

Title	Communication – Researcher
SOP Code	601.002
Effective Date	08-Mar-2016

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy

1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) communication with the Researcher and with his/her research team.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members and REB Office Personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

In the interest of enhancing human research participant protection, it is important for the REB to foster collaboration and open communication between and among the REB, Researcher, research staff, and organizational representatives. This applies not only to

communication related to a specific research project, but also to communication related to ethical issues and REB processes, policies and procedures.

All Researchers participating in REB approved research shall be informed, in writing, of all determinations made by the REB regarding specific research.

Feedback from Researchers should be encouraged and should be considered as an opportunity to review and to improve the function of the REB and of the REB office procedures.

In order to facilitate clear and accurate communication with Researchers and research staff, the REB will follow standardized notification and documentation procedures.

5.1 Notification of REB Decisions

- 5.1.1 The REB will notify the Researcher and/or his/her research staff of the REB's decision within a time frame specified by the REB, following the review (i.e., from the REB meeting or delegated review date) of new research, modifications, or amendments to currently approved research, applications for continuing review or reportable events;
- 5.1.2 The determinations of the REB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the disapproval of the submission (when appropriate);
- 5.1.3 If the research does not receive initial approval or is denied re-approval (for continuing review), the REB Chair or designee will notify the Researcher of the REB's decision as soon as possible following the REB meeting. Formal written notification will follow;
- 5.1.4 The REB Chair or designee will review the draft REB review letter, make revisions as necessary, and will indicate his/her approval;
- 5.1.5 The REB review letter will be issued to the Researcher(s);
- 5.1.6 The Researcher will be asked to include the REB number or equivalent designation assigned to the research in all subsequent correspondence with the REB;

5.1.7 Upon receipt of the Researcher response to the REB review letter, the REB will follow-up with the Researcher and/or his/her staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewers;

5.1.8 Once all of the REB conditions are satisfied, the REB will issue an approval letter.

5.2 Researcher Appeal of REB Decision

5.2.1 A Researcher may request a reconsideration or appeal the decision of the REB and/or any of the revisions to the research requested by the REB;

5.2.2 Appeals are conducted in accordance with established organizational policy at the applicable organization;

5.2.3 Only the REB may lift a restriction or re-review previously disapproved research. Delegated review procedures may not be used.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP601.001	15-Sept-2014	Original version
SOP601.002	08-Mar-2016	No revisions needed