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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 |  |  |

|  |  |
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| **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* |