Standard Operating Procedures (SOP)

Institutional Review Board
Sangath, India

Version number 12

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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[1]

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 proposals conducted in Sangath involving human participants to safeguard the rights, dignity, safety and welfare and well-being of all actual and potential research participants while ensuring the ethical conduct of research by the study team.

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 for 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 IRB's renewal. The SOP will also be revisited at the end of the third year, though this will not be the only time of SOPs revision. 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.

[1] Indian Council of Medical Research. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. New Delhi: ICMR; 2017.

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 The IRB will review all studies conducted by Sangath that involve human research participants. The types of studies conducted at Sangath are investigator-initiated studies or student fellowships/projects in psychological and social behaviour sciences.

2.8 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 the 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.

2.9 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.

2.10 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.

2.11 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.

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

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

2.14 The fee for all proposals, the IRB fee, would be ₹20000/. A fee waiver would be granted for projects that have a limited budget. A fee waiver may also be granted when

a request for the same is received from the project team after the review of the waiver request by IRB members.

Table 2.1

- 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. Some examples of vulnerable groups include

- Some vulnerable groups include - pregnant women, children, people with disabilities, refugees, and people who have been institutionalised, e.g., prisoners.

- The IRB is critical in identifying whether the proposed research involves any vulnerable participants and, if so, ensuring their safety and well-being are protected. The IRB can do this by
    - Assessing that the inclusion criteria to include vulnerable populations is justified
    - Ensure that all measure to minimise the risks and maximise the benefits to the research population is in place
    - Ensure that all proposed research that involves vulnerable populations undergoes full committee review only (including the continued review of proposals)
    - Add additional measures, such as more frequent monitoring of the study

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 requirement of Sangath IRB

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

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

4.3 The IRB shall consist of 7-10 members.

4.4 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.

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

4.6 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.

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

4.8 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) Ensuring adequate representation of gender and age

d) At least 4 Members from different specialities/disciplines as specified below:

i) Health scientists / Researchers/Scientific Members
ii) Clinicians / Health practitioners
iii) Legal expert
iv) Social scientist / Philosopher/ Writer /Priest/Bioethicist
v) Lay person (Representative of the community)

Member	**Membership requirement**
a) Chairperson from outside Sangath.	• Must be external/outside of Sangath and must have prior experience working with an EC/IRB
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.
d) At least 4 Members from different specialities/disciplines as specified	• Can be affiliated or non-affiliated to the institute

below: i) Health scientists / Researchers/Scientific Members	• Can be a Non-medical or medical person with qualifications in basic medical sciences
ii) Clinicians / Health practitioners	• Can be affiliated or non-affiliated to the institute • Must be an individual with a recognised medical qualification (e.g. MBBS) with expertise and training in clinical sciences
iii) Legal expert	• Can be affiliated or non-affiliated to the institute • Must have a basic degree in Law from a recognized university, with experience
iv) 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.
v) Lay person (Representative of the community)	• Must be a non-affiliated to 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.

4.9 At least half of the IRB Members will be non-affiliated to Sangath (i.e. not employed by Sangath) and at least half of the quorum would be constituted by non-Sangath Members.

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 The appointment letter issued by the Chairperson will specify the - Role and responsibility of the member in the committee, Duration of appointment and Conditions of appointment, amongst other things.

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

5.5 Members must also be committed and understanding to 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 ones that 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.

5.17 All members who sit in an IRB meeting will be given an honorarium of 2000 INR after the meeting from the IRB budget.

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 are required to compose a quorum.

6.3 Quorum should include psychiatry/psychology and non-psychiatry/psychology professionals (i.e. technical 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 fulfilment of the quorum.

6.6 All decisions should ideally be taken in meetings except in case 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. 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.

d)Regarding receiving annual reports, clarifications, etc.??
e)communications and actions related to various renewals, etc..

7.3 All IRB records will be maintained by the Member Secretary for a period of 5 years from the date of the end of the project.

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 specialized 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 and duly signed by the Principal Investigator (PI) (and Co-investigators/ Collaborators, where appropriate) along with all relevant documents should be electronically submitted to the IRB Secretary at least 2 weeks before the date of the IRB meeting. The application should include dates and records of all relevant permissions including that of the Sangath Managing Committee (MC). All meeting dates will be announced to Sangath investigators at least 15 days in

advance. There can be a late submission fee or a letter asking for a provision.

9.4 The date of the IRB meeting shall be intimated to the researcher/PI. On that day, the PI or person designated by PI will have to make an oral presentation to the IRB and take questions for clarifications. Presentations over Skype or oral presentations through conference mode are also acceptable. He/she 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) Internal (Sangath) proposals: ₹20000/-
b) External (Non-Sangath) proposals: ₹25000/-
c) Expedited (Internal or external) proposals: ₹35000/-
d) Student applications: ₹15000/-

The fees should be ideally paid before the meeting date or latest within 2 weeks of receiving the decision of the IRB.

9.6 It will be the prerogative of the IRB to revise these figures (including requests for fee waiver for any submission) 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 which would then have to be approved by the Sangath MC.

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.
c) Detailed protocol of the proposed research.
d) Ethical issues in the study and plans to address these issues.
e) Proposal should be submitted with all relevant enclosures like proforma,

case report forms, questionnaires, follow - up cards, etc.

f) Informed consent process, including patient information sheet and informed consent form/ assent in local language(s).

g) Curriculum vitae of all the investigators with relevant publications in the last five years.

h) Any regulatory clearances required.

i) Sponsor(s) and source(s) of funding;

j) Other financial issues including those related to insurance.

k) An agreement to report Serious Adverse Events (SAE) to IRB.

l) Statement of conflict(s) of interest, if any.

m) Agreement to comply with the relevant national and applicable international guidelines, as applicable.

n) 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.

o) Plans for publication and dissemination of results-positive or negative- while maintaining the privacy and confidentiality of the study participants.

p) Any other information relevant to the study.

11. Review procedures

11.1 The meeting of the IRB shall be held once per month and any additional meetings may be held if and when required. Such additional meetings will be convened by the Chairperson of Sangath in consultation with the Chair of the IRB.

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 clarifications. 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.

11.8 All Sangath IRB Members, including those who were not present at the meeting, will be informed of the decision via email.

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:

12.14 Justification for placebo in control arm, if any.

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

12.16 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 the need for an expedited review. A sub-committee will then be convened by the Chairperson to review the proposal and make a decision. Approval given in such situations will be provisional and subject to ratification at the next full IRB meeting. 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 prior to the review of the application and recorded in the Minutes.

14.3 Decisions shall be made only in meetings when quorum is complete.

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) conditional acceptance subject to receipt of further information/modifications. Specific suggestions for modifications and reasons for rejection should be duly communicated to the researcher.

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 proposals may be reviewed by an expedited review by the Chairperson and he/ she can invite other Members to examine the revised application and if the IRB recommendations have been adhered to, the applicant will be given the required approval by the Chairperson.

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:

16.1.1 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.

16.1.2 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 below steps.

16.1.2.1 If the Researcher wishes to appeal 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.

16.1.2.2 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.

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

16.1.2.4 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 projects that have been given ethical approval have to submit their annual reports to the IRB at 12 months after approval was granted. These would then be tabled at the next IRB meeting.

17.2 A Final report should be submitted at the completion of the study.

17.3 All SAEs (Serious Adverse Events) and the action/interventions undertaken for the same should be intimated to the IRB Chairperson and/ or Member Secretary, ideally immediately, or within a maximum of 72 hours of occurrence. In the event of non-availability of the Chairperson and/or the Member Secretary, the same shall be notified to other Sangath IRB Member, which shall, in turn, be notified to the Chairperson and/or the Member Secretary by the same Member with a week after the reporting of the SAE by the research team member. If case of a delay in reporting the SAE by the researcher/research team member occurs, prompt and appropriate action against the researcher shall 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 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[1]. All protocol divergence(s), if any, should be promptly informed with adequate justifications for the same to the IRB Chairperson. The Chairperson will then decide if fresh approval is indicated. Any major divergence (such as change in design, target sample, inclusion of a new intervention component) will require resubmission for fresh approval.

17.5 All serious adverse events have to be reported to the IRB. However, in response to PI's sufficient justification in the protocol for anticipated adverse events based on the natural history of the disease or population, there could be a waiver of the detailed evaluation process. (For instance, in a study involving elderly participants, if anyone is admitted to the hospital (in-patient hospitalisation) for a planned cataract surgery (expected condition in the defined population), the event has to be reported to the IRB as an SAE (Expedited reporting), however no follow up independent evaluation will be required.

17.6 Minor amendment(s) to the protocol (such as increasing or decreasing number of people to be interviewed) do not need fresh approval from the IRB – the Chairperson

and the Member Secretary can give the necessary permission for inclusion of the change to the original protocol. All such information should be recorded and communicated to the IRB through the annual reports.

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 Any change of investigator(s) / site(s)/ sponsor(s) / funding(s) should be duly informed to the IRB within one week; failing which, appropriate and prompt action against the investigator shall be initiated by the IRB.

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 might be appropriate. It is for the IRB to determine which Members should be involved.[2]

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.

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

18.1.2 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.

18.1.3 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).

[1] Bhatt A. Protocol deviation and violation. Perspectives in clinical research. 2012 Jul; 3(3):117.

[2] National Research Ethics Service, Health Research Authority, NHS, UK, Jan 2015

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).

18.1.4 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.

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

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

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

18.1.8 All publications related to a particular proposal should be submitted to the IRB for record purposes. Academic outputs/manuscripts from the approved study must acknowledge the ethics approval of Sangath IRB.

19. Professional development of Sangath IRB Members

19.1 Any relevant updates/ guidelines in the processes of the IRB shall be brought to the immediate attention of all Members. Members shall be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review by being updated with the latest development in this milieu.

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.

20. Remuneration to Sangath IRB Members

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

INR 2000 per meeting (up to a maximum of 3 new proposals reviewed).

INR 1000 for every additional proposal reviewed.

21. Review of external (Non-Sangath) proposals:

The Sangath IRB will not be reviewing proposals that are external- both, external individuals and other institutions.

CONTACT DETAILS

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All Sangath IRB form templates are available at : https://sangath.in/irb-documents/

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