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| **A close-up of a logo  Description automatically generated****Independent Ethics Committee** | **Research Project Progress Report & Continuing Review Form** |

The first report should be submitted ONE year from the date of issue of the IEC decision notification form for full approval and thereafter annually if the research project has not been closed. For studies with higher risk to the subject, IEC may require progress reports to be submitted more frequently.

|  |  |
| --- | --- |
| Title of research  |       |
| Research study protocol number |        | NMRR ID :       |
| Name of principal investigator |       |
| Name of sub investigators |       |
| Study site  | [ ]  Subang Jaya Medical Centre Others:       |
| Name of sponsor |       |
| Initial IEC approval number to conduct this research project |       |
| Date Of Initial Approval: |       |
| Official start date of research:  |       | Date of Initiation: |       |
| Official scheduled date of research project closure/end |       |
| Research Duration (Months): Recruitment Duration:       | Research Duration:      |
| Reporting Period:

|  |  |  |
| --- | --- | --- |
|  Start date of trial |  | To |
| dd | mm | yy |  | dd | mm | yy |
|         |       |       |  |       |       |       |

 |
| **Current Research Status**. Check all that apply[ ]  Research has not been initiated/ is put on hold. Explain why:      [ ]  Data Collection [ ]  Data Analysis [ ]  Active Enrollment [ ]  Closed Enrollment. Follow up of enrolled subjects (Applicable for Clinical Trials only) |
| 1. **Patient/Subject recruitment details: Total subjects approved by IEC**
 |
| 1. Total patients enrolled (Country):
 |       |
| 1. Screened patients
 |       |
| 1. Screen Failure
 |       |
| 1. Total number of subjects enrolled/randomised at this research site
2. (*for non interventional: number of records/biological specimens/data accessed*)
 |       |
| 1. Number of subjects enrolled and subsequently withdrawn from this research at this research site (*Please provide details in Table B of this report)*
 |       |
| 1. Number of serious and/or unexpected adverse events reported at this research site from (*Please provide details in Table C of this report*)
 |       |
|  |
| 1. **ACTION REQUESTED:**

[ ]  Renew – New subjects enrollment to continue[ ]  Renew – Enrolled subjects follow up only[ ]  Terminate – Study discontinued |
| 1. **Have there been any amendments since the last review?**

[ ]  NO [ ]  YES (Describe briefly in attached narrative)       |
| 1. **Have There Been Any Changes In The Participant Population, Recruitment Or Selection Criteria Since The Last Review/Approval?**

[ ]  No[ ]  Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s )      |
| 1. **Have There Been Any Changes In The Informed Consent Process Or Documentation Since The Last Review/ Approval?** Attach latest version of participant information sheet and informed consent form/ document

 [ ]  No [ ]  Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)      |
| 1. **Has Any Information Appeared In The Literature, Or Evolved From This Or Similar Research That Might Affect The Panel’s Evaluation Of The Risk/Benefit Assessment Of Human Participants Involved In This Study Protocol?**

 [ ]  No [ ]  Yes **(**Describe briefly and provide copy of literature cited, including the Investigator’s Brochure if applicable**)**      |
| 1. **HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?**

[ ]  No[ ]  Yes (Summarize and indicate date/s of SUSAR report submission/s **)**      |
| 1. **HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR REMOVED SINCE THE LAST REVIEW?**

[ ]  No[ ]  Yes (Identify all changes and provide an explanation of changes in attached narrative**)**      |
| 1. **Has the study clinical trial insurance been updated since the last IEC initial approval/ renewal?**

[ ]  Not applicable[ ]  No[ ]  Yes

|  |  |
| --- | --- |
| **Trial Insurance Policy No**  | **Date of Expiry** |
|       |       |

 |
| **Comments by Principal Investigator** Has the risk vs. benefit to subjects changed significantly since this research project was first approved by IEC due to new information or new findings since then? |
|       |

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.

**I declare that the information provided above is true & correct to the best of my understanding**

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

**Table A**. Study Informed consent

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.**  | **Title**  | **Version date**  | **Language**  | **IEC approval Date**  |
|       |       |       |       |       |
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**Table B:**

Number of subjects enrolled and withdrawn from this research at this research site ( Please add attachment if required)

|  |  |  |
| --- | --- | --- |
| Start date of trial |  | To |
| dd | mm | yy |  | dd | mm | yy |
|         |       |       |  |       |       |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Subject ID** | **Date subject withdrawn** | Reasons for withdrawal | **Was study drug re-started again? (if applicable)** |
|  |       |       |       |       |
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**Table C**:

Summary of Serious and/or Unexpected Adverse Events reported in this research project at this research site

|  |  |  |
| --- | --- | --- |
| Start date of trial |  | To |
| dd | mm | yy |  | dd | mm | yy |
|         |       |       |  |       |       |       |

Total Number of Serious Adverse Event:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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 ID | AER Number  | **Date of SAE onset** | **Date reported** **to IEC****(dd/mm/yy)** | **Outcome** |
|       |       |       |       |       |       |       |
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**Table D**

Protocol Deviations

|  |  |  |
| --- | --- | --- |
| **Subject ID**  | **Visit Designation**  | **Description of Deviation**  |
|       |       |       |
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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 sjmc.iec@asia1health.com

Should you require further clarification, please do not hesitate to contact The Secretariat at

03- 5639 1988 / 1989