

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 02/28/2019
	Non-Compliance in Human Subjects Research		Policy 802
			Version: 2.1

POLICY

1. Purpose

Establish a process to ensure the prompt reporting of non-compliance to the RSRB, the consistent investigation and review of such report(s) by the RSRB, and the compliant reporting of RSRB determinations of serious or continuing non-compliance to appropriate institutional officials and regulatory authorities, such as the Office for Human Research Protection (OHRP) and the Food and Drug Administration (FDA).

2. Scope

This policy applies to any member of the University of Rochester (UR) human research protection program (HRPP), or any individual or organization that may observe or otherwise become aware of apparent non-compliance in connection with UR human subjects research.

3. Definitions

3.1. *Allegation of Non-Compliance:* An unproven assertion of non-compliance.

3.2. *Non-Compliance:* Failure to follow the federal, state, or local regulations or laws governing the protection of human subjects in research, institutional policies related to human subject research, or the requirements or determinations of the RSRB/Reviewing IRB with respect to the conduct of the research as approved.

3.3. *Serious Non-Compliance:* Non-compliance that, in the judgment of the convened board, results in any of the following:

- a) an increased risk to subjects or others,
- b) adversely affects the rights, welfare and safety of the research subjects,
- c) adversely affects the scientific integrity of the study.

Non-compliance may also be deemed serious when it involves fraud and/or scientific misconduct, even in research posing minimal risk to subjects.

3.4. *Continuing Non-Compliance:* Non-compliance that, in the judgment of the convened board, persists when there is:

- a) evaluation by the convened board,
- b) notice to the Investigator,
- c) prior submission of a corrective action plan(s), and
- d) lack of evidence of effective efforts towards resolution by the Investigator.

These events may or may not result in increased risk to subjects and may be due to a variety of factors. The non-compliance might imply that an Investigator is either unwilling or unable to develop and apply successful corrective measures.

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4. References

- 4.1. [Policy 402 RSRB Meetings](#);
[Policy 403 Notification of RSRB Determinations](#);
[Policy 504 RSRB Reliance for Review](#)
- 4.2. [Guideline for RSRB Review of Allegations of Non-Compliance](#);
[Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance and UPIRTSO](#)

5. Responsibilities

- 5.1. The University recognizes the implicit and paramount importance of compliance with laws, regulations and policies when conducting human subject research. Therefore, it is the responsibility of the Investigator, research team, any member or component of the human research protection program, or any individual or organization within the UR who suspects possible non-compliance, to report such an occurrence.
- 5.2. The RSRB must assess all allegations of non-compliance (e.g., concerns, complaints, reportable events) when the RSRB is the reviewing IRB.
 - 5.2.1. It is the responsibility of the relying IRB to review and assess allegations of non-compliance that are reported to the RSRB Office, per the relying IRB policy (see *Policy 504 RSRB Reliance for Review*).
- 5.3. The convened board is responsible for reviewing and evaluating each allegation of potentially serious or continuing non-compliance, as outlined in the RSRB *Guideline for Review of Allegations of Non-Compliance*. The board will determine: a) whether the allegation is valid and, if the allegation is valid, b) whether the non-compliance is serious or continuing.
- 5.4. The Office of Counsel is responsible for the review and assessment of alleged non-compliance that pertains to research misconduct or violations of scientific integrity (see [University of Rochester Policy on Research Misconduct](#)).

6. Requirements

- 6.1. Allegations of non-compliance may be initiated in any of the following ways:
 - a) RSRB review of a continuing review or modification (convened board or expedited review process)
 - b) Direct report to the RSRB by an individual or an organization
 - c) Quality improvement (QI) review or audit by the Office for Human Subject Protection (OHSP)
 - d) QI review or audit by another department or organization
 - e) Integrity hotline or other report from the Medical Center Office of Compliance
 - f) Other mechanism of report

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- If an allegation of non-compliance is reported through a mechanism other than that noted above, the RSRB Chair, RSRB Director and OHSP Director, with consultation with Office of Counsel as necessary, will determine the process for evaluation and review of the report.
- 6.2. Once an allegation of non-compliance is initiated, it is reviewed and evaluated by the board Chair, RSRB staff, and/or the convened Board in accordance with the RSRB *Guideline for Review of Allegations of Non-Compliance* to determine whether it may be valid.
 - 6.2.1. If the allegation has merit, the convened board which has oversight for that study, Investigator, or Department (as applicable), will further review the case to determine potential serious or continuing non-compliance.
 - 6.2.2. Board members will be provided written materials regarding any allegation of serious or continuing non-compliance that is referred to a convened board meeting.
 - 6.2.3. In each case involving potential serious or continuing non-compliance, the study member (investigator/other) being investigated shall be provided with advance notice of the issue, a listing of the materials to be reviewed/considered by the board, and the opportunity to appear before the board or to offer a response or written statement addressing the materials and issues to be reviewed by the board.
 - 6.2.4. Because serious and continuing non-compliance must be reported to federal agencies and may negatively affect Investigators, prior to review by a convened board of potentially serious or continuing non-compliance, the RSRB Director will arrange a consultation regarding the allegation with the Office of Counsel. The consult will include a summary of the facts of the case and a review of the records. The purpose of this consultation is to ensure due process and is not meant to impede, nor influence, the board's decision.
 - 6.3. All determinations of serious or continuing non-compliance are made by the convened board after (i) a formal investigation into non-compliance has been opened by the board; and (ii) all pertinent materials have been reviewed by the board.
 - 6.3.1. All board determinations will be made by way of a vote and will be recorded in the meeting minutes (see *Policy 402 RSRB Meetings*).
 - 6.4. The Principal Investigator is notified of all board determinations pertaining to the allegation of non-compliance (see *Policy 403 Notification of RSRB Determinations*).
 - 6.5. Appropriate institutional officials and regulatory authorities will be notified of RSRB determinations of serious or continuing non-compliance (see *Policy 403 Notification of RSRB Determinations* and *Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance and UPIRTSO*).

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Appendices:

None

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5/2016: Sect 3.3 and 3.4 definitions; hyperlinks added; editorial changes
2/2019: Sect 4 removal of HHS and FDA regulatory reference; removed T. Gommel as author and signatory; updated IO as signatory

Supersedes Date:

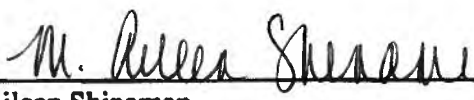
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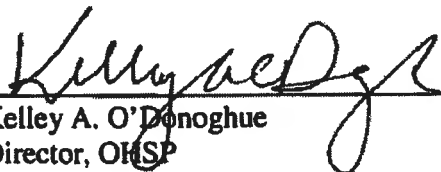
Richard Waugh
Institutional Official and Vice Provost for Research

3/12/2019
Date



Aileen Shinaman
Office of Counsel

3/18/19
Date



Kelley A. O'Donoghue
Director, OHSP

3/13/2019
Date