

Cornell requirements for training for human participant research for trainees on NIH grants

Overview: Cornell University regards the use of human participants in research to be integral to the continued mission of the university. All trainees using human participants for research that requires approval by the Cornell Institutional Review Board (IRB) at Cornell University must be adequately trained, educated and/or qualified in the principles and their responsibilities related to the ethical treatment of human participants as laid out in the Belmont Report and the Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Human Subjects research regulations, in the specific procedures that they are expected to perform with human participants, and, in the University policies and procedures governing research with human subjects.

Protocol specific training requirements for use of human participants: Training requirements for personnel involved in use of human subjects for research are determined by the Institutional Review Board (IRB). All trainees named on a protocol involving the use of human subjects must complete the assigned mandatory training prior to protocol approval. This training is valid for five years, and has several components, as described below.

At a minimum, this training comprises an online course developed by CITI covering the ethical concepts and required practices in accordance with the provisions of the Belmont Report and the 45 CFR 46, for the involvement of human subjects in research including a description of the need (both ethical and regulatory) for employing research methods that assure voluntary informed consent, beneficence and justice. This online course also contains information about considerations when using special populations, unexpected or adverse events and the role of the IRB in the oversight of human subjects research. This training is completed online; however, in many cases, the Principal Investigator conducts further training with researchers in the specific procedures for the research project. In cases where the procedures are biomedical in nature, research protocols must include Standard Operating Procedures (SOP) that must be followed; these SOPs include the procedures, as well as instructions on how to manage any unexpected events or emergencies. In cases where the research is to be done in international settings, the IRB will ask for information on how the local research team will be trained in the principles of the Belmont Report and in the specific research procedures. Completion of all such training is required before a protocol can be approved.

Ensuring trainees are compliant with required training for IRB protocols: Any individual who wishes to use human participants for research, teaching or testing must be named on an IRB protocol and approved by the IRB to conduct those procedures. Protocols and personnel named on those protocols cannot be approved until every person named on the protocols have completed the training assigned by the IRB.

All PIs with protocols are advised during their training, and during the protocol review process and renewal, that they are required to add any new personnel, including students, to their protocol, before those personnel can conduct any procedures or access any data on human subjects. Once an individual is added to the protocol, the protocol is reviewed by the IRB, and training is assigned to the individual. Once the individual has completed the training identified during the review process, the IRB grants approval for the individual to begin the research.

For all NIH trainees: In addition to the protocol specific training requirements described above, all trainees on NIH grants are required to complete the online course in Responsible Conduct of Research (RCR), which includes a module on human subjects research. Regardless of whether

these trainees ever use human subjects in research, this basic information about the ethical principles and applications of the Belmont Report are a key component of the RCR training. All trainees are also required to attend the semester long course in Bioethics (**BioMG 7510 Scientific Ethics**). At least one session of that course is dedicated to the ethics of human participants in research and is taught by faculty members who have deep experience with human participants research and with the Cornell IRB.

Each year, all trainees are required to participate in a symposium on responsible conduct of research, which provides an avenue for highly interactive case based discussions on complex issues regarding research integrity. Topics for the symposium have included authorship, research misconduct and the ethical considerations in the use of data and materials from human subjects in research.

For all Cornell graduate students: As a condition of graduation, all graduate students whose research involves human subjects are asked to provide evidence to the graduate committee, of IRB approval for the use of human subjects in their thesis research.