SOP 401: Initial Review of Research

Terms and Abbreviations

CFR: Code of Federal Regulations
FDA: Food and Drug Administration
FERPA: Family Educational Rights and Privacy Act
Full board: A convened meeting of the IRB at which a quorum of members is present
HIPAA: Health Insurance Portability and Accountability Act
IO: Institutional Official
IRB: Institutional Review Board
Minimal risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

PI: Principal Investigator

UWM: University of Wisconsin – Milwaukee

Overview

For all review of research, the IRB bases its determinations on upholding the Belmont principles of Respect for Persons, Justice, and Beneficence, as well as complying with all applicable federal and state laws and university policies.

Regulations

In order to approve a new research protocol involving human subjects, the IRB must determine that all of the criteria from 45 CFR § 46.111 are satisfactorily met:

1. Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result from the research.
3. Selection of subjects is equitable. In making this assessment the IRB takes into account the purposes of the research and the setting in which the research will be conducted. The IRB is particularly cognizant of the special problems of research that involves subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.
4. Informed consent will be sought from each prospective subject or their legally authorized representative, as required by §46.116.

5. Informed consent will be appropriately documented or appropriately waived in accordance with §46.117.
6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

For research that falls under the purview of the FDA, the IRB determines that the criteria from 21 CFR § 56.111 are met.

For research that is not federally funded or subject to FDA oversight, the IRB may use flexible policies in granting exceptions to the requirements of 45 CFR 46 when deemed appropriate.

Risk Level

Research involving more than minimal risk must be reviewed by the IRB at a convened meeting ("full board" review).

Research involving minimal risk that fits into one or more expedited or exempt review categories may be reviewed by a designated IRB reviewer rather than by the full IRB.

Compliance

Principal Investigators must not start any aspect of research involving human subjects (e.g., recruitment, screening, etc.) until they have received written notification of IRB approval.

The PI is responsible for compliance with other laws and institutional rules (such as compliance with HIPAA, FERPA, biosafety regulations, etc.) and must provide the documentation of any other reviews to the IRB upon request.

Communication

The IRB communicates all its findings and actions to the PI and notifies the Institutional Official in writing.

When projects are federally funded, the PI is responsible for sending a copy of the approval letter to the Grants and Contracts Office and/or the funding agency, as needed.

Details and Procedures

Review Process for New Research Protocols

Principal Investigators who intend to conduct research involving human subjects must submit a research protocol and any other supporting documentation to the IRB for review and approval using the designated electronic system.

Upon receipt of a new protocol submission, the IRB office staff conducts an initial review. The office staff determines the review level required (Exempt, Expedited, Full Board, or Not Human Subjects Research). Depending on the review level and completeness of the submission, IRB office staff may either request revisions or process the submission to the next stage of review.

Exempt Review

Certain types of research protocols may be eligible for review under exempt review procedures. The research must involve no more than minimal risk and fit one or more of the categories for exempt research as outlined in 45 CFR §46.104(d).

IRB office staff review the protocol and may assign an IRB member as an additional reviewer if needed. IRB office staff work with the PI until the study satisfactorily meets the same requirements for approval as expedited and full board studies. The IRB office staff then notify the PI of this approval in writing.

Exempt studies are generally required to follow 45 CFR 46, but flexibility in compliance with these regulations is left to the discretion of IRB office staff and/or reviewing IRB member, who may waive one or more requirements when such a waiver does not negatively impact the rights or welfare of human subjects.

Limited IRB Review

Certain exempt studies may qualify for exemption only with a "limited IRB review". For this type of review, the IRB will make the following determination(s):

- For Exempt categories 2, 3, or 8, where the information is recorded by the investigator in such a manner that the identity of the human subject can readily be ascertained, directly or through identifiers linked to the subjects; or for secondary research for which broad consent is required, the IRB will make the following determination as required by § 46.111(7):
    1. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- For Exempt category 7, the IRB will make the following determinations as required by § 46.111(8):
    1. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the relevant requirements in § 46.116;
    2. Broad consent is appropriately documented, or a waiver of documentation is appropriate;
    3. If there is a change made for research purposes in the way the information / specimens are stored or maintained, that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of the data;
    4. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Expedited Review

Certain types of research protocols may be eligible for review under expedited review procedures as governed by 45 CFR 46.110. The research must involve no more than minimal risk and fit one or more of the categories for expedited review procedures as specified in the Federal Register.

IRB office staff complete an initial review of the study submission and will assign one or more reviewers from among the IRB members, in consultation with the Chair when needed. IRB members are assigned to review research protocols based on the nature of the research and the expertise of the IRB member.

IRB office staff may act as the sole reviewer if they feel they have adequate expertise to complete the review without input from additional reviewers.

> *Examples*: research involving only records review, or where study procedures involve extremely low or no risk.

Assigned IRB members review the research application and all supporting materials to determine whether the research:

1. Meets the definition of minimal risk,
2. Meets the criteria of one or more of the eligible categories, and
3. Fulfills the regulatory criteria for approval

This determination is documented in reviewer checklists and/or notes in the electronic submission system.

IRB members reviewing a study may:

- Ask questions about the research,
- Require modifications to the protocol and other study materials,
- Recommend approval,
- Request additional IRB members to review the protocol, or
- Request that the study be reviewed by the full board.

Reviewers may not disapprove a study via expedited procedures; disapproval may only occur by a majority vote at a convened IRB meeting. If the reviewer recommends disapproval, the study must be referred to the full board for review.

If there are multiple expedited reviewers and their determinations conflict, IRB office staff communicates with the members to determine whether concordance can be reached. If not, the IRB Chair also reviews the research protocol and may either make the final decision or refer the matter to the full board for review.

The IRB office staff communicate the determinations of the IRB in writing to the investigator(s). If instructed by the IRB member(s) that reviewed the study, IRB office staff may review submitted revisions.

Full Board Review

The IRB office staff completes an initial review and may either:

- Request clarifications or additional documents, or
- Place the study on the next available meeting agenda

IRB office staff assigns one or more IRB members as primary reviewers, based on the nature of the research and the expertise of the IRB member. Primary reviewers are encouraged to contact the PI to ask questions or seek clarification about the research prior to the full board meeting.

Each IRB member receives the protocol and all supporting documents prior to the meeting.

Investigators are invited to attend the meeting at which their protocol will be reviewed. If present, a researcher will be asked to describe the research project, and the IRB will ask any questions or request clarifications about the study.

After sufficient discussion, the members vote on each research protocol and the votes are recorded in the meeting minutes.

The full board IRB may make the following determinations:

1. Approved: Approve as submitted.
2. Approved with Conditions: The study meets regulatory criteria for approval, as long as the specified conditions are met. The IRB may grant either the primary reviewer(s) or IRB office staff the authority to review the revisions to ensure compliance with the conditions required by the IRB.
3. Tabled: Table the discussion of the research because additional information and/or protocol revisions are required.
4. Disapproved: The research protocol cannot be approved as proposed.

The IRB's determinations are documented in reviewer checklist(s) and in the IRB meeting minutes.

The decisions will be based on the votes of the majority (more than 50%) of the voting members present at a full board IRB meeting.

Communication of IRB Findings and Actions to the Investigator and the Institution

IRB office staff communicate the IRB's findings and actions to investigators and the Institution in writing and retain copies of these communications in the study's files.

All expedited and exempt reviews are noted on the next available IRB meeting agenda and documented in the IRB meeting minutes. This inclusion serves as documentation of the reviews that have been completed and notification to the full IRB. This notification does not require action by the convened IRB. However, the IRB may raise questions about any research that was previously acknowledged under exempt or expedited procedures.

All meeting minutes are sent to the IO and made available to others within the institution upon request.

Expiration dates

Full board studies: The approval period begins the date of the convened meeting at which the IRB voted to approve the study or approve with conditions. The default approval period is one year, but the IRB may determine that a shorter review period is appropriate.

> *Example 1*: The IRB votes to approve a study with conditions on October 5, 2019. The expiration date will be October 4, 2020, regardless of how long it takes the PI to make the IRB's requested revisions.
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> *Example 2*: The IRB votes to approve a study with conditions on October 5, 2019, but grants only a 6-month approval period. The expiration date will be April 4, 2020, regardless of how long it takes the PI to make the IRB's requested revisions.

Expedited studies receive a one-year approval, beginning on the date IRB office staff determine that any conditions for approval have been met and issue the approval letter.

> *Example*: The reviewers complete a review on February 18, 2020 and require revisions. The PI submits the revised materials March 3. IRB office staff review these revisions March 7, determine the revisions are acceptable, and issue the approval letter. The approval date is March 7, 2020, and the study's IRB approval will expire March 6, 2021.

Exempt studies receive a 3-year approval, beginning the date IRB office staff issues the approval letter.

References

45 CFR 46

21 CFR 56 (FDA)

45 CFR 164 (HIPAA)

34 CFR 99 (FERPA)

Revision History

Version	Date	Summary of Changes
1	19 Feb 2020	Initial version