1.0 PURPOSE

This SOP describes GREB communication with researchers and with research teams.

2.0 SCOPE

The scope of this SOP is restricted to the review of the ethical conduct of research involving humans that falls under GREB’s oversight. GREB primarily has research ethics oversight over Humanities, Social Sciences, Science, Engineering, and administrative research conducted under the auspice of Queen’s University. The scope of GREB’s oversight is limited to those activities defined in the TCPS2 (2014) as “research” involving “human participants.”
3.0 RESPONSIBILITIES

All GREB members and GREB office personnel are responsible for ensuring that the requirements of this SOP are met.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURES

In the interest of enhancing human research participant protection, it is important for GREB to foster collaboration and open communication between and among GREB, researchers, research staff, and Queen’s University representatives. This mandate extends not only to communication related to a specific research project, but also to communication related to ethical issues and GREB processes, policies, and procedures.

To facilitate clear and accurate communication with researchers and research staff, GREB will follow standardized notification and documentation procedures. Researchers participating in GREB-cleared research shall be informed, in writing, of all determinations made by GREB regarding specific research. Feedback from researchers should be encouraged and be considered as an opportunity to review and improve the function of GREB and GREB office procedures.

5.1 Notification of GREB Decisions

5.1.1 GREB will notify researcher and research teams of GREB’s decision following the review (i.e., from the full board or delegated review date) of new research, modifications, or amendments to currently ethically cleared research, applications for renewal, and reportable events;

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5.1.2 The determinations of GREB will be summarized noting any concerns or requests for clarification including recommended changes to the consent form, and clarifying the reasons for the submission not being cleared (when appropriate);

5.1.3 If the research does not receive initial ethics clearance or is not cleared for renewal of ethics clearance, the Ethics Coordinator will notify researchers of GREB’s decision by formal written notification;

5.1.4 The GREB Chair or designee will review the draft GREB Review Letter, make revisions as necessary, and indicate his/her approval;

5.1.5 The GREB Review Letter will be issued to the researchers;

5.1.6 Researchers will be asked to include the GREB ROMEO number assigned to the research in all subsequent correspondence with GREB;

5.1.7 Upon receipt of the researchers’ response to the GREB Review Letter, GREB will follow-up with researchers and their research staff to request any additional clarifications as requested by the GREB Chair or designee, or the reviewers;

5.1.8 Once all of the GREB conditions are satisfied, the Ethics Coordinator or designee will issue an Ethical Clearance Letter on behalf of GREB.

5.2 Research Appeal of GREB Decision

5.2.1 Researchers may request a reconsideration or appeal of the decision of GREB and of any revisions to the research requested by GREB;

5.2.2 The appeal process is outlined in SOP 402.001, GREB Review Decisions and is conducted in accordance with established Queen’s University policies and procedures;
5.2.3 Only GREB full board review may lift a restriction or re-review previous research that was not granted ethics clearance. Delegated review procedures may not be used.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

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<tr>
<th>SOP Title</th>
<th>Version</th>
<th>Updates</th>
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<td>Communication – Researcher</td>
<td>v.601.001</td>
<td>Original: Adoption of standardized SOPs developed by CAREB/N2 with an effective date of 2014SEP15. Minor modifications were made to the CAREB/N2 SOPs to reflect institutional policies.</td>
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