	RESEARCH ETHICS BOARD **STANDARD OPERATING PROCEDURES**	
	SOP Number	601
	Communication - Researcher	
	Date of Issue	2022 07 13

Purpose: This standard operating procedure (SOP) describes the Research Ethics Board's (REB) communication with the Researcher and with their research team.

Directive: Fraser Health Policy "The Ethical Conduct Of Research And Other Studies Involving Human Participants"

Reference: 2019 10 08 CAREB SOP 601.003

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

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.

1.0 Notification of REB Decisions

1.1 The REB will notify the Researcher and/or their research staff of the REB's decision in a timely manner, 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;

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);

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;

1.4 The REB Chair or designee will review the draft REB review letter, make revisions as necessary, and will indicate their approval;

1.5 The REB review letter will be issued to the Researcher(s);

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;

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

1.8 Once all of the REB conditions are satisfied, the REB will issue a Certificate of Approval. Included in the Certificate of Approval is the study title and REB number, name of the Principal Investigator and any co-Investigator(s), funding agency/trial sponsor, study sites, and a list of the approved documents.

2.0 Researcher Appeal of REB Decision

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;

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

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

3.0 Communications Concerning Non-compliance

Researcher non-compliance may be the result of communication difficulties. The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the study, especially if the rights and welfare of participants may be jeopardized. However, if it appears that a Researcher is intentionally non-compliant with the protocol, SOPs, TCPS 2, REB, and/or other applicable requirements, the REB, through the REB Chair or their designee, will notify the Researcher in writing, detailing the alleged non-compliance, specifying corrective action, and stating the consequences. Such actions may be the result of an onsite audit conducted by the Office of Research Ethics. When appropriate, copies of such correspondence shall also be sent to the Researcher's Administrative Supervisor at Fraser Health, the study Sponsor, the Director of Evaluation and Research Services, and the Vice-President responsible for Research.