POLICY

1. Purpose
   Describe the types of submissions received and reviewed by the Research Subjects Review Board (RSRB) and the materials required for the RSRB to conduct a thorough review.

2. Scope
   This policy applies to all Investigators conducting human subject research under the University of Rochester Human Research Protection Program (HRPP), the RSRB, and the RSRB office.

3. References
   3.1. Policy 402 RSRB Meetings; Policy 501 Levels of RSRB Review; Policy 504 RSRB Reliance for Review; Policy 901 Investigator Responsibilities; Guideline for Determining Exempt Research; Guideline for Expedited Review of Research; Guideline for Convened Board Review of Research; Guideline for Reporting Research Events; Guideline for Notification of RSRB Determinations
   3.2. RSRB Protocol Templates

4. Responsibilities
   4.1. Investigators are responsible for including the necessary materials when submitting new applications, amendments, continuing reviews, and reports of study completion or closure to the RSRB when the RSRB is the Reviewing IRB, as outlined in the sections below. These responsibilities are applicable to all types of research applications, including just-in-time, multi-center, coordination center, umbrella, and international research.
   4.1.1. When the RSRB is the Relying IRB, Investigators are responsible for following the submission requirements of the Reviewing IRB as described in Policy 504 RSRB Reliance for Review, as well as the submission requirements for RSRB institutional review as described in Section 5.2 below.
   4.1.2. The RSRB utilizes an online protocol submission system, the RSRB Online Submission System (ROSS), which enables Investigators to track submitted applications throughout the review process.
   4.2. The RSRB office will conduct an initial screening of all research applications to ensure the information is complete based on the type of submission received.
5. Requirements for New Applications/Initial Review

5.1. For all new submissions (i.e., exemption request, expedited or convened board review) in which the RSRB is the Reviewing IRB, the RSRB requires the following:

- RSRB New Application form;
- A research protocol (see RSRB Protocol Templates for reference);
- Full grant application, if proposal is federally or foundation-funded;
- All informed consent documents (i.e., consent, permission, assent, information sheet, verbal script, etc.), as applicable;
- Any recruitment materials, if used, (e.g., flyers, posters, scripts, social media ads);
- Subject completed measures used to collect study information such as surveys, interview forms, questionnaires, assessments;
- Data collection sheets for research involving retrospective use of data;
- Supporting approval or letter of support from non-UR sites where the research will be conducted, as applicable;
- Ancillary committee approval(s), as applicable;
- For new submissions involving drugs or devices,
  - Investigational Drug Brochure(s), package insert, or Device Information, as applicable;
  - Documentation of IND or IDE approval by the FDA, or documentation to confirm exemption from FDA IND or IDE requirements, as applicable;
- For new submissions when the RSRB is the Reviewing IRB for a multi-center study additional documents may be required, such as the following, if applicable:
  - Model Informed Consent(s)
  - Participating site’s consent form(s)
  - Participating site’s IRB questionnaire
- For DHHS sponsored research, the researchers must submit the DHHS-approved sample consent document, protocol, and any relevant grant application.
- Any other documents as indicated in the New Application form or as required by the RSRB.

5.1.1. Initial submissions that are incomplete, or for which the Investigator is non-responsive to RSRB requests, may be withdrawn from consideration for RSRB approval after 90 days of inactivity, or at the discretion of the RSRB Director. The RSRB will notify the Investigator regarding withdrawal of the project. If the Investigator decides to proceed with the project, it must be submitted to the RSRB as a new/initial submission and be given RSRB approval prior to initiation.

5.2. For new submissions for which the RSRB is the Relying IRB, the RSRB requires the following review materials:

- RSRB Central IRB Application form;
- Research protocol;
Types of RSRB Submissions

- All informed consent documents (i.e., consent, permission, assent, information letter, etc.);
- Documentation of ancillary committee approval(s);
- Additional materials as applicable to the submission.

5.3. An RSRB number will be assigned to the research and will be referenced in future communications between the RSRB and the Investigator.

5.4. The process for RSRB review of new applications when the RSRB is the Reviewing IRB, includes the determination of approval period (as applicable) and notification of RSRB determinations, according to Policy 402 RSRB Meetings, the Guideline for Exempt Status Determination, the Guideline for Expedited Review of Research, and the Guideline for Convened Board Review of Research, as applicable to the level of review.

6. Requirements for Amendments

6.1. During the conduct of an RSRB approved study, amendments/modifications to the protocol may be proposed or unplanned changes may be discovered that require RSRB notification. Any proposed amendment to an RSRB approved research protocol must be submitted to the RSRB by the Investigator (or an authorized individual) using the Amendment Form in the online submission system.

6.1.1. In addition to completing the Amendment Form and submitting the revised study materials, changes may also be necessary to the Application Form.

6.1.2. When the RSRB is the Relying IRB, amendments/modifications must be submitted to the Reviewing IRB for review and approval.

6.2. Regardless of the nature of the change, RSRB review of the amendment must occur. The RSRB must approve the amendment prior to implementation of the changes.

6.2.1. An exception to this prior approval requirement is when a change is necessary to eliminate an apparent immediate hazard to a research subject or study personnel. Such events are to be reported promptly to the RSRB according to the Guideline for Reporting Research Events.

6.3. Amendments require review according to the study risk level and whether the revision changes the risk/benefit assessment of the study, as determined during initial review by the RSRB Specialist with confirmation by the RSRB Chair.

6.3.1. Changes to research previously granted an RSRB exempt determination will be reviewed according to the Guideline for Exempt Determinations.

6.3.2. Minor changes to previously approved research may be reviewed by expedited review procedures according to Policy 501 Levels of RSRB Review and the Guideline for Expedited Review of Research (definitions and examples of “minor changes” are described within the guideline).
6.3.3. Amendments that do not meet the criteria for expedited review will be reviewed by the convened board according to Policy 501 Levels of RSRB Review and the Guideline for Convened Board Review of Research (examples of amendments requiring convened board review are included within the guideline).

6.3.4. Amendments involving study personnel changes (except changes to the PI or non-UR personnel), and no other protocol documents require revision as a result of the personnel change, will be administratively reviewed and confirmed by delegated RSRB staff.

6.4. The Investigator will be notified of the RSRB review determination for the requested amendment according to the Guideline for Notification of RSRB Determinations. The approval letter (or review determination, as applicable) and revised protocol materials are available to the Investigator electronically in ROSS.

- **Note:** Approval of an amendment does not change the original approval period of the study.

7. **Requirements for Reportable Research Events**

7.1. Investigators are required to report research events according to the Guideline for Reporting Research Events, and to include materials indicated within the guideline and the RSRB Reportable Events form.

8. **Requirements for Continuing Review**

8.1. Continuing review allows the RSRB to review the progress of the entire study including any approved changes or reportable events since the last review, when the RSRB is the Reviewing IRB. All expedited or convened board approved research studies must undergo continuing review at intervals appropriate to the degree of risk, but no less than once per year. Federal regulations do not allow for an extension of the study approval period without the RSRB conducting review of the progress report and related study materials and granting re-approval of the study.

8.1.1. In addition to the risk/benefit assessment, the RSRB may also consider the following in determining the duration of approval and when a more frequent review may be required:

- prior RSRB interaction with the Investigator
- the experience of the Investigator
- the subject population and disease/condition under study
- stage of the study and subject disease states
- prior research events

8.2. Continuing review must occur for all non-exempt human subject research that remains active for long-term follow-up of subjects; even if the research is permanently closed.
to enrollment of new subjects and all subjects have completed all research activities or interventions.

8.3. Continuing review must occur for research that includes the collection of private, identifiable data.

8.4. Continuing review must occur for research that includes the analysis of private, identifiable data. Once the primary analysis has been completed and results reported to the RSRB, the study can be closed as long as identifiers have been removed from the analysis dataset.

8.5. The Investigator will be notified when RSRB approval is approaching expiration and is due for continuing review according to the Guideline for Notification of RSRB Determinations.

8.6. The Investigator must provide the RSRB with the information listed below through the RSRB Online Submission System, preferably 6 to 8 weeks prior to the study expiration date. Failure to allow sufficient time for RSRB review may result in a lapse in approval.
   - Continuing Review Form (or progress report), including all associated documents requested within the form and as applicable to the research activities.
   - A complete copy of the consent form signed by the last subject enrolled in the study, when applicable. Note: Redact the subject’s name after making a copy of the original signed consent to protect subject confidentiality.
     - For studies involving more than one consent document, such as a patient consent and a healthy volunteer consent, submit a complete copy of the signed consent for each document used for subjects enrolled at the time of continuing review.
     - For studies using more than one version of the consent form, such as English and Spanish, submit a complete copy of the signed consent for each version used for subjects enrolled at the time of continuing review.
   - Documentation to support the data and safety monitoring plan, as applicable, and if not previously submitted prior to the time of continuing review (e.g., data safety monitoring board report).
   - Any other documents that the RSRB may request.

8.6.1. The Investigator may indicate within the Continuing Review Form any consent, recruitment, or other subject material that does not require re-approval (e.g., the study is no longer using a specific recruitment document). Materials that are no longer used may then be archived by the RSRB.
8.7. Continuing reviews that meet the requirements for expedited review may be reviewed and re-approved by the RSRB Chair (or designee) using the expedited review procedures according to the Guideline for Expedited Review of Research. All other research will undergo continuing review by the convened board according to the Guideline for Convened Board Review of Research.

8.7.1. The RSRB may not re-approve the research prior to 30 days of study expiration.

8.8. Upon re-approval of the study, documents still in use will be given an updated approval stamp/watermark with the new expiration date, as applicable. Studies that continue to enroll subjects are required to use the most recently approved consent documents and recruitment materials.

8.8.1. The expiration date is determined according to the Guideline for Expedited Review of Research or the Guideline for Convened Board Review of Research, as applicable.

8.9. The Investigator will be notified of the RSRB review determination for the continuing review according to the Guideline for Notification of RSRB Determinations.

8.10. A notice of study expiration will be sent if no progress report is submitted by the expiration date, according to the Guideline for Notification of RSRB Determinations, which will also indicate that study termination is pending.

8.10.1. **Research activities must stop upon study expiration (including recruitment enrollment, interventions, interactions and data analysis).** Investigators may request the continued participation of subjects enrolled to expired studies, if there is an overriding safety concern or ethical issue that would make such continuing participation in the subject’s best interest. The RSRB will review the Investigator’s request to determine whether there are safety concerns or ethical issues that may apply if research activities are stopped, and, if none, the RSRB will also consider whether continued participation is in the best interest of the individual subjects. The board determination will be communicated to the Investigator.

8.10.2. **Notification of RSRB Closure of Expired Research is issued after the study has been expired for over 30 days, with copy to the Investigator’s department chair and Division Chief, as applicable.**

8.10.2.1. Investigators with a study closed due to failure to submit a progress report, or failure to respond to questions regarding the progress report, will not have new studies reviewed by the RSRB until the Continuing Review Form is completed and submitted to either reapprove the study or close the study.

9. **Requirements for Study Completion or Closure**

9.1. The RSRB requires submission of a final report to close a study, regardless of the reason (i.e., completed, closed before completion, not initiated/not conducted).
9.1.1. A study is considered completed when subjects are no longer being recruited (or data/specimens being collected), no longer being followed, primary data analysis has been completed according to the protocol, and identifiers have been removed from the analysis dataset (e.g., identifiers destroyed or identifiers maintained in a separate dataset).

9.2. The Investigator will submit a final report by completing the Continuing Review Report at any time during the approval period, but no later than the expiration date of the study. One of the following study status options must be selected, as applicable.

9.2.1. **Study Completed** – Interventions, data collection, data analysis and other activities were completed as described in the protocol. If the primary analysis of the study has been completed, but additional analyses may be conducted, the study may be closed as long as all identifiers are removed from the analysis database and kept in a separate location.

9.2.1.1. Date of study completion should be included when submitting the closure report. Date of completion is when all subjects completed all interventions and the Investigator completed the primary data analysis as described in the study protocol.

9.2.2. **Study Closed Before Completion** – Study began (i.e., open for enrollment and subject participation/data collection), but the study was stopped before activities and analysis as described in the protocol were achieved.

9.2.2.1. Date of closure should be included when submitting the closure report. Date of closure is when it was determined that the study would not move forward and no additional study activities will be completed. The reason the study was closed before completion should be included.

9.2.3. **Study Has Not/Will Not Be Conducted** – Study never began (i.e., no subject participation/data collection).

9.2.3.1. The reason the study has not/will not be conducted should be included (e.g., lack of funding, study personnel changes).

9.3. The RSRB will review the continuing review closure report by convened board review or expedited review procedures, as appropriate.

9.4. The Investigator will be notified of the RSRB review determination for the closure report according to the *Guideline for Notification of RSRB Determinations*.

9.4.1. The Investigator is responsible for maintaining study records after study closure according to *Policy 901 Investigator Responsibilities*. The RSRB closure date serves as the starting point for this requirement. The closure date is the date of the closure letter to the Investigator to confirm that the RSRB reviewed the study completion report and confirms study closure.
9.5. Once a study is completed or closed by the RSRB, all study activity must cease (i.e., no further data collection). Data analysis is permitted if identifiers have been removed from the analysis dataset (e.g., identifiers destroyed or identifiers maintained in a separate dataset).
Originator/Authors:
  Emily Flagg, Senior Regulatory Specialist

Appendices:
  None

Revision History:
  12/2016: add hyperlinks; add reference to Policy 504; language regarding Reviewing IRB; add Sect 6.3.4 administrative review of study personnel changes; Sect 9.2 add definitions of closure; editorial changes and updates to reflect current practice

Supersedes Date:
  10/09/2014

Approved By:

Kelley A. O'Donoghue
Director, CHSP

Tiffany L. Gommel
Director, RSRB

Page 9 of 9

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.