SOP 202: Researcher Education

Terms and Abbreviations

CITI: Collaborative Institutional Training Initiative (CITI Program); an organization that provides web-based educational courses in research ethics, regulatory oversight, responsible conduct of research, research administration, etc.

GCP: Good Clinical Practice

HIPAA: Health Insurance Portability and Accountability Act of 1996; federal legislation relating to the privacy and security of medical records.

IRB: Institutional Review Board

IRB office staff: the IRB Manager, IRB Administrator, and any other IRB office staff, either collectively or individually

NIH: National Institutes of Health

PI: Principal Investigator

SPI: Student Principal Investigator

UWM: University of Wisconsin - Milwaukee

Overview

To ensure that individuals conducting research with human subjects are sufficiently qualified to protect the safety and wellbeing of those subjects, researchers must complete training in human subjects protections on a regular basis.

In addition to the required training, the IRB office staff offers a range of optional in-person or online training.

Details and Procedures

Scope

The Required Training outlined below applies only to PIs and SPIs or other primary contacts on a study.

For other research personnel, the PI determines what training is necessary for the individual's specific role and ensures that it is completed.

The PI's discretion regarding training is superseded when:

- Specific training is required by external funding agencies (e.g. GCP training for all key personnel on NIH-funded clinical trials); or

- The IRB determines that specific additional training is necessary to ensure the protection of human subjects and/or the scientific validity of the data.

PIs are required to keep training records of all personnel working on their research studies and may be asked to provide these training records to the IRB.

Required Training

At the time of initial study submission, the IRB office staff verifies that the PI and SPI / primary contact have completed IRB CITI training within the last 3 years. Any one of the following UWM-specific CITI courses fulfills this requirement:

- IRB-Biomedical Researchers
- IRB-Biomedical and Social & Behavioral Combined Researchers
- IRB-Social & Behavioral Researchers
- IRB Members
- Refresher courses for any of the above.

CITI training completed through another institution may be accepted in lieu of the courses listed above, if the completed course is similar to the UWM required modules. IRB office staff make this determination.

If the researcher has not completed CITI training within the last 3 years, the IRB office staff notifies the researcher that this needs to be completed.

- For exempt studies, approval may be issued in rare cases with CITI training incomplete at the discretion of the IRB office staff.
  Example: A student project where the SPI has completed CITI training and the faculty PI agrees to complete the training within the next month.
- For expedited and full board studies, IRB approval of the study is not issued until CITI training is complete and current.

GCP

GCP training is required for all key personnel on NIH-funded clinical trials, and strongly recommended for all key personnel on all other federally-funded clinical trials. Any one of the following CITI courses fulfills this requirement:

- GCP – Social and Behavioral Research Best Practices for Clinical Research
- GCP for Clinical Investigations of Devices
- GCP for Clinical Trials with Investigational Drugs and Medical Devices (US FDA Focus)
- Refresher courses for any of the above.

HIPAA

HIPAA training, available through UWM's legal department, is strongly recommended for any PI or SPI using medical records in research.

Optional Education

1. The IRB office staff offers multiple in-person training sessions each year on a variety of topics. Researchers are encouraged to attend these sessions to learn more about a specific area of human subjects research, refresh current knowledge, and to ask questions.
2. Self-paced online training on select topics is available for researchers through the UWM IRB website.

References

45 CFR § 160 (HIPAA)

45 CFR § 164 (HIPAA)

Revision History

Version	Date	Summary of Changes
1	13 Feb 2020	Initial version