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| **HKU/HA HKW IRB** |
| **🙞 Initial Serious Adverse Event (SAE) Report Form for Phase 1 Clinical Trials 🙜** |
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| **This initial SAE report form is applicable to phase 1 clinical trials as defined under Section 8.6.1 of the HKU/HA HKW IRB SOP** |

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| **A. Reminder to Study Site Personnel** | | | | | | | | | | | | **For HKU/HA HKW IRB Office Use** | | | |
| **Upon completion of this initial SAE report form, please**:   1. **Fax** to the **IRB** (2255 4735) and **Clinical Trials Centre** (2986 3447) directly.   *(Remarks: Enclosure of Case Report Form (SAE Reporting Form) submitted to the Sponsor is highly recommended)*   1. **Supplement SAE follow up information** to Clinical Trials Centre for follow up reporting to the IRB until the SAE is resolved. | | | | | | | | | | | | Date received:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Application Reference No:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| **B. Study Particulars** | | | | | | | | | | | | | | | |
| **Study Title:** | |  | | | | | | | | | | | | | |
| **Protocol No:** | |  | | | | | | | | | | | | | |
| **REC/IRB:** | |  | | | | | | | | | | | | | |
| **Study Site:** | |  | | | | | | | | | | | | | |
| **C. Subject Information** | | | | | | | | | | | | | | | |
| **Subject Code** | | | | | | **Subject Initials** | | | | **Age** | | | | **Sex** | |
|  | | | | | |  | | | |  | | | |  | |
| **D. SAE Information** | | | | | | | | | | | | | | | |
| **Onset Date** | | | | | **Hospitalization Date**  (if applicable) | | | | **Investigator’s First Awareness** | | | | | | **Term of SAE** |
| DAY | MONTH | | YEAR | | DAY | | MONTH | YEAR | DAY | | MONTH | | YEAR | |  |
|  |  | |  | |  | |  |  |  | |  | |  | |
| **Narrative of SAE (if any):** | | | |  | | | | | | | | | | | |

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| **D1. Seriousness of the SAE** | | **D2. Outcome of the SAE** | |
|  | Death |  | Resolved (Date: ) |
|  | Life threatening |  | Resolved with Sequelae (Date: ) |
|  | Persistent or Significant Disability / Incapacity |  | Ongoing |
|  | Hospitalization / Prolonged Hospitalization |  | Death (Date: ) |
|  | Congenital Anomaly / Birth Defect |  | Unknown |
|  | Other Medically Important Condition |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **D3. Causality with Study Drug** | | | **D4. Action Taken with Study Drug** | | |
|  | Definite | |  | None | |
|  | Probable / Possible | |  | Dosage Adjusted | |
|  | Unrelated | |  | Interrupted Temporarily | |
|  | Unknown | |  | Discontinued | |
|  | | | | | |
| **E. Confirmation by Investigator** | | | | | |
|  | |  | | |  |
| *Printed Name* | | *Signature* | | | *Date* |