SOP 201: IRB Member 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.

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

Overview

IRB members participate in both initial and continuing education. These programs focus on:

- the ethical principles and regulatory requirements underpinning human subject protections
- applying those principles and requirements to the review of research

In addition, the IRB will use initial and continuing education to ensure that there is general consistency among the IRB members and IRB office staff in applying human subject protections.

Details and Procedures

Initial Education Program

The initial education program consists of in-person training provided by the IRB office staff and on-line training provided by CITI. All IRB Chairs, Vice Chairs, members, and alternates must complete the training in the following areas before actively participating in the IRB:

1. Ethical Principles and the Belmont Report
2. Regulatory Requirements
3. UWM Federal Wide Assurance (FWA)
4. UWM Institutional Policies and Procedures
5. IRB's Role and Responsibilities
6. Application of the Principles and Regulations to the Initial and Continuing Review of Research and Modifications
7. Research Protocol Review Criteria and Review Process
8. Informed Consent Process and Document
9. Vulnerable Populations: Pregnant Women, Fetuses, Prisoners, Children and Others

10. Investigator Responsibilities
11. HIPAA Policies and Procedures

In addition, new members are assigned to review at least one protocol along with an experienced member before reviewing protocols on their own.

Continuing Education Program

IRB members complete a CITI training course every 3 years, and the IRB office staff provides continuing education specifically for IRB members at least once annually.

IRB members are also encouraged to take advantage of the following continuing education opportunities:

- Scheduled short current topics (case studies and current events)
- Just-in-Time training, in response to specific issues raised during the review of research protocols
- Regional and national educational conferences
- Training sessions for researchers offered by the IRB office staff

Continuous Quality Improvement

The IRB office staff will meet with the IRB Chair and/or IO on a regular basis to identify common issues and concerns of the IRB and to work towards improvements. Targeted quality improvement activities may involve groups of members or the entire IRB membership.

If IRB office staff identify an issue with a specific review, they may reach out to the reviewer to address any concerns or misunderstanding about the IRB's role or the review process. If the issue seems to be likely to be widespread among membership, continuing education will be developed.

IRB office staff communicate regularly to ensure internal consistency in office reviews. Formal norming exercises may be conducted as needed to verify this internal consistency.

References

45 CFR § 160 (HIPAA)

45 CFR § 164 (HIPAA)

Revision History

Version	Date	Summary of Changes
1	5 Dec 2018	Initial version
2	1 Feb 2022	Adding section on Continuous Quality Improvement
	date	
	date	

	date	