**External Serious Adverse Event (SAE) Report**

**Submission:**

Complete this report for unanticipated serious adverse events as defined by ***CAREB Adverse Events Guidance (Final), July 2010*** document, outlining any proposed protocol changes, informed consent form changes or other corrective actions to be taken by the sponsor in response to the unanticipated problem. Submit the signed document to the REB along with the more detailed reports of the event(s) provided to the external study sponsor (if any).

Submit 2 additional copies to the REB Office, who will determine whether further review is required or not. The REB will acknowledge receipt of this submission. Non-Local reactions or events Not Serious, Not Related to study intervention or Expected, do not need to be reported to the REB.

**Reporting Timeline:** Periodic safety update reports, individual reportable external adverse events (i.e., those that represent unanticipated problems), and other unanticipated problems should be reported to the REB within 15 calendar days of the sponsor (i.e., Health Canada Clinical Trial Application holder) becoming aware of or receiving the event/the report.

1. **REB #:** **Protocol Title:**
2. **Sponsor Name:**
3. **Principal Investigator:**
4. **Person Completing the Form:**

**Phone #:** **Fax #:** **Date Submitted:**

1. **Investigational Drug/Device/Intervention:**
2. **Data Safety Monitoring Board: Yes** **[ ]  or No** **[ ]**
3. **Participant Code/SAE Identifier:**
4. **Onset Date of SAE:** **Resolution Date of SAE:**
5. **Event Type: Initial** **[ ]  Follow-up** **[ ]  Final** **[ ]**
6. **Medical Term for SAE:**
7. **Patient Outcome** (1=Fatal; 2=Hospitalization; 3=Medical Intervention; 4=Recovered; 5=Ongoing; 6=Other (Specify)**:**
8. **Study Action** (1=None; 2= Dose Adjusted; 3= Discontinued from Study; 4=Other (specify)**:**
9. **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 REB***

1. **Does the SAE require a change to the Protocol? Yes** **[ ]  or No** **[ ]**

**Please outline the change(s) required.**

1. **Does the SAE require a change to the Consent Form? Yes** **[ ]  or No** **[ ]**

**Please outline the change(s) required.**

***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.**

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 **SUBMIT COMPLETED FORM TO:**

Glenn A. Robitaille, M.Div., D.Min., RP

Chair, Research Ethics Board

Waypoint Centre for Mental Health Care

500 Church Street,

Penetanguishene, ON L9M 1G3

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**External Serious Adverse Event (SAE) Report**

***(This box to be completed by the Local Principal Investigator)***

**REB Project #:**       **Locally Responsible Investigator:**

**Title of Study:**

**Event #:**

**REVIEW BY REB PHARMACIST REPRESENTATIVE**

***(This box to be completed by the Research Ethics Board Pharmacist Representative)***

 **[****[ ] ] Further review is NOT required by the REB**

 **[****[ ] ] Further review is required by the REB**

 **COMMENTS:**

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**Signature of REB Pharmacist Representative Date**

**FURTHER REVIEW OF ADVERSE EVENT BY REB**

***(This box to be completed by REB Chair only for projects requiring further review)***

**Recommendations:**

 **Protocol change: [****[ ] ] YES [****[ ] ] NO**

 **Consent Form change: [****[ ] ] YES [****[ ] ] NO**

**Description of Changes Required:**

**Final Disposition by Research Ethics Board following further review:**

**[****[ ] ] Approved for continuation**

**[****[ ] ] Approved conditional on changes**

**[****[ ] ] Suspended pending further review**

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**Signature of Chair, Research Ethics Board (OR Designate) Date**