**SERIOUS ADVERSE EVENT (SAE)**

**REPORT FORM**

Note:

1. This form is to be used between 16 Mar 2024 and until ECOS is rolled out.

2. Please email this form to the [IRB Secretariat](https://www.singhealthdukenus.com.sg/research/rice/contact-us) of the IRB that reviewed the study.

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| **IRB Reference No:** | Click or tap here to enter text. |
| **Study Title:** | Click or tap here to enter text. |
| **Principal Investigator:** | Click or tap here to enter text. |
| **Department:** | Click or tap here to enter text. |
| **Institution:** | Click or tap here to enter text. |

*All sections must be completed.*

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| **Section A: Determination of SAE** | |
| **A1. Please determine if the event is related:**  *This should be checked for this form to be used.* | |
| Related: Related means there is a reasonable possibility that the incident, experience or outcome may have  been caused by the procedures involved in the research. Also includes reasonable possibility that the event  occurred as a result of participation in the research. | |
| **A2. Please classify the SAE** **into at least one of the following categories:** | |
| Resulted in or contributed to death  Was life-threatening  Required inpatient hospitalisation or prolongation of existing hospitalisation  Resulted in or contributed to persistent or significant disability or incapacity  Resulted in or contributed to a congenital anomaly or birth defect  Resulted in transmission of communicable disease  Resulted in any misidentification or mix-up of any type of tissue, gametes or embryo  Required intervention to prevent permanent impairment or damage (devices)  Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above  Others  Please specify:  Text Field | |
| **A3. Please determine the expectedness of the event:** | |
| Expected | These are risks or events reported and listed in the study protocol, informed consent form or other study documents. |
| Unexpected | These are any unexpected untoward event or medical occurrence in a participant that is not consistent with the known, predicted possible effects of the research protocol. An unexpected adverse event can therefore be any unanticipated, unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study that was not listed in the protocol, informed consent document or Investigator’s Brochure (IB). This includes adverse drug reactions, the nature or severity of which is not consistent with the applicable product information (e.g. IB for an unapproved investigational product or product insert/ summary of product characteristics for an approved product) and any experience that suggests a significant hazard, contraindication or side effect. In addition to this definition, the IRB will interpret any adverse event not included in the Informed Consent Document as a risk to be “unanticipated” or “unexpected”. |

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| **Section B: Basic Information** | |
| **B1. Study site where the SAE occurred:** | Click or tap here to enter text. |
| **B2. Onset Date:** | Click or tap here to enter text. |
| **B3. Date of First Knowledge by Investigator:** | Click or tap here to enter text. |
| **B4. Type of Report:** | Initial Report  Follow-up Report |
| **B5. Research participant Number/Code:** | Click or tap here to enter text. |
| **B6. Age:** | Click or tap here to enter text. |
| **B7. Gender** | Male  Female |
| **B8. Is the research participant still in the study?** | Yes  No |
| **B9. Which study arm is the research participant in?** | Study Intervention (i.e. drug, device and experimental  procedures)  Comparator (including Placebo)  Unknown (Research participant is blinded)  Not applicable as there is no study arms  Others  Please specify: Click or tap here to enter text. |

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| **Section C: Investigational Product (Drug/Device/Biological/Other Agent)** | |
| **C1. Does this event involve an investigational product?** | Yes  No.  ***Note: If this event does not involve investigational product, question C2 to C5 need not be filled up.*** |
| **C2. Investigational Product Name:** | Click or tap here to enter text. |
| **C3. Was the study blind broken?** | Yes  No  This is not a blinded study |
| **C4. Is the investigational product registered in Singapore?** | Yes  No |
| **C5. The investigational product was:** | Continued  Discontinued  Stop Date: Click or tap here to enter text.  Temporarily Stopped  Stop Date: Click or tap here to enter text. |

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| **Section D: Event Summary** |
| **D1. Please use keywords, e.g. Liver Failure, to concisely describe the event.** |
| Click or tap here to enter text. |
| **D2. Please provide a detailed description of the event (including details on what actions were taken to resolve the problem).** |
| Click or tap here to enter text. |
| **D3. Did the event have any impact on the research participant? E.g. Research participant was withdrawn from study.** |
| Yes  Please specify the impact:  Click or tap here to enter text.  No |
| **D4. Did the event have any impact on the other research participants in the study?** |
| Yes  Please specify the impact:  Click or tap here to enter text.  No |
| **D5. Outcome of the event:** |
| Resolved  Unresolved  Unable to assess  Death |
| **D6. Resolution/End Date of Adverse Event:**  ***Note: If event is unresolved and investigation is ongoing, the date may be left blank. A Follow Up Report must be submitted.*** |
| Click or tap here to enter text. |

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| **Section E: Comments by Investigator** |
| **E1. Has the study’s risk-benefit ratio changed?** |
| Yes  No  Unable to assess |
| **E2. Should past and/or current enrolled research participants be notified about this event or be re-consented for study participation?** |
| Yes  Please explain and describe the mechanism to be employed.  Click or tap here to enter text.  No  Please explain your rationale.  Click or tap here to enter text. |
| **E3. Is this event already listed/described in the informed consent document/protocol?** |
| Yes  Is the frequency and/or severity of the event consistent with the consent document/ protocol?  No    Yes  State where the information on this expected event can be found (e.g. Informed Consent Form / Protocol;  Section X, Page XX etc.):  Click or tap here to enter text.    No |
| **E4. Should the protocol and/ or informed consent document be revised?** |
| Yes  An amendment should be submitted. Please contact the IRB secretariat (secretariat will advise on a case-by-  case basis).  No  Please explain the rationale for your decision.  Click or tap here to enter text. |
| **E5. Any other Comments:** |
| Click or tap here to enter text. |

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| **Section F: Investigator’s Declaration** |
| **I confirm that the information submitted in the above Serious Adverse Event report is true and accurate at the date of submission of the report.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Investigator’s Signature/ e-Signature and Date    Full Name: Click or tap here to enter text.  Designation: Click or tap here to enter text.  Department: Click or tap here to enter text.  Institution: Click or tap here to enter text. |