**Form RC/65**

(Feb 2024)

**Report of Serious Adverse Event (SAE)**

|  |
| --- |
| **Types of Report** *(Please tick as appropriate.)* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Initial\* | |  | Follow-up (case not completed) |  | Follow-up (case completed) |
|  |  | |  |  |  |  |
| **Date of Report** | |  | | | |  |
|  | | *dd-mmm-yyyy* | | | |  |
|  | |  | | | | |
| \**An initial report should be sent to the Institutional Review Board (IRB) via Research and Innovation Office (RIO) as soon as possible* ***no later than 48 hours after the time of incident****.* | | | | | | |

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| **Section A: Project Information** |

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| --- | --- | --- | --- | --- | --- | --- |
| Project Title |  | | | | | |
|  |
|  |  | | | | | |
| HSEARS Application No: | HSEARS |  | Reference No. of the University’s Master Clinical Trial Insurance | | |  |
|  |  | *e.g., HK-2324-DEPT-XX* |
|  | | | | | | |
| Project Duration |  | | |  |  | |
|  | *Start Date (dd-mmm-yyyy)* | | |  | *End Date (dd-mmm-yyyy)* | |

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| **Section B: Information on the Human Subject** |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject No. / Code |  | | |  | | Gender | | | |  | |  | Age |  |
|  |  | | |  | |  | | |  | | | | | |
| Subject Initials |  | | |  | | Date of Recruitment | | | | |  | | | |
|  |  | | |  | |  | | | | | *dd-mmm-yyyy* | | | |
| Relevant medical history and concomitant drugs / treatments, if any |  | | | | | | | | | | | | | | |
| *Please tick as appropriate.* | | | | | | | | | | | | | | | |
| Subject’s Condition at Time of Report |  | Events not yet resolved | | | | |  |  | Required hospitalisation | | | | | |
|  |  | | | | |  |  |  | | | | | |
|  | Died, | cause of death: | |  | | | | | | | | | | |
|  |  | | | | | | | | | | | | | | |
| Subject’s Condition to Date |  | Complete recovery | | | | |  |  | Recovery with sequelae | | | | | |
|  |  | | | | |  |  |  | | | | | |
|  | Prolonged hospitalisation | | | | |  |  | Significant disability / incapacity | | | | | |
|  |  | | | | |  |  |  | | | | | |
|  | Unknown | | | | |  |  | Died | | | | | |
|  |  |  | | | | |  |  |  | | | | | |
|  |  | Others, please specify: | | |  | | | | | | | | | |

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| **Section C: Details of the Serious Adverse Event (SAE)** |

*^Please delete as appropriate.*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAE Start Date |  | |  | SAE Stop Date | | |  | | | / not resolved^ |
|  | *dd-mmm-yyyy* | |  |  | | | *dd-mmm-yyyy* | | |  |
|  |  | |  |  | | |  | | |  |
| Detailed Description  *(use extra paper if necessary)* | 1. Diagnosis/Syndrome 2. Full description of SAE 3. Describe temporal relationship with intervention and other concomitant therapies 4. Provide sketches or photos, if any 5. Name of hospital/clinic where the human subject concerned received medical treatment/procedure, if applicable 6. Were the police notified? Please provide details. 7. Name and contact information of witness, if any. | | | | | | | | | |
|  | | | | | | | | | |
| *Please tick as appropriate.* |  | |  |  | | |  | | | |
| Frequency |  | One episode only | | |  | Intermittent | |  | Continuous | |
|  |  |  | | |  |  | |  |  | |
| Causal relationship between SAE and the study |  | Definite | | |  | Probable | |  | Possible | |
|  |  | | |  |  | |  |  | |
|  | Not related | | |  | Not assessable | |  |  | |
|  |  | |  |  | | |  | | | |
| **Section D: Remedial Actions** | | | | | | | | | | |

**On the affected subject:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | None |  |  | Dosage / Treatment adjusted |
|  |  |  |  |  |
|  | Temporarily suspended from the study |  |  | Discontinued / Withdrawn from the study |

**For all subjects / overall study design:**

|  |  |  |
| --- | --- | --- |
|  | No | |
|  |  | |
|  | Yes, please specify: |  |
|  |  |

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| **Section E: Filing an Insurance Claim** |

|  |  |
| --- | --- |
|  | No |
|  |  |
|  | Yes4, please ensure that your project has been properly registered for the University Master Clinical Trial Insurance and read the *Notes* below. |
|  |

*Notes:*

1. The policy excess of the current University’s Master Clinical Trial Insurance is HK$150,000 each and every claim. Such amount, if required, should be borne by the relevant department.
2. The insurers only indemnify PolyU against its liability to pay compensation and costs pursuant to the conditions of compensation in respect of **bodily injury** to a research subject. Please refer to the insurance certificate for more details.
3. For SAE leading to a claim, you **must attach** the following documents to this report:
   * details of the incident, including the time, date and location of the trial;
   * detailed study protocol (step by step) of the project;
   * informed consent forms of all related human subjects; and
   * details of the complaint, if any, received from the human subjects concerned.
4. This report together with the required attachments as specified in (3) above must be sent to FO as soon as possible for filing an insurance claim.

**Details of the claim:**

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|  |

**Reported by:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Name of the Principal Investigator (Department) |  | Signature |  | Date |

**Reported to:**

*Please tick as appropriate.*

|  |  |  |
| --- | --- | --- |
|  | Head of Department on |  |
|  |  | *dd/mmm/yyyy* |
|  | Finance Office (FO) on |  |
|  |  | *dd/mmm/yyyy* |