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## HRPP Education and Training

This document describes how UW-Madison ensures that its research teams, IRB members and staff, and other personnel maintain continuing knowledge of, and comply with, their legal and ethical obligations to protect human participants when conducting research.

- I. IRB members and staff receive training in ethical standards and legal obligations.
  - A. New UW-Madison IRB members and IRB staff participate in orientation and training programs covering research review and human research protection through the following mechanisms.
    1. UW-Madison IRB members and staff receive training materials and have access to reference books and journal articles that cover issues in human subjects protection, federal regulations governing human subjects research, the Belmont Report, institutional policies, and IRB standard operating procedures.
    2. IRB members participate in ongoing education and training through continuing education provided by the IRB chairs and staff, as well as during discussion of submissions at IRB meetings, CITI human subjects protection and IRB member training, and attendance at meetings and workshops relating to human research protection ethics.
    3. IRB staff participate in ongoing education and training through continuing education provided by the IRB Offices, CITI human subjects protection, and attendance at meetings and workshops relating to human research protection ethics.
  - II. Investigators and study teams have the educational opportunities and training requirements below.
    - A. UW-Madison's HRPP website and the websites of the campus IRBs provide educational and instructional material, including online tutorials, CITI Good Clinical Practice training, and information on educational events for investigators and research staff.
    - B. UW-Madison requires that all personnel engaged in human participants research, as defined in the Engagement in Human Participants Research at UW-Madison Policy, to complete human participants training and maintain valid training throughout their engagement.
      1. UW-Madison personnel are required to take the UW-Madison CITI human participants course that addresses the Belmont Report and pass it with an average score of 85%.
        - a. UW-Madison CITI human participants course expires after 3 years and must be re-taken to remain valid.
      2. For personnel engaged in human participants research who have dual appointments with the William S. Middleton Veteran's Affairs Hospital and the UW-Madison ("dual appointees"), satisfying the VA human participants training and re-training requirements will satisfy the UW-Madison human participants training requirements.
      3. For personnel at other institutions collaborating with UW-Madison researchers, UW-Madison IRBs may accept certification of the completion of a comparable human research training program as a substitute for completion of UW-Madison's required training. UW-Madison IRBs accept the following substitutes:
        - a. The Veterans Affairs Human Participants Protection training,
        - b. Training taken at another institution that uses CITI Human Participants training,
        - c. National Institutes of Health training, and
        - d. Training from other institutions holding a Federalwide Assurance.
        - e. Other training programs with permission from the reviewing IRB.
          - i. For example, a different substitute training program might be approved, if other personnel would have difficulty accessing one of the training programs listed above because they are not located in the U.S.
      4. For studies submitted to UW-Madison IRBs, human participants training is monitored using the electronic protocol submission system.
        - a. UW-Madison IRBs monitor training at several points.
          - i. Initial submissions, changes of personnel, and continuing reviews are not processed unless all those individuals listed on the IRB application have valid human participants training.
    - C. UW-Madison requires personnel conducting (defined as screening/enrolling, consenting, or interacting with subjects) research that meets the NIH definition of a clinical trial to complete Good Clinical Practice (GCP) training. This requirement will assist researchers in complying with the NIH's GCP training mandate.
      1. Personnel conducting clinical trial research involving drug, device, biologic, or radioisotopes interventions must complete CITI's "Good Clinical Practice for Drug/Device Researchers." This course will also satisfy the requirement immediately below.
      2. Personnel conducting NIH-supported clinical trial research involving social or behavioral interventions must complete CITI's "GCP-Best Practices for Social and Behavioral Clinical Research."
- III. UW-Madison's designated Institutional Official and IRB chairs should review the online Assurance Training offered by the OHRP.

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Research Policy and Compliance