POLICY

1. Purpose

1.1. Define the levels of review assigned to an application by the Research Subjects Review Board (RSRB) based on the risks posed to subjects by the research activities to ensure their protection during and after participation in the research.

1.2. Describe the general process for review of submissions for initial and continuing review and for amendments to previously approved research, as applicable.

2. Scope

This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester (UR), the RSRB, and the RSRB office, when the RSRB is the Reviewing IRB.

3. Definitions

3.1. Approval Date – The first possible date research can be performed (following notification from the RSRB), consistent with federal regulations, state and local laws, and University policy (i.e., other approvals/notices may be required before the research may proceed).

3.2. Approval Period – For initial review, the interval of approval which begins on the day research is approved by the convened board or the RSRB Chair, Vice Chair, or Experienced member. The approval period may not be longer than one year after that effective date. For continuing review, a fixed date for expiration of the annual RSRB approval will be used.

3.3. Convened Board Review – Review of proposed human subject research by an Institutional Review Board that meets the membership requirements specified in federal regulations as described in Policy 302 RSRB Membership and Composition.

3.4. Expedited Review – Process by which a RSRB Chair, Vice Chair, or an experienced RSRB member approves minimal risk research that falls into one or more types of research categories designated by the Office for Human Research Protections.

3.5. Experienced Board Member – A member who has demonstrated during a period of active participation, a broad understanding and competency with human subject protection ethics, board operations, and regulatory requirements, including expedited review procedures and is so designated by the Chair.
3.6. **Expiration Date** – The last date on which the research protocol is RSRB approved and research activities can be performed. An expiration date may not be more than one year from the date the approval period begins.

3.7. **Minimal Risk** – The probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

3.8. **Minor Changes** – Changes to the research that, in the judgment of the RSRB, do not substantially alter the research aims or methodology, nature of subject participation, level of risk, proposed benefits, or subject population such that the increase of risk is more than minimal, or there is the addition of procedures in research categories that do not qualify for expedited review.

4. **References**
   4.1. HHS 45 CFR 46.101; HHS 45 CFR 46.110; FDA 21 CFR 56.110
   4.2. Policy 301 RSRB Scope and Authority; Policy 302 RSRB Membership and Composition; Policy 401 Functions of the RSRB Office; Policy 402 RSRB Meetings; Policy 502 Types of RSRB Submissions
   4.3. Guideline for Determining Human Subject Research; Guideline for Exempt Status Determination; Guideline for Expedited Review of Research; Guideline for Convened Board Review of Research; Guideline for Notification of RSRB Determinations

5. **Responsibilities**
   5.1. Investigators are responsible for submitting any human research activity that might fall under the authority of the University of Rochester’s Human Research Protection Program to the RSRB for review.

   5.2. Qualified RSRB staff (*Policy 401 Functions of the RSRB Office*) and the RSRB have the authority to review all proposed research activities to make a determination whether the activity meets the federal definition for research and/or involves human subjects and is therefore subject to RSRB review and oversight as described in *Policy 301 RSRB Scope and Authority.*

   5.3. The RSRB has the authority for a review level determination that may exceed the minimum standard permissible under the federal regulations. For example, an activity...
that may qualify for exemption may instead receive expedited review, or the RSRB may choose to review research that may qualify for expedited review at a convened meeting.

5.4. The RSRB is responsible for assessing the level of risk posed to subjects by the research in making a review level determination. Risks include, but are not limited to the probability and severity of possible harm or discomfort to the subject’s physical, psychological, social, legal, or economic welfare.

5.5. Investigators have the responsibility to ensure that research activities involving human subjects are not initiated until notice of RSRB approval (or exempt determination if applicable) is received.

6. Requirements for Exempt Status Determinations

NOTE: Research that is regulated by the FDA does not qualify for exempt status.

6.1. The RSRB will review research activities conducted under one or more of the regulatory categories in 45 CFR 46.101(b) which meet the additional institutional standards for exemption. The regulatory categories and institutional standards are outlined in the Guideline for Exempt Status Determination.

6.1.1. Exemptions under 45 CFR 46.101(b) apply to 45 CFR 46 Subpart B (pregnant women) [45 CFR 46.201(b)].

6.1.2. Exemptions under 45 CFR 46.101(b) may apply to 45 CFR 46 Subpart D (children) [45 CFR 46.401(b)] under the following categories:

6.1.2.1. Categories 1, 3, 4, 5 and 6 if the conditions of the exemption are otherwise met.

6.1.2.2. Category 2 for research involving educational tests.

6.1.2.3. Category 2 for research involving observations of public behavior when the Investigator(s) do not participate in the activities being observed.

- Category 2 for research involving survey or interview procedures may not be applied to children.

6.2. Investigators must submit materials necessary for the initial review of the application for exemption in order for the RSRB to determine whether the research qualifies for exempt status. (see Policy 502 Types of RSRB Submissions)

6.2.1. At any point during the review process the application may be re-assigned by the RSRB staff for expedited or convened board review.

6.3. Qualified RSRB staff will review the RSRB application, including all submitted documents, to determine if the activity is consistent with one or more of the exempt status categories of research as per 45 CFR 46.101(b), and meets the institutional standards for
exempt status determination according to the *Guideline for Exempt Status Determination*. The application will be returned to the study team if more information or documentation is required to consider the application complete for purposes of exempt review.

6.3.1. Qualified RSRB staff may determine that the activity does not involve human subject research. If so, the review process will be conducted according to the *Guideline for Determining Human Subject Research* and notification to the Investigator will occur according to the *Guideline for Notification of RSRB Determinations*.

6.3.2. Qualified RSRB staff may determine that the research does not meet the exemption criteria and request that an Investigator submit the protocol for expedited or convened meeting review (see Section 7 and Section 8 below).

6.3.3. Qualified RSRB staff may request modifications and the Investigator may respond indicating that requested modifications have been addressed or provide justification for not doing so.

6.4. The RSRB Senior Specialist (or designee) will confirm the final exempt determination and the Investigator will be notified according to the *Guideline for Notification of RSRB Determinations*.

6.5. Research activities (e.g., recruitment of subjects, enrollment, data collection, data analysis) may not be initiated until the Investigator receives written notification of exempt determination from the RSRB.

6.6. If changes are desired to a research activity that has been granted an exempt determination, Investigators must submit an amendment to the RSRB and receive notification of continued exempt status prior to initiating any of the proposed changes. These changes and confirmation of continued exemption are reviewed by the RSRB Specialist.

6.6.1. If an amendment alters the research such that it no longer qualifies for exemption, the modified protocol will be reviewed using the procedures for expedited or convened board review, as applicable.

7. **Requirements for Expedited Review**

7.1. The RSRB may use the expedited review procedure to review the following research activities as authorized by HHS 45 CFR 46.110 and FDA 21 CFR 56.110 when:

7.1.1. Some or all of the research activities appear in one or more of the categories listed in *Appendix 1 of the Guideline for Expedited Review of Research*. Research activities in the categories eligible for expedited review should not be considered minimal risk simply because they are included on the list. The activities must be
considered within the context of the proposed research when determining that the research involves no more than minimal risk to human subjects.

7.1.2. Minor changes (amendments) to previously approved research during the period for which approval is granted.

7.1.3. The requirement for informed consent, or for altering or waiving the requirement for informed consent.

7.2. The RSRB may not conduct expedited review procedures under the following conditions:

7.2.1. Research involving procedures that are greater than minimal risk, even if those procedures are routinely conducted as standard of care;

7.2.2. Research involving prisoners (unless the RSRB prisoner representative member will be a designated reviewer of the application and the RSRB Chair or Vice Chair has given the prisoner representative the authority to review research involving prisoners using the expedited review process); or,

7.2.3. Activities involving classified research involving human subjects.

7.3. Investigators must submit materials necessary for the initial or continuing review of research, as well as amendments, when using the expedited review process (see Policy 502 Types of RSRB Submissions).

7.3.1. The RSRB reserves the right to determine that research activities should be reviewed by the convened board rather than using expedited review procedures.

7.4. An RSRB Specialist will review the RSRB application, including all submitted documents, to determine (in consultation with the Chair or Vice Chair, as necessary) whether the research may be reviewed by expedited review procedures, as well as to determine that the information is complete. The application will be returned to the study team should more information or documentation be required to consider the application complete for purposes of expedited review.

7.5. The RSRB Chair, Vice Chair, or one or more experienced RSRB members designated by the Chair per Policy 302 RSRB Membership and Composition, will use the expedited review procedures to approve research activities at the time of initial review, an amendment, and continuing review, according to the Guideline for Expedited Review of Research.

7.5.1. The Chair, Vice Chair (or experienced member) must, as part of the review, determine that the research satisfies all of the regulatory requirements outlined in Policy 404 Criteria for Approval, represents one or more of the approvable expedited categories of research in Appendix 1 of the guideline, and meets the definition for minimal risk.
7.5.2. The possible review determinations that may be made by an RSRB expedited reviewer for initial reviews, continuing reviews, and review of amendments to previously approved research include the following:

7.5.2.1. **Approve as submitted:** Research study is approved as reviewed (i.e., without any stipulations required by the expedited reviewer).

7.5.2.2. **Approve with stipulations:** Research study is approved pending minor modifications or consent document changes that require concurrence by the Investigator and that can be confirmed by the expedited reviewer.

7.5.2.3. **Request changes or additional information:** Research study requires additional information in order to determine whether the study may be approved or requires referral to convened board.

7.5.2.4. **Refer to convened board:** The expedited reviewer may choose to defer any action to a meeting of the convened board (refer to Policy 402 RSRB Meetings).

7.5.3. The Chair, Vice Chair (or experienced member) may not disapprove research through the expedited review process.

7.5.4. RSRB review determinations following expedited review will be documented in writing through correspondence with the Investigator according to Policy 403 Notification of RSRB Determinations.

7.6. The approval date and expiration date will be established according to the Guideline for Expedited Review of Research.

7.7. Research activities (e.g., recruitment of subjects, enrollment, data collection, data analysis) may not be initiated until the Investigator receives written notification of RSRB approval.

7.8. RSRB members and the Institutional Official, or designee, periodically receive a report of expedited actions that occur between convened meetings.

### 8. Requirements for Convened Board (Full Board) Review

8.1. Investigators must submit materials necessary for the initial or continuing review of research, as well as amendments, when using the convened board review process (see Policy 502 Types of RSRB Submissions).

8.2. An RSRB Specialist will review the RSRB application, including all submitted documents, to determine (in consultation with the Chair or Vice Chair, as necessary) whether the research must be reviewed at a convened meeting, as well as to determine that the information is complete. The application will be returned to the study team...
should more information or documentation be required to consider the application complete for purposes of board review.

8.3. The RSRB must provide substantive and meaningful review of research that is approved by convened review on a continuing basis, at the interval established by the RSRB at the initial review (at least once a year). The RSRB review must be conducted by the convened board unless research meets the criteria for expedited review (see Section 7).

8.3.1. The RSRB will conduct convened board review for the following activities:

- New applications that are not eligible for exempt status or expedited review procedures;
- New applications eligible for expedited review procedures that the RSRB Chair or Vice Chair chooses to send for convened board review;
- New applications approved with stipulations by the convened board, which upon review of the revised application by the Chair, Vice Chair, or experienced member, contain considerable revisions beyond the scope of the convened board’s stipulations;
- Any substantive changes to research that have undergone convened board review, or any change that increases risk to subjects or others;
- Continuing review of research that does not qualify for expedited review;
- Disapproval of research;
- Suspension or termination of research;
- All research involving the use of investigational drugs, devices, or biologics for which an IND/IDE is required (e.g., Phase 1 – Phase 4 clinical trials, use of devices posing significant risk);
- Findings of serious or continuing non-compliance.

8.4. The process for research undergoing convened board review will be followed according to Policy 402 RSRB Meetings and the Guideline for Convened Board Review of Research, in regard to selection of primary reviewers, selection of consultants (as needed), materials provided for review, preparation and conduct of the convened board meeting, establishment of approval period, and post-review procedures.

8.4.1. To be approved, research reviewed by the convened board must satisfy all of the regulatory requirements outlined in Policy 404 Criteria for Approval.

8.4.1.1. When research involves the use of articles or agents regulated by the Food and Drug Administration (FDA), e.g., drugs, devices, and biologics, or is otherwise regulated by the FDA, the convened board will also consider the following:

- Marketing status of the drug or device (e.g., investigational, FDA-approved for an approved indication);
- For drugs, the appropriateness of the dose, formulation, and route of administration for the targeted subject population;
- For devices, the recommended risk status of the device (i.e., significant or non-significant);
- For investigational agents, safety and efficacy data supporting the proposed phase of testing;
- For investigational agents, a description of the plan for assuring appropriate accountability, storage, access and control of the investigational agent(s).

8.5. The Investigator, Institutional Official (or designee), and regulatory authorities as applicable, will be notified of the RSRB determinations made during the convened board review process according to Policy 403 Notification of RSRB Determinations and the Guideline for Notification of RSRB Determinations.
Originator/Authors:
Emily Flagg, Senior Regulatory Specialist

Appendices:
None

Revision History:
01/2015: Sect 6.3 regulatory refs added in response to AAHRPP
06/2018: Sect 2 and throughout added language for Reviewing IRB; added Vice Chair
throughout; Sect 4.2 and 4.2 hyperlinks added; Sect 6.1 added subsections to clarify when
exemptions apply; Sect 7.5.2 and 7.5.4 were added with expedited review determinations
(moved from Policy 402); additional editorial changes

Supersedes Date:
01/30/2015

Approved By:

Kelley A. O'Donoghue
Director, OHSP

Tiffany L. Gommel
Director, RSRB

Date
07/05/2018

Date
6/29/2018