POLICY

1. Purpose

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

2. Scope

This policy applies to RSRB employees.

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

4.3. RSRB Fee Structure

5. Responsibilities

RSRB employees are responsible for promoting the protection of the rights and welfare of research subjects throughout their job duties.

5.1. The RSRB Director is responsible for providing leadership and maintaining compliance of Office for Human Subject Protection (OHSP), RSRB, and Institutional policy and guidelines in the review of research involving human subjects.

5.2. The Senior Specialist is responsible for providing guidance to the research community and the RSRB employees regarding the review of research, maintaining research policies as they relate to University, local, state and federal regulations and guidelines; and assisting the RSRB Director in their responsibilities, as necessary. The Senior Specialist is responsible for the activities and processes associated with the management and review of research protocols as they relate to Institutional policy, local, state and federal guidelines, ethical principles, and regulatory compliance. Responsibilities may vary amongst employees in this role.

5.3. The Reliance Specialist is responsible for managing the Reliance process, including negotiating Reliance Agreements, as it relates to compliance with Institutional policy, local, state and federal guidelines, ethical principles, and regulatory compliance.

5.4. The Specialist is responsible for the activities and processes associated with the management and review of research protocols as they relate to Institutional policy, local, state and federal guidelines, ethical principles and regulatory compliance.

5.5. The Assistant Specialist is responsible for supporting Specialists with the activities and processes associated with the management and review of research protocols as they relate to Institutional policy, local, state and federal guidelines, ethical principles and regulatory compliance

5.6. The OHSP Administrative Assistant is responsible for manage Board Member rosters and administrative files to ensure continued accuracy for regulatory authorities.

6. Requirements

6.1. RSRB Director: Activities include, but are not limited to, those listed below and are 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 Human Research Protection Program (HRPP).
- 6.1.2. Ensure the Federalwide Assurance documentation with HHS is maintained and current.
- 6.1.3. Provide direction and oversight to University research policy and the research community to ensure the University meets its obligations in the review of human subject research.
- 6.1.4. Represent the University at national meetings through presentation and posters.
- 6.1.5. Supervise RSRB employees and ensure initial and continuing training of assigned employees.
- 6.1.6. Assign new study submissions to Specialists. *This may be delegated as needed.*
- 6.1.7. Attend RSRB meetings to provide regulatory guidance and review meetings minutes for regulatory compliance.
- 6.1.8. Additional activities as delegated by the OHSP Director to support the functions of the office.

6.2. Senior Specialist: Activities include, but are not limited to, those listed below and are conducted to fulfill the responsibilities of the Senior Regulatory Specialist (see UR Position Description for additional details):

- 6.2.1. Confirm exemption requests to ensure compliance with regulation and University policy, as appropriate.
- 6.2.2. Facilitates the University's HRPP accreditation.

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

6.2.4. 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 as needed.

6.3. Reliance Specialist: Activities include, but are not limited to, those listed below and are conducted to fulfill the responsibilities of the Regulatory Specialist (see UR Position Description for additional details):

6.3.1. Manage and facilitate the Reliance process with external research sites when the UR is the Reviewing IRB.

6.3.2. Serve as a point of contact between the RSRB, research community, external research sites and organizations for reliance issues and in preparation of applications and consent document for RSRB review.

6.3.3. Facilitate the review process through independent review, interpretation, and application of relevant federal and state laws, regulations, and institutional policies and guidelines,

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

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

6.3.6. Communicate with external IRBs and facilitate institutional review of research when UR is the Relying Institution.

6.3.7. 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. Specialist: Activities include, but are not limited to, those listed below and are conducted to fulfill the responsibilities of the Regulatory Specialist II (see UR Position Description for additional details):

6.4.1. Support the HRPP, the IO, and the Board Chairs' objectives for the protection of human subjects.

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 and education on regulations and the preparation of applications and consent documents for RSRB review.

6.4.5. Facilitate the review and approval process through independent review, interpretation, and application of relevant federal and state laws, regulations, and institutional policies and guidelines.

6.4.6. Manage board meetings, including preparation for meetings, ensuring quorum, taking minutes at convened board and other meetings, and notification of RSRB determinations to Investigators and study team members 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.

6.4.10. Conduct review of exemption requests to ensure compliance with regulation and University policy, as appropriate.

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

6.5. Assistant Specialist: Activities include, but are not limited to, those below and are conducted to fulfill the responsibilities of the Regulatory Specialist I (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, study team members, and others personnel across the University involved in the conduct of research to resolve issues related to the review of human subject research.

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

6.6. OHSP Administrative Assistant: Activities include, but are not limited to those listed below:

6.6.1. Provide support for board member administrative functions.

6.6.2. Manage Board Member rosters and administrative files

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 Reviewing IRB, the RSRB applies review fees for the review of Non-UR sites according to the *RSRB Fee Structure.*

7.1.1. For single-site research, fees are associated with industry and foundation-funded.

7.2. When the RSRB is the Relying Institution, the RSRB applies a review fee for institutional review of industry-sponsored studies according to the *RSRB Fee Structure*.

7.3. The RSRB office maintains a Conflict of Interest table itemizing Institutional, Investigator, and sponsor-specific financial interests identified by the University of Rochester Conflict of Interest Committee and the URMC Conflict of Interest Advisory Group. 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 employees 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:

None

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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
11/2022: Job descriptions updated with current practice; replace Board Secretary with OHSP Administrative Assistant; add RSRB Fees when RSRB is Reviewing IRB; remove Just-in-time (section 7.2) add to policy 502; remove Appendix 1; administrative and editorial changes

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Kelley O'Donoghue
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Kelley A. O'Donoghue
Director, OHSP

Date