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| A close-up of a logo  Description automatically generated  **Independent Ethics Committee** | Application for  Amendment& Updates to Research Project |

Any change to an approved research protocol, including the research plan, consent process and form, co-investigators, other research personnel, and/or methods of subject recruitment, requires the submission of an Amendment.

* Please clarify the change(s) to be made and the rationale for the change. The revised protocol, consent form, advertisements, and/or Investigator Brochure with the changes clearly identified, using a highlighter, must be submitted.
* A cover letter or additional information may also be attached. If revisions are not summarized and if the revised portions of the pertinent documents are not highlighted, the amendment package will be returned to the submitting investigator.

**Amendments to protocols may not be initiated until IEC approval has been obtained**

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| Title of Project |  | |
| Protocol Number |  | NMRR ID for Clinical Trials/ drug related research: |

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| Principal Investigator’s (PI) Name |  | Institution: |
| Contact No: |
| IEC Approval Reference No. |  | Sponsor: |
| IEC Approval Date |  |  |

**Part 2: Summary of amendment(s) requested**

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| **Amendment description (check all applicable)** | | **New** |
|  | Amendment to currently approved ***Protocol***  Amendment Number:  Version Date: | Amendment Number:  Version Date: |
|  | Amendment to currently approved ***ICF, PIS,*** Amendment Number:  Version Date: | Amendment Number:  Version Date: |
|  | Amendment to currently approved ***CRF***  Amendment Number:  Version Date: | Amendment Number:  Version Date: |
|  | Other (please specify)  Amendment Number:  Version Date: | Amendment Number:  Version Date: |
|  | Other (please specify)  Amendment Number:  Version Date: | Amendment Number:  Version Date: |
|  | Other (please specify)  Amendment Number:  Version Date:  Other (please specify)  Amendment Number:  Version Date: | Amendment Number:  Version Date:  Amendment Number:  Version Date: |

If a list of proposed changes or amendments is available, please attach the document and tracked changes

**(Please HIGHLIGHT all amendments)**

Amendment Details

|  |  |  |  |
| --- | --- | --- | --- |
| Page and section to be amended | Before proposed amendment | After proposed amendment | Reason(s) for proposed amendment |
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| The section below must be filled by the Principal Investigator for this application will be considered valid |
| Are the risks to subjects affected (increased or decreased) by the amendment?  Yes  No  Will this amendment adversely affect the safety, rights or welfare of subjects?  Yes  No  If yes, describe how the amendment will affect the risk-benefit ratio for the subjects.   |  | | --- | |  | |
| Does the amendment(s) affect the scientific aspects of this research project?  Yes No  If yes, describe how the amendment will affect the scientific aspects.   |  | | --- | |  | |

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| --- | --- | --- |
| Name of applicant | Signature of applicant: | |
| Investigator’s Name & Stamp | Date: | |
| **IEC Submission Requirement**  If the amendments in this application may negatively affect the safety, rights or welfare as well as scientific value of this research project, kindly submit:   * 1 copy (1 original and 8 photocopies) of this form and amendment summary of changes with 1 set of soft copy of full documents to The Secretariat at [sjmc.iec@asia1health.com](mailto:sjmc.iec@asia1health.com) with supporting documents. * 1 Full set of documents in hard copy   **NOTE:** If the amendments do not negatively affect the safety, rights or welfare as well as scientific value of this research project, submit **ONLY ONE COPY** this application form with supporting documents, and e-mail a soft copy of the submission to The Secretariat at [sjmc.iec@asia1health.com](mailto:sjmc.iec@asia1health.com).  Please contact the Secretariat at [sjmc.iec@asia1health.com](mailto:sjmc.iec@asia1health.com) or *603-5639 1988 / 1989 9* if further clarification is required.  Thank you. | | |

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