SOP 001: The Role of the Institutional Review Board

Terms and Abbreviations

FDA: Food and Drug Administration

FWA: Federalwide Assurance

HRPP: Human Research Protection Program

IO: Institutional Official – individual who is legally authorized to act for the institution and ensures the effective functioning of the IRB

IRB: Institutional Review Board

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

UWM: University of Wisconsin – Milwaukee

Overview

Role

The role of the UWM IRB is to protect the rights and welfare of human subjects in research conducted by UWM faculty, staff, and students. This is accomplished by reviewing and overseeing research studies involving human subjects to ensure compliance with ethical principles and federal regulations.

The IRB's decisions are based on the ethical principles in the Belmont Report and the Declaration of Helsinki. IRB operates under the rules of conduct established by the Code of Federal Regulations, Wisconsin state laws, and UWM policies.

The IRB is also responsible for ensuring that the standards of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) are met when protected health information is used or disclosed for research purposes.

The IRB exercises autonomy in decision-making.

Authority

The IRB has the authority to:

- approve research, require modifications to protocols in order to approve research, or disapprove research;
- require progress reports or other information from investigators regarding the conduct of the research and the informed consent process;

- place restrictions on, suspend, or terminate the approval of research that:
  - is not being conducted in accordance with IRB requirements, or
  - has been associated with unanticipated problems that involve serious risks to subjects or others.

Jurisdiction

The IRB has jurisdiction over research involving the use of human subjects, which includes identifiable data and biospecimens from human subjects, when UWM is considered "engaged" in research.

Details and Procedures

Independent Review

The HRPP in the Department of University Safety and Assurances is the administrative home of the IRB and supports the IRB's independence from external influences.

The IRB Chair fosters an environment that encourages the free and full participation of all IRB members in its deliberations.

As an integral component of the HRPP, the IRB maintains an open line of communication with the IRB Manager, Administrator, and/or the HRPP staff (individually and collectively, the "IRB office staff"). The IRB office staff is the primary liaison between the IRB and campus researchers, staff, and any others who require assistance or desire interaction with the IRB.

The IRB also has a direct relationship with the Associate Vice Chancellor of Facilities Planning & Management, who serves as the Institutional Official (IO). The IO is the University officer, designated by the UWM Chancellor, who is ultimately accountable for the IRB and the HRPP. The IRB reports directly to the IO and is supported by the IRB office staff and the University Safety and Assurances Department.

The IRB is constituted by the IO and is registered with Department of Health and Human Services, Office for Human Research Protections (OHRP) under the UWM's Federalwide Assurance FWA #00006171 and IRB Registration # IRB00000263.

Functions

The IRB ensures human subject protections by conducting the initial and continuing review of research protocols, and determining which research protocols require review more frequently than once per year. The IRB requires that proposed changes in research are promptly reported and that changes in approved research are not initiated without prior IRB review and approval, *except* when necessary to eliminate apparent immediate hazards to subjects.

The IRB may require verification from sources other than the investigator that no material changes have occurred since the most recent IRB review and approval.

The IRB reports its determinations and decisions in writing to investigators and the institution.

The IRB requires the following for ongoing research:

- Unanticipated problems involving risks to subjects or others (UPIRSOs) must be promptly reported to the IRB Chair by the IRB office staff.
- Any serious or continuing noncompliance with UWM HRPP Policies and/or federal regulations, or the requirements or determinations of the IRB, must be promptly reported to the IRB, the IRB office staff and the IO.
- Any suspension or termination of IRB approval must be promptly reported to the IO and the IRB office staff.

When appropriate, the IO will also report these to pertinent federal agencies and/or internal University Administrators.

Definition of Human Subjects Research

UWM follows the definition for human subjects research outlined in the federal regulations (45 CFR § 46).

Research to satisfy a requirement imposed by UWM for the award of a degree (such as theses and dissertations) requires IRB review, if it also meets the definition of human subjects research.

Class projects done solely to fulfill an individual course requirement do not typically require IRB review.

Definition of "Engaged"

UWM is "engaged" in research when the research is conducted by:

- UWM faculty (any appointment, including adjunct, emeritus and non-salary);
- UWM staff; or
- UWM students

AND when the research results are:

- used to fulfill a UWM degree requirement; or
- published, presented, or otherwise disseminated using UWM credentials.

References

45 CFR § 46 (Common Rule)

21 CFR § 50 (FDA)

21 CFR § 56 (FDA)

45 CFR Parts 160 and 164 (HIPAA)

The Belmont Report

Declaration of Helsinki

Revision History

Version	Date	Summary of Changes
1	5 Dec 2018	Initial version