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| **SANGATH INSTITUTIONAL REVIEW BOARD**  (Provisionally registered with the Department of Health Research, Govt. of India, EC/NEW/INST/2022/3063) |
| **Protocol Deviation and Violation Form** |

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| Title of the Project |  |
| Sangath IRB Reference number |  |
| Name of the Principal Investigator |  |
| Date of Application (DD/MM/YYYY) |  |
| Application type | ☐ Protocol Deviation  ☐ Protocol Violation  *Any divergence from an already approved protocol counts as a deviation. When such divergence (s) significantly affect the data or the safety of the participants, it is a protocol violation.* |
| Date/s on which the Deviation/Violation happened/may have happened |  |
| Deviation/Violation detected/identified by |  |
| Deviation/Violation detected/identified on (DD/MM/YYYY) |  |
| Description of Protocol deviation/Violation |  |
| Reason for Protocol deviation/Violation |  |
| Actual and potential impact on research participants due to deviation/Violation |  |
| Corrective measures taken and/or planned by the project team |  |