

Instructions - Initial Review Application:
Social and Behavioral Sciences

Office of Sponsored Programs (OSP)

Northeastern Illinois University

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

I. Introduction

The following are directions for completing the Initial Review Social and Behavioral Sciences Application.

If you are not familiar with the application form, please carefully read these. Please note: OSP will return any incomplete application to the investigator without any determination regarding the research application.

University policy requires that all research meeting the federal definitions for human subjects research be reviewed and approved by the IRB prior to initiation of the research (which includes initiation of the consent and/or recruitment processes, interventions or interactions with potential subjects or recording of human subjects' data for the purposes of the research.

Please 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 documenting IRB approval for the initiation of your proposed research.

The initial review application form will assist the IRB in reviewing your proposed research and making determinations that are required for approval under federal regulations and University policies. The checklist will ensure that the application is complete.

A. Investigator and Key Research Personnel Education in Human Subjects Protections

Initial submissions will not be accepted by OSP for review if the PI, Faculty Sponsor (when a student researcher is the PI) and/or student researcher do not have documentation of initial and/or continuing education training in Human Subject Protections on file. NEIU requires that all Principal Investigators and Key Research Personnel comply with the initial human subject protections training and continuing education requirements. In addition, persons listed as key research personnel on this application will not be allowed to participate in the research unless they are current in terms of the initial training and continuing education requirements.

Key Research Personnel is defined as including all persons who will have a significant role in the design or conduct of the research, and includes at a minimum all Principal Investigators and Co-Investigators, and any individuals who are individually named on a grant or contract application, who are named as contact persons in the informed consent documents or recruitment materials for research, or who provide supervision of the persons who are obtaining informed consent to participate in research.

B. Legally Effective Fully Informed Consent

Informed consent is an ongoing process and is not complete once the subject signs the consent document, but rather continues for the duration of the subject's participation in the research. At NEIU, researchers are usually required to develop consent documents that are written using simple declarative sentences at a 6th to 8th grade reading level. Foreign language versions should be prepared for any research that would anticipate enrollment of subjects from specific populations whose primary language is not English. An interpreter may be used for the rare, unexpected non-English speaking subject. However, when groups of non-English speaking subjects are going to be approached for enrollment in the research, it is required that informed consent documents be translated into their primary language. Translated consent documents must be submitted to the IRB for approval before their use.

C. Consent/Assent Forms

Please note that NEIU consent templates are available for your use. You should review the templates carefully and modify or remove any language that does not specifically pertain to your research. You do not need to use the NEIU templates if there is another format you wish to use, but you will be required to include all of the required elements of informed consent unless you are applying for a waiver or alteration of the usual requirements of informed consent. Please prepare and attach consent document(s), parental permission document(s), and assent document(s) for IRB review. If this is a multi-institutional or sponsored study and there is a model consent document(s), please include reference copies and then prepare the NEIU-specific consent document(s) by editing the model document(s) to include NEIU IRB standard language. See the NEIU Office of Sponsored Program (OSP) website for informed consent information:
<http://www.neiu.edu/~sprogram/>

D. Funding/Support

If the research is supported by a grant proposal or contract, OR if support for the research protocol has been requested under a grant proposal that is pending approval, please attach a copy of the entire grant application, including the signature page, which was sent to the agency, committee, or sponsor for peer-review of scientific merit. If the research is industry sponsored, please attach the sponsor protocol, with signature page signed by the Principal Investigator. If the research is student research, a copy of the thesis/dissertation proposal should be submitted, including as many of the following sections as are applicable. If the research is not externally funded, please provide a copy of the investigator-initiated protocol (including title page containing a version number and date). In all documents, whenever possible, please clearly identify a version and date for the document submitted.

Please include the following sections of the grant/contract proposal or research prospectus/plan:

- Face page, abstract, and lists of performance sites and key research personnel
- Biographical sketch (Principal Investigator only)
- Research plan – specific aims/objectives, background and significance
- Preliminary studies and progress reports
- Research design and methods including statistical design and plans for subject recruitment and/or data procurement
- Literature cited
- Gender/minority inclusion (rationale for subject selection)
- Collaboration/support letters or institutional/organizational approvals where appropriate

E. School and Classroom Research

Research activities conducted in a school setting normally requires documentation of the permission of the local school principal or officials in the school district where the research will be conducted. Likewise, in the University setting, a letter of support from the class Instructor or Department Chair is often requested. In addition to letters of support, when these research activities involve the use of classroom time, please complete and submit Appendix A along with the protocol application.

F. International Research

Research conducted by NEIU investigators falls under University purview and guidelines even when conducted elsewhere. Research projects must have been approved by the local equivalent of an IRB before they can receive final approval from the NEIU IRB. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. The IRB requires documentation of this "local approval" before it gives its approval. In addition, international performance sites will require that Appendix E be completed and submitted along with this application.

G. Please use the following checklist to ensure that you have completed and included all of the items required for review of your Application Form for Initial Review

Please collate your submission and include the required number of copies (see below) in accordance with the order of documents in the following checklist.

Completed, typewritten Application Form for Initial Review (all pertinent questions have been answered, and all relevant appendices).

Obtained appropriate departmental approval signatures (and signature of faculty sponsor for student research).

Included copies of a separate protocol, including thesis/dissertation proposal, or relevant Grant/Contract application (if applicable), or a Sponsor's protocol (when applicable), including signature pages.

Included copies of all supporting documents, including letters of support and approval notices from other institutions.

Included all proposed recruitment materials (advertisements/flyers), and NEIU-specific consent/assent documents

Included copies of all questionnaires, survey instruments, interview guides, discussion guides and/or data collection instruments that will be used.

Retained a copy of this application for your records (Investigator's file).

H. Number of Required Copies

A. Full (Convened) IRB Review (research that involves greater than minimal risk), requires **8** total collated and complete applications with supporting documentation (see checklist above).

Please note that Only 2 of the 8 packages need to contain:

- Complete research proposal/protocol/grant which was submitted for funding, sponsor protocol, or investigator initiated protocol;
- Investigational brochures, if appropriate.

B. Expedited IRB Review (research that involves no greater than minimal risk), requires **2** total collated and complete applications.

****If you have questions, please do not hesitate to call OSP at (773) 442-4670**