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 802 Non-Compliance;
   University of Rochester Policy - Faculty Conflict of Commitment and Interest
4.2. Guideline for Submitting to Central IRB;
   Guideline for RSRB Audits;
   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 the RSRB policies and guidance related to the review of all biomedical, social and behavioral research involving human subjects conducted at the University of Rochester (UR) and its affiliates.

5.2. The Senior Specialist(s) is responsible for promoting the protection of the rights and welfare of subjects participating in research activities at the UR 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 Specialists are responsible for promoting the protection of the rights and welfare of subjects participating in research activities at the UR 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.
5.4. The RSRB Data Manager is responsible for managing the information contained in the RSRB online system (ROSS) pertaining to the applications for research conducted at the UR.

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), OHSP Director, and 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 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 ensures 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.

6.2. 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.

6.2.2. Manage the University’s human subject protection program accreditation.

6.2.3. Manage the policies and guidelines for the RSRB as pertains to the University’s human research protection program and federal regulations.

6.2.4. In coordination with the Director, develop and conduct educational programs for faculty and staff.

6.2.5. Represent the RSRB office on various University and/or hospital committees.

6.2.6. Additional activities as delegated by the Director, and as noted in Section 6.3 below to support the functions of the RSRB office and to provide back-up support to Specialists as needed.
6.3. 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):

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

6.3.2. Assist RSRB Director and Board Chair with orientation and training of Board members.

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

6.3.4. 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.

6.3.5. 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.

6.3.6. 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 (Policy 402 RSRB Meetings, Policy 403 Notification of RSRB Determinations) to ensure compliance with regulatory requirements.

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

6.3.8. Verify that grant proposals are consistent with RSRB applications.

6.3.9. Schedule emergency meetings or cancel meetings, when necessary.

6.3.10. 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).

6.3.11. Conduct review of requests for exemption for projects conducted by University personnel.

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

6.4. 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):

6.4.1. Review of research applications to ensure an efficient and effective review process.

6.4.2. Communicate with the RSRB Chair and board Specialist to ensure adequate and appropriate reviews of research and timely approval and re-approval.
6.4.3. 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.

6.4.4. 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.

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

6.5.1. Perform initial screening of proposals submitted in ROSS for completeness (e.g., departmental approval granted, ancillary reviews completed as applicable, research staff have completed human subject education requirements) and assign for board review.

6.5.1.1. Study assignments are based on the submitting department as designated by the Board Assignments chart (Appendix 1), type of sponsored research, and IRB Authorization Agreements.

6.5.2. Conduct final processing activities for research applications in ROSS at the time of initial approval, continuing reviews, amendments and study closures.

6.5.3. Manage change control process for ROSS.

6.5.4. Provide ROSS training to new board members and the research community.

6.5.5. Manage quality assurance of regulatory documentation in ROSS; including the conduct of RSRB audits and other HRPP QI assessments as needed.

6.5.5.1. Internal audits will be conducted at least annually, using an audit checklist (Appendix 2), to review the administrative and material integrity of its study files. Any inconsistencies or omissions uncovered as a result of the audit will be addressed/corrected and documented by the Specialist on the Board where the file was originally assigned. Refer to the Guideline for RSRB Audits for additional information on the procedures for an audit.

6.5.6. Additional activities as delegated by the Director, Senior Specialist, or Specialists 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, including informing Specialists regarding potential issues with quorum and providing Specialists with minutes templates.

6.6.2. Provide support for board member administrative functions such as drafting appointment and re-appointment letters, monitoring member term expiration dates, and managing board rosters.

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. The RSRB office applies a review fee to industry-sponsored studies. In general, the RSRB does not apply a fee for review of federally funded, foundation funded, or non-funded research.

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 ROSS application 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 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 and central IRB liaisons 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
Appendix 2: Sample RSRB Audit Checklist

Revision History:
February 2016: Sect 4.1 and 4.2 hyperlinks added to references; Sect 6.5.1.2 deleted; editorial changes

Supersedes Date:
10/07/2013

Approved By:

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

[Signature]
Tiffany Gommal
Director, RSRB

3/11/16
Date

3/11/2016
Date

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### Appendix 1: Sample Board Assignments Chart

<table>
<thead>
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<th>Board</th>
<th>Medical</th>
<th>BASS</th>
<th>Medical</th>
<th>Cooperative</th>
<th>Medical</th>
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- **Board 01: Medical**
  - Center for Aging
  - Behavioral Medicine
  - Family Medicine
  - Infectious Disease (Dept Med)
  - Neurology (non CCTC)
  - OB/GYN
  - Oral Health
  - Psychiatry (medical-related)
  - Pulm/Critical Care

- **Board 02: BASS**
  - Biomedical Engineering (non-med)
  - Brain & Cognitive Sciences
  - Clinical & Social Psychology
  - Comm. & Preventive
  - Eastman School
  - Highland Path - Behavioral
  - Minority Student Affairs
  - Physical Med. & Rehab
  - Political Science
  - Psychiatry
  - River Campus
  - School of Nursing
  - SMH - Nursing Practice
  - Warren School

- **Board 03: Medical**
  - Audiology
  - Biomedical Engineering
  - Cardiology
  - Cardiovascular (Dept Med)
  - Endocrinology (Dept Med)
  - Gastroenterology (Dept Med)
  - General Medicine (Dept Med)
  - Geriatrics (Dept Med)
  - Humanitarian Use Devices
  - Microbiology & Immunology
  - Neuroradiology
  - Optometry
  - Ophthalmology
  - Pathology & Lab Medicine
  - Pharmacology/Physiology
  - Surgery
  - Urology

- **Board 04: Cooperative**
  - ACTG (Adult/Ped)
  - ECOG
  - HFN
  - HIV/AIDS Specific Infections
  - RTDG
  - Single Print Emergency Use
  - SWOG
  - CRCC

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

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Appendix 2: Sample RSRB Audit Checklist

<table>
<thead>
<tr>
<th>WEBRIDGE AUDIT FORM</th>
<th>RSRB Office:</th>
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<tbody>
<tr>
<td><strong>PREVIOUS AUDIT</strong></td>
<td></td>
</tr>
<tr>
<td>• Date of last audit (if applicable):</td>
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<tr>
<td>• Check here if these were any findings?</td>
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<tr>
<td>• If yes, were findings addressed?</td>
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<tr>
<td>• □ Yes □ No □ N/A</td>
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</tbody>
</table>

| **APPLICATION**     |             |
| Section 1.1         |             |
| • Type of finding   |             |
| Section 7.1         |             |
| • Check here if prisoners are involved.         |             |
| • If yes, was the study assigned to a Board?    |             |
| • Check here if vulnerable populations are involved. |     |

| **FRONT PAGE**      |             |
| View Initial Approval Letter |     |
| • Approval period dates are correct? | Yes No |
| • Approval letter is signed and dated?       | Yes No |
| • If expedited study, is the expedited category listed? | Yes No |
| • If no, is the initial approval done □ before or □ after 1/1/06? | Yes No |
| • Does “Date Expire” on the front page match the expiration date on approval letter? | Yes No |

| **RSRB ONLY TAB / HISTORY TAB INITIAL APPROVAL** |
| Spocilist Checklist |     |
| • Is specialist checklist uploaded/filled out? (can also be located under “History” tab) | Yes No |
| • If study is expedited, what is the category selected? |       |
| • If study is expedited and 7.1 is checked (look above), are protocol and consent forms filled? | Yes No |

| Chair’s Checklist |     |
| • Is the chair’s checklist filled out? (under “History” tab) | Yes No |
| • Is the Length of Review mentioned on the checklist? | Yes No |
| • If study is expedited, does the category selected match the category that was selected by the specialists? | Yes No |
| • Check here if study is full board and the chair indicated that the study should be expedited at next review (Category 9)? | Yes No |
| • Are there vulnerable populations listed on the checklist? | Yes No |

| **AMENDMENT TAB**  |             |
| There have been no amendments | Yes No |

| View amendment approval letter for each amendment | Yes No |
| The expiration date is correct | Yes No |
| Approval letter signed and dated | Yes No |
| Is specialist checklist uploaded under RSB only tab? | Yes No |
| Is the chair checklist filled out under RSB only tab? | Yes No |

| Notes: |     |
|       |     |
DOCUMENT TAB

- Is there one version of the protocol uploaded? □ Yes □ No □ N/A
  (When revised protocol should be replaced not added. OK to have修改 & clean version)
- Are there only measures uploaded in this area? □ Yes □ No □ N/A
- Foundation Grants
  □ If funded by Gov. Agency or Foundation does one of the following apply? □ Yes □ No □ N/A
  - Complete grant including the face page uploaded.
  - Foundation letter uploaded.
  - Funded by Co-Funded Grant ( Umbrella study)(RSRB# referenced in section 7.3) □ Yes □ No □ N/A
  - The IR is a subcontractor for study (section 6.1) *
  - *No grant needed.

Notes:

CONTINUING REVIEW TAB

- There have been no continuing reviews □ Yes □ No
- Approval letter is signed and dated □ Yes □ No
- Is the length of review and the study status listed on the letter? □ Yes □ No □ N/A
- If expedited study, is the expedited category listed on the letter? □ Yes □ No □ N/A
- If the study was initially reviewed by the full board and is now expedited, in Category 8 or 9 listed on the re-approval letter? □ Yes □ No □ N/A
- Is principal investigator listed under RSB? □ Yes □ No □ N/A
- Is the expedited category consistent with the initial approval? □ Yes □ No □ N/A
- Is the clinical checklist filled out under History tab? □ Yes □ No □ N/A
- Is the Length of Wave mentioned on the Chair’s checklist? □ Yes □ No □ N/A
- Does the category match the category that was selected by the specialist? □ Yes □ No □ N/A
- Are vulnerable populations listed on the Chair’s checklist? □ Yes □ No □ N/A
  - *children/minors, pregnant women & prisoners*
- If yes, are they noted on the re-approval letter? □ Yes □ No □ N/A

If there is a problem, please note the specific OK #: __________

Notes:

STUDY FILE BUTTON

- If a continuing review was done, have the last signed consent(s) been uploaded? □ Yes □ No □ N/A
  (Can also be located in the Progress Report section 7.2)
  *If the study has more than one approved consent document, the last signed form for each type of consent document should be submitted, if enrollment occurred with this form, a *
  *Note: In the progress report # 1.3 shows enrollment and # 1.1 shows they have a consent form."
- Do all documents uploaded under the Study File belong to this study? □ Yes □ No □ N/A
  (If the consent number is changed, the study file number should be changed)

Notes:

Actions necessary: □ File in order □ No changes required □ Information required. Audit form forwarded to: _____________________

Audit performed by: _____________________ Date: ______________

Revised: 08/2010

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