**TBRHSC Research Ethics Office Use Only**

On behalf of the Thunder Bay Regional Health Sciences Centre REB, I acknowledge receipt of the above noted Local Serious Adverse Event (SAE).

Signature of Chair:

Date:

**Please complete, sign and submit this form to the** **[Research Ethics Office](#TBRHSC:  Mail to:  Research Ethics Office, TBRHSC, 980 Oliver Road, Thunder Bay,  ON   P7B 6V4)**

If you require any assistance, please contact: **TBR\_REO@tbh.net**

|  |  |  |  |
| --- | --- | --- | --- |
| **TBRHSC REB** #: |       | Current expiry date: |       |
| Principal Investigator: |       |
| Full Study Title: |       |

|  |  |  |  |
| --- | --- | --- | --- |
| **Relevant Dates to Report** | Month | Day | Year |
| Date of Serious Adverse Event (SAE) |       |       |       |
| Date Principal Investigator was made aware |       |       |       |
| Date of Submission to REB |       |       |       |

|  |  |  |
| --- | --- | --- |
| Participant Description |  | Report Status |
| Patient ID # |       |  |  | check | ReportNumber |
| Age |       |  | Initial Report | [ ]  |
| Sex |       |  | Follow-up Report | [ ]  |       |

| Description of SAE (provide a brief overview of the event): |
| --- |
|       |

|  |  |  |
| --- | --- | --- |
| Check here | MC900432528[1] |  |
| Was the SAE Expected or Unexpected? | [ ]  | Expected* Identified in regulatory documents
* Identified in REB submission and letter of information to participants
* Not related to study intervention
 |
| [ ]  | Unexpected* Note indentified in regulatory documents or occurring with more than expected frequency
 |

|  |  |  |
| --- | --- | --- |
| Check here | MC900432528[1] |  |
| In the opinion of the Principal Investigator, is the SAE related to the study drug, device or procedure? | [ ]  | Yes – definitely related |
| [ ]  | Yes – probably or possibly related |
| [ ]  | Uncertain or Unknown |
| [ ]  | No – Not related |

|  |  |  |
| --- | --- | --- |
| Check here | MC900432528[1] |  |
| What actions were taken? | [ ]  | Hospitalization – Initial or Prolonged |
| [ ]  | Study Treatment Altered (i.e. drug dose changed) |
| [ ]  | Study Treatment Stopped Temporarily |
| [ ]  | Study Treatment Stopped Permanently |
| [ ]  | Study Blind Broken |
| [ ]  | Other (specify):       |

|  |  |  |
| --- | --- | --- |
| What was the outcome of SAE? | [ ]  | Recovered/ Resolved |
| [ ]  | Recovering/Resolving |
| [ ]  | Not Recovered/ Resolved with Sequela |
| [ ]  | Fatal |
| [ ]  | Other (specify):       |

|  |  |  |
| --- | --- | --- |
| In the opinion of the Principal Investigator, does the event warrant changes?  | [ ]  | Protocol |
| [ ]  | Consent  |
| [ ]  | Discontinuation of Study  |

|  |  |  |
| --- | --- | --- |
| Did the research participant remain on study? | [ ]  | Yes |
| [ ]  | No - Is participant being monitored  | [ ]  | Yes |
|  | [ ]  | No |

|  |  |
| --- | --- |
| Principal Investigator’s Signature:*(sign final hard copy after printing)* |  |
| Print Name:  |       |
| Date: [month day, year ]  |       |