SANGATH INSTITUTIONAL REVIEW BOARD

**APPLICATION FOR APPROVAL OF A RESEARCH PROJECT**

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| **1. Study details** |
| **1.1 Date of application** |  |
| **1.2 Version number** |  |
| **1.3 Project title** |  |
| **1.4 Lead Investigator** (name, professional designation, contact details) |  |
| **1.5 Other Investigators** (including Supervisors) (name, professional designation, contact details) |  |
| **1.6 Sangath-based Investigator** (name, professional designation, contact details) |  |
| **1.7 Sponsoring organisation** (name and address) |  |
| **1.8 Partnering organisations** (name and address) |  |
| **1.9 Permanent contact details for future correspondence** (email address, phone number, and organisational address) (if different from the Lead Investigator’s contact details) |  |

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| **1.10 Sangath-level approvals**  |
| **Have you received approval from the Sangath Managing Committee for the study?** | [ ]  Yes [ ]  No  |
| **Have you paid the IRB review fees?** | [ ]  Yes [ ]  No  |

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| **Section 2: Project details**  |
| * 1. **Lay description of the research study** (max. 300 words)
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| * 1. **Why is this research important?** (Describe the evidence base, scientific background and relevance to policy/practice) (max. 300 words)
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| **2.3 What are the specific aims of the research?** (max. 200 words) |
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| **2.4 Where will the research activities take place?** (List all sites) (max. 100 words) |
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| **2.5 Methodology** |
| **2.5.1 Study design** (max. 100 words) |
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| **2.5.2 Proposed duration of the study** (max. 50 words) |
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| **2.5.3 Participant groups** (List all the types of participant groups who will be engaged with in the research study) (max. 200 words) |
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| **2.5.4 What is the total number of participants that will be recruited in the study? What sample size calculations were done to determine the number of participants? What is the total duration of involvement with each of the participant groups?** (max. 200 words) |
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| **2.5.5 What are the participant inclusion and exclusion criteria for the study? Please provide justifications for the same.** (max. 300 words) |
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| **2.5.6 Study procedures** (Provide a detailed plan of the screening, recruitment, and follow-up procedures, including tools used for data collection and timeline) (max. 500 words) |
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| **2.5.7 What are the primary and secondary outcomes? What is the plan for data analysis?** (max. 400 words) |
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| **2.5.8 On completion of the planned research activities, are there any plans for long-term follow up? If yes, please specify.** (max. 200 words) |
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| **2.5.9 Will participants or the communities they belong to receive any debriefing and/or support after participating in the study? If yes, please specify.** (max. 200 words) |
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| **2.6 Dissemination plan** (What are the plans to disseminate the findings from the study? How will findings from the study be shared with participants/communities they belong to?)(max. 400 words) |
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| **3. Vulnerable populations**[*Vulnerability in research pertains to individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability, environmental burdens or social injustice, lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so.[[1]](#footnote-1)*] |
| **3.1 List all the vulnerable populations who will be engaged with in the proposed research study.** (max. 200 words) |
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| **3.2 What safeguards and provisions will be in place to protect their rights, wellbeing and welfare?** (max. 400 words) |
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| **4. Risks and benefits** |
| **4.1 What are the potential risks to the participants and/or the community?** (Consider social and emotional risks as well as more obvious physical risks).(max. 400 words) |
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| **4.2 What is the probability/likelihood and estimated magnitude of each risk?** (max. 200 words) |
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| **4.3 What provisions will be made to minimize each of the risks described above?** (max. 400 words) |
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| **4.4 Will there be any costs that participants may incur during the study?** (max. 300 words) |
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| **4.5 Will there be any reimbursement/ remuneration/incentive provided? If yes, specify the amount, method and justification.** (max. 300 words) |
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| **4.6 What are the potential benefits to participants and/or the community?** (max. 400 words) |
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| **4.7 If the intervention to be used in the study is not the medically-accepted ‘treatment of choice’ within the local context, explain why a novel intervention is being tested, and what arrangements will be made to switch participants over to the ‘treatment of choice’ if the experimental intervention is not effective.** (Applicable only to clinical trials) (max. 300 words) |
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| **5. Consent** |
| **5.1 How will consent/assent be obtained from participants?** (max. 300 words) |
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| **5.2 Will there be a written explanation of the study?** (max. 100 words) |
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| **5.3 How will risks and benefits be explained?** (max. 100 words) |
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| **5.4 How will it be made clear that participants are under no compulsion to participate and may withdraw at any time without jeopardizing any service delivery or their relationship with the researcher?** (max. 100 words) |
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| **5.5 How will you ensure that the participant has comprehended/understood the content of the informed consent documents?** (max. 100 words) |
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| **5.6 What data will be collected from those who refuse consent?** (max. 100 words) |
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| **5.7 What will be done if the participant is not able to provide consent?** (e.g. involving a legally accepted representative) (max. 100 words) |
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| **5.8 If in case the participant cannot provide consent for themselves (e.g. individuals living with severe mental illness or children), what plans do you have to include a Legally Acceptable Representative (LAR)[[2]](#footnote-2) in the consent process?***[A person who, under applicable law or judicial authority, can give consent on behalf of a prospective participant who, for either legal or medical reasons, is unable to give consent herself/himself to participate in research or to undergo a diagnostic, therapeutic or preventive procedure as per research protocol, duly approved by the ethics committee][[3]](#footnote-3)* |
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| **6. Privacy and confidentiality** |
| **6.1 How will the participants’ privacy be protected?** (max. 300 words) |
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| **6.2 What procedures will ensure the confidentiality of participants?** (max. 300 words) |
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| **6.3 Are there any limitations of these procedures? If yes, how will the limitations be explained to the participants?** (max. 300 words) |
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| **7. Safety and other controls** |
| **7.1 Does this study involve ionizing radiation, hazardous substances, or hazardous or invasive procedures (including radiological imaging, venipuncture, or intimate physical examination)? If yes, please specify.** (max. 300 words) |
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| **7.2 Describe the data and safety monitoring plan.** (max. 300 words) |
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| **8. Serious Adverse Events** |
| **8.1 What are the potential adverse events (AEs) and serious adverse events (SAEs)anticipated in this study?** (max. 300 words)*[Adverse event (AE): 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 product under investigation. Serious Adverse event (SAE): 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.][[4]](#footnote-4)* |
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| **8.2 What measures will be in place to handle any such events? How and to whom will you communicate information about these events? (max. 300 words)** |
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| **9. Data security** |
| 9.1 Who will be responsible for the security of data collected? (max. 300 words) |
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| **9.2 Name all the parties who will have access to the research data.** (max. 300 words) |
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| 9.3 How will the data be stored? Where will the data be stored? In what format will the data be stored? (max. 300 words) |
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| **10. Research Team** |
| **10.1 Investigators’ relevant research experience and skills** (max. 500 words) |
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| 10.2 Describe the Investigators’ experience of conducting research at the study location/s, familiarity with the local research context, and any existing partnerships which will aid the research study. (max. 300 words) |
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| **10.3 Describe the training and supervision plan for the study team (to ensure that they are adequately trained and supported in the study-related procedures and ethical considerations).** (max. 300 words) |
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| **10.4 If the applicant is an early career researcher or a student, please provide a detailed supervision plan** (max. 500 words) |
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| **10.5 Please describe any conflict of interest any of the Lead Investigators or the Research Team might have.** (max. 300 words) |
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| **11. Other details**  |
| **11.1 What is the source of funding for the proposed research? What is the status of the funding?** (max. 300 words) |
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| **11.2 Which approvals or permissions with collaborating institutions/governments, individuals, and other ethics committees are required? Which of these approvals or permissions are currently in place? What is the timeline for these approvals?** (max. 300 words) |
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| **12. Supporting documents** |
| **Reference list (for any research cited above)** | [ ]  Yes [ ]  No If no, please explain why  |
| **Information sheet** | [ ]  Yes [ ]  No If no, please explain why |
| **Consent/Assent forms**  | [ ]  Yes [ ]  No If no, please explain why  |
| **External approvals and permissions** | [ ]  Yes [ ]  No If no, please explain why |
| **Study tools (including questionnaires, interview guides)** | [ ]  Yes [ ]  No If no, please explain why |
| **CVs of Investigator Team** | [ ]  Yes [ ]  No If no, please explain why |
| **Project budget**  | [ ]  Yes [ ]  No If no, please explain why |
| **Covering letter (optional)** |  |
| **Other (please specify)** |  |

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| **12. SANGATH IRB SECRETARIAT USE ONLY** |
| **Review eligibility** |  |
| **Application number** |  |
| **IRB fees** |  |
| **Decision** |  |

1. National ethical guidelines for biomedical & health research involving human participants. New Delhi. Indian Council of Medical Research (ICMR);2017. [↑](#footnote-ref-1)
2. [↑](#footnote-ref-2)
3. National ethical guidelines for biomedical & health research involving human participants. New Delhi. Indian Council of Medical Research (ICMR);2017. [↑](#footnote-ref-3)
4. National ethical guidelines for biomedical & health research involving human participants. New Delhi. Indian Council of Medical Research (ICMR);2017. [↑](#footnote-ref-4)