

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 12/01/2024
	Types of RSRB Submissions		Policy 502
			Version: 2.2

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, when the RSRB is the Reviewing Institutional Review Board (IRB).

3. References

- 3.1. HHS 45 CFR 46.104; HHS 45 CFR 46.109; FDA 21 CFR 56.109
- 3.2. [Policy 402 RSRB Meetings](#)
[Policy 501 Levels of RSRB Review](#)
[Policy 504 IRB Reliance and Collaborative Research](#)
[Policy 901 Investigator Responsibilities](#)
- 3.3. [Guideline for Exempt Status Determination](#)
[Guideline for Expedited Review of Research](#)
[Guideline for Convened Board Review of Research](#)
[Guideline and Flow Chart When UR Relies on a Non-UR IRB](#)
[Guideline for Reporting Research Events](#)
[Guideline for Notification of RSRB Determinations](#)
- 3.4. [RSRB Protocol Templates](#)

4. Responsibilities

- 4.1. Investigators are responsible for providing the RSRB with the necessary materials when submitting new applications, modifications, continuing reviews, study closures, and reports of new information, as outlined in the sections below. These responsibilities are applicable to all types of research applications, such as just-in-time, multi-center, coordination center, and international research.
 - 4.1.1. When the RSRB is the Relying IRB, Investigators are responsible for adhering to the submission requirements of the Reviewing IRB as described in *Policy 504 IRB Reliance and Collaborative Research*, as well as the submission requirements for RSRB institutional review as described in Section 5.2 below.
 - 4.1.2. The RSRB utilizes an electronic review system which enables Investigators to track submitted applications throughout the review process.
- 4.2. The RSRB office conducts an initial screening of all research applications to ensure that the information is complete based on the type of submission received.

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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 will be the Reviewing IRB for the research activities, the RSRB requires the following materials:

- RSRB New Application form
- A research protocol (see [RSRB Protocol Templates](#) for reference)
- All consent documents (i.e., consent, permission, assent, information sheet, verbal script, etc.), as applicable (see [RSRB Consent Form Templates](#) for reference)
- All recruitment materials, if used (e.g., flyers, posters, scripts, social media ads)
- Subject-completed measures used to collect study information (i.e., surveys, interview forms, questionnaires, assessments)
- Data collection sheets for research involving use of information or biospecimens
- Supporting approval/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 Food and Drug Administration (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:
 - Model Informed Consent(s)
 - Participating site's consent form(s)
 - Participating site's local context survey documenting any local context issues related to the site and/or the study
- For DHHS-sponsored research, the researchers must submit the DHHS-approved sample consent documents and protocols.
- Additional 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 that the submission will be discarded. 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.

5.1.2. 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

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be in the fundable range. The IRB submission should be completed once the Investigator is in receipt of the funding notice.

- 5.2. For new submissions for which the RSRB is the Relying IRB and conducts an institutional review, the RSRB requires review materials as indicated within the RSRB application and per the *Guideline and Flow Chart When University of Rochester Relies on a Non-UR IRB*.
- 5.3. An IRB study 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, the determination of approval period (as applicable), and notification of RSRB determinations, is 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*, per the applicable level of review.

6. Requirements for Modifications

- 6.1. Any proposed modification to an RSRB approved research protocol must be submitted to the RSRB by the Investigator (or an authorized individual) using the Modification Form in the IRB electronic review system.
 - 6.1.1. In addition to completing the Modification Form and submitting the revised study materials, changes may be necessary to the Application.
- 6.2. When the RSRB is the Relying IRB, modifications must be submitted to the Reviewing IRB for review and approval.
- 6.3. Regardless of the nature of the change, RSRB review and approval of the modification must be received prior to implementation of the change.
 - 6.3.1. The only exception to this prior approval requirement is when a change is necessary to eliminate an apparent immediate hazard to research subjects or study personnel. Such events are to be reported promptly to the RSRB according to the *Guideline for Reporting Research Events*.
- 6.4. Modifications require review according to the study risk level as proposed by the RSRB Specialist with confirmation by the RSRB Chair, Vice Chair, or Experienced Member, and whether the revision changes the risk/benefit assessment of the study.
 - 6.4.1. Changes to research previously granted an RSRB exempt determination will be reviewed according to the *Guideline for Exempt Determinations*.
 - 6.4.2. Minor changes to previously approved research may be reviewed by expedited review procedures according to *Policy 501 Levels of RSRB Review* and the

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Guideline for Expedited Review of Research (definitions and examples of “minor changes” are described within these documents).

6.4.3. Other modifications to previously approved research that do not require full board review nor are they considered “minor” changes in research, may be administratively reviewed and approved by the RSRB Specialist according to the *Guideline for Expedited Review of Research*. For example, changes to study team members (except PI-Principal Investigator).

6.4.4. Modifications 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 modifications requiring convened board review are included within the guideline).

6.5. The Investigator will be notified of the RSRB review determination for the requested modification according to the *Guideline for Notification of RSRB Determinations*. The approval letter or confirmation of continued exemption as applicable, and revised protocol materials are available to the Investigator in the electronic review system.

- *Note:* Approval of a modification does not change the approval period of the study.

7. Requirements for Research Events/Reports of New Information

Investigators are required to report research events according to the *Guideline for Reporting Research Events* and to include materials indicated within the guideline to the RSRB through the IRB electronic review system.

8. Requirements for Continuing Review

8.1. Continuing review allows the RSRB to review the progress of the entire study including any approved changes and reports of new information since the last review. All convened board and FDA- and Department of Justice regulated approved research studies are required to undergo continuing review at intervals appropriate to the degree of risk, but not less often than once per year, since the last review [45 CFR 46.109(e); FDA 21 CFR 56.109(f)]. 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. In addition to the approval criteria, the RSRB may consider other factors when determining if a more frequent review is 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

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8.1.1. For research that is not FDA regulated, *continuing review is not required* under the following circumstances [45 CFR 46.109(f)]. Note that requirements pertaining to reports of new information and modifications still apply:

8.1.1.1. Research eligible for expedited review according to *Policy 501 Levels of RSRB Review*;

8.1.1.2. Research eligible for limited IRB review as a condition of exemption under 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), and (d)(8);

8.1.1.3. Research that has progressed to involve one or both of the following:

- a) Data analysis, including analysis of identifiable private information or identifiable biospecimens; or,
- b) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

8.2. If the RSRB requires continuing review when it is not required as described under Section 8.1.1 above, the RSRB must provide rationale and document this requirement.

8.3. 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*.

8.4. The Investigator must provide the RSRB with the following information for continuing review through the IRB electronic review system, preferably 8 weeks prior to the end of the approval period:

- Continuing Review Form, 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: The subject's name should be redacted 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 to support continuing review of the protocol.

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- 8.5. Research approved using expedited review that requires continuing review may be reviewed and re-approved by the RSRB Chair, Vice Chair, or Experienced Member 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*.
- 8.6. Upon re-approval of the study, documents still in use will be given an updated approval stamp/watermark. Studies that continue to enroll subjects are required to use the most recently approved consent documents and recruitment materials.
- 8.6.1. 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.
- 8.7. The Investigator will be notified of the RSRB review determination for the continuing review according to the *Guideline for Notification of RSRB Determinations*.
- 8.8. A notice of lapse in approval will be sent, as applicable, if a continuing review is not completed and the study is not re-approved by the end of the approval period, according to the *Guideline for Notification of RSRB Determinations*, which will also indicate that the study will be administratively closed. The study may be re-opened if a continuing review is provided within 90 days.
- 8.8.1. **Research activities must stop upon study expiration (including recruitment enrollment, interventions, interactions and data analysis)**. Investigators may request the continued participation of subjects enrolled in expired studies, if there is an overriding safety concern or ethical issue that would make 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.

9. Requirements for Closure

- 9.1. The RSRB requires submission of a final report to close a study that was initially reviewed by the expedited or convened board procedure, regardless of the reason (i.e., completed, closed before completion, not initiated/not conducted).
- 9.1.1. A study is considered completed, and therefore may be closed with the RSRB, 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).

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- 9.2. The Investigator will submit a final report to close the study by completing the Continuing Review form at any time, but no later than the expiration date of the study (when applicable).
- 9.3. The RSRB will review the request for study closure 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 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 closed, 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).

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Appendices:

None

Revision History:

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

01/2019: Section 3 hyperlinks added; updates for Common Rule; revisions for processing under new electronic IRB system; administrative changes throughout; removed T. Gommel as signatory

10/2019: Revised section 5.1 to remove requirement for grant application; update signatories; editorial changes


12/2024: Updated sections 3.2, 3.3, and 3.4; revised section 5.1; editorial changes; and updated signatories

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Approved By:

Signed by:
Elizabeth Kipp Campbell


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Signing Reason: I approve this document
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Elizabeth Kipp Campbell
Associate Vice President for Human Subject Protections

Date

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