



GUIDELINE FOR NOTIFICATION OF RSRB DETERMINATIONS (AND INVESTIGATOR RESPONSES)

According to OHSP Policy 403, all determinations or actions made when the RSRB is the Reviewing IRB will be communicated to Principal Investigators and other University officials or regulatory bodies as applicable. Any Investigator appeal of RSRB decisions noted below are reviewed by the convened board. This guideline details the various types of RSRB actions and notifications and the information that will be included in each type of notification.

Notification Categories

1. *Letter of Approval*

The following information will be included in letters of approval, as appropriate:

a) Initial and Continuing Approval

- Assigned study ID, study title and Investigator
- Initial approval date
- Effective date
- Study expiration date
- List of materials approved by the RSRB, as necessary (e.g., protocol, consent documents, investigator brochure)
- Statement of any regulatory findings regarding informed consent (e.g., waiver of informed consent, waiver of documentation of consent/parent permission), as applicable
- Statement of any regulatory findings regarding compliance with HIPAA regulations, as applicable (e.g., waiver of HIPAA authorization, alteration of HIPAA requirements).
- Reminders regarding Investigator responsibilities and reporting of unexpected serious problems or events.
- Any other information deemed appropriate.

b) Modification Approval

- Study title and Investigator
- Date of approval
- Study expiration date
- New or revised materials approved by the RSRB, as necessary
- Requirements for re-consent, including the group notified and method of notification, as applicable
- Any other information deemed appropriate.

2. *Notification of Approval with Modifications*

When a study requires modifications in order to secure approval, notification to the Investigator shall include the following information, as appropriate. This applies to initial review, continuing review, or review of a modification.

- Assigned study ID, study title and Investigator
- Requested clarifications, modifications or issues that must be addressed
- Any other information deemed appropriate

RSRB Review of Investigator Responses to Requested Modifications

When the RSRB requires modifications to research to secure approval, Investigators' responses will be reviewed to verify that the conditions for approval have been satisfied. The RSRB Specialist will perform this subsequent review/verification and may request additional review by the RSRB Chair or defer to the convened board, as necessary). When the conditions for approval are not met, Investigators will be notified.

3. *Notification of Deferred Study*

When a study requires resolution of more substantive issues in order to meet the criteria for approval and thus has been deferred for review at a subsequent board meeting, notification to the Investigator shall include the following information:

- Assigned study ID, study title, and Investigator
- Date when the convened board made the determination
- Statement that the study was deferred
- Reason(s) for deferral and actions needed to resolve the issues
- Any other information deemed appropriate

RSRB Review of Investigator Response to Deferred Study

When research is deferred by convened board review, only the convened board may reconsider the clarifications and/or modifications made to the submission. When possible, the original RSRB reviewer(s) will be reassigned review of the response.

4. *Notification of Disapproval*

Notification of disapproval to the Investigator shall include the following information:

- Assigned study ID, study title, and Investigator
- Date when the convened board made the determination
- Statement that the study was disapproved
- Reason(s) for disapproval
- Statement that the Investigator has the right to respond to the determination in person or in writing
- Any other information deemed appropriate

RSRB Review of Investigator Responses to Disapproved Study

When research is disapproved, an Investigator may choose to respond to the disapproval by submitting a revised or new application. Review of such applications will be by the convened board unless the

research meets the criteria for expedited review, as described in *Policy 501 Levels of RSRB Review*. Investigator appeals of RSRB decisions are reviewed by the convened board, regardless of review level.

5. *Notification of Suspension of Approved Research*

Notification of suspension to the Investigator shall include the following information, as applicable (see *Guideline for Reporting Suspension, Termination and Non-Compliance*)

- Assigned study ID, study title, and Investigator
- Date when the convened board made the determination
- A statement whether only some or all project activities are suspended; if only some activities have been suspended, those activities will be listed. Determination of suspension may include, but is not limited to the following:
 - All study activities (i.e., no new enrollment, no further research procedures, no data collection, no data analysis, etc. Note that activities involved in protecting subjects should continue, e.g., reporting/analysis of adverse events, provision of medical/psychological care, follow-up with subjects to ensure safety/welfare, etc.)
 - Subject recruitment procedures (e.g., record review, referrals, advertising)
 - Enrollment of new subjects (i.e., obtaining consent, screening, and initiation of study procedures)
 - Providing or administering the study drug/device/procedure to currently enrolled subjects
 - Activities in a certain arm or phase (e.g., stopping a “comparator arm” or “wash-out” phase)
- The reason(s) for suspension, which may include, but is not limited to the following (see also *Guideline for Reporting Research Events*):
 - A suspension at the instruction of the board Chair in order to protect the rights and welfare of current or future subjects.
 - A suspension at the instruction of the Director of OHSP, or the Director of RSRB with concurrence from the Office of General Counsel and the IO in order to protect the rights and welfare of current or future subjects or to protect the institution.
 - A voluntary suspension of an active study initiated by the Investigator (Investigator-Initiated Suspension) to examine the study and its procedures, protect the rights and welfare of subjects, ensure proper study conduct, and/or to maintain scientific validity of the study.
- Actions required of the Investigator when it involves additional interactions with or the withdrawal of current subjects from the research
- Actions required of the Investigator to have the suspension lifted
- List of any other individuals or agencies that will be notified of the RSRB determination
- Any other information deemed appropriate

6. *Notification of Termination of Approved Research*

Notification of termination to the Investigator includes the following information (see *Guideline for Reporting Suspension, Termination and Non-Compliance*)

- Assigned study ID, study title, and Investigator
- Date when the convened board made the determination

- Statement that the determination of the RSRB is to terminate all study activities
- The reason(s) for termination
- Actions required of the Investigator when it involves additional interactions with or the withdrawal of current subjects from the research
- List of any other individuals or agencies that will be notified of the RSRB determination
- Any other information deemed appropriate

7. *Notification of RSRB Approval Approaching Expiration*

Investigators are automatically notified by the online submission system two months (60 days) before approval of a study is due to expire to complete the online continuing review report. If the continuing review is not submitted within one month (30 days) of expiration, a final notice that the study is due to expire is automatically sent.

8. *Notification of Study Closure*

The Investigator will receive a closure letter from the online review system when research is closed by the study team through the continuing review process.

9. *Notification of Expiration of Study Approval*

If a study has not been reapproved by the study's expiration date, the Investigator is automatically notified by the online review system that RSRB approval has lapsed. Notification to the Investigator will include the following:

- A statement that, as of the expiration date, approval of the research expired.
- A statement that all research activities must stop, including recruitment, enrollment, interventions, interactions, and collection or analysis of private identifiable information, unless the RSRB Chair or the convened RSRB finds that there is an over-riding safety concern or ethical issue that would make continuing participation in the best interest of the subject(s).
- A statement that the continuation of research activities is a violation of federal regulations.
- A statement that the Investigator must inform the RSRB of any over-riding safety concern or ethical issue that would make continuing participation in the best interest of the subject(s).
- Statement requesting that the Investigator submit a continuing review to request continued RSRB approval or study closure.

10. *Notification of Administrative Study Closure*

Submissions that are incomplete, or are lacking a response to RSRB requests for stipulations or changes, or have lapsed in study approval, may be administratively withdrawn from consideration for RSRB approval according to [Policy 502 Types of RSRB Submissions](#). The RSRB Director will send notification to the study team through comment 60 days after a period of inactivity for a new study submission indicating that the study may be administratively withdrawn after 90 days. If there continues to be no activity on the submission by the study team after a 90 day period, the Investigator will receive an automatic notification from the online submission system that the RSRB office administratively discard the study.

11. *Notification of RSRB Determinations to Other Individuals or Agencies*

The OHSP Director has full access to all meeting agenda and meeting minutes within the online review system. Sensitive determinations or other information of particular importance will be communicated either orally or through e-mail as soon as possible after the RSRB determination is made. The OHSP Director keeps the Institutional Official (IO) informed of all pertinent RSRB determinations as necessary. Appropriate University leadership are notified regarding research in their organization. The RSRB office will communicate review determinations of suspensions and terminations to the appropriate UR individuals or agencies as outlined in the *Guideline for Reporting Suspension, Termination, and Non-Compliance*.

12. *Notification of Exempt Determination*

The Investigator will receive notification for research determined to meet the federal criteria for exempt status, or amended research that continues to meet the criteria for exemption.

13. *Notification of Determination the Project is not “Human Subject Research”*

The Investigator will receive notification if it is determined that a project does not qualify as “research” or does not include “human subjects” (*Policy 301 RSRB Scope and Authority*).

14. *Notification of Human Research, Not Engaged*

The Investigator will receive notification if it is determined that a project qualifies as “research”; however, the University is not engaged in the research activities.

15. *Notification of Institutional Review*

When the University of Rochester defers to an external IRB and the RSRB is the Relying IRB, the Investigator will receive notification once institutional review is completed, as per [Policy 504 IRB Reliance and Collaborative Research](#) and the [Guideline When UR Relies on a Non-UR IRB](#).