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| **A close-up of a logo  Description automatically generatedIndependent Ethics Committee** | **Research Protocol Deviation / Violation Report**  *Please submit this form with a cover letter* |

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| Research Title |  | |
| NMRR ID |  | Protocol Number (if available) |
| IEC Reference No |  | Approval Date: |
| Principal Investigator: |  | Contact information (H/P Number):  Email: |
| Sponsor |  | Contact information (H/P Number):  Email: |
| **Date of Report**: | | |

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| **Protocol Deviation or Violation Information** | | |
| Date of protocol deviation / violation: | | Date of awareness: |
| Site No : | Site Name : | Study participant ID number: |
| **A. Nature Of Report**  1.  MINOR PROTOCOL DEVIATION (*nonsystematic protocol noncompliance with minor consequences, in terms of its effect on the participant’s/subject’s rights, safety or welfare, or the integrity of study data; includes deviations that are administrative in nature*)  2.  MAJOR PROTOCOL DEVIATION OR PROTOCOL VIOLATION (*persistent protocol noncompliance with potentially serious consequences that could critically affect data analysis or put patients’ safety at risk*) | | |
| **B. Types of Protocol Deviations or Violation (check all that applies)**  Administrative non-compliance  Conducted research activity without IEC SJMC approval  Continuation of research activities during lapse of IEC SJMC approval  Enrollment of participants ineligible under approved protocol  Incorrect research treatment or interventions given  Initiation of study prior to completion of informed consent process  IP compliance not within protocol range  Procedures were not performed as described in the currently approved protocol  Procedures were performed that were not described in the currently approved protocol  Randomisation error  Recruitment was over the number of correctly approved subjects  Use of expired or incorrect informed consent documents  Others: Please describe: | | |

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| **C. Description of Event.** *Additional narrative can be provided as additional attachments (if required)* |
| 1) Please provide a thorough description of the event. |
| 2) Explain why or how this event occurred. |
| 3) Describe the outcome of this event. |
| 4) In your judgment, did this event increase risk/cause harm to the participant or others and/or affect the rights or welfare of the participant?  No  Yes. *If Yes, please describe* |
| 5) Does this this protocol deviation / violation affects the integrity (i.e. scientific validity and ethics) of the study data?  No  Yes. *If Yes, please describe* |
| 6) Please explain the corrective action you have done in response to the event |
| 7) Please explain the preventive action plan that you have put in to prevent the event from recurring in future |
| Any other comments: |

**Investigator’s Declaration**

*I certify that I have reviewed the information provided in this report and that the above parts are true and correct to the best of my knowledge and belief*

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| Signature: |  | Date signed: |  |
| Full Name: |  | | |

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| Please send this completed report along with a softcopy 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](mailto:sjmc.iec@asia1health.com)  Should you require further clarification, please do not hesitate to contact The Secretariat at  03- 5639 1988 / 1989 |