Example

Protocol ID
PI
PI Type
Department
PI Institution

External PIs

Review Type
Approval Status
Based On
Submitted By
Date Received
Date of Completion
Date Approved
Final Approval Date
Proposed Start Date
End Date
Date Closed
Risk Level
Funding Source
Grant Number
Consent Waived
Waiver of Documentation of Informed Consent
HIPAA
Subjects
Other Subjects Type
Number of Subjects
Searchable Keywords

Conflict of Interest

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

Options: 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

Answer Required

1. Performance Sites

Name of Performance Site:

Answer

Required

Provide letter of IRB approval (using upload button above)

Options: Attached
Will Follow
Not Applicable

Answer Required

Requested Documents

- **Site IRB Approval Letter**
- **Site Letter of Support**

2. Performance Sites – Application Questions

Name of Performance Site:

Answer Required

Provide letter of IRB approval (using upload button above)

Options: Attached
Will Follow
Not Applicable

Answer Required

Requested Documents

- **Site IRB Approval Letter**
- **Site Letter of Support**

Project Description

Provide a brief description of the purpose of your research. Explain the major parts of your study and how the data will advance research in the area and fill the gap in the literature.

Answer Required

State your research question(s). The planned research protocol should be one that can realistically address the research question(s)

Answer Required

Describe the method of data collection and analysis

Answer Required

Provide detailed information on what subjects will be asked to do, what information will be collected about them, and when or how often research activities will be concluded (submit all instruments, surveys, interview questions, observation checklist, etc. that you plan to use for data collection).

Answer Required

Describe the location, setting, and timing of data collection. If research will be conducted in a classroom setting during class time, please describe what those who choose not to participate will be doing, and provide justification for use of class time for research.

Answer Required

List the activity, occurrence, and duration in which the subjects will be engaged, including a description of the data that will be collected.

Answer Required

Check the box(s) that best describe your study activities: a) Audio recordings, b) clinical trials, experiments, or randomized controlled trials, c) Documents and records, d) ethnographies, oral history, and case studies, e) interviews or focus group sessions, f) online (e.g., Qualtrics or other web-based collection method), g) observations, h) program evaluations, i) video recording, j) Other

Options:
- Audio Recordings
- Clinical Trials, Experiments or Randomized Controlled Trials
- Documents and Records
- Ethnographies, Oral History, and Case Studies
- Interviews or Focus Group Sessions
- Online (e.g., Qualtrics or other web-based collection method)
- Observations
- Program Evaluations
- Video Recording
- Other

Answer Required

Will subjects be compensated for their participation?

NOTE: If you plan to use a lottery system, please state odds of winning here and in the consent form. Also, if you will be offering course credit for study participation, you must discuss this here and include the alternative assignment for those who decline to participate in the study. Will compensation be pro-rated if the participant does not complete all aspects of the study? If you pay participants after their participation, please make it clear how you will link names/contact information confidentially to any record of the compensation.

Answer Required

Will deception be used? If so, please provide a rationale for its use.

NOTE: Upload a debriefing script as a separate document. Include a statement that gives your participants the opportunity to withdraw their participation at that time. Studies involving deception are given Full Board Review unless the deception is minor and risks are minimal.

Answer Required

Will you have a control group, or a comparison group?

Options:
- Yes
- No

Answer Required

Will you need bilingual interpreters or interviewers, and if so, what will you do to ensure participant confidentiality? What are your procedures for recruiting interpreters and interviewers?

Answer Required

Will this research be conducted at an international site?

Options:
- Yes
- No

Answer Required

Recruitment Procedures

Provide the inclusion criteria for the subjects (e.g., by gender, class, race, occupation, age range, etc.)/ Provide a rationale for selecting this population for research purposes. (Federal guidelines state that research cannot exclude any classes of participants without scientific justification)

Answer Required

Provide the maximum number of subjects you plan to enroll for each participant population and justify the sample size.

Answer

Required

Describe your recruitment methods. How and where will subjects be recruited (e.g., flyers, announcements, word-of-mouth, snowballing, etc.)? Submit a copy of all recruitment letters, scripts, emails, flyers, or social media posts you plan to use to recruit participants for your study.

Answer Required

Consent Procedures

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 (not collecting signed consent or assent form), provide justification.

Answer Required

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?

Options: Yes
No

Answer Required

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

Options: Yes
No

Answer Required

Waiver of Informed Consent

This research involves no more than minimal risk to the subjects?

Options: Yes
No

Answer Required

Explain why this study cannot practicably be carried out without the waiver/modification of informed consent.

Answer Required

Explain how this waiver/modification will not adversely affect the rights or welfare of the subjects.

Answer Required

If appropriate, how will subjects be debriefed after the conclusion of the study?

Answer Required

Description of Research Risks and Benefits

Describe the potential risks to your participants. Risks can be physical, psychological, economic, or social. What is the likelihood of these risks occurring, and/or their seriousness (e.g., exposure of sensitive data)? How will you work to minimize these risks?

NOTE: *The IRB regards no research involving human participants as risk-free. You may describe minimal risks for your study (such as discomfort, boredom, fatigue, etc.), or state that the research will involve minimal risk, similar to*

an activity (named) that participants would perform in their daily lives.

Answer Required

What are your plans for ensuring necessary intervention in the event of a distressed participant and/or your referral sources if there is a need for psychological and/or physical treatment/assistance?

Answer Required

What qualifications and preparations enable you to estimate and minimize risk to participants?

Answer Required

Describe any possible direct benefits to your participants. Most research will not have any direct benefits to participants. Occasionally, a study design will include a diagnosis, evaluation, screening, counseling or training, etc., that has a concrete benefit to participants, independent of the nature or results of a research study.

Answer Required

Confidentiality Procedures and Participant Privacy

Please check the box(s) that best describes your data. Note: Sensitive data potentially poses substantial threat to research subjects and can become problematic for the researcher, researched collection, and/or the dissemination of research data (Lee & Renzetti, 1990). Substantial threat may include threat to reputation, employment, or access to resources. Sensitive data may include studies of domestic violence, immigration status, political activism, homicide, death, trauma, assault, and/or mental, sexual, or physical health (Lee, R. M., & Renzetti, C. M. (1990). The problems of researching sensitive topics: An overview and introduction. The American Behavioral Scientist, 33(5), 510–528).

Options:
- Completely anonymous data (both sensitive and non-sensitive)
- Sensitive data with identifiers
- Non-sensitive data with identifiers
- Other (please explain)

Answer Required

For data with identifiers please describe your method for de-identifying the data to maintain confidentiality.

Note: The term de-identified data refers to subject data from which all information that could reasonably be used to identify the subject has been removed or replaced. For example, the researcher may use the safe-harbor method to remove specified identifiers (name, address, phone, or any other unique identifier, etc.) from a dataset; the partially de-identified method to remove most, but not all identifiers from the data set (may require a data use agreement); or the generation of variables method to replace study subjects' identifiers, like using a unique code or pseudonym. To be truly de-identified data, the investigator cannot have codes that link to identifiers.

Answer Required

If you are working with sensitive identifiable data, please explain why identifiers are necessary to carry out your research. Sensitive identifiable data should never be sent as an email attachment.

Note: If you are collecting private, identifiable heath information as part of your research, please see Guidelines for the Health Insurance Portability and Accountability Act (HIPAA) document.

Answer Required

Data Security

Please select what best describes how you will transfer your data.

Options:
- I will use a Virtual Private Network (VPN) for secure data transfer or other form of encryption (e.g., NEIU's secure remote network access).
- Not applicable (e.g., data will not be accessed remotely or transferred. It will exist only on a locally stored password-protected hard drive).

Answer Required

Please select what best describes how you will store your data.

Options:
On a password-protected local or external computer hard drive.
On NEIU's Google Drive, in a password-protected folder.
Other (e.g., cloud-based, password-protected storage) (please explain).
On NEIU's local password-protected network.
In Dropbox (faculty only).

Answer Required

Northeastern Illinois University classifies all data associated with ongoing research studies as confidential, meaning only project staff, academic advisors, collaborators and other individuals at the college on a need-to-know basis may have access to it. Confidential data at a minimum should be stored on a password-protected computer, or in a password-protected file or folder if the computer is shared. Paper and other physical media should be kept under lock and key. All computers accessing data should have anti-virus software installed.

Please affirm your data security plans.

Options:
I will encrypt my data (e.g., conceal data by converting it into a code).
I will block unauthorized access to my data (e.g., firewall).
I will delete old files from cloud-based backups and local hard drives.
I will use anti malware protections and automatic software updates.
I will disable file and media sharing if I do not need it.
I will take care of privacy settings immediately upon setup.

Answer Required

* Please check the box below:

Yes, I acknowledge and understand how Northeastern Illinois University classifies research data.

Answer Required

Privacy and Confidentiality

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)?

Options:
Yes - Describe these circumstances.
No

Answer Required

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

Answer Required

Application Checklist

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.)

Copy of IRB approvals from partner institutions

Support letters from performance sites

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

Investigator 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.

* I agree to all of the previous statements and requirements.

Answer Required