Standard Operating Procedures (SOP)

Institutional Review Board

Sangath, India

Version number 17

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1. Objectives of the Standard Operating Procedures

1.1 The Standard Operating Procedures (which shall be referred to as 'SOPs' henceforth in this document) aim to define the procedures that the Sangath Institutional Review Board (IRB) shall follow in order to ensure quality, consistency and transparency in the ethics review and approval of research proposals and the monitoring of ongoing research at Sangath. These SOPs are based on ICMR's National Ethical Guidelines for Biomedical & Health Research involving Human Participants

2. Role and terms of reference of the Sangath Institutional Review Board (IRB)

2.1 The IRB shall review and monitor all types of research activity conducted in Sangath involving human participants to safeguard the rights, dignity, safety, welfare and well-being of all actual and potential research participants while ensuring the ethical conduct of research by the study team. This includes all types of studies (qualitative, quantitative, mixed methods, rigorous evaluations (including trials), etc.) conducted at Sangath that involve human research participants (or their data). These could be studies that are collaborative, investigator-initiated, sponsor-initiated, academic clinical trials, and government-funded studies primarily focused on psycho- social thematic areas.

2.2 The Sangath IRB shall be registered with the Department of Health Research, Ministry of Health & Family Welfare, Government of India, and the IRB shall strive to continue its registration with the DHR at all times.

2.3 The IRB shall formulate the SOPs in accordance with the ICMR Ethical Guidelines 2017 and will adhere to them at all times. The SOPs will be reviewed and revised periodically, and the latest version will be available for the Sangath team and in the public domain via Sangath's website.

2.4 The tenure of the constitution of IRB will be 3 years from the date of registration. The IRB will be reconstituted at the end of the third year. New Member Secretary, Chairperson, and other Members may be reconstituted with the IRB's renewal. The SOP will also be revisited at the end of the third year, though this will not be the only time SOPs are revised. SOPs will be revised periodically. Some occasions of SOP revision include– a new guideline/directive is issued by ICMR (or other competent authority) that has bearing upon conduct or ethics review of health research, or when IRB members feel a particular revision is necessary for IRB to perform its duties in the light of ICMR Ethical guidelines

2.5 The IRB shall take care to ensure that the 4 cardinal principles of research ethics viz. autonomy, beneficence, non–maleficence and justice, are explicitly considered during the planning, conduct, reporting, monitoring, and review of the proposed research.

2.6 The IRB shall consider all aspects of the informed consent process (e.g., clarity, risk- benefit ratio, justice, privacy, confidentiality, distribution of burden/benefit and provision for appropriate compensation) with the utmost detail wherever required. Particular attention to this process will be paid where there is the involvement of vulnerable groups or individuals – see table 2.1 for more details

2.7 All proposals shall be reviewed before the start of the study. After due ethical clearance from the IRB, the study shall be monitored periodically (the timeframe for which shall be decided and notified promptly, as required by individual protocols) throughout its

implementation and until after the completion of the study. The minimum requirement is for an annual periodic review; with a study report submitted at the end of one year of approval for the IRB to look at. The approval after the first submission will be for a period of one year only. The Principal Investigator (PI) will have to table his report for the IRB meeting before the one-year period is over so that he has continuous approval for the project. However, if he fails to do so he has to provide a written explanation to the IRB Chair, who has the authority to then provide an extension of the approval until he gets formal approval for the next year of operations. The IRB requires that periodic/ annual update reports and final report(s) be submitted during and after the completion of the project, respectively. 2.8 The IRB will review all the progress reports, final reports, and AE/SAE and give necessary suggestions (including compensation for research-related injury) to the project team to uphold the rights and well-being of research participants.

2.9 Site visits for monitoring purposes might be initiated at the discretion of the IRB. The IRB shall also aim to ensure compliance with all regulatory requirements, applicable guidelines, and laws.

2.10 The IRB shall be responsible for acting in the full interest of the research participants and concerned communities while considering the interests and needs of the researchers and in line with the requirements of relevant regulatory agencies and laws.

2.11 The IRB would support the development of research projects that are responsive to local healthcare requirements while also discouraging replicative studies.

2.12 The IRB shall participate in research ethics training activities to stay updated on relevant guidelines and regulations.

2.13 All significant revisions to the IRB Standard Operating Procedures (SOPs) shall require approval by a majority of IRB members and the IRB Chairperson. Approval by the IRB Chairperson alone shall suffice for minor or administrative revisions, which shall be appropriately documented and communicated.

Table 2.1: When research involves vulnerable populations/individuals

Vulnerable people are at an increased risk of being harmed or wronged due to their relative or absolute inability to protect their interests. The vulnerability may be due to biological, socio-economic or environmental factors, amongst others. Individuals within the following groups are considered vulnerable.

a. People who are marginalised due to their social or economic circumstances, e.g. people below the poverty line, people from marginalised caste (such as scheduled caste or backward castes), gender or sexual minorities (the LGBTQIA+ population), etc.
b. Children (below 18 years of age) and women in special situations, like pregnancy or lactation
c. People who are terminally ill or have a stigmatising illness (such as sexually transmitted diseases or skin diseases, etc.)
d. Individuals who are not able to make a voluntary and informed decision for themselves due to compromised autonomy—whether temporarily or permanently, such as those who are unconscious or those with severe mental illness — or who may be unduly affected by the anticipation of benefits or fear of retribution, which could pressure them into giving consent.
e. People in institutionalised setups or at a power-compromised position in a hierarchy - e.g. students, prisoners, employees at an institute, etc.

Since the vulnerable population is at increased risk of being harmed/wronged, it is the responsibility of the IRB to oversee that all the additional safeguards are in place to ensure the safety, well-being and rights of vulnerable research participants at all times.

Before the review meeting, these include:

- An initial review of all submitted protocols by the Member Secretaries to ensure that all studies that involve vulnerable groups of people go for a full board review (including their continued review).
- The Chairperson will ensure that submissions involving vulnerable populations undergo a thorough and appropriate level of ethical review.
- Initial submissions and amendments that introduce more than minimal risk, alter the risk–benefit profile, or significantly affect participant protections shall be reviewed by the full board. Low-risk or administrative amendments may be reviewed by the Chairperson or through expedited review and shall be appropriately documented in IRB records. Such amendments need not be routinely reported to the full board but may be included in periodic summaries or presented information as deemed appropriate.

During the IRB review, the board will ensure:

- that the inclusion of the vulnerable group is adequately justified and that robust mechanisms to obtain and document informed consent, protect and uphold privacy and confidentiality at all times.
- that all measures to minimise the risks and maximise the benefits to the research population are in place.
- that recruitment strategies are adequate and do not pose any risk/harm to the communities/individual, to suggest additional safeguards, such as more frequent monitoring, including site visits, community consultation and using participatory approaches where possible, so that when potential participants cannot consent, a LAR should be involved in decision-making
- At no time should information that is unnecessary or hurtful be acquired from research participants

Additionally,

- It is desirable to have empowered representatives from the specific populations during IRB deliberations.
- Research that involves people with mental illness (such as depression) must have well- defined plans and referral pathways of support and care in case of any adverse events.
- The research design, consenting methods, consent documents, recruitment, and other study activities should ensure that participants are free from undue influence or coercion, such as fear of authority or an exaggeration of benefits.
- Ensure that COI at all levels do not increase harm or lessen benefits to the participants
- In case of research involving minors, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.
- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded. For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR in line with the ICMR Ethical Guidelines 2017

3. Authority under which the IRB is constituted

3.1 "The Chairperson of Sangath" is the appellate authority for the constitution of the Institutional Review Board. She will be responsible for the appointment of Sangath IRB Members in consultation with the Chairperson of the Institutional Review Board as

recommended by the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017.

4. Composition and Membership requirements of Sangath IRB

4.1 The IRB shall be interdisciplinary and multi-sectoral in composition.

4.2 IRB members should not have any known record of misconduct.

4.3 There should be adequate representation of age and gender.

4.4 Preferably, 50% of the members should be non-affiliated or from outside the institution.

4.5 The IRB shall consist of 7-10 members. A minimum of 5 persons shall be required to constitute a quorum without which the holdings and businesses of the IRB shall stand adjourned until such a number is available to conduct the same. It may be noted that the meeting could be either face-to-face and/or as a teleconference and would include the PIs of the proposed proposal.

4.6 The Chairperson of the IRB shall be from outside the Institution (Sangath).

4.7 Other Members shall be a blend of medical / non-medical, scientific and non-scientific persons, including at least one layperson representing the community to reflect different viewpoints.

4.8 The Member Secretary shall be from Sangath and shall coordinate the secretariat of the IRB in all its business.

4.9 Guided by the ICMR guidelines, the composition of the IRB shall thus be as follows:

A. Chairperson from outside Sangath.
B. Member Secretary from Sangath.
C. At least 4 Members from different specialities/disciplines as specified below:
    a. Health scientists / Researchers/Scientific Members
    b. Clinicians / Health practitioners
    c. Legal expert
    d. Social scientist / Philosopher/ Writer /Priest/Bioethicist
    e. Lay person (Representative of the community)

Member and Membership requirements	Responsibilities
A) Chairperson from outside Sangath. Must be external/outside of Sangath and must have prior experience working with an EC/IRB	• Conduct IRB meetings and take accountability for the independence and efficient functioning of the IRB. • Ensure active participation of all members (especially non-affiliated and non-technical) in all discussions and deliberations · Ratify minutes of IRB meetings • Ensure COI declaration from conflicted members and ensure quorum and fair decision-making • Attend to grievances and complaints against researchers, IRB members, conflict of interest issues, etc. • When the chairperson is absent, an acting Chairperson should be nominated by the Chairperson or elected by the members present during the meeting.

	• The Acting Chairperson should be a non-affiliated person
B) Member Secretary from Sangath Must be an employee of Sangath with knowledge and experience in human research (including clinical research) and ethics. Must have excellent communication skills and be motivated to take up the job as a member secretary	• Coordinate an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review • Schedule IRB meetings, and prepare the agenda and minutes • Organise IRB documentation, communication and archival • Ensure training of the IRB secretariat and IRB members • Ensure the update of SOPs as and when required • Ensure an overall adherence of IRB functioning to the SOPs • Prepare for and respond to audits and inspections • Examine the need for expedited review/exemption from review or full review.
C) At least 4 Members from different specialities/disciplines as specified below: a) Health scientists / Researchers/Scientific Members	• Scientific and ethics review focusing on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
b) Clinicians / Health practitioners Can be affiliated or non- affiliated to the institute. Can be a non-medical or medical person with qualifications in basic medical sciences	• Scientific review of protocols, including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) • Review referral pathways, medical care, facility and appropriateness of the principal investigator, provision for medical care, management and compensation. • Detailed review of the protocol, the investigator's brochure (where applicable) and other protocol details and submitted documents
c) Legal expert · Can be affiliated or non- affiliated to the institute. Must have a basic degree in Law from a recognised university, with experience	• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol-specific other permissions, such as HMSC for international collaboration, compliance with guidelines, etc. • Interpret and update IRB members about new regulations, if any
d) Social scientist / Philosopher/ Writer /Priest/Bioethicist Can be affiliated or non- affiliated to the institute Must be an individual with social/ behavioural science/philosophy /ethics and training and/or expertise, and be sensitive to local cultural and moral values	• Ethical review of the proposal, ICD, along with the translations. • Assess the impact on community involvement, socio-cultural context, religious or philosophical context, if any. • Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

e) Layperson (Representative of the community) Must be a non-affiliated of the institute. Must be someone who is literate and has not pursued a career in medicine or health sciences in the last five years. Must be someone who understands the local culture, language and values.	• Ethical review of the proposal, ICD, along with translation(s). • Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. • Serve as a patient/participant/ community representative and bring in ethical and societal concerns. • Assess societal aspects, if any.

4.10 All members will be selected based on their capabilities, interests, experience, training, and willingness to commit to their role.

4.11 Only the Chairperson and the Member Secretary can have a dual role (e.g. legal expert and chairperson or clinician and member secretary).

5. Roles and responsibilities of Sangath IRB Members and terms of membership

5.1 "The Chairperson of Sangath" is the appellate authority for the constitution of the Institutional Review Board. She will be responsible for the appointment of Sangath IRB Members, including the chairperson of the Sangath IRB. All other members will be appointed in consultation with the Chairperson of the Institutional Review Board as recommended by the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017.

5.2 The tenure of membership of individual members will be for a period of 3 years from the date of appointment. The appointment may be renewed by the appellate authority for up to 2 consecutive terms.

5.3 Members of the Institutional Review Board are appointed upon confirmation of willingness to serve communicated by email. The roles and responsibilities of members, as specified in the latest approved version of the Institutional Review Board Standard Operating Procedures, apply upon appointment.

5.4 All Sangath IRB Members shall be required to review research proposals, participate in meetings and business of the IRB, and monitor any ongoing research.

5.5 Members must also be committed and understand the need for research and for imparting protection to research participants.

5.6 All Sangath IRB Members shall commit to spending a minimum of 90 minutes per month on meetings for ethical review and additional time needed for reviewing proposals and visiting projects. All Sangath IRB Members shall be required to read all protocols sent to them and participate in the discussion during the meeting for ethical review to ensure that they conform to the guidelines used by the IRB. The only exception is for any Member with a conflict of interest with a particular proposal, as noted below.

5.7 Every IRB member is expected to share his updated CV, Training certificate in GCP, human research participants and ICMR Ethical Guidelines 2017.

5.8 The member secretary and the alternate member secretary will be equipped with all their responsibilities, including documentation and filing procedures, under the confidentiality agreement.

5.9 All Sangath IRB Members shall be expected to allocate the required time for meetings as per the agreed annual calendar of the meetings. If, for some unavoidable reasons, a Member is not able to attend the meeting, he/she should give prior intimation to the Member Secretary at the earliest so as to make arrangements for his/her substitution if required. Sangath IRB Members ideally should attend at least four out of the twelve meetings (i.e. 1/4th of all meetings) in the year.

5.10 At the end of the stipulated 3 years, as the case may be, the Board shall be reconstituted, and new Members shall replace Members who wish to discontinue or need to be replaced. New members should regularly be invited to join the IRB so that there are enough Members to replace those who have to step down, while also ensuring adequate representation of age.

5.11 A Sangath Member can be replaced in the event of death, resignation, long-term non-availability, inability to attend/ participate in even one meeting during the year, or if his/her actions are not commensurate with the responsibilities of the IRB membership as judged by a 2/3rd majority of the IRB Members.

5.12 To resign, a Sangath IRB Member can send a formal request to the IRB Chairperson. For the removal or replacement of a member, a formal email will be sent by the IRB secretariat to the concerned Member after the decision is approved by 2/3rd of the Sangath IRB Members. An opportunity will be provided to the concerned Member to share any grievance or appeal against the decision, which will be further reviewed by the Sangath IRB members. The decision will be taken based on the view of the majority of Members. On occasions, where the views are divided, the final decision will be made by the Chairperson.

5.13 All Sangath IRB Members must maintain absolute confidentiality of all discussions during the meeting and sign a confidentiality form at the time of joining of IRB. The Members should not discuss matters related to IRB deliberations with anyone other than other IRB Members. All personal copies of documents and emails related to the proposal should be destroyed immediately.

5.14 Conflict of interest(s) (CoI), if any, should be declared by Sangath IRB Members. As a rule, any Member who is directly associated with a research proposal must recuse themselves from discussions and decisions related to that particular protocol. An example of a conflict of interest would be when a Sangath IRB Member is also the PI/research team Member of the study in which the proposal is being considered by the IRB. All CoIs are declared to the IRB Chairperson, and are recorded in the minutes.

5.15 Every member must understand and abide by the confidentiality and CoI mitigation strategies of Sangath IRB. They must sign a CoI declaration and confidentiality agreement while joining the IRB.

5.16 Member must be willing to place her/his full name, profession and affiliation to the EC in the public domain; and be committed and understanding to the need for research and for imparting protection to research participants.

6. Quorum requirements

6.1 Quorum refers to the minimum number and/or kind of IRB Members required for decision-making during a meeting.

6.2 A minimum of 5 Members is required to compose a quorum.

6.3 Quorum should include both technical (experienced mental health professionals in research or clinical settings) and non-technical members.

6.4 A minimum of one non-affiliated Member, i.e. external Member, and preferably one layperson, should be part of the quorum.

6.5 No IRB decision will be considered valid without the fulfilment of the quorum.

6.6 All decisions should ideally be taken in meetings except in cases of expedited review required in special circumstances (see point 13).

7. Offices

7.1 All meetings of the IRB will be conducted in the presence of a chairperson. In the absence of the Chairperson, an alternate Chairperson shall be elected by the Sangath IRB Members present, who shall conduct the meeting.

7.2 The Member Secretary

The Member Secretary will be appointed by the Chairperson of Sangath in consultation with the IRB Chairperson. The Sangath IRB Members, the Executive Committee of Sangath and the Managing Committee of Sangath have to approve the appointment of the Member Secretary.

The Member Secretary-

a. Is responsible for issuing notices and organizing the meetings, maintaining the records and communicating with all those concerned including the PI and the research team.
b. Will assess the need for an expedited review for every submission and request.
c. Shall maintain a copy of the minutes/proceedings of the meetings prepared after approval by the Chairperson, before communicating the same to the researchers.
d. He/she/they shall issue decision notices to the research team whose project(s) has/have been reviewed after obtaining approval from the Chairperson within 2 weeks of the IRB meeting.

7.3 All Institutional Review Board records shall be maintained by the Member Secretary for a minimum period of three (3) years from the date of completion or termination of the project, or longer if required by applicable regulations, sponsor requirements, or institutional policy.

8. Independent consultants

8.1 The IRB may call upon such subject experts as independent consultants who may add or provide valuable opinions of selected research protocols, if need be. This includes experts from scientific or legal backgrounds and/or representatives of communities, e.g. transgender people or patient groups. They are required to give their specialised views, but do not take part in the decision-making process of the IRB.

9. Application Procedures

9.1 All proposals should be submitted in the prescribed application form, the details of which are given under Documentation (point 10).

9.2 All relevant documents should be provided along with the application form.

9.3 The application form in the prescribed format, along with all relevant documents, shall be electronically submitted to the IRB Secretary by the prescribed submission date by the Principal Investigator (PI) (and Co-investigators/Collaborators, where appropriate). The application should include dates and records of all relevant permissions including that of the Sangath Executive Council. All meeting dates will be announced to Sangath investigators in advance.

9.4 The date of the IRB meeting shall be intimated to the researcher/PI. On that day, the PI or person designated by the PI will have to make an oral presentation to the IRB over Zoom and take questions for clarification. He/she/they will then leave the room while the proposal is being discussed by the IRB.

9.5 The prescribed fees that need to be remitted along with the application are as follows:

a. Standard review fee for initial submission of a research project: ₹59000/- (inclusive of GST). Expedited review of an initial submission of a research project: ₹70800/- (inclusive of GST). Student applications (includes PhD students and student fellowships): ₹17700/- (inclusive of GST)
b. Initial review of a sub-study: ₹17700/- (inclusive of GST)
c. Continuation of review fee (to be paid at the time of submitting an annual report): ₹11800 (inclusive of GST). Note: this fee does not apply to continued review of sub-studies.

The fees should be ideally paid before the meeting date or at the latest within 2 weeks of securing project funds.

9.6 It will be the prerogative of the IRB to revise these figures as deemed fit, which would then have to be approved by the Sangath MC. It will also be a prerogative of the IRB to waive any fee upon request from the PI. Fee waiver requests can be made directly to the IRB with appropriate justifications, and it will be the prerogative of the IRB to make a decision on these requests.

9.7 The decision of the IRB shall be communicated in writing to the PI/researcher. If any revision is to be made in the proposal, the revised document should be submitted electronically within a stipulated period of time as specified in the communication or before the next meeting.

10. Documentation

10.1 For a thorough and complete review, all research proposals should be submitted with the following documents:

a. Name of the applicant with the designation.
b. Name of the Institute/ Hospital / Field area where the proposed research is to be conducted. Detailed protocol of the proposed research.
c. Ethical issues in the study and plans to address these issues.

d. Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow - up cards, etc.
e. Informed consent process, including patient information sheet and informed consent form/ assent in local language(s).
f. Curriculum vitae of all the investigators with relevant publications in the last five years.
g. Any regulatory clearances required.
h. Sponsor(s) and source(s) of funding; Other financial issues, including those related to insurance.
i. An agreement to report Serious Adverse Events (SAE) to the IRB.
j. Statement of conflict(s) of interest, if any.
k. Agreement to comply with the relevant national and applicable international guidelines, as applicable.
l. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study- related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions(e.g. those leading to a negative decision or modified protocol) by other ethics Boards or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an update of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.
m. Plans for publication and dissemination of results, positive or negative, while maintaining the privacy and confidentiality of the study participants.
n. Any other information relevant to the study.
o. The Institutional Review Board recognises that, in certain circumstances, an ethics review or approval may be required at an early stage of project development when participant information sheets and consent documents are not yet finalised. Such situations may arise due to funder requirements or the need to seek advisory or community input to inform the preparation of consent materials. In such cases, the IRB may accept a submission without consent documents, provided the reviewing committee is satisfied with the justification and the proposed plan for developing these materials. Final participant information and consent documents must be submitted to the IRB for review and approval prior to the initiation of any participant recruitment or research activities.

11. Review procedures

11.1 The meeting of the Institutional Review Board shall be held once per month. Additional meetings may be convened as required, subject to member availability and the availability of adequate time to ensure a thorough and meaningful review of submissions.

11.2 The proposals shall be sent to the Sangath IRB Members at least 10 days in advance of the scheduled IRB meeting.

11.3 Researcher/PI should make an oral presentation to the IRB and take questions for clarification. There should be no discrepancies between the submitted protocol (Word document/hard copy) and the oral presentations made to the IRB.

11.4 Researchers shall be invited by the member secretary to offer clarifications, if need be, at a later date.

11.5 Independent consultants/Experts shall be invited to offer their opinion on specific research proposals if and when needed.

11.6 Decisions shall be taken by consensus after discussions.

11.7 The decisions shall be recorded and approved by Sangath IRB Members present at the meeting, and the Chairperson will provide the approval in writing.

12. Element(s) of review

The following are the various elements which will be examined by the Sangath IRB Members while reviewing the research proposal:

12. 1 Scientific design and conduct of the study.

12.2 Approval of appropriate scientific review/regulatory boards.

12.3 Examination of predictable risks/harms.

12.4 Examination of potential benefits.

12.5 Procedure for selection of participants, including identifying/ recruiting, inclusion/ exclusion/ withdrawal criteria and other issues like advertisement details. Criteria for withdrawal of patients, suspending or terminating the study.

12.6 Proposed Management of research-related injuries, any adverse events and/or serious adverse events.

12.7 Compensation provisions.

12.8 Patient information sheet and informed consent forms in local language(s).

12.9 Protection of privacy and provision of confidentiality.

12.10 Involvement of the community, when and where necessary.

12.11 Plans for data analysis and reporting, along with safety and quality assurance report(s).

12.12 Competence of investigators, research and supporting staff.

12.13 Facilities and infrastructure of study sites.

12.14 Data storage and safety.

In case of Clinical trials:

12.15 Justification for placebo in control arm, if any.

12.16 Availability of products after the study (post-trial access), if applicable.

12.17 Adherence to all regulatory requirements and applicable guidelines.

13. Expedited review

13.1 For all the submitted protocols, the Member Secretary of the IRB will take a call whether it should go for an expedited review or a full IRB review. This decision shall be based on the actual and potential risks associated with the proposed study.

13.2 In exceptional circumstances, if an application requires urgent review and IRB approval (e.g. an urgent call for a proposal which cannot wait for the next quarterly meeting), in such cases, an expedited review may also be taken up after consideration of the circumstances by the Chairperson and the Member Secretary. The concerned PI should approach the Chairperson through the Member Secretary in writing and should be able to explain and convince the Chairperson of the need for an expedited review. A sub-committee, convened by the Chairperson, shall review time-sensitive proposals and make an interim decision. Study materials shall be circulated to sub-committee members at least five calendar days before review, unless an exceptional urgent situation warrants a shorter timeline as determined by the Chairperson. The sub-committee shall comprise at least three members, including one technical member, one non-technical member, and the Member Secretary. Any approval granted shall be provisional and subject to ratification at the subsequent full IRB meeting.

13.3 Expedited reviews are considered acceptable in minimal risk studies where minimal risk is defined as "Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely." (ICMR Ethical Guidelines 2017).

14. Decision-making procedures

14.1 Sangath IRB Members shall discuss the various ethical and scientific issues before arriving at a consensus.

14.2 A Sangath IRB Member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises, and this should be indicated to the Chairperson before the review of the application and recorded in the Minutes.

14.3 Decisions shall be made only in meetings when a quorum is complete (except expedited review)

14.4 Only Sangath IRB Members can make decision(s). The expert consultants shall only offer their opinions.

14.5 Decision(s) may be to: a) approve; b) reject; or c) provisional acceptance, subject to receipt and satisfactory review of further information and/or modifications.

14.6 In cases of conditional decisions, clear suggestions for revision and the procedures for having the application re-reviewed, if deemed necessary, should be specified.

14.7 Modified or amended proposals, particularly those involving low or no additional risk, may be reviewed through an expedited review process. Such reviews may be conducted by the Member Secretary under the guidance and delegated authority of the Chairperson, who may invite one or more IRB members to examine the revised application. Where the IRB's earlier recommendations have been satisfactorily addressed, approval may be granted accordingly. Further details regarding expedited review procedures are outlined in SOP Section 13.2.

15. Communication within the IRB and those concerned herewith

15.1 Decision(s) taken by the IRB shall be duly communicated by the Member Secretary in writing to all Sangath IRB Members and those concerned directly/ indirectly with such decisions.

15.2 Suggestion(s) for modifications in the proposal/ protocol, if any, should be duly communicated to the researcher by the IRB.

15.3 Reason(s) for rejection of the proposal/ protocol should be duly informed to the researcher(s) with reasons for the same.

15.4 The schedule/ plan of ongoing review by the IRB should be communicated to the Principal Investigator (PI).

16. Appeal procedures

16.1 This procedure is designed to deal with the following two situations:

16.2 Where the IRB has rejected an application for ethics approval (for reasons other than the application being incomplete), and the researcher applicant wishes to appeal.

16.3 Where the IRB has approved an application for ethics approval, subject to some changes being made, and the Researcher disagrees with the proposed changes. In this case, before making a formal appeal, the Researcher should initially confer with the Chairperson through the Member Secretary to clarify the reasoning of the IRB. The researcher is entitled to appeal if not satisfied after this consultation, following the steps below.

16.4 If the Researcher wishes to appeal to a decision made as part of the approval process, s/he must notify the Chairperson of the IRB through the Member Secretary. This appeal must be in writing and sent via post or email within two weeks of being notified of that decision.

16.5 The Chairperson of the IRB can appoint a committee/panel independent of the IRB who will then review the application and give recommendations to the IRB.

16.6 The panel membership shall be at the discretion of the Sangath IRB Chairperson.

16.7 Once the panel has reached its decision, the Chairperson can give the panel's recommendations to the IRB, and based on the recommendations, the IRB can make an amended decision. This decision shall be final and cannot be appealed against.

17. Follow-up procedures

17.1 All ongoing studies must submit an Annual Progress Report to the IRB before expiry of the current ethics approval (original or latest continuing review), in accordance with ICMR Ethical Guidelines (2017).

17.2 A Final Report must be submitted to the IRB upon study completion and before expiry of the current ethics approval (original or continuing review), in accordance with ICMR Ethical Guidelines (2017).

17.3 All SAEs (Serious Adverse Events) should be reported to the IRB via email to irb@sangath.in within 24 hours of knowledge. The intimation should be in the format of the IRB SAE reporting form (initial report). A report on how the SAE was related (or not related) to the research and the action/interventions undertaken by the project team must be submitted within 14 days. This report should also be in the format of the IRB SAE reporting form (final report). In case of a delay in reporting the SAE by the researcher/research team member, prompt and appropriate action against the researcher can be initiated by the IRB. The IRB has the authority to even suspend/ terminate the project. The decision of the IRB shall be final.

17.4 Non-serious adverse events (AEs), such as transient anxiety experienced during an interview, need not be reported to the IRB within 24 hours. However, the research team and the Principal Investigator (PI) shall exercise due caution and manage such AEs in accordance with the approved protocol. All AEs must be documented and reported to the IRB as part of the annual progress report, or in the end-of-study report for projects of less than one year's duration.

17.5 Any divergence from the 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. All protocol divergence(s), if any, should be promptly reported with adequate justifications for the same to the IRB. The IRB Chairperson, in consultation with other IRB members, can decide if fresh approval is indicated. Any major divergence (such as a change in design, target sample, or inclusion of a new intervention component) may require resubmission for fresh approval.

17.6 Minor amendment(s) to the protocol (language-related changes in consent document or change in number of participants for qualitative study) do not need fresh approval from the IRB, more so when the study does not involve a vulnerable group. The Chairperson and the Member Secretary can give the necessary permission for the inclusion of the change to the original protocol.

17.7 Premature termination/ suspension of the study should be duly notified with appropriate justifications along with the summary of the data obtained so far.

17.8 For any change of investigator(s) / site(s)/ sponsor(s) / funding(s) / inclusion criteria / other aspects of research design and methodology, an amendment application should be submitted to the IRB. For minor amendments, clause 17.5 will be applicable.

17.9 The IRB has the discretion to arrange a site visit for monitoring purposes. This might be appropriate where the studies carried out at the site involve significant risk to participants, the site is unfamiliar, and a visit is considered essential to gain an understanding of the context in which the research will be undertaken and assess the suitability of the staff and facilities. It may be helpful to arrange occasional visits to maintain the IRB's knowledge of the site, facilities, key personnel, and operating procedures. The frequency of visits is at the discretion of the IRB. As a guideline, annual visits may be appropriate. It is for the IRB to determine which Members should be involved.

18. Record keeping and Archiving

18.1 The IRB shall be required to maintain the following records for a period of at least 5 years (or as the quorum deems it necessary). The Member Secretary shall be responsible for the same.

18.2 Curriculum Vitae (CV) of all Sangath IRB Members.

18.3 Copy of all study protocols with enclosed documents, progress reports, reports on SAEs, protocol deviations and any further documents/reports that the IRB may require the researcher to provide.

18.4 Each application will be provided with a unique ID number which will be maintained for all documents related to that particular project/ application. (Example of an id: VP_2011_01 is the initial alphabet of First and Last Name of the PI _Year of submission of application_ serial

number of the application received in that year). All documents related to a particular project will be saved as a soft copy in a designated folder on the Sangath server. The folder will be password-protected and accessible only to the Sangath IRB Members. (All hard copies will be kept under lock and key).

18.5 Minutes of all meetings duly signed by the Chairperson of the IRB. The minutes of the meetings shall be noted down by the Administrative Secretary and consequently typed. The Member Secretary shall maintain the typed minutes prepared by the Administrative Secretary.

18.6 A copy of all existing relevant national and international guidelines/updates/amendments on research ethics and laws amendments.

18.7 A copy of written communication with Members, researchers and regulatory bodies.

18.8 Annual and final report(s) of all the approved projects.

18.9 Academic outputs/manuscripts from the approved study must acknowledge the ethics approval of Sangath IRB.

19. Professional development of Sangath IRB Members

19.1 The institute and the IRB secretariat, guided by the Chairperson, will strive to ensure that all IRB members receive appropriate training in human research protection, ethics committee functions, and standard operating procedures. Members are expected to be familiar with ethics principles, Good Clinical Practice (GCP) guidelines, Regulations and guidelines for the conduct of clinical trials in India (e.g. NDCT Rules 2019 and ICMR Ethical Guidelines 2017).

19.2 Any new Member who would join the IRB should provide training certificates in GCP and ICMR Ethical Guidelines 2017. Existing Members should also renew their ethics training upon the expiration of their training certificates. All training will be documented.

19.3 Any relevant updates/ guidelines in the processes of the IRB shall be brought to the immediate attention of all Members.

19.4 Members shall be encouraged to attend national and international training programs in research ethics to maintain quality in ethical review by being updated with the latest developments in this milieu.

19.5 A portion of the IRB budget should be allocated specifically for the ethics training of all its members, either through live workshops (in-person or virtual) or through online courses every year.

20. Remuneration to Sangath IRB Members

20.1 The sitting fees for Sangath IRB Members will be as follows:

- INR 3000 per (routine) IRB meeting.
- INR 2000 for every expedited review meeting.

21. Review of external (Non-Sangath) proposals

The Sangath IRB shall not review research proposals that are entirely external, including those submitted by external individuals or other institutions, and that do not involve Sangath in any capacity. Exceptionally, and under rare circumstances, the IRB may consider reviewing a

proposal (e.g. where the Principal Investigator is a current Sangath IRB member and the proposal forms part of their registered PhD research), provided that such an exception is agreed upon by the IRB Chairperson and approved by a majority of IRB members. In all such cases, the rationale for invoking this exception shall be formally documented in the IRB records.

CONTACT DETAILS

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