

SOP 601.001

Title	Communication – Researcher
SOP Code	601.001
Effective Date	

Site Approvals

Name and Title	Signature	Date dd/mm/yyyy

1.0 PURPOSE

This standard operating procedure (SOP) describes routine communication procedures between the Research Ethics Board (REB) and the Researcher and his/her research team.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable policies 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

For effective human research participant protection, it is important that the REB and Researcher and research team maintain open communication. This applies not only to

a specific research project, but also with respect to questions, concerns, ethical issues and REB processes, policies and procedures. 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. All REB decisions regarding specific research projects shall be documented in writing. Informal communications between the Researcher or research team and REB Chair or REB Office personnel may occur through email, over the phone or in person. Documentation should be created to ensure accurate reflection of discussions for future reference.

5.1 Notification of REB Decisions

- 5.1.1 The REB will notify the Researcher and/or research staff of the REB's decision within a time frame specified by the REB, following the review (REB meeting or delegated review) date of new research, modifications, or amendments to currently approved research, applications for continuing review or unanticipated event reports;
- 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 comments, make revisions as necessary, and will indicate his/her approval;
- 5.1.5 The REB review comments will be sent to the Researcher(s);
- 5.1.6 The Researcher may be asked to identify the protocol by REB number or title in correspondence with the REB regarding the research project;

SOP 601.001

- 5.1.7 Upon receipt of the Researcher’s response to the REB review comments, the REB or REB Office personnel will follow-up with the Researcher and/or research staff to request any additional clarifications as needed, or as requested by the REB Chair or designee, or the reviewer(s);
- 5.1.8 Once all of the REB conditions are satisfied, the REB will issue an approval letter or notification of acknowledgement, as determined by submission type.

5.2 Researcher Consultation

- 5.2.1 A Researcher and/or research team may request advice, guidance or clarification with the REB Chair, designee or REB Office personnel for current or future research projects. Such consultations may involve communications through email, phone or in person.
- 5.2.2 REB Chair, designee or REB Office Personnel should document such consultations in writing, including date, who was present and brief description of what the concerns were and how they were addressed. Such documentation should be kept by the REB Office for future reference, if needed.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP601.001		Original version