SANGATH INSTITUTIONAL REVIEW BOARD

**ANNUAL PROGRESS REPORT**

An annual progress report summarises details regarding the research activities conducted in the previous year of the approved research project, any amendments made to protocols and safety precautions taken.

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| **1. Details of study** | |
| **1.1 Project Title** |  |
| **1.2 Name of Principal Investigator** |  |
| **1.3 Sangath IRB reference number** |  |
| **1.4 Date of submission** |  |

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| **2. Study commencement and termination dates** | |
| 2.1 Has the study started? | Yes  No |
| 2.2 If yes, what was the start date? |  |
| 2.3 If no, what are the reasons for not commencing the study? |  |
| 2.3.1 What is the expected start date? |  |
| 2.4 Is the study complete? | Yes  No |
| 2.4.1 If no, what is the expected completion date?  (Note the requirement to submit an end of study report exists once the study is completed) |  |
| 2.4.2 If you do not expect the study to be completed, give reason(s) |  |
| 2.5 Progress period covered in the report |  |
| 2.6 What have been the main planned targets for this year that have been completed/achieved?  What planned targets could not be achieved? Why? |  |

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| **3. Study site information** | |
| 3.1 Total number of study sites proposed in the original application |  |
| 3.2 Name of the study sites (setting, location (e.g. city/village/country)) proposed in the original application |  |
| 3.3 Total number of study sites involved in recruitment to date |  |
| 3.4 Do you plan to increase the total number of sites proposed for the study?  3.4.1 If yes, please provide details and a justification | Yes  No |

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| **4. Recruitment of participants** | |
| **For intervention studies** | |
| 4.1 Number of participants recruited  4.1.1 Proposed in original application  4.1.2 Actual number recruited to date |  |
| 4.2 Number of participants entering the study |  |
| 4.3 Number of participants completing the study |  |
| 4.4 Number of treatment failures to date (prior to reaching primary outcome) due to adverse events |  |
| 4.5 Number of participants who withdrew from the study |  |
| 4.6 Reasons for withdrawal from the study (mention the number for each)   1. Withdrawal of consent 2. Loss to follow-up 3. Death |  |
| 4.7 Have there been any serious difficulties in recruiting participants? | Yes  No |
| 4.7.1 If yes, give details |  |
| 4.8 Do you plan to increase the number of participants to be recruited in the study? | Yes  No |
| 4.8.1 If yes, please provide details and justification |  |
| **For non-intervention studies** | |
| 4.9 Number of participants recruited (mention the number for each phase/method used in the study)  4.9.1 Proposed in original application  4.9.2 Actual number recruited to date |  |
| 4.10 Have there been any serious difficulties in recruiting participants? | Yes  No |
| 4.10.1 If yes, give details |  |
| 4.11 Do you plan to increase the number of participants to be recruited in the study? | Yes  No |
| 4.11.1 If yes, please provide details and justification |  |

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| **5. Safety reports** | |
| 5.1 Have there been any adverse events in this study?  Adverse event - Any untoward medical occurrence in a patient or participant involved in a study which does not necessarily have a causal relationship with the intervention. The adverse event can, therefore, be any unfavourable or unintended sign or experience, whether or not related to the investigation. | Yes  No |
| 5.2 Please mention the number and the nature of the adverse event, e.g., 1 participant had a nervous breakdown |  |
| 5.3 Have there been any Serious Adverse Events (SAEs) in this study?  An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage | Yes  No |
| 5.4 If yes, give details |  |
| 5.5 Have these SAEs been notified to the Board within 72 hours of the project team learning about it? | Yes  No |
| 5.6 If no, please coordinate with IRB urgently and provide reasons for late notification | |

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| **6. Amendments** | |
| 6.1 Have any substantial amendments been made to the study during the year? | Yes  No |
| 6.1.1 If yes, please give the following details:  a) Application date for each substantial amendment made  b) Summary of each substantial amendment made  C) Specify whether the amendments are approved by the IRB or are under review |  |

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| **7. Violations or serious breaches of the protocol or Good Clinical Practice or Protocol deviation** | |
| 7.1 Have any violations or serious breaches of the protocol or Good Clinical Practice occurred in relation to this study during the year? | Yes  No |
| 7.1.1 If yes, give details |  |
| 7.2 Have these been notified to the Board via the expedited report? | Yes  No |
| 7.2.1 If no, please coordinate with the IRB urgently and provide reasons for the late notification | |

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| **8. Other issues** | |
| 8.1 Are there any other developments in the study that you wish to report to the IRB? | Yes  No |
| 8.1.1 If yes, give details |  |
| 8.2 Are there any ethical issues on which further advice is required? | Yes  No |
| 8.2.1 If yes, give details |  |