POLICY

1. Purpose

1.1. Define the levels of review assigned to submissions received 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 modifications 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 date the IRB decision was made by the convened board, RSRB Chair, Vice Chair, or Experienced Member indicating all requirements of the approval criteria were met.

3.2. *Approval Period* –The duration of approval which begins on the day research is approved by the convened board or the RSRB Chair, Vice Chair, or Experienced member through and inclusive of the Expiration Date.

3.2.1. When continuing review is required, the approval period may not be longer than one year after that approval date.

3.2.2. When continuing review is not required, the approval period will continue until the date the study is closed (i.e., approval will not expire).

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. *Effective Date* - The date the RSRB decision takes effect. This is 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).

3.4.1. When the study is approved with no modifications, this date is the same as the approval date.

3.4.2. When modifications are required to secure approval, the effective date is the date the modifications are reviewed and accepted.

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

3.6. *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 and limited IRB review procedures and is so designated by the Chair (per *Policy 302 RSRB Membership and Composition).*

3.7. *Expiration Date or Last Date of Approval Period* – The last date of study approval and the last date on which RSRB approved research activities can be performed. An expiration date may not be more than one year from the date the approval period begins.

3.8. *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.

3.9. *Minor Modification* – 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 no more than minimal. Examples include, but are not limited to, addition of research locations or participating sites (for multi-site research), administrative changes to protocol or protocol related documents.

3.10. *Other Modification* – Changes to the research submission that do not fall under an expedited review category, or as a minor modification to the research. Examples include, change of study team members except for the Principal Investigator, documents requiring re-formatting only, administrative corrections to the application that do not change the research, corrections to approval dates.

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. RSRB Specialist (as determined in *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 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

6.1. The RSRB will review research activities conducted under one or more of the regulatory categories in 45 CFR 46.104 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 46.104 apply to 45 CFR 46 Subpart B (pregnant women) as long as all conditions of the exemption are met.

6.1.2. Exemptions under 45 CFR 46.104 may apply to 45 CFR 46 Subpart C (prisoners) when prisoners are incidentally included in the study population; the research cannot target prisoners as the primary population.

6.1.3. Exemptions under 45 CFR 46.104 may apply to 45 CFR 46 Subpart D (children) only for the following categories:

6.1.3.1. Categories 1, 4, 5, 6, 7, and 8 if the conditions of the exemption are otherwise met.

6.1.3.2. Category 2(i) and 2(ii) involving educational tests or observation of public behavior when the Investigator(s) do not participate in the activities being observed.

Note: Information obtained under category 2(iii) and 3 **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. RSRB Specialist (as determined in *Policy 401 Functions of the RSRB Office*) 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 46.104 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. RSRB Specialist 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. RSRB Specialist 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. RSRB Specialist may request modifications and the Investigator may respond indicating that requested modifications have been addressed or provide justification for not doing so.

6.4. RSRB Specialist (as determined in *Policy 401 Functions of the RSRB Office*), or Experienced RSRB member when limited IRB review is required as a condition of exemption under 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), and (d)(8), 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 exemption from the RSRB.

6.6. If changes are desired to a research activity that was granted an exempt determination, Investigators must submit a modification to the RSRB and receive notification of continued exempt status prior to initiating any of the proposed changes. These changes are reviewed by the RSRB Specialist (as determined in *Policy 401 Functions of the RSRB Office*) or Experienced RSRB member, as applicable to the initial exemption category.

6.6.1. If a modification 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*, unless the reviewer determines that the study involves more than minimal risk.

7.1.2. Minor modifications to previously approved research during the period for which approval is granted.

7.1.3. Research for which limited IRB review is a condition of exemption identified under Section 6.4.

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 is an Experienced Member and will perform the designated review). In some cases of minor modifications, the RSRB Chair can perform the review when it does not directly affect the prisoners as subjects.; 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 modifications, 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, Vice Chair, or Experienced Member, 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 Experienced Member may use the expedited review procedures to approve research activities at the time of initial review, a modification, and continuing review (when required) 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.

7.5.1.1. If the reviewer determines that research activities appearing on the expedited categories list (Appendix 1 referenced above) is more than minimal risk, the reviewer must provide rationale to document this determination.

7.5.2. The possible review determinations that may be made by an RSRB expedited reviewer for initial reviews, continuing reviews, and review of modifications to previously approved research include the following:

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

7.5.2.2. *Approve with modifications to secure approval:* Research study is approved pending minor modifications or consent document changes that require concurrence by the Investigator and that can be confirmed by the designated reviewer or RSRB Specialist.

7.5.2.3. *Request clarifications 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, effective date, and expiration date (when applicable) will be established according to this policy and 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 periodically receive a report of expedited actions that occur between convened meetings.

8. Requirements for Convened Board (Committee) Review

8.1. Investigators must submit materials necessary for the initial or continuing review of research, as well as modifications, 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 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;
- Unanticipated problems involving risk to subjects or others.

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*.

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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

01/2019: Sect 3 – definitions updated to align with new IRB online submission system; 2018 Common Rule changes throughout (Sections 6.1.1 – 6.1.3 added/revised accordingly); Sect 6.4 and Sect 7.1.1-7.1.3 revised for 2018 Common Rule; Sect 7.2.2 revised to reflect current practice; Sect 7.5.1.1 added for 2018 Common Rule; other editorial changes throughout; removed T. Gommel as signatory

03/2019: Sect 3.9 and 3.10 changes to examples of the definitions for consistency with regulatory definitions and current practice

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Approved By:

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3/11/2019
Date