POLICY

1. Purpose
Establish an administrative structure within the University of Rochester to support the planning, conduct and application of research conducted under the University of Rochester’s Human Research Protection Program (HRPP).

2. Scope
This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester (UR).

3. Definitions

3.1. Institutional Official (IO) - The individual who has the authority (as delegated by the President of the University of Rochester) to oversee the implementation and maintenance of the Human Research Protection Program.

3.2. Office for Human Subject Protection (OHSP) – The department at the UR delegated the authority by the IO for daily administration of the Human Research Protection Program and oversight of human subject research.

3.3. Research Education and Training (Education) – A division of OHSP.

3.4. Research Subject Review Board (RSRB) – A system of institutional review boards established by the University President and the Board of Trustees.

3.5. Research Subject Review Board Office – The OHSP division that operates the institutional review boards for the UR.

3.6. Quality Improvement (QI) – A division of OHSP.

3.7. Clinical & Regulatory Systems (Systems) – A division of OHSP.

4. References
4.1. HHS 45 CFR 46.103(c)
4.2. Policy 102 University of Rochester Human Research Protection Program
   Policy 201 Education Program
   Policy 401 Functions of the RSRB Office
   Policy 503 Ancillary Committee Reviews
   Policy 301 RSRB Scope and Authority
   Policy 901 Investigator Responsibilities
   Policy 1001 Quality Improvement Program
5. Responsibilities

5.1. The IO is responsible for ensuring the HRPP, under the auspices of the OHSP, functions effectively and that the Institution provides the resources and support necessary to comply with all requirements applicable to research involving human subjects. The IO is assigned the following responsibilities, including but not limited to those noted below, to accomplish this oversight:

- Serve as signatory for the UR’s Federalwide Assurance [HHS 45 CFR 46.103(c)]
- Serve as signatory (unless otherwise designated) for other Institutional documents related to the UR’s HRPP including inter-institutional IRB Authorized Agreements, Certificates of Confidentiality, IRB appointment letters, and reports to regulatory agencies. (See Appendix 1 IO Delegation of Responsibilities Form)
- Serve as signatory for the annual report to the Association for the Accreditation of Human Research Protection Programs (AAHRPP), which provides information regarding the status of the UR HRPP.
- Assure the UR RSRB complies with applicable ethical principles, federal and state laws and Institutional policies and procedures for the protection of human research subjects.
- Ensure the independence of the RSRB, including the authority to act without undue influence.
- Support RSRB authority and decisions.
- Support investigators in their right to a fair and impartial RSRB review.
- Set the tone for an Institutional culture of respect for human research subjects by ensuring the standing of the RSRB within the institution.
- Ensure effective institution-wide communication and guidance on human research.
- Receive reports of alleged undue influence on the RSRB process and intervene as needed.
- Receive and respond to concerns from investigators that could not be resolved by processes within the HRPP.

5.2. The OHSP is responsible for oversight and monitoring of human subject research to facilitate the application of ethical standards and practices in research by University of Rochester investigators and research staff, sponsors and research review units.

5.2.1. Research Education and Training is responsible for assisting researchers in protecting the rights, welfare, and safety of human subjects by providing programs and educational resources in research ethics and human subject safety, with an emphasis on the proper conduct of research (Policy 201 Education Program).
5.2.2. The Research Subjects Review Board is responsible for the review and approval of all human subject research conducted or supported by employees or agents of the UR to ensure the rights and welfare of the human subjects are adequately protected (Policy 301 RSRB Scope and Authority). The review process will be conducted in accordance with applicable federal, New York State (other states as applicable), and local laws and regulations, as well as University policies.

5.2.2.1. The RSRB office is responsible for the management and operation of the RSRB (Policy 401 Functions of the RSRB Office).

5.2.3. Quality Improvement is responsible for conducting a comprehensive, systematic, and independent assessment of studies to evaluate appropriate compliance with ethical principles, as well as applicable regulations and institutional policies and guidelines (Policy 1001 Quality Improvement Program).

5.2.4. Clinical & Management Systems is responsible for oversight and maintenance of the RSRB Online Submission System (ROSS) and to provide information technology systems support to the OHSP and RSRB staff.

5.3. Research support units (e.g., Office of Research and Project Administration, Clinical and Translational Science Institute) will provide research support and resources to the research community.

5.4. Ancillary committees (e.g., Humanitarian Use of Radiation Committee (HURC), Institutional Biosafety Committee (IBC)) will ensure appropriate expertise is applied to the review of the protocol, regulatory requirements for activities in the given field are met, and to ensure appropriate resources will be available to conduct the study (Policy 503 Ancillary Committee Reviews).

5.5. Investigators will ensure research is conducted in accordance with OHSP and University policies and guidelines, as well as federal regulation, as applicable (Policy 901 Investigator Responsibilities).

6. Requirements

6.1. The Director of OHSP will meet regularly with the IO to ensure that resources are adequate to maintain the proper functioning of the human research protection program under the functional divisions of Education, the RSRB, QI, and Systems.

6.2. The QI reviewers will conduct reviews to compare research records to approved documents, regulatory standards and policies, and to recommend corrective and preventative actions (Policy 1001 Quality Improvement Reviews).
6.3. The RSRB will interface, as necessary, with other departments in the UR that are responsible for the review and approval of research (Policy 102 Human Research Protection Program and Policy 503 Ancillary Committee Reviews).

6.4. The Research Subjects Review Board office will provide minutes of RSRB meetings to the Institutional Official (IO), or designee, to keep the administration appraised of Board actions.

6.4.1. The RSRB will provide the final and approved meeting minutes on a monthly basis. Clarifications to the minutes requested by the IO, or designee, will be provided to the RSRB Director and forwarded to the Board(s) for additional review and action, as required.

7. Organizational Structure of the UR Human Research Protection Program

Organization Chart
UR Human Subject Protection Program
Originator/Authors:
Kelley O'Donoghue, Director, OIISP
Emily Flagg, Senior Regulatory Specialist

Appendices:
Appendix 1: IO Delegation of Responsibilities Form

Revision History:
February 2016: Sect 4.2 list updated and hyperlinks added; Sect 5.2.3 modified to match policy; Sect 5.3 incorporated into 5.2.2; Research Education signatory updated; additional editorial changes and updates to reflect current practice

Supersedes Date:
08/13/2013

Approved By:
Robert Clark
Institutional Official and Senior VP for Research

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Director, OIISP

Tiffany L. Commel
Director, RSRB

Kelly Ursinworth
Director, Research Education and Training

Kathleen Wessman
Director, Quality Improvement

3/14/16 Date

3/15/16 Date

3/15/2016 Date

3/15/2016 Date

15MAR16 Date
Appendix 1: IO Delegation Form

Institutional Official Delegation of Responsibilities

To: [Director OHSP]
   Director, OHSP

From: [Institutional Official]

Date: [Date]

Re: Delegation of Responsibility from Institutional Official

As per the Office of Human Subjects Policy 103: Organizational Structure of the Human Research Protection Program (HRPP), the Institutional Official (IO) may designate signatory responsibilities for Institutional documents related to the University of Rochester’s HRPP.

The following activity (or activities) is/are delegated by the IO as indicated below.

<table>
<thead>
<tr>
<th>Activity Delegated</th>
<th>Delegated To</th>
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</table>

Signature of Institutional Official

Date

Signature of Director, OHSP

Date