

INSTRUCTIONS – Claim of Exemption Application

Office of Sponsored Programs (OSP)

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

I. Introduction

This Claim of Exemption application is to be used by investigators who are planning to conduct research involving human subjects, data, or tissues when the investigator believes that research may be exempt from the federal regulations and continuing IRB oversight. If you believe that your human subjects research may be exempt under the regulations, and you are not familiar with this form, please carefully read the directions in the first three pages of this application. Please note: OSP will return any incomplete application to the investigator without a determination regarding the claim of exemption.

If at any time in the process of completing this application, you determine that your research does not meet the requirements for exemption, please STOP and use the application form for initial IRB review (either the Social and Behavioral Sciences Application Form. Please note that you may not file for a claim of exemption if your research involves prisoners, fetuses, pregnant women, or human in vitro fertilization.

Investigator Education in Human Subjects Protections:

Initial submissions will not be accepted by OSP for review if the PI and/or Faculty Sponsor (when a student is the PI) or student researcher does not have documentation of initial or continuing training in Human Subject Protections on file. NEIU requires that all investigators and key research personnel comply with the initial human subject protections training and continuing education requirements (www.neiu.edu/~sprogram)

Note: You may not begin your research; including initiating recruitment, or consenting, or collecting data on potential subjects, until you receive a written letter from OSP approving your claim of exemption.

A. Categories of Research Involving Human Subjects, Data or Tissues That May be Reviewed for a Claim of Exemption:

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 harmful¹ to the subject:
 - 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 existing² 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 subjects³. 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-identified⁴. 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.

B. Informed Permission to Participate:

NEIU Policy requires investigators, whenever feasible, to provide information about the research protocol to subjects and to obtain their permission prior to their participation in the research. The information about the research protocol should be presented to subjects in writing or orally from a written script. The following information should usually be provided to potential research subjects participating in exempt studies:

- a. Information regarding the researchers’ affiliation; NEIU or other institutions,
- b. The general purpose of the research,
- c. The extent of the subject’s involvement and an explanation of the procedures that will be followed,
- d. Whether the information being collected will be used for any purposes other than the proposed research,
- e. Description of the procedures to protect the privacy of subjects and the confidentiality of the research information and data,
- f. Description of any reasonable foreseeable risks, as well as the anticipated benefit from the research,
- g. Statement that participation is voluntary and subjects can refuse to participate or can stop at any time,
- h. Statement that the researcher is available to answer any questions that the subject may have and which includes the name and phone number of the investigator(s). (Include Faculty Sponsor).
- i. Statement that the NEIU IRB is available if there are questions about subject’s rights, which includes the appropriate phone numbers (773-442-5844).

C. Funding/Support:

1. If the research is currently supported by a grant proposal or contract, OR if support for the research protocol has been requested under a grant proposal or contract, please attach a copy of the research proposal/protocol that was sent to the agency, committee or sponsor for peer-review of scientific merit. Please include the following sections of the grant proposal:
 - face page
 - abstract, performance sites and key personnel
 - biographical sketch (Principal Investigator only)
 - research plan – specific aims/objectives
 - background and significance
 - research design and methods including subject recruitment and/or data procurement
 - literature cited
 - gender/minority inclusion (rationale for subject selection)
 - collaboration/support letters or institutional/organizational approvals where appropriate

2. If the research is student research attach a copy of your prospectus or research plan, please include the following sections as applicable:

- performance sites and key personnel
- research plan – specific aims/objectives
- background and significance
- research design and methods including subject recruitment and/or data procurement
- literature cited
- gender/minority inclusion (i.e. rationale for subject selection)
- collaboration/support letters or institutional/organizational approvals where appropriate

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 subjects' financial standing, employability, or reputation.

²Existing data means the items exist before the research was proposed or was collected prior to the research for a purpose other than the proposed research. (For purposes of an HHS grant, this refers to data collected prior to the time the research was proposed.)

³Coded data, which can be linked to an individual's identity by either the provider or recipient of the data cannot be considered exempt and would require submission of either an Application for Expedited or Full IRB Review.

⁴In order for data to be considered de-identified per HIPAA privacy regulations, it cannot be coded with any of the following fields of data:

- Names
- All elements of dates (except year) for dates related to an individual, including birth date, admission date, discharge date, date of death
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial numbers
- Medical record numbers
- Health plan beneficiary numbers
- Account numbers
- Any other unique identifying number, characteristic, or code.
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes
- Telephone & Fax numbers
- Electronic mail addresses
- Social security numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images

Please use the following checklist to ensure that you have completed and included all of the items required for review of your claim of exemption (please submit one original and two identical copies in the following order):

- A complete, typewritten Claim of Exemption Application (all pertinent questions have been answered).
- Obtain appropriate departmental signatures (and signature of faculty sponsor for student research).
- Please include a completed "Exemption Screening Questions" form.
- Include copies of any relevant Grant/Contract proposal (if applicable), or Prospectus/Research Protocol
- Include copies of all supporting documents, including letters of support and approval notices from other institutions.
- Include all proposed recruitment materials (advertisements/flyers) and consent/assent documents
- Include copies of all questionnaires, survey instruments, interview questions, discussion guides and/or data collection instruments that will be used.
- Retain a copy of this claim of exemption packet for your records.