Allegations of Noncompliance

The purpose of this policy is to identify the standards and responsibilities for handling reports of noncompliance related to research involving human subjects, and the actions taken when the IRB makes a finding of serious or continuing noncompliance. If at any time during an investigation there are concerns regarding scientific misconduct, such concerns will be referred to the Human Protections Administrator and the Research Integrity Officer. Allegations of research misconduct are potentially related but a separate issue that is covered by Woman's Research Misconduct Policy.

This policy applies to all members of the research staff, investigators conducting research at Woman's, members of the medical staff, employees of Woman's, and IRB members.

Definitions

Allegation of Noncompliance: An assertion of noncompliance that has yet to be proved or supported by evidence.

Continuing Noncompliance: A pattern of noncompliance with repeated failure to adhere to the federal research regulations or institutional policies that may affect the rights or welfare of participants. The pattern of noncompliance is assessed by the number of incidents occurring during the course of implementation of a protocol, or across multiple protocols, conducted at Woman's, and if the same noncompliant action was repeated or many different noncompliant events occurred, especially after a remediation procedure such as training has been provided to the researcher or research staff.

Finding of Noncompliance: Noncompliance that is proven or supported by substantial evidence.

Noncompliance: A violation of any federal, state, or local regulation that governs human research, any institutional policy on human subjects research, or any deviation from the protocol approved by the IRB or stipulations imposed by the IRB as a condition of approval. Noncompliance that may affect subject safety, increase risks to subjects, affect the integrity of the data, violate the rights and welfare of subjects, or affect the subject's willingness to participate in research.

Serious Noncompliance: Noncompliance which, in the judgment of the convened IRB, significantly increases risk to participants, significantly decreases potential benefits, or compromises the integrity of the Human Research Protection Program (HRPP).

Procedures

All employees and agents of Woman's and institutions relying on Woman's IRB share the responsibility for reporting incidences of noncompliance with the regulations or the requirements or determinations of the IRB. Allegations of noncompliance in human subjects research may come from many sources including, but not limited to, the following:

- Investigators or study team members
- R&D/IRB members, study monitors, auditors, or sponsors
- Research participants or family members
- Individuals not directly involved in research
- Staff of the Woman's Hospital Research Center

Reporting allegations of noncompliance

Reports of allegations of non-compliance may be made to any of the following individuals:

- The Compliance Hotline: 225-924-8761
- Cindy Amedee, Compliance Officer, at 225-924-8361
- Human Protections Administrator, at 225-231-5296
- IRB Chair or any IRB member
- Research and Development Committee Chair
- Organizational Official (Vice President of Research)
- Any staff member at the Woman's Hospital Research Center: 225-231-5275; resesearch@womans.org

All reports of allegations of noncompliance must be documented by its recipient and forwarded to the IRB Chair (or designee). The report must contain sufficient information to perform an investigation of the allegations. Any conflicts of interest that may interfere with the IRB's review of the allegation should be assessed and documented. Anyone with a conflict of interest will be excluded from the review of the allegation.

NOTE: Allegations of noncompliance against IRB members or the IRB Chair will be forwarded to the Organizational Official, who will perform the initial gathering of information for review by the convened IRB.

Identity protection

The identity of the individual making an allegation of noncompliance will be protected to the extent possible when this individual makes a report in good faith. This protection holds even if the concerns or allegations are found, upon investigation, to be without merit.

Initial Review of Allegations of Noncompliance

The IRB Chair (or designee), Human Protections Administrator (HPA), and Compliance Officer are responsible for the initial review of allegations of noncompliance. The IRB Chair/designee informs the investigator of the allegation and the initial review and gathers additional facts (e.g. from an audit of the study records), when necessary, to better ascertain the nature and scope of the allegation of noncompliance.

The investigator should provide the following materials:

• A report about the investigator's research activities under examination and the associated protocol deviation submission, if one was filed;

• Current versions of applicable study documents (e.g. protocol, consent form(s) investigator's brochure, recruitment materials, data collection forms, etc.) and previous versions of these documents, if necessary; and

• Any other materials relevant to the potential noncompliance, including but not limited to: correspondence with the sponsor, other investigators, subjects, regulatory agencies or third parties; monitoring or audit reports; protocol deviations; safety reports; complaints from research subjects; or subject-specific information.

IRB Evaluation of Incidents of Noncompliance

The convened IRB will review any information submitted by the IRB Chair, Human Protections Administrator, and the Compliance Officer as well as materials submitted by the investigator. The convened IRB will make the determination if there is noncompliance that is serious or continuing, as defined in this policy.

The IRB may make one of the following determinations listed below as a result of its review:

(a) Acknowledge the report and allow the research to continue with no additional action required;

(b) Defer action pending additional information;

(c) Require modifications in the research (e.g. protocol, consent form);(d) Modification of information disclosed during the consent process;

(e) Require that subjects who are still participating in the research be re-consented or notified of the noncompliance when such information may relate to their willingness to continue participation;

(f) Require that subjects whose participation has ended be notified of the noncompliance;

(g) Modify the continuing review schedule;

(h) Suspend IRB approval of the research;

(i) Terminate IRB approval of the research;

(j) Require training for the PI or the PI and study team;

(k) Require periodic audits and monitoring of the research and/or consent process by the IRB audit committee and/or HPA; and/or

(l) Any other action the IRB deems appropriate to the noncompliance

The written report of findings and determinations of the IRB and required corrective action, if any, will be sent to the investigator. Modifications submitted by the investigator in response to the report will be reviewed by the IRB at the next convened meeting. The IRB's deliberations, findings, actions, and final determination will be documented in the convened meeting minutes and communicated in writing to the investigator as well as to the Organizational Official, Institutional Official, and other agencies (sponsor, OHRP, FDA) as appropriate.

Suspension of the Research

The investigator may voluntarily place the research on hold in whole or in part while the investigation of noncompliance is being conducted. Such temporary holds are not subject to the reporting requirements in 45 CFR 46.103(b)(5) and 21 CFR 56.108(b)(2) .

At any point during the investigation the IRB Chair or the IRB may suspend the research in whole or in part or terminate the research. Such suspensions or terminations must be reported to the appropriate regulatory bodies. Refer to the Termination and Suspension of Research policy for more information.

Reporting timeframes

Reports to Woman's Organizational Official and federal agencies, as appropriate, regarding noncompliance will not be delayed. An initial report may be submitted and a final report may follow with updated completed actions. The Human Protections Administrator will communicate to the investigator any determinations and corrective actions required by the IRB. The HPA will also report the IRB's determinations to federal agencies. A copy of this report will be provided to the investigator, Woman's Organizational Official, the Compliance Officer, and the IRB within 30 days.

For OHRP

The regulations at 45 CFR 46.103(a) and (b)(5) do not specify a time frame for reporting, except to say this must be done "promptly." For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be

appropriate to send an initial report and indicate that a follow-up or final report will follow by the earlier of a specific date or when an investigation has been completed or a corrective action plan has been implemented.

For guidance on reporting to OHRP: https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.htmlFor FDA

FDA does not specify a timeframe for reporting noncompliance, other than "promptly." For guidance on reporting to FDA:

https://www.fda.gov/science-research/report-problems-fda/mandatory-irb-reporting-fda-contacts

For AAHRPP

For reporting noncompliance to AAHRPP, the noncompliance findings should be reported as soon as possible, but generally within 48 hours after the institution or any researcher becomes aware of:

- Any negative actions by a government oversight office, including, but not limited to: OHRP Determination Letters, FDA Warning Letters, FDA 483 Inspection Reports with official action indicated, FDA Restrictions placed on the IRB or investigators, and corresponding compliance actions taken under non-US authorities related to human research protections.
- Any litigation, arbitration, or settlements initiated related to human research protections.
- Any press coverage (including, but not limited to radio, TV, newspaper, online publications) of a negative nature regarding Woman's HRPP.

DATE IMPLEMENTED	REVISION
2/7/22	Added Compliance Officer role and contact information; Added: The convened IRB will review any information submitted by the IRB Chair, Human Protections Administrator, and the Compliance Officer as well as materials submitted by the investigator.
2/7/22	Per AAHRPP, the convened IRB will make the determination if there is noncompliance that is serious or continuing, as defined in this policy.
2/21/2022	The HPA will report any findings of noncompliance to appropriate federal agencies, and this report will be sent to the investigator, Woman's Organizational Official, the Compliance Officer, and the IRB within 30 days