Section 400:	**Review of Research**
Title:	**Adverse Events related to GREB Applications**
SOP Code:	**406.001**
Effective Date:	**2016APRIL01**

Site Approvals

Signature of Responsible Individual:		
Ethics Compliance Advisor	Name: Anthony Wright	Date: 2016April01
Approval Authority:		
Chair, GREB	John D. Freeman Name: Dr. John Freeman	Date: 2016April01
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Director, Research Ethics Compliance	Name: Dr. Andrew Winterborn	Date: 2016April01

1.0 PURPOSE

This SOP is one that describes the procedures for the ongoing review activities that occur after the initial GREB Ethical Clearance of a research project and prior to the formally scheduled renewal of ethics clearance for the research project. This particular SOP describes the procedures used for adverse events.

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

Researchers are responsible for reporting to GREB any new information generated throughout the course of the research that might affect the rights, safety, and well-being of research participants, including adverse events that meet the reporting criteria as outlined in this SOP and/or in the research protocol.

4.0 DEFINITIONS

An Adverse Event (AE) is defined as any event, whether or not anticipated, that adversely affects the welfare (e.g., physical, psychological, and emotional) of participants and/or researchers.

5.0 PROCEDURES

There are three sources from whom GREB could receive notice of an adverse event: (1) participants or concerned citizens, (2) researchers, and (3) the Ethics Compliance Advisor (ECA). Concerns are treated as 'Adverse Events' (until determined to be otherwise), and an investigation is opened.

5.1 Adverse Events Reported by Participants or Concerned Citizens

5.1.1 Participants or concerned citizens are often the initial reporter of an AE because of concern over recruitment, procedures, ethics materials (e.g., Consent Forms, survey questions) or communications;

5.1.2 Complaints may be verbal, by phone, email, or letter and are typically received by either the Ethics Coordinator or the GREB Chair and copied to the Ethics Compliance Advisor (ECA);

5.1.3 When a complaint is received, the Ethics Coordinator or Chair must get as much information as possible (e.g., nature of the complaint, dates, times, people involved and impact on the complainant). The Ethics Coordinator or Chair shall treat the complainant's personal information as confidential;

5.1.4 The Chair or ECA will draft a letter to the complainant re-iterating the details of the concern, asking if these details are correct and stating that GREB will launch an investigation and get back to the complainant once the investigation is concluded;

5.1.5 The GREB Chair or ECA will review the study file re: original ethics applications, last date of project renewal, amendments on file, and any earlier reports of adverse events. The file review could provide information that does or does not support the substance of the complaint or it might indicate other areas of concern that could require investigation;

5.1.6 After collecting information from the complainant and reviewing the ethics file, the Principal Investigator of the research project will be informed in writing that a complaint has been received and that it is GREB policy to consider all complaints as 'Adverse Events' until they are evaluated for merit, and, if they are evaluated for merit, how they can be resolved;

5.1.7 After reviewing the file and complaint, the Chair or ECA develops some questions to ask the Principal Investigator (e.g., Were they aware of the concerns? Is there merit to the concerns? How might the concerns be resolved?);

5.1.8 The Chair or ECA will communicate with the Principal Investigator to discuss the concerns and obtain relevant information;

5.1.9 After gathering information, the Chair and ECA will meet to come to a decision about the merit of the complaint (valid or invalid) and to determine how best to resolve it;

5.1.10 The Chair or ECA will prepare a draft letter to the Principal Investigator outlining the process, complainant's concern, results of the Chair and ECA's investigation, and required or recommended actions to be taken by the researchers to address meritorious complaints;

5.1.11 At the next GREB meeting, the Chair will prepare and discuss all relevant correspondence and reports and seek advice of GREB;

5.1.12 Based on the GREB discussion, a letter to the Principal Investigator will be prepared and sent. The letter will request feedback on the required changes by a specified date;

5.1.13 If further delays occur, GREB has the authority to suspend or terminate ethics clearance (see SOP 410.001 Suspension and Termination of GREB Ethical Clearance);

5.1.14 Once the AE has been resolved to the satisfaction of GREB, the Chair or ECA will write the complainant to discuss the merits of the original complaint and describe what changes, if any, the researchers are making to address the concerns;

5.1.15 If a letter of apology is to be written by the Principal Investigator to the complainant, it must first be reviewed by the GREB Chair and ECA. Since the complainant's name may be held in confidence, the GREB Chair or ECA will send the Principal Investigator's apology along with the GREB final letter.

5.2 Adverse Events Reported by the Researchers

5.2.1 Researchers are responsible for submitting Adverse Events to GREB on an Adverse Event Form in TRAQ;

5.2.2 Researchers must report to GREB any complaints they receive about concerns regarding participant rights, conflicts of interest, or other ethical issues related to the research;

5.2.3 Researchers must report the following to GREB:

- Any AE that, in the opinion of the researchers, meets the definitions above,
- Any new or unexpected risk to participants' safety,
- A change to the research that was initiated to eliminate an apparent immediate hazard,
- Any non-compliance with an approved ethics application by members of the research team or research assistants,
- Any breaches in confidentiality or security of the data such as: stolen computers, disclosure of Personal Information (PI), unauthorized copying, modifications or disposal of data;

5.2.4 Any AE involving a privacy breach must be reported to GREB and, if applicable, to the appropriate organizational official(s) within one (1) working day of researchers becoming aware of the breach;

5.2.5 Privacy breaches are reviewed by the GREB Chair or designee, and any recommendations including remedial actions are determined in consultation with the ECA and the Director of Research Ethics Compliance. If applicable, the Queen's University's Office of the Privacy Officer will be contacted;

5.2.6 All other AEs must be reported to GREB within five (5) working days of when researchers become aware of them;

5.2.7 Any AE reported to the GREB must have participant identifiers removed (i.e., participant code number only);

5.2.8 The Ethics Coordinator or designee will screen the Adverse Event Form for completeness;

5.2.9 The Chair and ECA will review the Adverse Event Form and seek further information from researchers as required;

5.2.10 The GREB Chair or designee may route the submission back to researchers to request clarifications, missing documents, or additional information;

5.2.11 When reviewing an AE, the Chair and ECA should:

- Assess the appropriateness of any proposed corrective actions or preventative measures by the researchers,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the researchers,
- Consider whether or not the affected research still satisfies the requirements for GREB Ethics Clearance; in particular, whether or not risks to research participants are still minimized and reasonable in relation to the anticipated benefits, if any, to the research participants and the importance of the knowledge that may reasonably be expected to result,
- Consider whether or not some or all of the research participants should be notified of the events (i.e., if it may affect the participant's willingness to continue participation in the research), and
- Consider whether or not suspension or termination of the ethics clearance of the research is warranted;

5.2.12 The Chair and ECA may recommend additional remedial actions beyond the researchers' actions based on their review of the Adverse Event Form and/or communications with the researchers;

5.2.13 The GREB Chair shall add this AE to the agenda and prepare a report, if necessary. A verbal report may be adequate for AEs that were easily resolved. However, a written report should be submitted for more serious AEs or events that have not yet been resolved;

5.2.14 After the GREB meeting, the Chair will forward any further recommendations to the researchers for implementation.

5.3 Adverse Events Reported by the Ethics Compliance Advisor (ECA)

5.3.1 The ECA may undertake audits or site visits to follow-up on a GREB concern or spot-check various protocols and consent process;

5.3.2 During the natural course of this investigation, an AE may be observed;

5.3.3 The ECA must report this concern immediately to the GREB Chair;

5.3.4 Corrective action may occur, as determined by the GREB Chair in consultation with the ECA, in line with procedures outlined in Sections 5.1 and 5.2, as applicable;

5.3.5 As well, an Adverse Report Form must be submitted by the researchers.

5.4 Documentation of Adverse Events

5.3.1 Researchers are responsible for submitting an Adverse Event Form detailing the problem and the changes made to the application. If changes are made to attachments, then revised versions must be included with the file.

5.3.2 The Ethics Coordinator will attach to the Adverse Event Form all final copies of communications to the (anonymized) complainant, the researchers, and GREB.

5.3.3 The GREB minutes will be used to document the discussion and decisions made by the full board.

6.0 REFERENCES

See References.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
Adverse Events related to GREB Applications	v.406.001 2016APRIL01	Original: This SOP was developed based on information from the TCPS2 (2014) and Queen's University previous documents or policies (using the format of CAREB/N2).