POLICY

1. Purpose

Establish a program within the University of Rochester (UR) to ensure individuals involved with human subject research understand and apply their obligation to protect the rights, dignity, welfare, and privacy of research subjects at the University of Rochester (and its affiliates) by adhering to the highest ethical standards and by complying with applicable federal and state regulations, as well as institutional policies.

2. Scope

This policy applies to all human subject research conducted or supported by employees or agents of the UR.

3. Definitions

3.1. Employee or Agent - An individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities, including but not limited to staff, students, contractors, and volunteers, regardless of whether the individual is receiving compensation.

4. References

4.1. FDA 21 CFR 50, 56, 312, 600, 812 and 814;
HHS 45 CFR 46, 45 CFR 160 and 164;
DoD 32 CFR 219;
EPA 40 CFR 26;
42 USC § 289 Institutional Review Boards ethics guidance program.

4.2. New York Public Health Code – Article 24-A: Protection of Human Subjects; Article 28 § 2803(g)(viii)- Informed Consent; New York Surrogate Court Procedure – Article 17-A: Guardians; New York Civil Rights Code Article 7 – § 79-L;

4.3. Policy 301 RSRB Scope and Authority;
Policy 503 Ancillary Committee Review;
Policy 603 Research Involving Prisoners;
Policy 609 Research Supported by the Department of Defense;
Policy 801 Reviewing and Reporting Research Events; and
Policy 802 Non-Compliance

5. Responsibilities

5.1. Ethical Principles

5.1.1. The UR Human Research Protection Program (HRPP) is grounded in foundational ethical principles. These guiding ethical principles are embodied in the Nuremberg Code of 1947, the Declaration of Helsinki of 1964 and its subsequent revisions (World Medical Association), and particularly in the ***Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research***

issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. The *Belmont Report* principles of *respect for persons, beneficence* and *justice* are accepted as critical for the ethical conduct of human subject research:

- **Respect for Persons** – Individuals should be treated as autonomous agents. They should voluntarily participate in research only after being fully informed of the benefits and risks of participation. Respect also means honoring the privacy of individuals and maintaining the confidentiality of data obtained. Special protection should be given to individuals with diminished autonomy (e.g., children, prisoners, cognitively impaired).
- **Beneficence** – Researchers are obligated to maximize possible benefits and reduce or eliminate possible risks to subjects.
- **Justice** – The benefits and risks of research should be equitably distributed, and research with any risk should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

5.2. Compliance with Regulations and Laws

5.2.1. All human subject research conducted by or under the auspices of the UR will be performed in accordance with applicable federal regulations, as well as state and local regulations and law, including but not limited to:

- Food and Drug Administration (FDA) regulations published at 21 CFR 50 and 56 and applicable sections of 21 CFR 312, 600, 812 and 814 regarding investigational new drugs and investigational devices.
- For Department of Health and Human Services (HHS) sponsored studies, regulations published at 45 CFR 46 (all subparts), and for all other federally sponsored studies, the "Common Rule" regulations (i.e., 45 CFR 46, Subpart A, as published in the applicable department/agency regulations).
- For Department of Defense (DoD) sponsored studies, regulations published at 32 CFR 219 and Policy 609 Research Supported by the Department of Defense.
- For Environmental Protection Agency (EPA) sponsored studies, regulations published at 40 CFR 26.
- Health Information Portability and Accountability Act (HIPAA) "Privacy Rule" HHS regulations published at 45 CFR 160 and 164.
- 42 USC § 289 Institutional review boards; ethics guidance program.
- New York Public Health Code – Article 24-A: Protection of Human Subjects.
- New York Public Health Code – Article 28 § 2803 (g)(viii): Informed Consent
- New York Surrogate Court Procedure – Article 17-A: Guardians.
- New York Civil Rights Code Article 7 – § 79-L.

5.2.2. For research that is conducted or supported by the EPA and RSRB is the Reviewing IRB, researchers and the RSRB are responsible for ensuring the following:

- Research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance;
- Research applies the additional protections under 40 CFR 26 Subparts C and D for pregnant women and children as subjects in observational research (i.e., research that doesn't involve intentional exposure to any substance);
- RSRB determinations are submitted to the EPA human subjects research review official for final review and approval before the research begins;
- EPA regulations protecting human subjects under 40 CFR 26 are applied for research submitted to EPA, but that is not otherwise conducted or supported by any federal agency that has regulations for the protection of human subjects.

5.2.3. For research that takes place in jurisdictions other than the State of New York, the investigator is responsible for providing the Reviewing IRB information concerning any laws related to human subject research conducted within the jurisdiction. When there are differences between federal regulations and the jurisdiction's applicable law, the more restrictive code will be applied. In this regard, the RSRB will seek guidance from UR Office of Counsel or other sources available to RSRB, as needed, to assist in obtaining the necessary information.

5.3. Federalwide Assurance

5.3.1. The UR maintains a Federalwide Assurance (FWA), FWA00009386, that certifies the UR will comply with the HHS regulations for the protection of human research subjects [45 CFR 46, Subpart A] for all research conducted or supported by employees or agents of the University of Rochester.

5.3.2. The UR submits an annual Attestation to the NYS Commissioner of Health to affirm that all human research complies with federal regulations, regardless of funding source. Attestations are submitted by January 1st of each calendar year.

5.3.3. The UR is considered to be "engaged" in human research (*Policy 301 RSRB Scope and Authority*) as defined by the Office for Human Research Protection (OHRP).

5.3.4. The FWA also defines other responsibilities of the institution including: the provision of sufficient institutional support for the HRPP; the authority of UR's RSRBs to approve, require modification in, or disapprove human subject research; the existence of written procedures describing the RSRB's process for the review of research projects; and the reporting to OHRP of certain events (*Policy 801 Reviewing and Reporting Research Events* and *Policy 802 Non-Compliance*).

5.4. Intra-Institutional Relationships

5.4.1. The HRPP includes not only the Office for Human Subject Protection (OHSP), but a coordinated effort with other units and individuals within the Institution and its affiliates, as follows:

- Institutional Official (IO)
  The President, with the concurrence of the Board of Trustees, has appointed the Vice President for Research as the IO for the UR's HRPP. The IO has delegated the authority for daily administration of the HRPP and oversight of human subject research to the OHSP. The Associate VP for Human Subject Protection (OHSP Director) reviews the status of the HRPP with the IO on an ongoing basis through regularly scheduled meetings. At these meetings, the HRPP is reviewed and evaluated with respect to the adequacy of financial, personnel and physical resources, RSRB structure and membership, educational, and QA/QI activities.

- Office of Counsel
  The Office of Counsel is available as needed to provide consultation and counsel on regulatory and legal requirements associated with research activities conducted at the University of Rochester.

- Office of Research and Project Administration
  The Office of Research and Project Administration (ORPA) assists faculty in the preparation and submission of research proposals to external sponsoring entities in the form of a contract, grant, or agreement, and management of post award activities. ORPA ensures that proposals have undergone regulatory compliance committee review, as applicable, at time of submission or prior to receipt of the award.

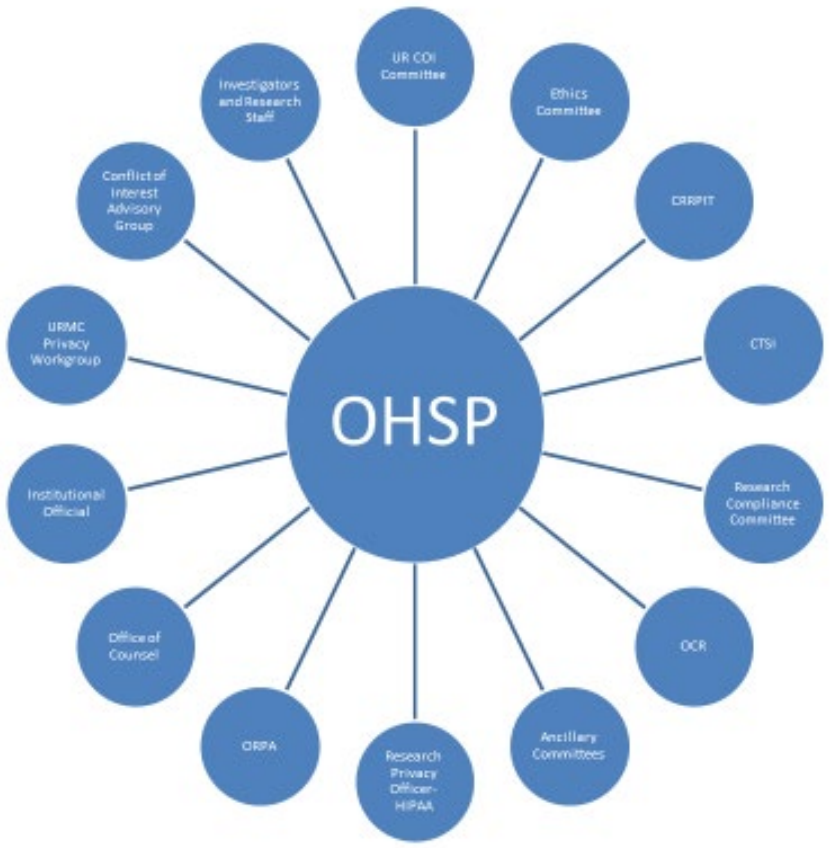
- Research Privacy Officer – HIPAA
  UR RSRB reviews research protocols for HIPAA compliance on behalf of the University. HIPAA forms and guidance are developed in collaboration with the URMC Privacy Office, which is responsible for Institutional compliance with HIPAA regulations. When a non-routine HIPAA issue arises, RSRB staff may consult with the research privacy officer regarding appropriate procedures. The research privacy officer may also consult with the RSRB staff when research related privacy issues arise.

- Other Institutional Committees
  The OHSP Director and RSRB Director represent the OHSP in collaboration with other institutional committees. These interactions serve to ensure that various departmental needs are met within the context of conducting human

subject research and to ensure compliance and consistency with University policies and procedures as applicable to human subject research.

5.4.2. HRPP Collaborations

Below is a schematic of the ancillary committees, groups, departments and staff who engage with OHSP to enhance the quality and effectiveness of the HRPP.



- URMC Privacy Workgroup = A committee of the University of Rochester Medical Center (URMC) and Affiliates privacy officers and departmental representatives.

- CIAG (Conflict of Interest Advisory Group) = A URMC committee that is advisory to the Dean of the School of Medicine and Dentistry that assists with the review and management of faculty, staff, and academic leader's potential conflicts of interest or commitment.

- UR COI Committee (University of Rochester Conflict of Interest Committee) = A committee that is advisory to the Provost, the Deans, and the Vice President for Research that assists with the review and management of faculty and academic leader's potential conflicts of interest or commitment.

- Ethics Committee = An advisory committee of individuals involved in medical and research ethics. This committee is available as an advisory resource for members of the professional staff regarding the ethical dimensions of patient care.

- CRRPIT (Clinical Research Review Process Improvement Team) = A committee with a mission to facilitate collaboration between central administrative departments that are responsible for the review of proposed clinical research projects and post-award administration of approved projects, and to encourage URMC faculty in their efforts to produce high-quality clinical research by ensuring an efficient review process that complies with necessary research proposal review policies.

- CTSI (Clinical & Translational Science Institute) = A department that provides funding, education, resources, and services to help research teams collaborate and produce results faster. Through the programs provided, the CTSI strives to advance science and medicine and improve the health of communities and populations.

- Research Compliance Committee = A committee of the leadership of the research enterprise with representation from faculty and the Office of Counsel, which is tasked with identification and management of key compliance issues facing the research enterprise.

- OCR (Office of Clinical Research) = A department of the CTSI that provides tools and services to help University of Rochester Medical Center faculty and staff with the administration of clinical trials.

- Ancillary Committees = Various institutional committees that review research activities, in addition to RSRB review, consistent with *Policy 503 Ancillary Committee Reviews*

Originator/Authors:

Kelley O'Donoghue, Director, OHSP
Emily Flagg, Senior Regulatory Specialist
Ann Marie Scorsone, Senior Regulatory Specialist

Appendices:

None

Revision History:

01/2015: Sect 1.0 added institutional policies; Sect 4.1 and 5.2.1 EPA regulatory references per AAHRPP; Sect 5.2.2 added per AAHRPP; Sect 5.2.2 becomes 5.2.3; URMC Privacy Workgroup definition editorial change
06/2017: Sect 4.3 added hyperlinks; Sect 5.4.1.6 remove CTSI Admin Committee and add Research Compliance Committee; updated privacy officer in the signatories
11/2019: Update Intra-Institutional Relationships, IO, signatories, and editorial
08/2023: Update References, Intra-Institutional Relationships, and Signatories; Editorial & Administrative revisions

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Stephen Dewhurst
Institutional Official and Vice President for Research

Date

DocuSigned by:
Signer Name: Gunta Liders
Signing Reason: I approve this document
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Gunta Liders
Associate Vice President for
Research Project & Administration

Date

DocuSigned by:
Nora Tabone
Signer Name: Nora Tabone
Signing Reason: I approve this document
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Nora Tabone
Chief Privacy Officer

Date

DocuSigned by:
Kelley O'Donoghue
Signer Name: Kelley O'Donoghue
Signing Reason: I approve this document
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2/19/2024 | 3:52:59 PM EST

Kelley A. O'Donoghue
Associate Vice President for Human Subject Protection

Date