SUTD Institutional Review Board (IRB)  
REPORT OF SERIOUS ADVERSE EVENT / ADVERSE EVENT

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Serious or unexpected adverse reactions or injuries experienced by subjects from their participation in a SUTD-IRB approved study resulting in death must be reported to SUTD-IRB within 24 hours. Other adverse events should be reported within 7 working days.  Where applicable, submission of detailed written reports whereby the PI is required to interpret the event and describe any precautions taken to prevent recurrence must be completed within 7 working days from the time PI was notified of the SAE/ AE. | | | | | | | | | | |
| **Principal Investigator** |  | | | | **IRB Approval No.** | | | |  | |
| **Protocol Title** |  | | | | | | | | | |
| **Study Site** | Local / Overseas \* Delete accordingly | | If ‘Local’, state which Study Site: | | | | | | | |
| **Details of Serious Adverse Event (SAE) / Adverse Event (AE)** | | | | | | | | | | |
| **Participant Identifier** | |  | | **Age** | | | | | |  |
| **Gender** | |  | | **Is the participant still in study?** | | | | | |  |
| **Event Onset date** | |  | | **Type of SAE/ Nature of injury to the subject** | | | | | |  |
| **Description of Serious Adverse Event (SAE) / Adverse Event (AE).** (*Please provide a detailed description)* | | | | | | | | | | |
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| **Relationship of the adverse event to the protocol.** *(Head of Pillar/Assoc. Provost (Research) signature required if SAE/AE is related to study)* | | | | | | | | | | |
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| **Treatment of the Subject.** (*Describe the treatment provided to the subject and indicate if the subject recovered)* | | | | | | | | | | |
|  | | | | | | | | | | |
| **Outcome of SAE / AE** | | | | | | | | | | |
|  | | | | | | | | | | |
| **Problem Assessment** | | | | | | | | | | |
| **Opinion of Investigator at Study Site where SAE / AE occurred** (Please state the name and role of the investigator at study site:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_) | | | | | | | | Related^ / Unexpected+ \*Circle whichever applicable | | |
| **Opinion of Principal Investigator (PI) of Study** | | | | | | | | Related^ / Unexpected+ \*Circle whichever applicable | | |
| **^ Related** – Includes possibly related problem. Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.  **+ Unexpected** – An unexpected problem is one, the nature, severity or frequency is not consistent with information in the study approved documents and relevant sources of information or the characteristics of the subject population being studied. | | | | | | | | | | |
| **Additional Comments** | | | | | | | | | | |
|  | | | | | | | | | | |
| **Signature of Principal Investigator** | | | | | | | | | | |
| Signature of Principal Investigator | |  | | | | | Date | | |  |
| Department / Pillar / Institution | |  | | | | | Contact Number | | |  |
| **Signature of Head of Pillar / Associate Provost (Research) required if SAE/AE related to study.** | | | | | | | | | | |
| Signature of Head of Pillar/Assoc. Provost (Research) | |  | | | | Date | | | |  |
| Name of Head of Pillar/Assoc. Provost (Research) | |  | | | | Department / Pillar / Institution | | | |  |