GUIDELINE FOR NOTIFICATION OF RSRB DETERMINATIONS
(AND INVESTIGATOR RESPONSES)

According to OHSP Policy 403, all determinations or actions made by the RSRB will be communicated to Principal Investigators and other University officials or regulatory bodies as applicable. Any Investigator appeals 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. Notification of Approval (system-generated)
   The following information will be included in letters of approval, as appropriate:
   a) Initial Approval
      • RSRB assigned number, study title (or short title) and Investigator
      • Initial approval date (i.e., date of board Chair’s electronic signature)
      • Study expiration date
      • Level of risk (i.e., greater than minimal risk or minimal risk)
      • Level of review (i.e., full board, expedited), including meeting date (if applicable)
      • For research meeting requirements for expedited review, the regulatory category(ies) under which the approval was granted
      • List of materials approved by the RSRB with version dates (e.g., protocol, consent documents, advertisements, investigator brochure)
      • Statement of any regulatory findings regarding informed consent (e.g., waiver of informed consent, waiver of documentation of consent), as applicable
      • Statement of any regulatory findings regarding HIPAA, as applicable:
        o Statement that HIPAA requirements are not applicable to the research
        o Statement of any regulatory findings regarding the Privacy Rule (e.g., waiver of HIPAA authorization, alteration of HIPAA requirements)
      • 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
      • Electronic signature of the RSRB Chair and date
      • Any other information deemed appropriate.
   b) Continuing Approval
      • RSRB assigned number, study title (or short title) and Investigator
      • Re-approval and date of re-approval
• Study expiration date
• Study status (e.g., accrual continues, no local accrual)
• Level of risk (i.e., greater than minimal risk or minimal risk)
• Level of review (e.g., full board, expedited), including meeting date (if applicable)
• For research meeting requirements for expedited review, the regulatory category(ies) under which the re-approval was granted
• List of materials re-approved by the RSRB with version dates (e.g., protocol, consent documents, advertisements, investigator brochure)
• Statement of any regulatory findings regarding informed consent (e.g., waiver of informed consent, waiver of documentation of consent), as applicable
• Statement of any regulatory findings regarding HIPAA, as applicable:
  o Statement that HIPAA requirements are not applicable to the research
  o Statement of any regulatory findings regarding the Privacy Rule (e.g., waiver of HIPAA authorization, alteration of HIPAA requirements)
• Reminders regarding Investigator responsibilities as pertain 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
• Electronic signature of the RSRB Chair and date
• Any other information deemed appropriate.

c) Amendment Approval
• RSRB assigned number, study title (or short title) and Investigator
• Study expiration date
• Review level of the amendment (i.e., full board, expedited)
• Date of the amendment (i.e., a date of reference such as version date of protocol amendment, or submission date if necessary)
• RSRB meeting date, if applicable
• Summary of requested changes, as well as new or revised materials approved by the RSRB with version dates
• Requirements for re-consent, as follows:
  o Re-consent of all subjects (former and active)
  o Re-consent of all active subjects
  o Amendment does not require re-consent of subjects
  o No current enrollment, re-consent not required
• Electronic signature of the RSRB Chair and date
• Any other information deemed appropriate.

2. Notification of Approval with Stipulations (RSRB staff-generated)
When a study requires modifications in order to secure approval, notification to the Investigator shall include the following information, as appropriate.
a) Initial Review
   • RSRB assigned number, study title (or short title) and Investigator
   • Full board meeting date at which study was approved pending modifications, if applicable
   • Requested clarifications, modifications or issues that must be addressed
   • Statement that the stipulations must be addressed in order to secure approval and reminder that the study may not be conducted until approval is obtained
   • Any other information deemed appropriate

b) Continuing Review
   • RSRB assigned number, study title (or short title) and Investigator
   • Full board meeting date at which study was approved pending modifications, if applicable
   • Requested clarifications, modifications or issues that must be addressed before approval may be granted
   • Reminder that the study may not be conducted beyond the current expiration date unless all pending issues have been resolved and re-approval is obtained
   • Any other information deemed appropriate

c) Amendment Review
   • RSRB assigned number, study title (or short title) and Investigator
   • Full board meeting date at which study was approved pending modifications, if applicable
   • Requested clarifications, modifications or issues that must be addressed before approval may be granted
   • Reminder that the changes may not be implemented until all stipulations have been resolved and approval is obtained
   • Any other information deemed appropriate

RSRB Review of Investigator Responses to Stipulations
When the RSRB requires clarifications or modifications to research, Investigators’ responses will be reviewed to verify that the conditions for approval have been satisfied. Depending on the nature of the modifications, this subsequent review/verification may be performed by the RSRB Chair or an experienced RSRB member (at any time the review may be deferred to the full board as deemed necessary). When the conditions for approval are not met, Investigators will be notified.

3. Notification of Tabled Study (RSRB staff-generated)
   When a study requires resolution of more substantive issues in order to be considered for approval and thus has been tabled for review at a subsequent board meeting, notification to the Investigator shall include the following information
   • RSRB assigned number, study title (or short title) and Investigator
   • Full board meeting date at which study was tabled
   • Statement that the study was tabled
• Reason(s) for tabling the study and actions needed to resolve the issues
• Any other information deemed appropriate

**RSRB Review of Investigator Responses to Tabling Study**

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

4. **Notification of Disapproval (RSRB staff-generated)**

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

- RSRB assigned number, study title (or short title) and Investigator
- Full board meeting date at which study was disapproved
- 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 submit a new or revised application to request approval. 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.

5. **Notification of Suspension of Approved Research (system-generated)**

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

- RSRB assigned number, study title (or short title) and Investigator
- Full board meeting date at which study was suspended
- 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):
  o A suspension at the instruction of the board Chair in order to protect the rights and welfare of current or future subjects.
  o 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.
  o 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 (RSRB Director and RSRB Chair-generated)
   Notification of termination to the Investigator includes the following information (see Guideline for Reporting Suspension, Termination and Non-Compliance)
   • RSRB assigned number, study title (or short title) and Investigator
   • Full board meeting date at which the study was terminated
   • 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 (system-generated)
   Investigators are automatically notified by the Research Subjects Review Board On-line Submission System (ROSS) three months (90 days) before approval of a study is due to expire to complete the online continuing review report. If the continuing review report form is not received by the RSRB office within two months (60 days) of expiration, another reminder notice is automatically sent to the Investigator. If the Investigator has not submitted the continuing review report within one month (30 days) of expiration, a notice of pending expiration of approval is automatically sent.

8. Notification of Expiration of Study Approval (system-generated)
   If the Investigator has not submitted a completed continuing review report form by the study’s expiration date, the Investigator is automatically notified by ROSS that RSRB approval has ended. Notification to the Investigator will include the following:
   • A statement that, as of the expiration date, approval of the research ended.
• A statement that, effective immediately, all research activities must stop, including recruitment, enrollment, interventions and interactions. In addition, data analysis on current subjects must stop, 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 final progress report if the study is completed to document this status with RSRB and request the study to be closed.
• Statement that study closure may require additional notification to institutional and federal officials, as applicable, and new study applications will not be considered until all issues are resolved (i.e., the study is closed by the Investigator, re-approved by RSRB, or closed by the RSRB).
  o Expirations of approval are not reported to OHRP or other federal regulatory agencies unless they constitute serious or continuing non-compliance.

9. Notification of RSRB Closure of Expired Research (RSRB Director-generated)

Step 1: If the Investigator does not submit a progress report, or respond to stipulations, within the deadline in the expiration notice, the RSRB Director (or designee) will send notification of study closure to the Investigator that will include the following information (see RSRB Director Email Closure Notification Template):
  • A statement that as of the expiration date, study approval ended.
  • Reminder about the notice of study expiration previously received and that failure to maintain RSRB approval is considered non-compliance, and may lead to a finding of continuing non-compliance, which may be reportable to federal regulatory authorities and sponsors, as applicable.
    o Expirations of approval are not reported to OHRP or other federal regulatory agencies unless they constitute serious or continuing non-compliance.
  • A request to complete a progress report by the deadline or the process to close the study will begin.
  • Statement that if the study is complete or inactive and should be closed, the Investigator must submit a progress report to document this status with RSRB.
  • Notice of pending closure will be forwarded to the Investigator, with a copy to the appropriate department chair.

Step 2: If the Investigator does not submit a progress report within the deadline in the closure notification sent above, the RSRB Director (or designee) will send a follow-up notification to the Investigator indicating that a response was not received to the previous request and the RSRB will begin the process to close the study (see RSRB Director Email Closure Notification Template). If your study is closed as a result of a failure to complete continued review, the RSRB will not review any new study applications from you until this issue is resolved. Failure to maintain RSRB-approval
(i.e., allowing RSRB approval to expire) is considered non-compliance, and continuing non-compliance may be reportable to federal regulatory authorities and to sponsors.

10. Notification of RSRB Study Closure (system-generated)
The final step in closing research applications due to study team request or expiration of approval period is an automatic notification from ROSS to the Investigator and to the study team. In addition, the RSRB staff will notify the Department Chair of the closure.

11. Notification of RSRB Determinations to Other Individuals or Agencies
Routine RSRB determinations are communicated to the Director of OHSP by providing a copy of the RSRB meeting minutes and expedited reports. 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 Director of OHSP keeps the Institutional Official (IO) informed of all pertinent RSRB determinations as necessary. Appropriate officials 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 Exemption and Amendment Confirmation (system-generated)
For research meeting federal and RSRB criteria for exempt status, or amended research that continues to meet the criteria, notification to the Investigator will include the following:
• For initial review, the regulatory category under which exempt status was granted
• For amendments, confirmation that there was no change in the risk level of the study (i.e., it remains minimal risk) and a description of the changes reviewed
• Electronic signature of the RSRB staff member or Chair and date
• Any other information deemed appropriate

13. Notification of Determination the Project is not “Human Subject Research” or Does Not “Engage” the University in Human Subject Research (system-generated or RSRB staff-generated as requested)
If it is determined that a project does not qualify as “human subject research” or does not “engage” UR in human subject research (Policy 301 RSRB Scope and Authority), and documentation is requested by the Investigator, the following information shall be provided:
• RSRB assigned number, study title (or short title) and Investigator (for applications completed in ROSS)
• Statement of the determination that the project does not meet the definition for “human subject research” or does not “engage” the University in human subject research
• Basis for the determination
• Electronic signature of the RSRB staff member or Chair and date
• Any other information deemed appropriate