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| A close-up of a logo  Description automatically generated | Independent Ethics Committee**Research Project Closure Report Form** |

Please submit research project closure reports to IEC within 90 days of scheduled study closure. In the case of premature suspension or termination, IEC should be notified within 15 days with reasons for suspension/termination and a summary of results provided

|  |  |
| --- | --- |
| **Title of Research Project** |          |
| **Research protocol number** |            | NMRR ID:            |
| **Name of principal investigator** |            |
| **Study site**  |        |
| **Name of sponsor** |         |
| Initial IEC approval number to conduct this research project |           |
| Start date of research (date when first subject is enrolled) |       |
| Closure date of research project (date when study is officially closed) |         |
| Total number of subjects actually enrolled at this research site |              |
| Targeted number of subjects to be enrolled at this research site |           |
| Total number of subjects enrolled and withdrawn from this research at this research site from start to end of this project (Provide details in Table A of this report) |            |
| Number of serious and/or unexpected adverse events reported at this research site from start to end of this project (Provide details in Table B of this report) |           |
| Is data collection completed as stated in the protocol? | [ ]  Yes [ ]  No |
|  [ ]  Study closure according to plan or  [ ]  Premature study closure. Please explain:            |
| Results: *(Use extra pages if more space is required)* |
|        |
| Brief comments by principal investigator on findings in this research project to date |
|         |

The above-stated research project has been carried out according to the IEC-approved research protocol and the requirements of Independent Ethics Committee (IEC) have been followed. All subjects enrolled have signed and received copies of the informed consent forms and written subject information (if applicable) approved by IEC for this project.

|  |  |  |
| --- | --- | --- |
| Signature & Stamp of Principal Investigator |  | Date |
|   |  |       |

**Table A:**

**Number of subjects enrolled and withdrawn from this research at this research site**

|  |  |  |
| --- | --- | --- |
|  Start date of research |  | stop date of research |
| dd | mm | yy |  | dd | mm | yy |
|       |       |       |  |       |       |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Subject initials** | **Date subject withdrawn** | *Reason for withdrawal* | **Was study drug re-started again? (if applicable)** |
|  |       |       |       |       |
| **2.**  |       |       |       |       |
| **3.**  |       |       |       |       |
| **4.**  |       |       |       |       |
| **5.**  |       |       |       |       |
| **6.**  |       |       |       |       |
| **7.**  |       |       |       |       |
| **8.**  |       |       |       |       |
| **9.**  |       |       |       |       |
| **10.**  |       |       |       |       |

**Table B:**

**Summary of Serious and/or Unexpected Adverse Events reported in this research project from**

|  |  |  |
| --- | --- | --- |
|  Start date of research |  | stop date of research |
| dd | mm | yy |  | dd | mm | yy |
|       |       |       |  |       |       |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Serious and/or unexpected adverse event** **(Where a diagnosis has been reached, state the diagnosis eg: lung cancer. If not available, state the sign or symptom that make up the adverse event , eg: hemoptysis)** |  *Subject initials* | **Date of SAE onset** | **Date reported** **to IEC****(dd/mm/yy)** |
|  |       |       |       |       |
|  |       |       |       |       |
|  |       |       |       |       |
|  |       |       |       |       |
|  |       |       |       |       |
|  |       |       |       |       |
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|  |       |       |       |       |

Please return this completed and signed form along with a soft copy submission to:

The Secretariat, Independent Ethics Committee, c/o Clinical Trial Office. 1st Floor, South Tower, Subang Jaya Medical Centre, No 1, SS12/1A, 47500 Subang Jaya.

Soft copy should be emailed to sjmc.iec@asia1health.com

Should you require further clarification, please do not hesitate to contact The Secretariat at 03- 5639 1988 / 1989.