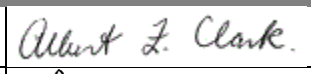
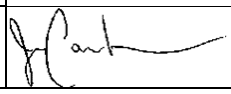
Section 400:	**Review of Research**
Title:	**Adverse Event Reporting**
SOP Code:	**410.003**
Effective Date:	**2022JAN06**

Site Approvals

Name and Title (typed or printed)	Signature	Date dd/Mon/yyyy
Albert F Clark		06JAN2022
Jennifer Couture		06JAN2022

1.0 PURPOSE

This standard operating procedure (SOP) describes the procedures for adverse event reporting to the REB.

2.0 SCOPE

This SOP pertains to the REB that reviews human participant research in compliance with applicable regulations, guidelines and current and emerging best practices.

3.0 RESPONSIBILITIES

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

The Researcher is responsible for reporting to the REB and applicable authorities new information generated throughout the course of the research that might affect the rights, safety, and well-being of research participants, including reportable events that meet the reporting criteria as outlined in this SOP and/or in the research protocol.

The REB Chair or designee is responsible for reviewing all reportable events submitted to the REB and for determining the type of review (i.e. Delegated or Full Board) or action required.

The REB Members are responsible for reviewing any new information and reportable events that are assigned to them or that are assigned to a Full Board meeting, and for recommending the appropriate course of action, as applicable.

4.0 DEFINITIONS

See Glossary of Terms

5.0 PROCEDURES

The REB must receive and review any new information generated throughout the course of the research that might affect the rights, safety, and well-being of research participants. Such information may include:

- Reports of local SAEs or external unexpected SAEs involving risks to participants or others, that meet the REBs reporting criteria or that are identified in the research protocol,
- Reports of any changes significantly affecting the conduct of the research or increasing the risk to research participants,
- Reports of any confidentiality and privacy breaches,
- Any other new information that may adversely affect the safety of the research participants or the conduct of the research;

Modifications to the ethically cleared research may not be initiated without prior REB review and ethical clearance except where necessary to eliminate apparent immediate hazards to participants. If changes are made to eliminate immediate hazards, the Researcher must notify the REB immediately.

5.1 Reportable Local Serious Adverse Events (SAEs)

5.1.1 Any local SAE that in the option of the Researcher meets the definition of an unanticipated problem (i.e. is unexpected and related or possibly related to participation) and suggests that the research places participants or others at greater risk of harm (physiological, psychological, economic or social harm) than was previously known or recognized, must be reported to the REB within **48 hours** after the Researcher becomes aware of the SAE(s);

5.1.2 Serious but non-life threatening local SAE(s) must be reported to the REB as soon as possible but no later than **15 working days** of the Researcher becoming aware of the SAE;

5.1.3 **External Unexpected SAEs:** Any external (non-local) adverse events that in the opinion of the Researcher meet(s) the definition of an unanticipated problem must be reported to the REB (i.e. is unexpected and related or possibly related to participation) and suggests that the research places participants or others at greater risk of harm (physiological, psychological, economic or social harm)

than was previously known or recognized. This may include unexpected external SAEs which require a change to the research and/or informed consent form and/or which require immediate notification to participants for safety reasons;

5.1.4 Non-local SAEs must be reported to the REB within **15 working days** after the Researcher becomes aware of the non-local SAE.

5.2 Confidentiality/Privacy Breaches: The Researcher must report to the REB any unauthorized collection, use, or disclosure of personal information including, but not limited to:

- The collection, use, and disclosure of personal information that is not in compliance with the jurisdictional legislation or its regulation,
- Circumstances where personal information is stolen, lost, or subject to unauthorized use or disclosure, or where records of personal information are subjected to unauthorized copying, modifications, or disposal,
- In the Researcher context, any collection, use or disclosure of personal information that was not authorized under the research and ethically cleared in the plan that was submitted to the REB;
- The breach must be reported to the REB and, if applicable, to the appropriate Organizational Official(s) within **one working day** of the Researcher becoming aware of the breach.

5.3 Breaking Participant Confidentiality

5.3.1 The Office of Research Ethics must be informed when researchers breach participant confidentiality in accordance with TCPS2 (2014) Article 5.1: “Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality. Application: The ethical duty of confidentiality must, at times, be balanced against competing ethical considerations or legal or professional requirements that call for disclosure of information obtained or created in a research context.”

5.3.2 The breech must reported using the Serious Adverse Event (SAE) Form(s) Local Form in TRAQ within **three working days** of the Researcher becoming aware of the breach.

5.4 Reporting SAEs to the REB

5.4.1 The Researcher is responsible for submitting reportable events that meet the REB’s reporting criteria on the Serious Adverse Event (SAE) Form(s) Local and Non-Local using TRAQ and the Serious Adverse Event - Multi-Event Reporting Form, which is available on the REB website, as applicable;

- The report submitted to the REB must include all of the following information:
    - The description of the SAE,
    - All previous safety reports concerning similar adverse events,
    - An analysis of the significance of the current SAE in light of any previous reports, and
    - The proposed research changes, informed consent form changes, or other corrective actions to be taken by the sponsor in response to the SAE,
    - If the SAE is cause for a modification to the protocol, Researchers must also submit a Multi-Use Amendment/Full Board Renewal From for any proposed changes;

5.4.2 The completed sponsor's SAE form (if applicable) must be appended to the reportable SAE form;

5.4.3 All reports submitted to the REB must have all research participant identifiers removed (e.g. name, date of birth, initials, etc., only include participant research number and/or study number);

5.4.4 The sponsor's SAE report (if applicable) must be signed by the Researcher or medical designee;

5.4.5 Once a local SAE is acknowledged by the REB, subsequent important follow-up reports related to the SAE should be submitted when available, as SAE updates. The sponsor's follow-up reporting form(s) signed by the Researcher or medical designee must be appended to the updated reportable event. All initial and subsequent follow-up reports will be retained with the reportable event.

5.5 Review of SAEs by the REB

5.5.1 The REB Ethics Coordinator or designee will screen the SAE submission for completeness;

5.5.2 Privacy breaches are reviewed and any recommendations including remedial action are determined in consultation with the Chair or designee and/or REB Office Personnel. The Queen's Privacy Officer and/or the respective Hospital Privacy Office will be contacted as applicable;

5.5.3 The REB Ethics Coordinator or designee may route the submission back to the Researcher to request clarifications, missing documents, or additional information;

5.5.4 The REB Ethics Coordinator or designee will forward the local SAE(s) to the REB Chair or designee;

5.5.5 The REB Chair or designee will conduct a review of the report and determine if any action or follow-up is required;

5.5.6 When reviewing SAEs, the REB should:

- Assess the appropriateness of any corrective or preventative measures proposed by the sponsor and/or Researcher,
- Consider any additional appropriate measures that may or may not have been identified or proposed by the sponsor and/or Researcher,
- Consider whether the affected research still satisfies the requirements for REB ethics clearance; in particular whether 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 some or all of the research participants should be notified of the events (i.e., if it may affect the participants' willingness to continue participation in the research), and
- Consider whether suspension or termination of the ethics clearance of the research is warranted;

5.5.7 If the event does not raise concerns and does not appear to involve risks to research participants or others, the REB Chair or designee acknowledges the report, and reports at the next REB meeting;

5.5.8 If the REB Chair or designee determines that the event meets the criteria for an SAE, and if immediate action is required to protect the safety of research participants, may suspend ethics clearance of the research pending review by the Full Board, providing the justification for such action is documented;

5.5.9 If the event raises concerns or involves risk to research participants such that REB action may be required, the item is added to the agenda of the next Full Board meeting;

5.5.10 For any SAE(s) reviewed at a Full Board meeting, the REB determines whether further action is required. Possible actions that could be taken by the REB include, but are not limited to:

- Placing a hold on the research pending receipt of further information from the Researcher,
- Requesting modifications to the research,
- Requesting modifications to the consent form,
- Providing additional information to past participants,
- Notifying current participants when such information might affect the participants' willingness to continue to take part in the

research, and requiring that current participants re-consent for ongoing participation,
- Altering the frequency for renewal of ethics clearance,
- Observing the research or the consent process,
- Requiring additional training of the Researcher and research staff,
- Termination or suspension of the research,
- If the REB determines that the event does not raise concerns about risks to research participants, the REB may decide that no further action needs to be taken;

5.5.11 When action is taken to ensure the protection of the rights, safety, and well-being of participants (e.g., for unexpected SAE(s)) the Researcher is responsible for reporting to the appropriate authorities. If it becomes known that no action has been taken by the Researcher, then the REB Chair or designee is responsible for reporting to the Queen's University and Affiliated Teaching Hospital Official(s) as applicable, and has the authority to notify the sponsor and the appropriate regulatory authorities, as applicable. The REB may delegate regulatory authority reporting as applicable.

6.0 REFERENCES

See references.

7.0 APPENDICES

None.

8.0 REVISION HISTORY

SOP Title	Version	Updates
REB Reporting Adverse Events	v.410.001 2016April 04	Original: Adoption of standardized SOPs developed by CAREB/N2. Replaces SOP404.001 Ongoing REB Review Activities, which is now divided between SOP 404.002, 408.001, and 410.001.
REB Adverse Event Reporting	v.410.002 2016SEP12	• Minor revisions to purpose, scope and responsibilities. • Definitions and references removed and added to glossary of terms and references. • All footnotes removed. • Appendix 1 added. • Procedures updated to reflect the differences in local and external SAEs and removed reporting instructions from 5.1. • Reporting SAEs to the REB now outlined in section 5.3.
Adverse Event Reporting	v.410.003 2022JAN06	• Removed 'HSREB' from SOP name • Changed all references o HSREB to REB • Site Approvals section updated • Appendix 1 removed and hyperlink revised for Serious Adverse Event - Multi-Event Reporting Form • 5.5.2: Removed references to Ethics Compliance Advisor and Director, Research Ethics Compliance