**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**](mailto: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 | Report  Number |
| 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 ] |  |