**Cornell Training Program for trainees on NIH grants on Ethical Treatment of Human Participants in Research**

**Overview:** Cornell University regards the use of human participants in research to be integral to the continued mission of the university. All trainees working with 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 human participant research are determined by the Institutional Review Board (IRB). All trainees named on a protocol involving the use of human participants 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 participants 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 participant 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 conduct research with human participants must be named on an IRB protocol and approved by the IRB to conduct those procedures. Protocols cannot be approved until every person named on the protocol has completed the training assigned by the IRB.

All PIs with protocols are advised 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 participants. Once an individual is added to the protocol, the protocol is reviewed by the IRB, and training records are checked. If an individual named on the protocol has not yet completed necessary training, the IRB will communicate the remaining training requirements to the PI. Only after the individual has completed the training will the IRB grant approval for that person’s involvement in 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 participant research. Regardless of whether these trainees ever use human participants 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, Ethical Issues and Professional Responsibilities**). 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 participant 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 participants in their thesis research.