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
         Policies 300 – 600
         Policy 1002 OHRP Audits
5. Responsibilities

5.1. The IO is responsible for ensuring that 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 that 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 to assist 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 reviewing research that is conducted or supported by employees or agents of the UR to ensure that the rights and welfare of the human subjects are adequately protected (Policies 300-600).

5.2.2.1. The RSRB office is responsible for managing the RSRB, including the assignment of human subject research study proposals to a specified board for review (Policy 401 Functions of the RSRB Office).

5.2.3. Quality Improvement is responsible for the ongoing evaluation of the effectiveness of the HRPP by promoting Institutional and investigator compliance with human subject protection regulations and requirements.

5.2.3.1. The QI team collaborates with members of the UR’s research community to improve the Institution’s efforts to uphold high ethical standards, to meet regulatory requirements, and to improve research practices for the protection of subjects participating in the research.

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 review units (e.g., Office of Research and Project Administration) will ensure that human subject research is reviewed and approved according to applicable federal, New York State (and other state) and local laws and regulations, as well as University policies.

5.4. Research support units (e.g., Office of Research and Project Administration, Clinical and Translational Science Institute, Strong Memorial Hospital) will ensure adequate and appropriate research support and resources are available to conduct research and protect human subject’s rights and welfare.

5.5. 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.

5.6. Investigators and research staff will ensure that only qualified and trained persons conduct research and apply the high standards expected by the University, which includes ensuring that all required approvals are in place before research begins.
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 team will conduct reviews to identify trends, common findings or other items necessary for reporting to the directors of OHSP and RSRB (Policy 1002 Audits).

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, OHSP
Emily Flagg, Senior Regulatory Specialist

Appendices:
Appendix 1: IO Delegation of Responsibilities Form

Revision History:
None

Approved By:

______________________________  8/13/13
Robert Clark
Institutional Official and Senior VP for Research

______________________________  8/13/13
Kelley A. O’Donoghue
Director, OHSP

______________________________  8/13/2013
Tiffany L. Gommel
Director, RSRB

______________________________  8/14/2013
Bill Kelvie
Director, Research Education and Training

______________________________  14 Aug 13
Kathleen Wessman
Director, Quality Improvement

Page 5 of 6

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the departmental shared network.
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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

__________________________  ________________________  
Signature of Institutional Official  Date

__________________________  ________________________  
Signature of Director, OHSP  Date