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Whenever there is any SAE event in any research approved by the National Center for Mental Health – Research Ethics Committee (NCMH-REC), it has to be reported by the Principal Investigator (PI) to the NCMH-REC.

**SECTION 1**

|  |  |
| --- | --- |
| Principal Investigator: |  |
|  |

|  |  |  |  |
| --- | --- | --- | --- |
| Study Title: |  | Protocol No.: |  |
|  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name of the study medicine / device: |  | Report Date: | |  | |
|  |  |  | Initial |  | Follow-up |
|  |  | Onset Date: | |  | |
|  |  |  | |  | |

|  |  |  |
| --- | --- | --- |
| Sponsor: |  | Date of first use: |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| Title of the Report |  | Date of the report |
|  |  |  |
|  |  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject’s initial / number: |  | Age: |  |  |  | Male |  | Female |

|  |  |  |
| --- | --- | --- |
| Subject’s history: |  | Laboratory findings: |
|  |  |  |
|  |  |  |
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| --- | --- | --- | --- | --- | --- | --- |
| SAE: |  | Treatment: | | | | |
|  |  | Outcome: |  | Resolved |  | On-going |
|  |  |  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Seriousness: | | | | |  | Relation to | | | | | | |
|  | | | | |  |  | | | | | | |
|  | Death | |  | Life Threatening |  |  | Drug | |  | Device |  | Study |
|  |  | |  |  |  |  |  | |  |  |  |  |
|  | Hospitalization: | | | |  |  |  | Not related | | | | |
|  |  | |  |  |  |  |  |  | | | | |
|  |  | Initial |  | Prolonged |  |  |  | Possibly | | | | |
|  |  | |  |  |  |  |  |  | | | | |
|  | Disability/Incapacity | | | |  |  |  | Probably | | | | |
|  |  | | | |  |  |  |  | | | | |
|  | Congenital Anomaly | | | |  |  |  | Definitely related | | | | |
|  |  | | | |  |  |  |  | | | | |
|  | Others | | | |  |  |  | Unknown | | | | |

|  |
| --- |
| *Note: PI should attach standard SAE report form (CIOM) to this NCMH-REC form.* |

**FOR NCMH-REC USE**

Received by:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name (REC Secretariat) |  | Signature |  | Date |
|  |  |  |  |  |
|  |  |  |  |  |

Reviewer’s Comments/ Recommendations

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Reviewer’s Name: |  | Signature |  | Date |
|  |  |  |  |  |

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| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| Changes to the protocol recommended? | |  | No |  | Yes |
| Comments: | |  |  |  |  |
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|  |  |  |  |  |  |
| Changes to the informed consent form recommended? | |  | No |  | Yes |
| Comments: | |  |  |  |  |
|  |  |  |  |  |  |
|  | Recommendation |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Reviewer |  | Signature |  | Date |
|  |  |  |  |  |
|  |  |  |  |  |

To be filled up by the Secretariat

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|  |  | |  |  | | |
|  | REC Final Action: | | Type of review: | | |
|  |  | |  | | |
|  |  | Request an amendment to the protocol or the consent form |  | Expedited review | |
|  |  |  | Full board review | |
|  |  | Request further information |  |  | |
|  |  | Suspend enrolment of new research participants | Date of meeting | | |
|  |  | Suspend all trial-related procedures |  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  |  | Termination of the Study |  |  |  |
|  |  | Take note and continue monitoring |  |  |  |
|  |  | Conduct Study Site Visit |  |  |  |
|  |  | Others: |  |  | |
|  |  |  |  |  | |
|  |  |  |  |  | |