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