

University of Rochester	Office for Human Subject Protection		
	Research Subjects Review Board		Effective Date: 08/04/2021
	Notification of RSRB Determinations		Policy 403
			Version: 1.3

POLICY

1. Purpose

Describe the process for communicating RSRB determinations to Principal Investigators and other University personnel or regulatory bodies as applicable.

2. Scope

This policy applies to the RSRB office staff and Principal Investigators when the RSRB is the Reviewing IRB.

- For research that is deferred to an external IRB and the RSRB is the Relying IRB, additional responsibilities and requirements regarding notifications are outlined in *Policy 504 IRB Reliance and Collaborative Research*.

3. References

- 3.1. [Policy 402 RSRB Meetings](#);
[Policy 501 Levels of RSRB Review](#);
[Policy 504 IRB Reliance and Collaborative Research](#)
- 3.2. [Guideline for Notification of RSRB Determinations](#);
[Guideline for Determining Exempt Research](#);
[Guideline for Expedited Review of Research](#);
[Guideline for Convened Board Review of Research](#)

4. Responsibilities

The RSRB office is responsible for notifying the Principal Investigator, study personnel, as applicable, institutional officials and regulatory authorities, as applicable, of review determinations made by the RSRB for initial review, continuing review, modifications, as well as RSRB findings that may require additional reporting.

5. Requirements

5.1. The RSRB office will communicate the following determinations that result from a convened RSRB meeting, review by the Chair/Vice Chair (or designee), or review by RSRB staff, as applicable:

- Notification of Approval (initial, continuing and modification)
- Notification of Approval with Modifications
- Notification of Deferral
- Notification of Disapproval
- Notification of Suspension of Approved Research
- Notification of Termination of Approved Research
- Notification of Exempt Determination
- Notification of Continued Exempt Determination (for modifications)
- Notification of Not Human Subject Research Determination

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- Notification for Not Engaged
- Notification of Study Closure

5.1.1. Notifications above will include, at minimum, the following information:

- RSRB assigned number, project title (or short title) and Investigator
- Type of submission reviewed, as applicable (e.g., initial review, continuing review, review of modification to previously approved research)
- RSRB action
- Reminders regarding Investigator responsibilities pertaining to the conduct of approved research, continuing review of research, requests for modifications to the approved research, maintaining study documents and signed consent forms, reporting of unexpected serious problems or events, and reporting study completion, as applicable

5.1.2. Notifications may include any of the following information, as appropriate:

- Level of risk, as applicable (e.g., greater than minimal risk, minimal risk)
- RSRB approval date, determined according to the *Guideline for Exempt Status Determination*, *Guideline for Expedited Review of Research* and *Guideline for Convened Board Review of Research*
- RSRB effective date, determined according to the *Guideline for Exempt Status Determination*, *Guideline for Expedited Review of Research* and *Guideline for Convened Board Review of Research*
- RSRB expiration date assigned according to the *Guideline for Exempt Status Determination*, *Guideline for Expedited Review of Research* and *Guideline for Convened Board Review of Research*
- Any associated approvals requiring specific regulatory findings (e.g., findings regarding informed consent and compliance with HIPAA)
- Modifications or clarifications required, or other conditions that must be satisfied by the Investigator, if any, for RSRB approval
- Any conditions under which the research may be conducted (e.g., milestone to prompt quality improvement review or reporting requirements)
- For research that is deferred, a statement of the reasons for deferring the study and a description of how the investigator may respond
- For research that is disapproved, a statement of the reason(s) for the decision of disapproval and a statement giving the Investigator an opportunity to respond to the RSRB in person or in writing
- For research that is suspended, a statement of the activity (or activities) that is suspended, reason(s) for the suspension, as well as a description of how the Investigator may respond in person or in writing
- For research that is terminated, a statement of the reason for termination and a description of any further actions required of the Investigator.

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5.2. The RSRB office informs Investigators of the following additional RSRB actions:

- Notification of Study Inactivity
- Notification of Study Administrative Withdrawal
- Notification of RSRB Approval Approaching Expiration
- Notification of Expiration of Study Approval
- Notification of RSRB Closure of Expired Research Notification of RSRB Findings to Other Individuals or Agencies (e.g., serious or continuing non-compliance, suspension)

5.2.1. Notifications above will include, at minimum, the following information:

- RSRB study number, project title (or short title) and Investigator
- RSRB action

Refer to the *Guideline for Notification of RSRB Determinations* for details pertaining to each type of determination or action, as well as additional information that may be necessary to include in the notification, as applicable.

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Originator/Authors:

Kelley O'Donoghue, Director OHSP
Emily Flagg, Senior Regulatory Specialist
Ann Marie Scorsone, Senior Regulatory Specialist

Appendices:

None

Revision History:

11/2014: Removed Section 3 Definitions, Sections 3.2 and 5.4 added references
01/2019: Sect 2 added language regarding RSRB as reviewing versus relying IRB; Sect 3.1 and 3.2 added hyperlinks; Sect 5 revised to align with current practice; editorial changes; removal of T. Gommel as signatory
08/2021: Additional references to the Guideline for Determining Exempt Research in sections 3.2 and 5.1.2; editorial changes

Supersedes Date:

01/21/2019

Approved By:

Kelley A. O'Donoghue

Kelley A. O'Donoghue
Director, OHSP

09/08/2021

Date