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.

3. **References**
   3.1. Policy 402 RSRB Meetings;
       Policy 501 Levels of RSRB Review
   3.2. Guideline for Notification of RSRB Determinations;
       Guideline for Expedited Review of Research;
       Guideline for Convened Board Review of Research

4. **Responsibilities**

   4.1. 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 of proposed research, continuing review, amendments, 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 or review by the Chair (or designee):
       - Notification of Approval (initial, continuing and amendment)
       - Notification of Approval with Stipulations
       - Notification of Tabled Study
       - Notification of Disapproval
       - Notification of Suspension of Approved Research
       - Notification of Termination of Approved Research

   5.2. The RSRB office informs Investigators of the following additional RSRB actions:
       - 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)
5.3. Notifications will include, at minimum, the following information:

- Notification of Exemption and Amendment Confirmation
- Notification of Determination the Project is not “Human Subject Research” or Does Not “Engage” the University in Human Subject Research, as requested

5.4. Notifications may include, as appropriate, the following information:

- Level of risk, as applicable (e.g., greater than minimal risk, minimal risk)
- RSRB approval date (i.e., date of Chair’s signature)
- RSRB expiration date, assigned according to the Guideline for Expedited Review of Research and Guideline for Convened Board Review of Research.
- Any associated approvals requiring specific regulatory findings (e.g., waiver of the requirement for obtaining informed consent)
- 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 audit or reporting requirements)
- For research that is tabled, a statement of the reasons for tabling the study and a description of how the investigator may respond
- For research that is disapproved, a statement of the reasons 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.

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.
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.
# Office for Human Subject Protection

**Research Subjects Review Board**

**Effective Date:** 11/05/2014

**Notification of RSRB Determinations**

| Policy 403 | Version: 1.1 |

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### Originator/Authors:

- Kelley O'Donoghue, Director OHSP
- Emily Flagg, Senior Regulatory Specialist

### Appendices:

- None

### Revision History:

- Removed Section 3 Definitions, Sections 3.2 and 5.4 added references

### Supersedes Date:

- 10/10/2013

### Approved By:

- Kelley A. O'Donoghue
  - Date: 11/5/2014
  - Director, OHSP

- Tiffany L. Gommel
  - Date: 11/10/2014
  - Director, RSRB

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