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 UR) 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 the OHSP responsible for education and training of the research community at the UR.

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 – A division of the OHSP that operates the institutional review boards for the UR.

3.6. Quality Improvement (QI) – A division of the OHSP responsible for reviewing research conducted by the UR to assess that activities are conducted in accordance with IRB requirements, the approved protocol, applicable Federal regulations, UR policies, and good clinical practice (GCP) standards.

4. References

4.1. HHS 45 CFR 46.103(b)

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 504 IRB Reliance and Collaborative Research
Policy 301 RSRB Scope and Authority

Policy 901 Investigator Responsibilities
Policy 1001 Quality Improvement Program

4.3. Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance, UPIRTSO

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, including but not limited to staff, consultants, equipment, and space sufficient to support the IRB's review and record keeping responsibilities. 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(b)]
- Serve as signatory (unless otherwise designated) for other Institutional documents related to the UR's HRPP including IRB Authorization 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. The OHSP Director is responsible for the University's Human Research Protection Program (HRPP), which involves high-level coordination with a wide range of offices, committees and senior managers to ensure the preservation of rights and physical and/or psychological wellbeing of subjects involved in research.

5.2.2. 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*).

5.2.2.1. The Director of Research Education and Training is responsible for all aspects of OHSP research education and training to promote protection of the rights, welfare, and safety of human subjects participating in research at the University.

5.2.3. 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, or as delegated through an IRB reliance agreement (*Policy 504 IRB Reliance and Collaborative Research*), 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

5.2.3.1. The Director of the RSRB and other positions within the RSRB are described in *Policy 401 Functions of the RSRB Office*.

5.2.4. Quality Improvement is responsible for conducting 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).

5.2.4.1. The Director of Quality Improvement is responsible for all aspects of the OHSP Quality Improvement (QI) program including conducting internal audits and consultations to assess and improve compliance with Institutional Review Board (IRB) requirements, federal/state regulations and guidance and University policies and procedures to promote the protection of the rights, welfare, and safety of human subjects participating in research at the University.

5.2.4.2. The Quality Improvement Specialist conducts internal audits and consultations to assess and promote compliance with IRB requirements, the approved protocol, applicable federal regulations, University policies, and best practice (Good Clinical Practice) standards.

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. University Information Technology (University IT) is responsible for management of the IRB review system and provides information technology support to OHSP employees. The IRB review system is used to track all open studies, even if ongoing review is not required.

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 (*Policy 503 Ancillary Committee Reviews*).

5.6. 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.

6.2. The Director of OHSP will ensure the University's human research protection program (HRPP) accreditation is maintained.

6.3. The OHSP Director's will meet regularly to ensure divisional responsibilities, as described above, are met.

6.4. The Director of Research Education and Training will ensure the research education curriculum meets its obligation to train and support faculty and staff through the development and routine evaluation of education materials (e.g., online/in-person training, seminars, and reference materials); assessment against professional standards and emerging human subject research topics; and consultation with HRPP stakeholders.

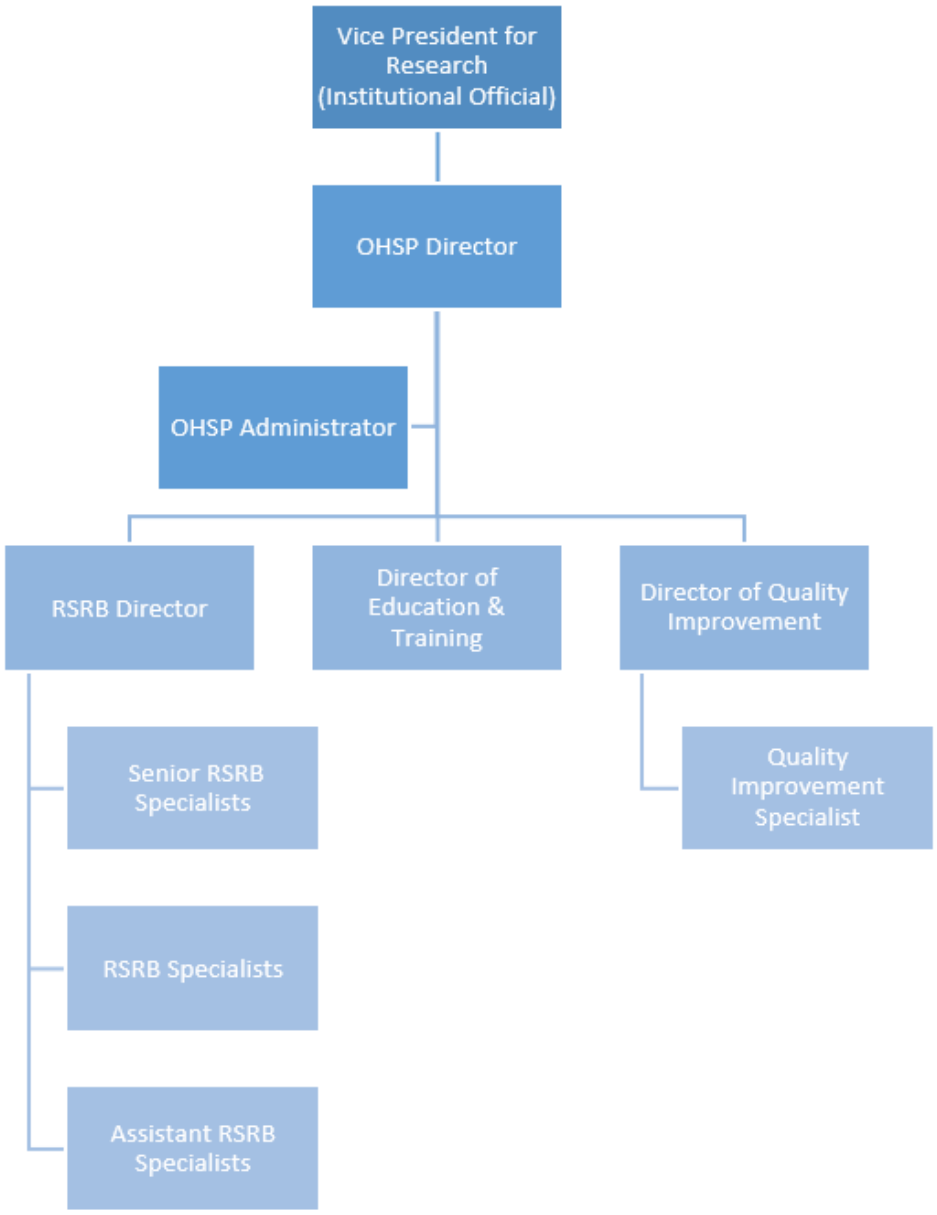
6.5. The QI reviewers will conduct reviews to compare research records to approved documents, regulatory standards and policies, and to recommend corrective and preventative actions (*Policy 1001 Quality Improvement Reviews*).

6.5.1. The QI reviewers will also provide consultation to study teams as an additional resource to attain compliance in the conduct of human subject research.

6.6. 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*).

6.7. The Institutional Official (IO), or designee, will have full access to the IRB review system, including meeting minutes, to allow access to all Board actions.

7. Organizational Structure of the UR Human Research Protection Program



Originator/Authors:

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Appendices:

Appendix 1: IO Delegation of Responsibilities Form

Revision History:

02/2016: 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

01/2019: Sect 5.1 addition of Revised Common Rule reference to space for meetings and record storage; Sect 5.2.2 added reference to Policy 504; Sect 5.2.4 updated language; Sect 6.2.1 added; Sect 6.4 revised to reflect current practice, including removal of Sect 6.4.1; Sect 7 revised with current org chart; Signatories changed IO and removed T. Gommel

10/2019: Sect 5.2.4 and 6.4 revised to reflect current practice; Update signatories

11/2022: Include job responsibilities for OHSP Directors and for QI specialist: Remove Clinical & Regulatory Systems and add University IT; Additional editorial and administrative changes; Update signatories

Supersedes Date:

10/25/2019

Approved By:

DocuSigned by:
Signer Name: Stephen Dewhurst
Signing Reason: I approve this document
Signing Time: 12/20/2022 | 3:27:35 PM EST
E217A323058C451895F16072D41E27E0

12/20/2022 | 3:27:40 PM EST

Stephen Dewhurst — Date
Institutional Official, Vice President for Research

DocuSigned by:
Signer Name: Kelley O'Donoghue
Signing Reason: I approve this document
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01BA85BD9A444F09983AC84603B8E36E

12/20/2022 | 7:50:29 PM EST

Kelley A. O'Donoghue — Date
Director, OHSP (and Acting RSRB Director)

DocuSigned by:
Signer Name: Kelly Unsworth
Signing Reason: I approve this document
Signing Time: 12/21/2022 | 8:18:45 AM EST
38BA26DFB30A42DD991D31DED11A82EA

12/21/2022 | 8:19:05 AM EST

Kelly Unsworth — Date
Director, Research Education and Training

DocuSigned by:
Signer Name: Kathleen Wessman
Signing Reason: I approve this document
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23649B5586354D349599202232741C12

12/21/2022 | 9:18:57 AM EST

Kathleen Wessman — Date
Director, Quality Improvement

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.

Activity Delegated	**Delegated To**

_____ _____
Signature of Institutional Official Date

_____ _____
Signature of Director, OHSP Date