POLICY

1. Purpose
   Describe the operations of the Research Subjects Review Board (RSRB) administrative office.

2. Scope
   This policy applies to RSRB office staff.

3. Definitions
   None

4. References
   4.1. Policy 402 RSRB Meetings;
        Policy 403 Notification of RSRB Determinations;
        Policy 504 IRB Reliance and Collaborative Research;
        Policy 802 Non-Compliance;
        University of Rochester Policy - Faculty Conflict of Commitment and Interest
   4.2. Guideline When University of Rochester Relies on Non-UR IRB;
        Guideline When University of Rochester is the Reviewing IRB;
        Guideline for Reporting Research Events

5. Responsibilities
   5.1. The RSRB Director is responsible for promoting the protection of the rights and welfare of research subjects by providing executive leadership and maintaining interpersonal capital in directing all OHSP and Institutional policies and guidance related to the review of all research involving human subjects.

   5.2. The Senior Specialist(s) is responsible for promoting the protection of the rights and welfare of subjects participating in research by advising and providing guidance to the research community and office staff, maintaining research policies as they relate to University, local, state and federal guidelines, and to assist the RSRB Director in his/her responsibilities as necessary.

   5.3. The Reliance Specialist is responsible for promoting the protection of the rights and welfare of subjects participating in research through the activities associated with managing Reliance Agreements and the Reliance process as it relates to compliance with institutional policies and regulations protecting the rights and welfare of human research subjects.
5.4. The Specialists are responsible for promoting the protection of the rights and welfare of subjects participating in research through the activities and processes associated with the management and review of research protocols as they relate to risk assessment, local, state and federal guidelines, ethical principles and the compliance with regulations protecting the rights and welfare of human research subjects.

5.5. The RSRB Board Secretary is responsible for supporting the overall operations of the RSRB office.

6. Requirements

6.1. RSRB Director: Activities including but not limited to those listed below, may be conducted to fulfill the responsibilities of the RSRB Director (see UR Position Description for additional details):

6.1.1. Assist the Institutional Official (IO), Office for Human Subject Protection (OHSP) Director, and Chairs/Vice Chairs in program development, implementation, and evaluation of the HRPP.

6.1.2. Ensure the Federalwide Assurance documentation with HHS is maintained and current.

6.1.3. Ensure the University’s human research protection program (HRPP) accreditation is maintained.

6.1.4. Provide executive direction and oversight to University research policy and the research community to ensure that the University meets its obligations in the review of all human subject research.

6.1.5. Represent the University at national meetings through presentation and posters.

6.1.6. Supervise RSRB office staff and ensure the initial and continuing training of assigned staff as appropriate.

6.1.7. Attend RSRB meetings to provide regulatory guidance and advice.

6.1.8. Review minutes of RSRB meetings.

6.1.9. Additional activities as delegated by the OHSP Director to support the functions of the OHSP office.

6.2. RSRB Senior Specialist: Activities including but not limited to those listed below, may be conducted to fulfill the responsibilities of the RSRB Senior Specialist (see UR Position Description for additional details):

6.2.1. Oversee exemption requests for projects conducted at the University, including confirmation of exempt determinations, as appropriate.

6.2.2. Manage the University’s HRPP accreditation.

6.2.3. Manage the policies and guidelines for the RSRB as it pertains to the University’s Human Research Protection Program and federal regulations.

6.2.4. Represent the RSRB office on various University and/or hospital committees.
6.2.5. Additional activities as delegated by the RSRB Director, or OHSP Director, and as noted in Section 6.3 and 6.4 below to support the functions of the RSRB office and to provide back-up support to Specialists as needed.

6.3. RSRB Reliance Specialist: The following activities, including but not limited to those listed below, may be conducted to fulfill the responsibilities of the RSRB Reliance Specialist (see UR Position Description for additional details):

6.3.1. Manage and facilitate reliance agreements and institutional requirements between UR and external IRBs, both when UR is the Relying IRB and Reviewing IRB.

6.3.2. Serve as a point of contact between the RSRB, research community, external research sites and organizations as pertain to RSRB reliance issues.

6.3.3. Provide guidance to Investigators according to Policy 504 IRB Reliance and Collaborative Research.

6.3.4. Facilitate and conduct institutional review of research when UR is the Relying IRB.

6.3.5. Additional activities as delegated by the RSRB Director to provide support or back-up to the functions of the RSRB office as necessary.

6.4. RSRB Specialist: The following activities, including but not limited to those listed below, may be conducted to fulfill the responsibilities of the RSRB Specialist (see UR Position Description for additional details):

6.4.1. Support the HRPP, the IO, and the Chairs’ objectives for human subject protection.

6.4.2. Assist the RSRB Director and Board Chairs with orientation and training of Board members.

6.4.3. Provide Board Chairs/Vice Chairs and members with guidance on the regulations and ethical principles essential to the review process as necessary.

6.4.4. Serve as a point of contact between the RSRB and the research community to provide guidance regarding regulations, and on preparation of applications and consent documents for RSRB review.

6.4.5. Facilitate the review and approval process through independent review and interpretation and application of relevant federal and state laws, regulations, and institutional policies and guidelines, including when the UR is the Reviewing IRB for multi-site research, according to Policy 504 IRB Reliance and Collaborative Research.

6.4.6. Manage board meetings, including preparation for meetings, taking minutes at convened board and other meetings, and notification of RSRB determinations to Investigators and study team according to Policy 402 RSRB Meetings and Policy 403 Notification of RSRB Determinations to ensure compliance with regulatory requirements.

6.4.7. Process reportable events in conjunction with the board Chair and convened board, as applicable (see Guideline for Reporting Research Events).

6.4.8. Schedule emergency meetings or cancel meetings, when necessary.
6.4.9. Assign primary reviewer responsibilities, when appropriate, to ensure that individuals who review protocols have sufficient familiarity and expertise in the area of research under review (this task may be delegated to another member or RSRB staff, based on his/her expertise and experience).

6.4.10. Conduct review of requests for exemption for projects conducted by University personnel, and confirm exemption requests as deemed appropriate by the RSRB/OHSP Director.

6.4.11. Additional activities as delegated by the RSRB Director or Senior Specialist to provide support or back-up to the functions of the RSRB office as necessary.

6.5. RSRB Assistant Specialist: Under the general direction of a Senior Specialist or Specialist, activities including but not limited to those below may be conducted to fulfill the responsibilities of the RSRB Assistant Specialist (see UR Position Description for additional details):

6.5.1. Review of research applications to ensure an efficient and effective review process.
6.5.2. Communicate with the Board Chair and Board Specialist to ensure adequate and appropriate reviews of research and timely approval and re-approval.
6.5.3. Collaborate with Investigators, research teams, and others across academic and medical center departments involved in the conduct of research to resolve issues that affect subject’s rights and welfare and to ensure compliance with federal and state regulations and University policies.
6.5.4. Additional activities as delegated by the Director, Senior Specialist, or Specialist to provide support or back-up to the functions of the RSRB office as necessary.

6.6. RSRB Board Secretary: Activities including but not limited to those listed below, will be conducted to fulfill the responsibilities of the RSRB Board Secretary (see UR Position Description for additional details):

6.6.1. Support for all board related functions.
6.6.2. Provide support for board member administrative functions.
6.6.3. Additional activities as delegated to provide support or back-up to the functions of the RSRB office as necessary.

7. Additional Functions of the RSRB Office

7.1. When the RSRB is the Relying IRB, the RSRB applies a review fee for institutional review of industry-sponsored studies.

7.2. The RSRB office will defer consideration of federally funded or foundation funded studies that qualify for Just-in-Time review until the Investigator provides written documentation to the RSRB that the funding source has determined the activity to be in
the fundable range. The IRB on-line system should be completed once the Investigator is in receipt of the funding notice.

7.3. The RSRB office maintains a Conflict of Interest table itemizing Institutional, Investigator, and sponsor-specific financial interests identified by the Conflict of Interest Advisory Group committee. The table is updated each time the RSRB office receives a management plan or transparency policy checklist (see UR Policy Faculty Conflict of Commitment and Interest). Appropriate Specialists are notified when new management plans/transparency checklists are received.

7.4. RSRB staff will report to the RSRB Director (or other designee as appropriate) any perceived allegations of undue influence on the actions of the RSRB or RSRB members (Policy 802 Non-Compliance).
Originator/Authors:
    Kelley O'Donoghue, Director OHSP
    Emily Flagg, Senior Regulatory Specialist

Appendices:
    Appendix 1: Sample Board Assignments Chart

Revision History:
    03/2016: Sect 4.1 and 4.2 hyperlinks added to references; Sect 6.5.1.2 deleted; editorial changes
    02/2019: Sect 5.3 and 6.3 added and references to data manager deleted to be consistent with current office structure; remove T. Gommel as signatory

Supersedes Date:
    03/11/2016

Approved By:

[Signature]
Kelley A. O'Donoghue
Director, OHSP

[Signature] 2/11/2019
Date

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## Appendix 1: Sample Board Assignments Chart

<table>
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<th>Board 01: Medical</th>
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<th>Board 03: Medical</th>
<th>Board 04: Cooperative</th>
<th>Board 05: Medical</th>
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- **Board 01: Medical**
  - Allergy/Immun/Rhino (Dept Med)
  - Center for Aging Board
  - Environmental Medicine
  - Family Medicine
  - Infectious Disease (Dept Med)
  - Neonatology (non-CFCC)
  - OB/GYN
  - Oral Biology
  - Psychiatry (medical-related)
  - Pain/Critical Care

- **Board 02: Bass**
  - Anthropology
  - Biomedical Engineering (non-medical)
  - Brain & Cognitive Sciences
  - Clinical & Social Psychology
  - Comm. & Perinatal
  - Eastman School
  - High School-Human Rights
  - Minority Student Affairs
  - Physical Med. & Rehab
  - Political Science
  - Psychiatry
  - River Campus
  - School of Nursing
  - SMH-Nursing Practice
  - Warner School

- **Board 03: Medical**
  - Anthropology
  - Biomedical Engineering
  - Cardiology
  - Cardiology (Dept Med)
  - Endocrinology (Dept Med)
  - Gastroenterology (Dept Med)
  - General Medicine (Dept Med)
  - Geriatrics (Dept Med)
  - Humanitarian Use Devices
  - Microbiology & Immunology
  - Nephrology (Dept Med)
  - Neurology
  - Neurology Optics
  - Otolaryngology
  - Pathology & Lab Medicine
  - Pharmacology/Physiology
  - Surgery
  - Urology

- **Board 04: Cooperative**
  - BCxGOG
  - ACTG (Adult/Ped)
  - CDG
  - LCOG
  - RVTH
  - IIT Specific Infectious Disease
  - RTOG
  - Single Pt Emergency Use
  - SWOG
  - SWC

- **Board 05: Medical**
  - Dermatology
  - Clinical Trials Coordination Center
  - Emergency
  - Neonatology
  - Ortho/Orthopedics
  - Pediatrics
  - Radiology - Imaging Sciences

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