SOP 502: Noncompliance

Terms and Abbreviations

Allegation of Noncompliance: An assertion of noncompliance that has not yet been investigated to determine whether it is true or false.

CFR: Code of Federal Regulations

Finding of Noncompliance: When an investigation into an allegation has determined the allegation to be true.

Full board meeting: A convened meeting of the IRB at which a quorum of members is present

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

Noncompliance: Any deviation from University of Wisconsin-Milwaukee IRB policies and procedures, federal regulations, or state law

UWM: University of Wisconsin – Milwaukee

Overview

Human subjects research must be conducted according to the plan submitted to and approved by the IRB, and in accordance with all applicable federal and state laws, University of Wisconsin System policies, and UWM policies and procedures.

Noncompliance is failure to follow the laws, university policies, or IRB SOPs governing human subjects research. Similarly, deviations from the approved research plan are also noncompliance, except when necessary to eliminate an apparent immediate hazard to research subjects.

There are three categories of noncompliance: Serious, Continuing, and General.

- Serious Noncompliance: All noncompliance that substantially affects participants' rights and / or welfare, or that impacts the risks or benefits of the research.
- Continuing Noncompliance: A pattern of noncompliance that indicates an inability or unwillingness to comply with the regulations or the requirements of the IRB.
- General Noncompliance: Noncompliance that is neither serious nor continuing.

General noncompliance may be reviewed by IRB office staff, in consultation with the IRB Chair, other IRB members, and the IO as needed.

Allegations of Serious or Continuing Noncompliance will be investigated by an IRB Noncompliance Subcommittee, who may resolve the investigation or refer the allegation of noncompliance to the Full Board.

Any actions taken by the IRB are limited to those directly related to human subjects research, such as requiring changes to the protocol, modifying the approval period, or suspending the research. Disciplinary actions related to researchers' employment or status will be governed by University policies and are not in the IRB's purview.

All findings of noncompliance that the IRB determines to be serious or continuing noncompliance will be promptly reported to the IO, who will then report the incident to the appropriate internal and external entities.

Details and Procedures

All reports and complaints of noncompliance should be directed to the IRB office staff. The IRB office staff will investigate all allegations of noncompliance.

Minor protocol deviations and their corrective actions may be reviewed by IRB office staff alone. These are deviations that are easily resolved and do not affect the regulatory criteria for approval.

Other types of noncompliance will be sent to one or more IRB members for review. The reviewers may:

- Recommend corrective actions
- Request further review by additional members or the convened IRB.

Notifications of all noncompliance reviews will be included in IRB meeting agendas and minutes.

Noncompliance Subcommittee Review

Allegations or findings of noncompliance will be referred to an IRB Noncompliance Subcommittee for evaluation in the following cases:

- All allegations of serious or continuing noncompliance will be investigated by a subcommittee, regardless of source.
- The researcher disputes that noncompliance has occurred
- The assigned reviewer of a noncompliance has requested further review by additional members or by the convened IRB.

This subcommittee will be composed of two or more members of the IRB, including (or in addition to) one IRB office staff member. The members of the subcommittee will:

- Review the nature of the noncompliance
- Complete a reviewer form/checklist to document their findings
- If the subcommittee members unanimously agree that the non-compliance is not serious or continuing, the subcommittee may make a determination and recommend corrective actions. Notifications of this type of noncompliance review will be included in the IRB meeting agendas and minutes.

- For serious or continuing noncompliance, or any other noncompliance where the subcommittee determines that the convened IRB should review the noncompliance, the subcommittee will provide a written statement to the IRB for consideration and vote. The statement will include the following:
    - Whether the subcommittee believes the allegation is true or false.
    - Whether the subcommittee believes the noncompliance is general, serious, or continuing.
    - Any recommended actions for the IRB to take.

Convened IRB Review

The IRB will review the recommendation of the IRB noncompliance subcommittee at a full board meeting. All IRB members will be provided with a copy of the approved protocol, all relevant IRB files and documents, and the report of the IRB noncompliance subcommittee. A member of the IRB noncompliance subcommittee will serve as a primary reviewer.

The IRB may accept or reject the subcommittee's recommendations. If the IRB rejects the subcommittee's recommendations, then the IRB may modify the recommendations or propose other actions.

The IRB will assess and vote, within two meetings, upon:

- whether any allegations of noncompliance were true
- whether any findings of noncompliance were general, serious, or continuing
- what corrective actions, if any, should be taken.

If necessary, the IRB may request additional information before issuing determinations. The IRB may request any appropriate additional consultation and expertise to resolve noncompliance.

Corrective Actions

Potential IRB actions are limited to the following:

- Requiring modification to the research protocol;
- Requiring modification to the consent process;
- Requiring researchers to contact past or current participants with additional information and providing them the opportunity to withdraw from participating or withdraw their data, if applicable;
- Requiring researchers to re-consent participants;
- Modifying the approval period;
- Suspending the research (may be either a specific protocol or multiple research studies conducted by the researcher); or
- Terminating IRB approval of the research.
    - Termination requires action by the convened IRB. If an individual reviewer or subcommittee feels that termination is warranted, the noncompliance must be sent to the convened IRB for review.

Temporary Suspension of Research

If the IRB, IRB Chair, and/or IO determines that the immediate suspension of some or all research activities is necessary while the noncompliance is reviewed, the IRB office staff will send the researcher a written notice detailing the specific activities to be halted and a rationale. The IRB Chair and the IO will be copied on all such notifications.

Institutional Official Responsibilities

The IO receives written notice of all noncompliance via the IRB meeting agendas and minutes. The IO has the discretion to request additional review of any instance of noncompliance.

In the event of Serious or Continuing Noncompliance, IRB office staff or the IRB Chair will notify the IO. The IO will notify, as applicable:

- The study sponsor
- Appropriate federal agencies (e.g., Office of Human Research Protections, Food and Drug Administration, etc.)
- Appropriate university administrators
- The Office of Research
- The researcher's department chair and dean

References

45 CFR 46.113

Revision History

Version	Date	Summary of Changes
1	1 Feb 2022	Initial version