# 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: | | |  | | | | | | | | | |
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|  | | | | | | | | | | | | |
| 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: |  | | | | | | | | | | | |
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| Description of event: | | | |  | | | | | | | | |
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|  | | | | | | | | | | | | |

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: |  | | |