Northeastern University
Human Research

Guidance: Working with Non-NU Collaborators on Exempt Research

Overview

The NU IRB does not typically provide oversight for non-NU collaborators on exempt research.

Collaborators who are under the oversight of another IRB or research ethics program should follow that program's requirements, which may include getting its own exemption determination before they take part.

When collaborators are not under the oversight of another IRB or research ethics program, the NU study team is responsible for making sure they are prepared, supervised, and following the procedures the IRB reviewed. The exempt application will ask you how you're planning oversight. This document is intended to help you plan this out.

Is your collaborator part of the study team?

Not everyone who helps with a project is a member of the research team. Use Investigator Manual, Section 3.4 to decide whether an outside partner is engaged in your research and should be considered a study team member. The expectations below apply to collaborators who are.

What should your oversight plan cover?

Roles

Start with a clear plan for who does what. Know who each collaborator is, where they work, and which research tasks they will and won't do.

Example: A site educator will co-facilitate two focus groups but will not recruit participants or see the list linking names to study codes.

Training

Before starting research activities, collaborators should complete some form of human subjects training and a study-specific orientation from you. Build in a way to confirm they understood it, such as a debrief, a short quiz, or observing their first session. See DHR Training for options to consider.

Example: Community partners complete the free online CIRTification and a 30 minute orientation with the research team on roles. The PI keeps CIRTification completion certificates on file.

Example: Community partners attend a 60 minute research ethics session developed by the NU study team. The PI observes their first data collection session to confirm they are following the procedures.

Oversight and data	Decide how you will supervise collaborators and confirm procedures are followed. Your protocol's data security plan should cover the entire study team, including collaborators. Best practices for all study team members include: limiting their access to what their role requires, keeping data in secure NU-managed storage, and ending access when their work is done. *Example: The collaborator uploads recordings to the PI's NU folder and keeps no copies. IT will grant them access to the folder, but will remove access as soon as their role is completed.*
Communication	Set a regular check-in schedule and make clear what collaborators must report to you, such as participant concerns, possible confidentiality problems, or requests to change procedures. *Example: Biweekly Zoom check-ins will be set up during data collection. We will clearly explain that any participant complaints or concerns need to be reported to the PI within one business day.*
Coercion	Your protocol's section on coercion should consider the entire study, including collaborators. A collaborator who supervises, evaluates, or teaches participants can create pressure to take part, even unintentionally. Address how you will reduce that pressure in that section. For strategies, see related guidance documents: Recruiting and Enrolling Your Students and Research Involving Employees, Colleagues, and/or Subordinates. *Example: A school principal is a collaborator on a study of her teachers. She does not recruit or interview them. The NU research team will send the recruitment email and conducts interviews off-site after school hours, and transcripts are de-identified before the principal sees them, so she does not know who took part.*
Conflicts of interest	If a collaborator has a financial stake in the project, describe it and how you will keep it from influencing the results. For more info, see related guidance: Conflict of interest & human subject research

Questions?

Bring them to IRB Drop-in Hours before you submit, or contact DHR.