Canadian SHIELD
Ethics Review Board
OHRP Registration IORG0003491
Registered with CAREB, NCEHR

501 Deerhurst Drive, Suite 102
Burlington, ON L7L 5T1:

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Serious Adverse Drug Reaction Report Form

Investigator: _____

Title of Protocol:

Date of Protocol: **Study #:**

Date of Report (w/in 48 hrs; 24 hrs for death): ____/____/____

Patient: **ID Number:** _____ **Date of Birth**: ____/____/____ **M**☐ **F**☐

Phase of Report: ☐ Initial ☐ Follow-up ☐ Final

A. Protocol Data

- Is the reaction listed in the Investigator's Brochure? ☐ **Yes** ☐ **No**
- Is the reaction listed in the Protocol? ☐ **Yes** ☐ **No**
- Is the reaction/risk listed in the informed consent? ☐ **Yes** ☐ **No**
- Number of participants to be enrolled overall _____
- Number of participants to be enrolled at your site _____
- Number of participants enrolled to date at your site _____.

B. Description of SAE

Date of occurrence: ____/____/____

The event was: ☐mild ☐ moderate ☐ severe ☐fatal

Relationship to study medications:
☐ not related ☐ unlikely ☐ possibly ☐ probably ☐ definitely ☐ unknown

Briefly describe, using a separate sheet if necessary.

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C. Changes Necessitated by the Event:

- Do you think that a change in protocol is necessary to reduce risk? ☐ No

  ☐ Yes (Please explain if Sponsor has agreed and when revisions will be submitted for review)

- Are any changes required in the informed consent documents to better inform and protect the rights and safety of the participants? ☐ No

  ☐ Yes (Please explain if Sponsor has agreed and when revisions will be submitted for review)

- Is it necessary to inform participants/legal representatives who have already consented to participate in the study, of the event? ☐No

  ☐Yes (If checked, subjects currently in the study must be informed and sign the new consent, once approved)

D. Additional Comments: (Attach a separate sheet with any additional comments)

Principal Investigator's Signature _____ Date _____