## SOP 1.1.4      **Communication**

**General Description:**

All formal Institutional Review Board (IRB) communications regarding the outcome of review of research activities will be in the form of written correspondence. The IRB communicates concerns, revision requests, and decisions regarding human subject protection issues to researchers following each step of the review process. This document describes the process for communicating results of protocol reviews and other IRB related correspondence to study teams, institutional officials and outside entities.

**Procedures:**

1. After the researcher has submitted an IRB application through IRBNet and the IRB staff has conducted a preliminary review, any requests for clarification or additional information will be communicated to the researchers who have access to the project submission via email through the IRBNet electronic system. (Note: messages will be sent to the email address the researcher used when he/she registered with IRBNet.)
2. Once a full review has been conducted by the Office of Research Development, Integrity and Assurance (RDIA) or the IRB, any additional requests for clarification or revisions will also be communicated to the researchers who have access to the project submission via email through the IRBNet system. When the reviewer requires modifications to the research project, the researcher's response will be reviewed to verify that the conditions for approval have been satisfied. Depending on the nature of the original review and the requested modifications, this subsequent review/verification may be performed by RDIA staff, an IRB member, the IRB Chair or the full IRB. Email communications will be retained as part of the IRBNet project in the project message section of the IRBNet project.
3. If an IRB application is disapproved by the IRB, this will be communicated to the PI in writing and the PI will have an opportunity to appeal the decision (see SOP 2.6.3).
4. Any email correspondence that is relevant to the review of the project but is conducted outside of the IRBNet system will be uploaded to the IRBNet package by IRB staff as a reviewer document so that it is part of the project record.
5. Once a review level determination has been made and the project has been exempted or approved, the IRB staff will convey the IRB's decision by designating the exemption/approval in the electronic system and creating an approval letter in the IRBNet package. The IRB staff will then publish the letter in IRBNet which will generate a PDF copy of the letter that is available to the PI in the IRBNet package. The actions of exempting/approving the project and publishing the letter will also generate email notifications to the researchers who have access to the project informing them that the project has been exempted/approved and that the approval letter is available.
6. The approval letter will include the following information:
   a. Date of review
   b. Type of submission reviewed (e.g. initial review, continuing review, amendment)
   c. IRB action or exempt determination
   d. Review level (e.g. exempt, expedited, full board)
   e. Approval and expiration date of the project (when applicable)
   f. A statement that researchers may not implement any changes in research activities without IRB review and approval
   g. A statement that unanticipated problems, serious unexpected adverse events, non-compliance and complaints regarding the project must be promptly reported to the RDIA/IRB.

7. The IRB staff makes IRB approval letters available to other offices and committees as needed either through the IRBNet system or by providing copies of materials to the relevant people.
8. IRB members and the Institutional Official have access to the IRB meeting minutes and full project information through their IRBNet accounts.
9. The IRB staff will acknowledge a request for closure by closing the project in the IRBNet system which will generate an email message to the researchers who have access to the project notifying them that the project has been closed. No formal letter will be issued for a closure.
10. IRB staff will send follow up messages to researchers to check on the status of revisions to study documents as necessary. If researchers do not respond to follow up messages and a project remains open and unapproved for 3 months, IRB staff will withdraw the submission from IRB review. Researchers will be notified of this action through IRBNet and can submit a new project when they are ready to proceed with the review process.
11. Any necessary IRB correspondence with external agencies will be in written format and sent by the IRB or the Institutional Official to the appropriate agencies. When communication with external agencies is required for specific projects, the PI will be notified in writing as appropriate.

Based on University of Georgia's IRB policy: http://research.uga.edu/docs/policies/compliance/hso/PP-Post-Review-Communication-Review-Results.pdf

**Related Forms, Guidance, and SOPs:**

- See other SOPs available on the website for more information about communication as it relates to those specific topics.

**Responsibility:**

Principal Investigators
Research Team Members
IRB staff/Research Development, Integrity and Assurance
Institutional Review Board

**Approval and Version History:**

Please contact irb@gmu.edu if you have any questions about this policy or the version and approval history.

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| **Date First Effective:** | December 14, 2016 |
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| Approved By | Title and Division | Date Approved |
|---|---|---|
| Aurali Dade | Associate Vice President, Research Development, Integrity and Assurance | December 14, 2016 |
| Laurie Meamber | IRB Chairperson | December 14, 2016 |