# MATER HEALTH SERVICES Human Research Ethics Committee

# INITIAL SERIOUS Adverse Event (SAE) Report

## This information refers to SAE / SUSAR REPORTS RELATED to sites under the Mater Health Services HREC approval.

### A cover letter / cover sheet is not required.

|  |  |  |
| --- | --- | --- |
| MHS HREC Ref No |  |  |
| Title of protocol: |  |
|  |
|  |
|  |
|  |
| Protocol version No.& Date:  |  | Participant Information Sheet & Consent Form Version no. and Date: |  |
| Study drug/s / device: |  |
| Principal Investigator/s: |  |
| Date of adverse event: |  | Date participant commenced on study: |  | Enrolment Number: |  |
| Date of report: |  |  Gender: F ⬜ M ⬜ | DOB: |  |
| Was Informed Consent obtained: Yes ⬜ No ⬜ |
| Event: |  |
|  |
|  |
| Description of event: |  |
|  |
|  |

Likely cause of event: *(Please tick all that apply)*

|  |  |  |
| --- | --- | --- |
| Study drug/treatment ⬜ | Standard treatment ⬜ | Progressive disease ⬜ |
| Concurrent medication ⬜ | Concurrent disorder ⬜ | Other ⬜ |
| Please specify:  |  |
|  |
|  |

Relationship to study:

|  |  |  |
| --- | --- | --- |
| Directly related ⬜ | Possibly related ⬜ | Not related ⬜ |

Outcome:

|  |  |  |
| --- | --- | --- |
| Fatal ⬜ | Life threatening ⬜ | Hospitalisation required/prolonged ⬜ |
| Permanent or significant disability/incapacity ⬜ | Other ⬜ |
| Please specify: |  |
|  |
|  |

|  |  |  |
| --- | --- | --- |
| Was this serious adverse event anticipated in the original study protocol? | Yes ⬜ | No ⬜ |
| Was it described in the Participant Information Sheet? | Yes ⬜ | No ⬜ |
| Do you believe this report raises any safety concerns for the participants enrolled in the study? | Yes ⬜ | No ⬜ |
| Will there be changes to the study as a result of this event e.g. Participant Information Sheet and Consent Form / Protocol etc.? *If yes, these must be submitted as an amendment ASAP* | Yes ⬜ | No ⬜ |
| Will you continue to recruit/study participants to this study? | Yes ⬜ | No ⬜ |
| Has the relevant site RGO i.e. site where the participant was recruited, been notified of this SAE. | Yes ⬜ | No ⬜ |
| Additional information: |  |
|  |
|  |
|  |
| Name of Principal Investigator: |  | Signature: |  |
|  |  | Date: |  |