**STUDY DEVIATION/ NON-COMPLIANCE REPORT FORM**

Note: 1.This form is to be used between 16 Mar 2024 and until ECOS is rolled out.

2. Please email this form to the [IRB Secretariat](https://www.singhealthdukenus.com.sg/research/rice/contact-us) of the IRB that reviewed the study.

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| **IRB Reference No:** | Click or tap here to enter text. |
| **Study Title:** | Click or tap here to enter text. |
| **Principal Investigator:** | Click or tap here to enter text. |
| **Designation/ Department/ Institution:** | Click or tap here to enter text. |
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| **Description of Event** | |
| 1. **Which study site(s) this/ these Study Deviation/ Non-Compliance occurred?**   Click or tap here to enter text. | |
| 1. **Date of Occurrence of Study Deviation/ Non-Compliance.**   Click or tap here to enter text. | |
| 1. **Number of research participant(s) affected.**   Click or tap here to enter text. | |
| 1. **Please describe in detail the nature of the Study Deviation/ Non-Compliance and chronology of events, including why or how the Study Deviation/ Non-Compliance occurred.**   Click or tap here to enter text. | |
| 1. **Did the Study Deviation/ Non-Compliance cause harm/death to the research participant and/or others?**   Yes. Please explain.  Click or tap here to enter text.  No. Please explain.  Click or tap here to enter text. | |
| 1. **Will the Study Deviation/ Non-Compliance potentially increase the risk or cause harm to the research participant and/or others?**   Yes. Please explain.  Click or tap here to enter text.  No. Please explain.  Click or tap here to enter text. | |
| 1. **Did the Study Deviation/ Non-Compliance affect the rights or welfare of the research participant and/or others?**   Yes. Please explain.  Click or tap here to enter text.  No. Please explain.  Click or tap here to enter text. | |
| 1. **Corrective Action Plan: Please describe the steps taken to rectify/correct Study Deviation/ Non-Compliance.**   Click or tap here to enter text. | |
| 1. **Please explain/describe the outcome of the Study Deviation/ Non-Compliance.**   Click or tap here to enter text. | |
| 1. **Preventive Action Plan: Please describe any follow up action taken to prevent the recurrence of the Study Deviation/ Non-Compliance in future.**   Click or tap here to enter text. | |
| 1. **If this Study Deviation/ Non-Compliance had been reported to the Study Sponsor or Regulatory Authorities, please describe if there were any comments from the Study Sponsor or Regulatory Authorities?**   Click or tap here to enter text. | |
| 1. **Any other comments.**   Click or tap here to enter text. | |
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| **Declaration of Principal Investigator:** | |
| **I confirm that the information submitted in the above report is true and accurate at the date of submission.**   |  |  |  | | --- | --- | --- | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | *Principal Investigator’s Signature/ e-Signature and Date* | |  | |  |  | | | *Full Name:* | Click or tap here to enter text. | | | *Institution:* | Click or tap here to enter text. | | | *Department:* | Click or tap here to enter text. | | | |

| **Guidance for Study Deviation/ Non-Compliance Report Form** |
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| This report form should be submitted once Principal Investigator is aware of the non-compliance/ study deviation according to the reviewing IRB’s requirement. All sections must be completed. Principal Investigators are obliged to suspend their research immediately pending their report to the IRB if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the research participants.  Definitions  Study Deviation: is an unplanned excursion from the protocol that is not implemented or intended as a systematic change.   * A study deviation could be a limited prospective exception to the protocol (e.g. agreement between sponsor and investigator to enrol a single participant who does not meet all inclusion/ exclusion criteria). Like study amendments, deviations initiated by the investigator must be reviewed and approved by the IRB and the sponsor prior to implementation, unless the change is necessary to eliminate an immediate hazard to the participants. * Study deviation is also used to refer to any other, unplanned, instance(s) of study non-compliance. For example, situations in which the investigator failed to perform tests required by the protocol or failures on the part of the research participant(s) to complete scheduled visits as required by the protocol.   Non-Compliance: is a failure by an investigator or any study team member to abide by the policies and procedures of IRB or applicable regulations governing the protection of human subject research. Some examples of non-compliance include but are not limited to:   * Failure to obtain prior approval for research * Failure to obtain informed consent when required * Failure to use the latest IRB approved version of the protocol or consent form * Failure to report an adverse event report according to IRB timeline and procedure * Performance of research at an unapproved study site * Performing an unapproved research procedure * Failure to adhere to the approved protocol * Failure to submit study amendments for review and approval * Performance of a drug trial without a valid HSA Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC). * Any other failure to adhere to regulations, policies and procedures related to research |