Northeastern University
Human Subject Research Protection

Guidance: Modifications to IRB protocols

After receiving the written approval from the NU IRB to begin a research project, investigators may follow the protocol procedures and use only the versions of the recruitment materials, consent and assent forms and study instruments as approved. However, if you need to make changes to the study, you may do so by completing the modification form and providing all new and revised documents. Depending on the requested modification and risk to study participants, modifications may either be reviewed expeditedly or by a convened IRB.

All documents are to be submitted to IRBReview@northeastern.edu. **The modification must be approved by the NU IRB before you institute the change.**

✓ Complete the modification form
✓ Indicate changes to the documents through track changes
✓Submit all revised or new documents that pertain to the requested modification
✓Submit all revised and new documents in Word format

Updating research team members

The Principal Investigator and the student researcher are to be noted on the protocol application form. All investigators engaged in the research study, including those from other institutions, are to be listed on the Research Team Form. Please update this form when new members are added to the research team and when individuals are no longer involved in the research. Include all people who will be: (i) directly responsible for the project's design or implementation, (ii) recruiting potential participants; (ii) obtaining informed consent; and, (iv) involved in the data collection, data analysis, or follow-up.

Collaborators, outside consultants, and all graduate and undergraduate students are to be listed as research team members when responsible for the activities identified above. In addition, [lease include all investigators named on grant proposals who will be engaged in human subject research.

Note: Changes made to the Principal Investigators require a revised protocol application form and modification form.

Modifying exempt protocols

If the IRB determined that a study meets one or more of the Exemption categories, the study team may edit project procedures and documents without re-submitting to the IRB, so long as the research remains minimal risk and remains within the boundaries of the exemption categories that the IRB found applied to the research.

The Office of Human Subject Research Protection recommends that researchers make a note in the research record of any changes made and the Principal Investigator's determination that these updates did not change the scope of the study or risk to participants.

If your changes may increase the risk level of your Exempt protocol or involve…

- Revisions to the consent process, or use of deception or incomplete disclosure.
- Significant changes to the recruitment procedures and additions of new data collection sites.
- Adding sensitive questions to a survey or interview process (e.g., questions regarding illegal activities; traumatic events such as childhood, sexual, or domestic abuse; suicide; or other probing questions that could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation).
- Collection of new or additional identifiable information.
- Add new types of participants to your study that include vulnerable populations (e.g., adding children, individuals with cognitive impairments, prisoners, etc.)
- Changes to the data storage plan which may affect confidentiality.

There are also instances where modifications will not impact risks to participants or impact exempt determination, however, must still be reported to the office. Examples of these include:

- Change of Principal Investigator
- New data collection sites where a letter of support is required
- Addition of external funding source

Modification request not needed if…

The research remains minimal risk and within the boundaries of the exemption categories under which the project was originally reviewed.

For example,

- Changing recruitment criteria without including new vulnerable populations
- Updating recruitment materials or consent documents
- Adding, removing, or revising non-sensitive questions on surveys or interview/focus group scripts
- Changes to the study team, other than the Principal Investigator

Still not sure? Contact IRBReview@northeastern.edu with questions.