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| **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 RESPONSIBILITIESnd /P <</MCID 0 >>BDC -05.53 Tm0 g0 [3h)4(a)3(t )3(rev)6(iew)10(s

## 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

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

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

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 knowics

research, and requiring that current participants re-consent for ongoing participation,
Altering the frequency