifiable Health Information" (45 CFR Parts 160 and 164) excludes approval of research using protected health information (i.e. medical records) from exempt review unless the data is de-identified. This category may include children.
5. Research and demonstration projects that are conducted by or are subject to the approval of Department or Agency heads, and which are designed to study or evaluate public benefit or service programs (e.g., evaluation of public benefits programs like Medicare, or Public Assistance). This category refers to projects under Federal Department or Agency Heads. This category may include children.
6. Research involving taste and food quality evaluation and consumer acceptance studies. This category may include children.

XIII. Abstract/Lay Summary and Exempt Category Rationale

Provide a description and the rationale for each exempt category claimed for this research. The information must include sufficient detail to demonstrate that the research protocol meets the requirements for each category of exemption claimed in this application. If you are using existing data, records or pathological specimens, explain the source of the data, the type of tissue used, and the means of access to the data. Use non-technical language that can be understood by a person unfamiliar with the area of research. Please include any additional information that you believe will assist the reviewer in making a determination.

IX. Protocol Information

1. Purpose: Please provide a detailed description of the research that includes background, aims/objectives, and description of how the research will be conducted (hypothesis and methodology).

2. Subject Population:
 - a. If relevant/known, please state the age range of the subjects, or the age range of subjects whose data or specimens will be collected.

- b. Please indicate any known classes of vulnerable subjects who will participate in this research:

- | | | |
|---|---------------------------------------|--|
| <input type="checkbox"/> Cognitively Impaired | <input type="checkbox"/> Mentally Ill | <input type="checkbox"/> Minors (0 – 17 years) |
| <input type="checkbox"/> Severely Ill | <input type="checkbox"/> Students | <input type="checkbox"/> Employees |

- c. Please indicate the approximate number of subjects, existing records, or specimens required for the analysis of this research.

- d. Will there be equal representation of:

Gender Yes No

Racial/ethnic groups Yes No

If you answered "NO" for either of the above questions, please explain:

3. Recruitment: If relevant, please describe from where and how the subjects will be identified or recruited and who will make the initial contact with the subjects?

4. If relevant, please describe how you plan to distribute or display any recruitment materials for this research (e.g., bulletin board, e-mail, newspaper advertisement, etc.).

Attached is a copy of any material(s) that will be given to subjects or used to recruit subjects for this research

- Advertisement Flyer Telephone Script Letter Information Sheet

5. Consent: Please describe the methods you plan to use in order to obtain informed permission to participate in this research and attach a copy of the written description or written script for oral presentation. If you cannot obtain informed permission for this study, please explain why it cannot be obtained (e.g., the data are de-identified).

6. Confidentiality:
a. Describe provisions taken to maintain confidentiality of data. Who will have access to data? Will data be made available to anyone other than the principal investigator and research staff? If yes, explain below and in the consent document.

- b. Where will data be stored and for how long?

7. Outcomes: Describe the outcome measures and analysis including “products” you plan to generate (i.e. manuscript, report to an agency, etc.).

X. CONTACT INFORMATION

Who should be contacted by OSP if further information about this protocol is needed?

Name (Last, First)

Title

E-mail Address

Date

Campus Phone Number

Campus Fax Number

XI. ASSURANCES

A. 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 and the ethical performance of the research. I agree to comply with all applicable NEIU policies and procedures, and applicable federal, state and local laws. I also agree to the following:

- The research will only be performed by qualified personnel according to the approved research protocol,
- No changes will be made to the research protocol (except when necessary to eliminate apparent immediate hazards to the subject), or the consent process (if one is required) without prior approval by the NEIU IRB/OSP,
- Legally effective consent/assent will be obtained from human subjects, if applicable and appropriate,
- Unanticipated problems involving risks to subjects or others (including adverse events) and subject complaints will be reported to the NEIU IRB/OSP as required.

I certify that I have completed the required educational program on ethical principles and regulatory requirements in Human Subject Protections. I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Signature of Principal Investigator

Date

B. Faculty Sponsor's Assurance

By my signature as faculty 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 research in accord with the approved research protocol.

In addition,

- I agree to meet with the Principal Investigator on a regular basis to monitor study progress,
- Should problems arise during the course of the study, I agree to be personally available to supervise the Principal Investigator in resolving them,
- I will ensure that the Principal Investigator promptly reports unanticipated problems involving risks to subjects or others (including adverse events) and subject complaints to the NEIU IRB/OSP in a timely manner according to OSP policies,
- 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 have verified that the investigator has completed the required educational program on ethical principles and regulatory requirements for human subject protections.
- I further certify that the proposed research is not currently underway and will not begin until approval has been obtained.

Signature of Faculty Sponsor* (if PI is a student or a fellow)

Typed Name

Date

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

C. Department Head Signature

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

Signature Department Head/Dean*

Typed Name of Dept. Head/Dean

Date

Dept. Name

Address

M/C

**If a Principal Investigator, Faculty Sponsor, or Co-Investigator is also the Department Head, this signature must be that of the College Dean.*