

## Requirements for Human Subject Protection Training

BRANY IRB will ensure that each member of the research team has been educated in the protection of human subjects. The NIH has mandated, and OHRP strongly recommends, that all investigators and those identified as “key personnel” in human subject research must provide evidence of education in the protection of human subjects.

“Key personnel” are defined as individuals who are responsible for the design and conduct of a study. Therefore, all investigators and key personnel, including sub-investigators, co-investigators, and others participating in the conduct of the research, must satisfy this requirement. The IRB will deny the privilege of participation to investigators or key personnel until proof of certification is submitted. The IRB will maintain a record of all those who have been certified. Every new and continuation application that is submitted to the IRB will be assessed to ensure that all individuals who will participate in the conduct of the research have been certified.

BRANY IRB ensures key personnel have satisfied the training requirements from their institution, and that key personnel are in compliance with their institution’s re-certification policies.

In the absence of an institutional certification program, BRANY IRB will consider other forms of education in protection of human subjects on a case-by-case basis. For example, an independent investigator may have completed comprehensive such education while previously affiliated with an Institution or other organization; in such cases, prior research education completed at an Institution may be accepted by BRANY IRB. The IRB Director (or designated IRB staff), with consultation from the IRB Chairperson(s) and/or the Institutional Official as needed, will evaluate and make determinations of acceptable forms education in protection of human subjects beyond those defined below, based on program content.

Examples of acceptable evidence of training include, but are not limited to:

- CITI Course Completion: Basic Biomedical Research Module (or equivalent)
- Certified Principal Investigator (“CPI” designation offered currently by ACRP)
- Certified Clinical Research Coordinator (“CCRC” designation offered currently by ACRP)
- Completion of the online National Institutes of Health (NIH) Office of Extramural Research module entitled “Protecting Human Research Participants,” or a certificate evidencing completion of appropriate
- Other equivalents that include training in the US federal research regulations, informed consent requirements, process, and documentation, The Belmont Report, The Declaration of Helsinki, and The Nuremberg Code

Additionally the BRANY IRB encourages Investigators and research staff to complete Good Clinical Practice Training and HIPAA (Health Insurance Portability and Accountability Act) training. Certificates evidencing completion of such training programs should be submitted to the BRANY IRB.

Please note that HIPAA training or prior research experience alone do not satisfy the requirement for training in protection of human subjects.

Contact BRANY IRB if you have any questions about whether your training will fulfill BRANY IRB’s requirements for training in protection of human subjects.

**v. 20180606**