



Local Serious Adverse Event (SAE) Report

Submission:

Complete this report for each adverse event that is serious, has a definite or possible causal relationship to the study intervention and/or is unexpected (where the affected individual has been exposed to a level of risk above that which is normal for them in their everyday life). Once completed, sign it and submit to the JREB along with a copy of the 'Incident Report Form' (REBSubmissions@ontarioshores.ca). The JREB Office will acknowledge receipt of this SAE submission and will determine whether further review is required or not. A copy of the 'Incident Report Form' must also be submitted to Abilities Centre Research Ethics (researchethics@abilitiescentre.org) and Abilities Centre Joint Health and Safety Committee (gburrows@abilitiescentre.org).

Reporting Timeline:

48 hours for Fatal/Life Threatening SAEs

10 business days for Non-Fatal SAEs

1. REB Project #: _____

2. Title of Study: _____

3. Principal Investigator: _____

4. Local Contact: _____

5. Date Local SAE Report was Submitted: _____

6. Participant Code/SAE Identifier: _____

7. Onset Date of SAE: _____ Resolution Date of SAE: _____

8. Event Type: Initial Follow-up Final

9. Study Action

(1=None; 2= Adjustments Made to Study; 3= Discontinued from Study; 4=Other (specify): _____

10. Causal Relationship to Study Intervention

Definitely/Probably Related

Possibly Related

Unlikely/Unrelated

Events that are 'Not Serious', 'Not Related', or are 'Expected' do not need to be reported to the JREB

11. Does the SAE require a change to the Protocol? Yes or No:

12. Does the SAE require a change to the Consent Form? Yes or No:

Amended Protocol and/or Consent form should be submitted to the REB.

The signature attests that the Principal Investigator reviewed the SAE and the safety implications of the study and attests to the accuracy of the information.

Signature of the Principal Investigator

Date (yyyy/mmm/dd)

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FURTHER REVIEW OF ADVERSE EVENT BY JREB

(This next section to be completed by JREB Chair only for projects requiring further review)

Recommendations:

Protocol change: YES NO

Consent Form change: YES NO

Description of Changes Required:

Final Disposition by Joint Research Ethics Board following further review:

Approved for continuation

Approved conditional on changes

Suspended pending further review

Signature of Chair, Research Ethics Board (OR Designate)

Date