

SOP 301: Operations

Terms and Abbreviations

HSR: Human Subjects Research, as defined in 45 CFR 46

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

Overview

The IRB office staff supports the IRB in the following ways:

- Protocol reviews
- Providing expertise in regulations and laws related to human subjects research
- Post-approval reviews
- Facilitating IRB meetings
- Administrative Functions

The IRB office staff may be voting members of the IRB.

Details and Procedures

Protocol Reviews

The IRB office staff receives and processes all submissions to the IRB and performs the initial review. This includes new studies, amendments, continuing reviews, reportable events, and requests for HSR determination.

Where a primary reviewer is required, the IRB office staff assigns a reviewer from among the IRB members, in consultation with the Chair when necessary.

For studies requiring review by the convened IRB, the IRB office staff places the submission on the next available meeting agenda.

IRB office staff serve as non-compliance subcommittee members when reports of noncompliance are received. They may be tasked with investigating details of instances of non-compliance so that the subcommittee and/or the IRB may make an informed decision.

Regulatory Expertise

The IRB office staff regularly participates in continuing education, ensuring that UWM IRB remains aware of current thought and changes in regulations related to human subjects research.

The IRB office staff shares this knowledge and expertise with IRB members and researchers through formal in-person training sessions, guidance documents, communications with the research community about new events or changes, and individual consultation on questions or concerns researchers and members may have.

Post-Approval Monitoring

The IRB office staff schedules and conducts post-approval monitoring reviews to ensure compliance with the appropriate regulations and the approved protocol.

Facilitating IRB Meetings

The IRB office staff schedules IRB meetings, records member attendance, monitors to ensure quorum is maintained, documents the IRB's decisions and discussion, and creates the meeting agenda and minutes.

The IRB office staff notifies investigators of the IRB's decisions and any conditions or stipulations of approval. The IRB may designate the IRB office staff to review requested revisions and determine that all conditions of approval are met.

Administrative Functions

The IRB office staff maintains all required records for individual studies until at least 3 years past the end date of the study, or longer if required by regulations. The IRB office staff also maintains all records of IRB meetings in accordance with Wisconsin open records laws and federal regulations.

The IRB office staff maintains and updates the IRB website as needed, creates and updates SOPs, and publishes and disseminates important communications to IRB members and the research community.

The IRB office staff arranges reliance agreements with other institutions, in cooperation with the IO.

References

45 CFR 46.102

Wis. Stats. §§ 19.21-19.39 (Wisconsin open records law)

SOP 201 – IRB Member Education

SOP 202 – Researcher Education

SOP 302 – Record Retention

SOP 303 – IRB Meetings
SOP 401 – Review of Research
SOP 306 –Post-Approval Monitoring

Revision History

Version	Date	Summary of Changes
1	13 Feb 2020	Initial version
2	1 Feb 2022	Updating references to Post-Approval Monitoring
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