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


   3.2. *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/IRB of record with respect to the conduct of the research as approved.

   3.3. *Serious Non-Compliance:* Non-compliance that results in an increased risk to subjects or others, adversely affects the rights, welfare and safety of the research subjects, or 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:* A pattern of non-compliance that continues despite identification by the RSRB, notice to the Investigator, or prior submission of a corrective action plan. This pattern may or may not result in increased risk to subjects. Although it may be due to a variety of factors, continuing non-compliance implies that an Investigator is either unwilling or unable to develop and apply successful corrective measures.

4. References
   4.1. HHS 45 CFR 46.103 (b)(5); FDA 21 CFR 56.108(b)(2)
   4.2. Policy 402 RSRB Meetings; Policy 403 Notification of RSRB Determinations
   4.3. 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).

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 b) if the allegation is valid, 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) Continuing review
   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
      • 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 will first be reviewed and evaluated by the board Chair, RSRB staff, and/or the 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 and a finding of potentially serious or continuing non-compliance, the case shall be referred to the RSRB convened board which has oversight for that study, Investigator or Department, as applicable.

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 will not impede, nor influence, the board’s decision.

6.3. All findings of serious or continuing non-compliance are made by the convened RSRB after (i) a formal investigation into non-compliance has been opened by the convened 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).
Originator/Authors:
Kelley O'Donoghue, Director OHSP
Tiffany Gommel, Director RSRB
Emily Flagg, Senior Regulatory Specialist

Appendices:
None

Revision History:
None

Supersedes Date:
Not Applicable

Approved By:

Robert Clark
Institutional Official and Senior VP for Research

[Signature]
Date: 4/2/14

Aileen Shinaman
Office of Counsel

[Signature]
Date: 4/10/14

Kelley A. O'Donoghue
Director, OHSP

[Signature]
Date: 4/2/2014

Tiffany L. Gommel
Director, RSRB

[Signature]
Date: 4/2/2014

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