

ARMMAN's Ethics Review Board

2021

Standard Operating Procedures (SOP)

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I. Terms of Reference (ToR)

ARMMAN's work focuses on improving the well-being of pregnant women, new mothers, infants, and children under the age of 5 years. Sustainable interventions are designed and implemented to

reduce maternal, neonatal, and child mortality and morbidity in underprivileged urban and rural communities in India. Studies are undertaken to identify and address systemic gaps in health service delivery and community healthcare-seeking practices. The impacts of these interventions are rigorously studied, analysed, evaluated, and monitored for midterm correction.

ARMMAN's Ethics Review Board (ERB) has been constituted to ensure an appropriate and sustainable system for reviewing the ethics of its research.

The members of the ERB, as well as the researchers, during the course of their work, will follow the **Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants** (ICMR, 2017); the guidelines laid down by the World Medical Association's (WMA) the **Declaration of Helsinki** (2013); and the **International Committee of Medical Journal Editors** (ICMJE) guidelines on authorship for publications; the present **Standard Operating Procedures (SOP)**; and the prevailing **applicable regulations and laws**.

The SOPs are laid down to ensure quality and consistency in ethics review as well as standardise the governance and functioning of the ERB.

I.A. The Role and Purpose of the ERB

Ethics guidelines establish standards of conduct for research, and the role of the ERB is to **ensure that these standards in ethics are upheld**. No research can be more valuable than the **protection of the rights of the participants and their well-being**. The ERB will help **facilitate and enable quality research** by helping teams evolve measures to address ethical issues in their work.

I.A. i. The ERB will review **all health research involving human participants** done by ARMMAN to ensure that it **safeguards participants' dignity, rights, safety, and well-being** especially when they are **marginalised, disadvantaged, and vulnerable**. It will also maintain and promote the **highest possible ethical and scientific standards** and **guide** researchers towards upholding the same.

I.A. ii. The members of the ERB shall have the **collective expertise** needed to realise this objective. They will be **aware of prevailing laws, culture, and practices** relevant to the project under review. The members should proactively **inform themselves** where such awareness is lacking.

I.B. Responsibilities of the ERB

I.B. i. The ERB should be **competent, unbiased, and independent** in its functioning.

I.B. ii. Quality scientific research is an essential part of research ethics. The **ERB is responsible for both, the scientific and ethical review of research** being done by ARMMAN. It will review the benefits and implications of the various aspects and components of the study.

I.B. iii. Though the ERB will review the scientific aspects of the study, nevertheless, each project, prior to its submission to the ERB, will undergo scientific review by a Scientific Review Board (SRB). **No proposal will be reviewed by the ERB without it having been reviewed by the Scientific Review Board**. Minutes of the discussion should be signed by its Chairperson/lead and these need to be attached to the submission being made to the ERB. Critical feedback received from the SRB must be **incorporated into the research protocol before** it is submitted to the ERB.

I.B. iv. ERB members are required to **prepare in advance** by reviewing each submission before the meeting at which it is scheduled for discussion. Every ERB member is expected to **actively participate** in discussions and offer their perspectives during meetings.

I.B. v. Members have to sign **Conflict of Interest and Confidentiality agreements** as part of the ToR of their appointments (see section III and IV; and Forms 5).

I.B. vi. ERBs and Collaborative Research

- a. The ERB can play a key role in guiding ARMMAN in its collaborative research work and in drafting **memoranda of understanding (MOUs)** for research within the country or with international collaborators. For collaborations where there is a **difference in levels of expertise, infrastructure, and so on**, the focus should be on creating an equitable relationship.
- b. For this purpose, the ERB (and the SRB) should be consulted regarding the roles and responsibilities of ARMMAN and the collaborators in the context of the various components of the study, responsibilities towards study participants, sharing techniques, ownership of data, intellectual property rights, joint publications, and so on. The ERB should also be called upon if an issue arises during the implementation and conduct of collaborative research or with the collaboration itself (also see V.A. iii and V.A. iv).
- c. In case **multiple ERBs are involved**, the information should be made available to the ARMMAN ERB along with the details of the review.
- d. All stakeholders should be aware of various international and national **ethical, regulatory, legal, and funding requirements** in the context of collaborative research.

I.B. vii. ERB and Multicentric Studies

- a. The **local or regional appropriateness** of a study and protocol is important, particularly so in the case of multicentric studies. Research teams and members of the ERB should be **aware of, or make themselves better informed about, local, social, and cultural norms as well as emerging ethical issues**. The ERB may give suggestions where protocols may need to be adapted to different centres/locations.
- b. While the ERB can do a **common review** for the participating centres in a multicentric study, it is recommended that a local team member be part of the core team submitting and participating in the review.
- c. **Training or orientation of the regional team on ethical issues** is pertinent along with training in research processes.

I.B. viii. Consent in Certain Research Settings

- a. In certain research contexts and settings, **community consent** and/or **gatekeeper consent** plays an important role. The rationale for such consent (from whom, why and how it will be taken) should be clearly explained by the research team in its submission to the ERB. This adds a different dimension for the ERB members to review. Inter-community and intra-

community dynamics and differential power relations need to be considered for the protection of study participants as well as the research team.

- b. Community consent, group consent, or gatekeeper consent **cannot replace** the individual consent of participants.

I. B. ix. Monitoring Projects

- a. It is the responsibility of the ERB to **monitor** approved projects, not just to ensure compliance, but also to provide guidance. For this reason, projects are reviewed at different stages. The stages of review required for each project will be recommended by the ERB at the time of the first review based on the context and needs or based on the annual reports shared by the team. Only if the ERB is of the opinion that an annual meeting with the team is required, then a **monitoring meeting** can be called for (for details please refer to V.D. iii). The ERB may also recommend a **milestone-based review** or report wherein a research team may be asked to share a report / be called for a review in case of reaching a project-related milestone.
- b. Members of the ERB are **encouraged to visit the project sites** while the study is being undertaken. These visits can be part of routine monitoring, to be decided at the time of the stage 1 review (see V below), or could be specially planned based on an emerging need during the course of the study.

I. C. Evolving Practices, Revision of SOPs, Biennial Reports, Audit and Review of the ERB

I.C. i. The ERB should regularly devote time to having free and open discussions among themselves about their work and functioning to **improve and evolve their practices**. These discussions should be documented and revisited at the time of audits (see I.C. iv below).

I.C. ii. Over time, ERB members and researchers may feel the need to **revise the present SOPs** based on their experiences and developments in the field of research and research ethics. This is essential and should be encouraged. It should be done through a consultative process involving ERB members and colleagues at ARMMAN.

I.C. iii. **ERB biennial reports** are to be prepared, and the Secretariat can put together a draft to be discussed by the rest of the ERB prior to revision and finalisation (for further details, see VII.B. xvi).

I.C. iv. The members of the ERB should make themselves available for an **audit/review**, which should be undertaken by a two-member independent committee appointed for the purpose at regular intervals. ARMMAN should facilitate such a review. Documents and minutes of the ERB reviews conducted during the relevant period should be made available to the committee. The purpose of such a review is not to allocate blame, but to constantly **strive to improve practices and raise the standards of ethics review**. The **focus should be on learnings** from reviews, **compliance with SOPs**, analysis and addressing of any **emerging needs**, and so on. The report should maintain the confidentiality of proceedings and the anonymity of all stakeholders. The final report should highlight the reviews done, key perspectives that emerged from the reviews, and learnings and takeaways, and should be made available in the public domain.

I.C. v. As part of **continued learning**, ARMMAN should facilitate the development of a shared **repository of resources**, wherein members of the ERB, SRB, and other colleagues at ARMMAN can share recent developments and publications and other relevant reading in their areas of work and research. All colleagues at ARMMAN should have access to the same. It is also a good practice to

organise study groups to discuss new developments or interesting resource material as and when possible.

II. MEMBERSHIP REQUIREMENTS FOR ERB

II.A. Appointment of Members

II.A. i. The Chief Executive Officer (CEO) of ARMMAN, so as to maintain independence, the head of the institution should not be part of the EC but should act as an appellate authority to appoint the committee or to handle disputes.

II.A. ii. There will be **5 external members** and **2 internal members**. The 2 internal members are part of the organisation (Member Secretary and Additional Member Secretary) and form **the Secretariat**.

II.A. iii. External members are appointed in their **personal capacities** and the selection should be based on their interest and commitment towards ethics.

II.A. iv. The ERB should be **multi-disciplinary and multi sectoral (refer to the ICMR guidelines for the same)**, and the members should have the requisite experience as well as **requisite collective experience** relevant to the research been done at the organization. There should be adequate representation of age and gender and a balance of expertise amongst the members as per the needs of ARMMAN.

II.A.v. The constitution of the ARMMAN ERB

- The **Chairperson** of the committee should have had prior experience of being part of an ethics committee and be a non - affiliate member. The Chairperson is in charge of conducting the meeting and to ensure the ERB's independent and efficient functioning. S/he is in charge of the decorum and fair decision making during reviews and ensuring participation from members as well as ratification of minutes. S/he should ensure that complaints are handled fairly and deftly as per procedure laid down and members have signed conflict of interest agreements. An Acting Chairperson can be nominated for a meeting in her / his absence by the members.
- The Member Secretary and the Alternate Member Secretary should be from ARMMAN and have relevant research experience as per the work being done by ARMMAN. Should have good organizational and communication skills. They should establish clear and efficient procedures to receive, prepare and circulate proposals being submitted for review to the ARMMAN ERB. They are in charge of scheduling meetings, preparing the agenda and minutes. Organize documentation maintain archives; organize relevant trainings for staff and members, in charge of regularly updating SOPs and ensuring adherence of ARMMAN ERB and its functioning in line with the SOPs. Review each submission for completeness and assess proposals for expedited review or for exemption. The Member Secretary and the Alternate Member Secretary are required to facilitate scientific review of proposals, need for subject matter expert and / or community representatives prior to their submission to the ERB. They are required to ensure that the meetings are held with required quorum and record discussions and decisions (for more details see VII. **Role of the Secretariat**).

- Basic Medical Scientist(s) (affiliated / non-affiliated) should be individuals with non-medical or medical qualifications in at least basic medical sciences. Should have expertise in reviewing studies particularly intervention studies, benefit-risk analysis, research design, methodology and statistics, continuing review process, adverse events or serious adverse events (SAE), protocol deviation, progress and completion report.
- Clinician(s) (Affiliated/ non-affiliated) should be individuals with medical qualification, expertise and training. They are required to undertake the Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics. They should also oversee ongoing and thorough review of the protocol (SAE, protocol deviation or violation, progress and completion report) and all other protocol details and submitted documents.
- Legal expert/s (Affiliated/ non-affiliated) should have a basic degree in Law from a recognized university, with experience with relevant exposure or training in scientific studies and / or public health and / or social sciences. They are required to contribute towards the ethical review of the proposal and peruse informed consent documents (ICD) along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions or collaborations or compliance as required and inform and guide members about new and relevant regulations if any.
- Social scientist/ philosopher/ ethicist/theologian (Affiliated/ non-affiliated) with social/ behavioral science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities. They contribute to the ethical review of the proposal, ICD along with the translations; assess impact on community involvement, socio-cultural context, religious or philosophical context, if any and serve as a patient/participant/ societal / community representative and bring in ethical and societal perspectives and concerns.
- Lay person(s) (Non-affiliated) should be a literate person from the public or community or having had experience of working closely with the community at the grass – roots level. May be a representative of the community from which the participants are to be drawn and is aware of cultural and moral values of the community. It is desirable that they are involved in social and community welfare activities. They along with the rest of the members are responsible for ethical review of the proposal, ICD along with translation(s) and evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. They serve as patient/participant/ community representative and bring in ethical and societal concerns.

There should a scientific review undertaken prior to the ethical review. However, the ARMMAN ERB can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

II.B. Subject Matter Experts

II.B. i. As and when required, the ERB can call upon **subject matter experts**, including community representatives or local health workers, or others; that may be needed to offer insights and expertise on a matter that is beyond the collective expertise of the ERB.

II.B. ii. The research **team may also express such a request** in writing along with other submission documents.

II.B. iii. The special invitee/subject matter expert **may be affiliated or non-affiliated to ARMMAN**.

II.B. iv. They need to be unbiased and function independently. They have to sign the **Conflict of Interest and Confidentiality agreement** (Form 5B).

II.B. v. The subject matter expert can also be requested to attend the meeting/specific project review virtually.

II.B.vi. Their opinion/perspective will be noted as part of the discussion; however, they **cannot take part in decision-making**. Any decision-making will be done once the non-member special invitee has exited the meeting.

II.C. Tenure

II.C. i. All members serve on the ERB for **3 years**. However, for the first newly constituted ERB, tenure should be **extended** for 3 members (including one member of the Secretariat) by a period of 1 year to ensure continuity of reviews and proceedings. New members are invited to join accordingly. This decision is to be taken by the ERB in consultation with the CEO. Once the extended tenure is completed, new members are invited to take their place.

II.C. ii. At the end of the fourth year of the ERB, and, henceforward, tenure is to be maintained as 3 years. The ERB will therefore have a mix of old and new members.

OR,

II.C. iii. The tenure of the entire ERB can be extended by a maximum of one more term (i.e., 3 more years), in which case, at the end of the 5th year, 4 members will be replaced by new members (including one member of the Secretariat). At the end of the sixth year, the rest of the ERB members will be replaced by new members.

II.D. Training, Orientation and Collective Learning of Members

II.D. i. Members need to ensure **continued competence in both ethics and scientific aspects through regular trainings and orientation**. This is pertinent especially when there are new developments in research, researched areas, and methodologies and technologies.

II.D. ii. **Ethics training** should be done at the time of the formation of the new ERB and subsequently as and when needed.

II.D. iii. It is the responsibility of ARMMAN to **organise such needs-based ethics trainings for ERB members as well as research staff**.

II.E. Resignation

II.E. i. An external member can tender a resignation in writing/mail addressed to the Chairperson of the ERB. In case it is the Chairperson tendering the resignation, she/he should write to the Co-chairperson. The resignation is then forwarded to the other members and the CEO. The concerned member will need to serve a one-month notice period from the date of acceptance of the resignation. A new member should be appointed at the earliest.

II.E. ii. If a member of the Secretariat resigns from the organisation, or wishes to discontinue as part of the Secretariat, a new internal member should be appointed at the earliest. All the documents/work should be handed over and explained by the outgoing member in the presence of both members of the Secretariat.

II.F. Disqualification of a Member

II.F. i. Grounds for Disqualification

- a. The Chairperson and the Co-chairperson, in consultation with the rest of the ERB, can initiate the process to disqualify a member on the grounds of not having attended 3 consecutive meetings.
- b. Grounds for investigation (and disqualification) also include repeated failure to fulfil ERB responsibilities; any information of unprofessional behaviour or misconduct sent in writing to any of the members by any person known or unknown; or any other unprofessional behaviour including failure to disclose a conflict of interest.

II.F. ii. The Process

- a. The Chairperson and the Co-chairperson can initiate a discussion on the said behaviour with the rest of the members. If ascertained to be true, then the grounds for disqualification should be communicated by the Chairperson and Co-chairperson to the CEO in writing by letter/mail. The dates of the relevant meetings and meeting numbers, along with other relevant details, should be explicitly mentioned in the letter.
- b. The CEO, in consultation with the Chairperson and/or Co-chairperson, can terminate the tenure of the said member with immediate effect. Alternatively, they can send a letter of concern stating the eligibility for disqualification. A failure to not attend the next meeting or a repeat of unprofessional behaviour would lead to the initiation of the final disqualification process.
- c. The concerned member should be allowed to resign.
- d. In case the member eligible for disqualification happens to be the Chairperson, then the Co-chairperson and any other external member can do the needful.

II.G. Dissolving the ERB

II.G. i. Under special circumstances, the CEO of ARMMAN can **dissolve the ERB** and the same should be communicated to members in writing; clear details and the rationale for the decision should be provided.

II.G. ii. Such a step should not be taken unless all other options have been explored and the issues that led to the situation are investigated impartially and objectively.

II.G. iii. The ERB is automatically dissolved if ARMMAN ceases to exist.

III. CONFIDENTIALITY AND CONFIDENTIALITY AGREEMENTS

III.A. Confidentiality

III.A. i ERB members are required to **maintain confidentiality** and to proactively protect as well as not utilise (directly or indirectly) any information/sensitive documents, including but not limited to proposals, meeting deliberations, and details about research participants from meetings, during their role as active ERB members as well as after their tenures have ended.

III.A. ii. Any documents/proposals shared for discussion in meetings should be **password-protected and/or stored in a safe place.**

III.B. Confidentiality Agreements

III.B. i. Each ERB member is required to sign a **Confidentiality Agreement** as part of their ToRs (Form 5A).

III.B. ii. These forms also need to be signed by experts/independent consultants and observers who are invited to attend ERB meetings (Forms 5B and 5C).

III.B. iii. All administrative staff privy to or who have access to proposals, data, proceedings, minutes, and other documentation concerning the work of the ERB should also sign the agreement (Form 5D).

IV. CONFLICT OF INTEREST

IV.A. A **conflict of interest** is said to exist when ERB members are part of the research team that has submitted a proposal; or when they are in any other way associated with the project or proposal; or when they have interpersonal or financial links with the members of the research team or with the project/proposal that may potentially affect the research review. It should be noted that a conflict of interest is a result of a prevailing situation and is not a personal reflection on the individual.

IV.A. i. Any member(s) of the ERB who has a conflict of interest with respect to a proposal should make it known at the earliest. If such a conflict evolves later, then the same should be declared immediately. Such a disclosure is to be noted in the minutes. The member needs to abstain from attending the meeting as part of the ERB but can attend it as a part of the research team if required.

IV.A. ii. However, if any such association existed either in the past or is insignificant, the concerned member can declare it and request to continue being part of the meeting as an ERB member. The Chairperson, along with the rest of the members, can then take a call.

IV.A. iii. An **ethics consultation meeting** (See V.1.iv below), if done before a submission, does not amount to a conflict of interest.

IV.A. iv. **Failure to divulge** a potential conflict of interest can be grounds for disqualification.

IV.A. v. All members need to sign a **Conflict of Interest** form (Form 5A).

V. MEETINGS

V.A. Types of Meetings

V.A. i. Regular/Plenary Review Meetings¹

- a. The ERB will meet every **3 months** for a scheduled discussion of the studies submitted for review. The dates need to be confirmed at the time of the first meeting and subsequently at the time of the last meeting of each tenure year.
- b. Physical (as in offline) meetings are mandatory unless the situation requires otherwise. The decision rests with the ERB and virtual meetings can be done only in exceptional circumstances. The decision and rationale for it should be noted as part of the minutes.
- c. Members are discouraged from cancelling last minute. However, in case of unforeseen circumstances or emergencies that require cancellation, they should make an effort to be available virtually if required and possible.
- d. They should also try to send in their detailed comments before the meeting. It is the responsibility of the Secretariat to share these at the time of project discussion.

V.A. ii. Expedited Meeting

- a. An **expedited** review may be urgently required in some circumstances — such as a need to initiate a study as a result of a humanitarian crisis, a natural or man-made disaster, or in a situation wherein a project that was approved earlier has undergone minor modifications. An expedited review can also be done for studies involving **no more than minimal risks**, such as studies based on non-identifiable data or records, amendment or minor changes to protocols of studies already reviewed, etc.
- b. Any project that does not fall under these criteria and involves a vulnerable population cannot be eligible for an expedited review unless it has already been approved by a collaborator's ERB (registered). In such cases, a complete scientific review report and ethics review report needs to be shared with the ERB along with a mail explaining the situation and the grounds for requesting an expedited review.
- c. An expedited review meeting can be arranged at the request of the project's principal investigator through a mail addressed to the Chairperson through the Secretariat **justifying** such a need, with required supporting documents and form duly filled (Form 1).
- d. The Secretariat will immediately scrutinise the request, and if all is in order, forwards the same to the ERB. The ERB will then decide whether the project/proposal is eligible for an expedited review and will proceed accordingly. The Secretariat should enable the

¹ For other relevant details see V.E, VI and VII.

completion of such a review within 3 weeks from the date of submission or as urgently necessary.

- e. An expedited review can take any of the following forms, and the ERB can take a call as soon as it receives the request. The review could be
 - a **full-strength face-to-face meeting** (in case of an already scheduled meeting wherein the team has not had a chance to share the submission in advance as stipulated for regular meetings),
 - or a **full-strength online meeting** called for the purpose of expedited review or,
 - a **special sub-ERB meeting** can be held with 2 or 3 external members, one member of the Secretariat, and 2 members of the team including the principal investigator. A full ethics review should follow in the immediate next regular meeting.

V.A. iii. Emergency Meeting in Case of an Adverse Event or a Serious Ethical Issue

- a. Any **unforeseen serious ethical issue or an adverse event, incident, or situation** (such as abuse/backlash faced by participants or researchers, several participants opting out of the study, unrest in the community, etc.) in the field during conduct/implementation of an **ongoing research of a study that has been previously reviewed** needs to be reported to the ERB within 24 hours of it having occurred. This should be accompanied by an explanation about how the incident is, in the team's opinion, linked to the research study and efforts made to mitigate it. The ERB can provide guidance on additional steps that may be further required to be taken. This needs to be followed up by a report within 15 days by the research team. Alternatively, when the team reports to the ERB within 24 hours along with the explanation of the ethical issues link to the study, the team can also request an **emergency meeting** of the ERB. A two-member sub-ERB or a full virtual meeting with the ERB can be set up at the earliest and not later than 7 days of such a request, whichever is deemed required under the circumstances.
- b. An emergency meeting can also be called when there are changes in the field of an **ongoing study** due to unanticipated circumstances that may require a departure from the decided course and that may even have an impact on the participants and/or the study (such as health emergencies including epidemics and pandemics, the launching of a new government programme or policy, a development in the field of science and public health, course correction on any aspect of the study, etc.). Communication regarding the same needs to be sent immediately to the ERB stating the desired course of action and way forward. The members will then take a call whether it requires an emergency meeting or the proposed action or way forward can be directly approved.

V.A. iv. Ethics Consultation

Ethical dilemmas may arise while planning the study, in the field, at the time of data collection, or even at the publication stage. Teams are encouraged to resolve these through informed team discussions and in accordance with the ethical guidelines. They can seek help from the ERB and **reach out to any ERB member(s) and initiate an ethics consultation**. The team is then required to submit a brief report regarding the same at the time of the next regular meeting.

V.B. Quorum

V.B. i. The presence of **5 members** constitutes the quorum, with **at least one member from the Secretariat**. No meeting, and therefore no decision, is valid if the quorum is not reached.

V.B. ii. In the case of a physical meeting, virtual participation of any member through video conferencing cannot be counted as part of the quorum unless they attend the full meeting with complete involvement.

V.B. iii. Where the quorum has been met in a physical meeting, then any other member can participate virtually.

V.C. Decision-making

V.C. i. Decision-making during an ethics review is by **consensus**, and all efforts should be made to achieve this. A consensus implies that all members find a particular decision or course of action acceptable, even when they might not entirely be in support of it. Thus, no member should consider the decision unacceptable. The role of the Chairperson is vital in bringing about consensus.

V.C. ii. Despite all efforts, if no consensus can be reached, voting (majority voting) by all members present, including the Secretariat, may be used. In case of a tie, the Chairperson will have the **deciding vote**.

V.D. Stages of Review

V.D. i. Exemption from Review

a. Exemption from Review for Studies with Less than Minimal Risks

Studies that carry **less than minimal risks can be declared exempt from review**. These studies may be based on information or data already in the public domain or may make use of data from a study wherein consent had already been sought for such an anticipated use of the data. It also includes **clinical audits** as well as **monitoring and evaluation** research. Evaluation research that involves screening documents and or other information or data (such as programmatic data) to improve and refine the programme is exempt from ethics review. Similarly, the clinical audit may be exempted in so far that it does not involve human participants nor aim at gaining new knowledge but seeks to improve quality against established benchmarks.

If such research happens to be a component of a larger primary research study, the component needs to be reviewed along with the primary research study.

- b. Studies involving vulnerable groups; research on sensitive, private, and personal issues; research using control groups; research that requires taking any kind of recordings and research using information that was previously assured as confidential, etc.; cannot be exempted from review.
- c. Permission for exemption needs to be sought and a form for the same (Form 3) needs to be filled and sent to the Secretariat. The Secretariat will peruse the request along with the documents shared by the team. The same is to be shared with the Chairperson and Co-chairperson, who along with the Secretariat, will decide whether the application needs a full review or can be exempted.

- d. The decision should be communicated to the team within 7 working days of receipt of an exemption request by the Secretariat. In case the ERB decides that the study requires a full review, the team needs to prepare the submission for a regular ERB meeting and make the submission according to the required timelines.
- e. In case the study is exempted, the Secretariat will issue an exemption certificate (Annexure 1) and inform the rest of the ERB during the next regular meeting.
- f. Any departure from the protocol in an exempted study should be communicated to the ERB immediately along with the reasons for the departure. Resubmission may need to be considered. Research ethics and scientific integrity need to be continually maintained despite the exemption.

V.D. ii Stage 1: Before Data Collection

This is the first review of the study. This is after teams have **implemented the feedback received from the SRB**. Revised protocols, tools, informed consent process details, and other details and documents are to be sent to the Secretariat. The Secretariat will review all project-related documents as well as Forms 1 & 2, filled by the team, before sending them to the ERB (see “V.E. Guidance for Applicants”).

V.D. iii. Stage 1.1, 1.2, and so on: Annual Review for the Purpose of Monitoring

- a. At the end of each successive year of the project, from the time data collection actually begins, the team is required to send in a brief report describing the status and progress of the project and the problems and ethical issues faced and how they were dealt with. The local team in a multicentric study should also be involved in drafting this report.
- b. Teams need to proactively send these reports to the Secretariat. The Secretariat also needs to keep track of these reports and follow up with the research teams if needed. They need to inform the ERB if any team fails to send in their annual report(s).
- c. **Monitoring meeting:** In the case of certain studies, the ERB may want to discuss the above by way of an annual in-person monitoring meeting (Application form for Annual Reviews, Form 4) scheduled at the same time as a regular ERB meeting. This can be decided at the time of the first regular review meeting of the project (i.e., Stage 1) and communicated to the team accordingly or such a decision can be taken based on the annual reports shared by the team or based on any events occurring during the course of the study. Such a review can be scheduled for at the next regular meeting for the ERB.

V.D. iv. Stage 2: End of the Project Review

- a. The team shares in **detail** the project outcomes, data, findings, conclusions, learnings, experiences, and ethical dilemmas faced and how they were resolved.
- b. The team is also required to **present a plan** on how the findings will be shared with the research participants in a way that they can comprehend and will be useful to them.
- c. It is important at this stage to share with the ERB a tentative plan to **disseminate and use findings**. This could be in the form of, but not limited to, improving the overall protocol

and/or content of other ongoing or planned interventions, widely distributing the study report, publishing articles in peer-reviewed journals, etc.

- d. The ERB may recommend a way forward on this.

V.D. v. Stage 3: Draft Study Report

- a. Prior to publication, draft reports **could** be shared with the ERB (these should be password-protected). The team may choose to send the report for the purpose of feedback and learning, as well as to be better prepared for submissions to peer-reviewed journals. This can be done at the time of a scheduled meeting. Alternatively, the team can also send an email to the Secretariat, which will forward the same to the ERB. The members need to respond with any comments within 15 days of receipt of the report.

V.E. Guidance for Applicants

V.E. i. Each **team has to prepare their submissions** depending on the stage of the review. Thus, a submission could include the research proposal, research protocol, project reports, memorandum(s) of understanding, signed minutes and review certificate of the SRB, ethics review certificate of any other ERB, annual study reports, draft publication, and so on, along with duly filled and relevant review forms. Any special consideration, such as a waiver of consent, expedited review or exemption from review; should be communicated and due process followed.

V.E. ii. The submissions must adhere to the Indian Council of Medical Research's **National Ethical Guidelines for Biomedical and Health Research Involving Human Participants** (ICMR, 2017), the World Medical Association's (WMA) **Declaration of Helsinki** (2013), the **International ERB of Medical Journal Editors'** (ICMJE) guidelines on authorship for publications, the present Standard Operating Procedures (SOP).

V.E. iii. The team **should discuss internally and attempt to anticipate** the aspects of their project that can raise ethical concerns across the timeline of the study. They also need to ensure that all aspects of the study, including processes and procedures used during as well as after the study, align with the relevant ethical guidelines.

V.E. iv. Completed submission packages need to reach the Secretariat at least 25 days before the date of the scheduled ERB meeting. While the teams are required to ensure that the submissions are complete, the Secretariat too needs to ensure this before forwarding it to the ERB. In case of any missing document/information, the Secretariat needs to inform the team, and the team is expected to send it at the earliest to avoid delays.

V.E. v. Any request for a subject matter expert needs to be facilitated by the Secretariat in consultation with the ERB in time for the meeting.

V.E. vi. Once submission packages of all the studies scheduled for review have been perused and approved by the Secretariat, these need to reach the external members as one complete package, along with the agenda, at least 12 - 15 days ahead of the meeting.

V.E.vi. On the day of the meeting, the principal investigator, and at least one more individual from the research team, is required to be present (though it is encouraged that the entire team be present for the meeting).

V.E. vii. The ERB members will be fully prepared for the meeting and discuss and review the submission from a scientific and ethical perspective. The entire ERB can review each submission together and have a collective discussion in one go, **or** the Chairperson could designate 2 members as primary and secondary reviewers for any project as soon as the submission is received by the external members. The Chairperson may choose to do so due to the subject matter expertise of the member/s or if there are several reviews/items on the agenda. The rest of the members still need to come prepared for the meeting. The primary and secondary reviewers will share their detailed comments, observations, concerns, and suggestions. There will then be a collective discussion and the rest of the members will also share their comments and perspectives. In both cases, the teams can be called in to provide clarifications on certain aspects of the study. Once the clarifications are sought and discussions among the ERB members are complete and a consensus (see V.C.) has been reached, the team can be called in for sharing feedback and review.

V.E. xiii. At this point, the team is orally informed of the decision. If the project is cleared without reservations or changes, the ERB may choose to suggest that the team go ahead with the study with immediate effect.

V.F. ERB Recommendations/Certification

The ERB, post-review, can make any of the following recommendations:

V.F. i. Approved as Submitted

This implies that approval has been given unconditionally and the study can begin with immediate effect. The team is called in and informed. A Certificate of Approval (Annexure 2) is to be issued within 10 days of the meeting, signed by the Chairperson and Member Secretary.

V.F. ii. Approved Conditionally with a Request for Minor Modification/s

This implies that some minor changes are required. The team is called back in and informed of the same. The team needs to re-submit only the revised and relevant documents highlighting the specific changes. The Secretariat will go through the same and share it with the ERB over mail. Once approved, a Certificate of Approval is to be shared with the team. The entire process should not take more than 10 days.

V.F. iii. Resubmission with Major Modifications

The ERB may find the rationale and/or value of the proposed study pertinent; however, there may be scientific or ethical issues in its present form. This requires resubmission by the team after making the required changes. In such cases, the team is brought in and the ERB shares their views. Subsequently, the details of the required changes also need to be communicated by email with the team by the Secretariat after finalisation and approval of the minutes. The revised study, as a resubmission, requires full review in a regular meeting.

V.F. iv. Decline Granting Approval

If the ERB finds the submission ethically or scientifically problematic, they can reject it. The team is called in and informed of the decision. Once the minutes are approved, the Secretariat emails the team details of the rationale for the ERB decision for the purpose of learning and understanding.

V.F. v. Special Reporting Requirements

If a study needs special reporting on progress or on a specific aspect, or if a site visit by the ERB is required, then this is communicated with the team at the time of sharing feedback during the

meeting and later when the minutes are approved. The team then needs to report to the ERB as required, and the Secretariat needs to be coordinate with the team to plan the visit.

VI. Responsibilities of the Research Team

VI.G. i. Research teams must make efforts to ensure continued competence **on matters of science as well as ethics**.

VI.G. ii. The proposals and protocols should be in line with **relevant laws, regulations, and ethical guidelines and sensitive** to the culture of the community where they work and do research.

VI.G. iii. The teams should work with **integrity and be accountable** to research participants as well as the scientific community at large.

VI.G. iv. They need to make an effort to **understand and anticipate possible ethical issues** that may arise during their research and work and make well-thought-out and complete submissions to the ERB and on time.

VI.G. v. Despite all efforts, unanticipated ethical issues may emerge in the field, and **being alert to these** is of paramount importance. The team should deal with these as and when they arise, while at all times **protecting the participants** and their rights and **protecting the team** from harm as well. While these issues need to be reported to the ERB, the team should not hesitate to **contact the ERB** for guidance (see V.1.iii and V.1.iv).

VI.G. vi. Any **changes to the protocol** after review or on the field should be immediately communicated to the ERB citing reasons. Any major changes need approval from the SRB as well as the ERB with re-consent from participants (if applicable).

VII. Role of the Secretariat

VII.A. As Members of the ERB

VII.A. i. The Secretariat, i.e., the Member Secretary and Additional Member Secretary, are internal members affiliated to ARMMAN. As members of the ERB, they must uphold **the highest possible scientific and ethical standards** in research.

VII.A. ii. Like external members, they need to **actively participate** in ethics review meetings and engage in **unbiased and objective decision-making**.

VII.B. As Internal Members: Coordination, Logistics, and Administrative Role

VII.B. i. The Secretariat is the core team responsible for the **coordination, logistics, and administrative work** of the ERB as has been detailed at various points in the present SOPs.

VII.B. ii. They are required to send relevant communication including letters duly signed by the CEO inviting new members to join the ERB and ensure that confidentiality and conflict of interest forms are duly filled and signed by all those who have access to ERB documents and are part of the meetings.

VII.B. iii. The Secretariat will share a copy of the present SOPs with the relevant people in advance and explain their roles and responsibilities. Thus, for instance, a copy should be shared with the

subject matter expert along with information on the proposal for which their expertise is needed, the confidentiality and conflict of interest forms that need to be signed, a brief on their role and how the reviews are done, etc.

VII.B. iv. The Secretariat is responsible for scheduling and organising the meetings. They are required to keep track of the requirements of the SOPs and prepare accordingly (such as appointing new members, organising trainings, keeping track of special requests, lapses, and project and submission timelines, scheduling meetings and so on).

VII.B. v. The Secretariat receives the project proposals and are required to go through each submission to ensure completeness. The Secretariat can send the material back to the teams if required. The completed submission needs to reach the ERB members 12 – 15 days before the meeting along with the agenda.

VII.B. vi. While preparing the agenda, the minutes of the previous meetings are to be revisited to ensure continuity and that any pending issues are covered.

VII.B. vii. The Secretariat, at the start of every meeting, will briefly share the day's agenda, including projects to be reviewed, the stages they are at, any pertinent issues that have developed, or from previous review details and other pending matters and issues carried over from previous meetings. To maintain continuity, the Secretariat should keep relevant files of previous minutes, deliberations, and reviews at hand during meetings.

VII.B. viii. The deliberations and decisions of all meetings are to be documented and the minutes are to be prepared by the Secretariat. Where a special sub-committee is involved (possible in an expedited review or emergency review), the discussion and decisions need to be documented by the special sub-committee members and shared by them in the subsequent regular meeting. The ERB may decide to convert the subject matter of the expedited or emergency meeting into a regular meeting agenda or sign off on it.

VII.B. ix. Draft minutes need to be prepared by the Secretariat within 15 days of a meeting and sent to ERB members who will then send in any missed observations or decisions within 7 days. The Secretariat finalises the minutes, and once the ERB okays them, the minutes are to be circulated. This process should be completed within 30 days of the meeting.

VII.B. x. Detailed descriptions of the deliberations are to be noted by the Secretariat but kept confidential and stored securely.

VII.B. xi. Certificates of Approval need to be prepared and shared as per decisions in the meetings (See V.F. above).

VII.B. xii. The Secretariat should **evolve and establish effective and sustainable systems for maintenance and protection** of data and records, tracking proposals for review across stages, and ensuring these are included in meeting agendas.

VII.B. xiii. All documentation and ERB-related communication should be **filed, stored, maintained, and retrieved securely to maintain confidentiality**. Since the documents shared and reviewed during ERB meetings are of a sensitive nature, **appropriate and secure archiving facilities should be maintained**.

VII.B. xiv. All ERB files and documents are to be retained for at least 5 years after the completion of the project or more if required by a sponsor/collaborator or as per ARMMAN policy.

VII.B. xv. **ERB biennial reports** are to be prepared at the end of every 2 years. The Secretariat can put together a draft to be discussed with the rest of the ERB before revision and finalisation. The report should be uploaded on the website and should not include any harmful or personal details of participants or of communities where they work or the details of the deliberations. The purpose of the report should be **educational and introspection**, and, therefore, besides objective and official updates (changes in procedure, new members, reporting of conflicts of interest, invitation of experts, insights and learnings, and so on), the report should carry an anonymous discussion of the project-wise ethical issues discussed in the meetings and how they were resolved.

VII.B. xvi. The Secretariat, as they are affiliated to ARMMAN, should be allocated time for ERB duties, and it should be considered one of their core tasks as part of the organisation. They should also be adequately supported by administrative staff. One administrative staff should be made available on the day of the meeting.

VII.B. xvii. In consultation with the organisation, ethics training should be arranged for the ERB members and ARMMAN staff as and when needed.

VII.B. xviii. The Secretariat should maintain a file of all their curriculum vitae as well as those of relevant experts who may need to be contacted.

VII.B. ix. The ARMMAN website needs to carry the details of the ERB members, including their email-ids, the SOPs, and various forms to be filled by the research teams.

VIII. Special Section: Ethics of Implementation Research

Implementation research (IR) looks to improve access to proven interventions that have not reached many of the target population who could benefit from it. It addresses questions of accessibility, acceptability, appropriateness, and feasibility in communities along with cost-effectiveness, health education, policy-level implementation, etc. **While the fundamental principles of ethics remain the same, their applications are different and the principles cannot be simply extrapolated.**

Situation analysis of the context is needed where IR is required. IR is justified when such analysis reveals that the intervention is the best possible strategy and, therefore, a full-scale implementation is the way to go. It should aim at strengthening the health system and making use of data for policy-level strengthening.

IR involves a much deeper engagement with all stakeholders across all phases of research and varied contexts (social, cultural, economic, political, legal, and physical). Demography and relevant epidemiology play an important role in implementation and outcomes. The same project may also have multiple institutional settings affecting and influencing the interactions among various stakeholders and making the context more variable. The aim of IR is to maximise the health impact to the maximum possible and also entails studying how and why a policy or an innovation works and how best to scale it and widen its scope. This necessitates adaptation and flexibility, particularly as a result of changing contexts in order to be responsive to that particular context and population. **Therefore, pre-decided protocols may not work, and ethically one needs to be vigilant and creative.**

The ERB and Implementation Research

VIII.A. The ERB needs to take into account this **need for adaptation and flexibility** and understand the roles played by each stakeholder in IR projects.

VIII.B. Though adaptation and flexibility are important, the research team and the ERB should ensure that in the process, the **core of the intervention is not diluted or altered**.

VIII.C. IR concerns those actually using the research to change practices, systems, behaviours, etc. Thus, they are not and should not be treated as just targets of the dissemination of research results. Representatives should be **involved** across the stages of IR from design to conducting research to dissemination.

VIII.D. The ERB and the research team should also be mindful of the fact that while IR requires the participation of multiple stakeholders; including the target population, community leaders, policymakers, and those associated with health systems including health professionals; there exist **asymmetries of power and knowledge**. This leads to several factors that are important to consider for the ERB as well as the research teams:

VIII.D. i. **Governance, accountability, and rights** of all stakeholders towards the intervention gains importance.

VIII.D. ii. The research team and the ERB have to be clear about from whom all **informed consent** is required while ensuring autonomy and voluntariness in light of benefits and unequal power relationships.

VIII.D. iii. **Balancing risks and benefits** will be different for different stakeholders.

VIII. D. iv. **Vulnerable populations may have to be included** as part of research as the intervention may be specifically for their benefit, and, therefore, in fact, recommended for promoting overall equity.

VIII.D. v. Since IR research entails a successful intervention, i.e., where benefits are known to be proven, the **ethics of randomisation need to be addressed**.

VIII.E. Since the context of the intervention will change from region to region, the team will face **different standards of care** at different places, which they and the ERB need to take into account.

VIII.F. Scaling-up successful interventions may lead to unexpected **ancillary findings** that the study team needs to take into account and address. These findings need to be shared with the ERB as well.

VIII. G. At the core of IR is **scalability and sustainability** which is not only an important outcome but also an ethical responsibility.

VIII.H. Given the impact of IR, the team must have a **strong dissemination plan** in place that involves all stakeholders from the community level to policy level. Thus, engagement across all levels right from the planning stage is imperative.

IX. Special Section: Doing Research with Vulnerable Populations

“Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power understanding or ability to communicate or are in a situation that prevents them from doing so” (ICMR, 2017).

The Declaration of Helsinki (2013) states that “Medical research involving a underprivileged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.”

For research with vulnerable populations, the ERB and the research team need to be mindful of the following:

IX.A. Research with vulnerable populations is **encouraged where it seeks to benefit** their situation directly or indirectly. However, it is discouraged in situations where a non-vulnerable population could have made up the sample and the study has no direct or indirect benefit to the vulnerable population.

IX.B. Researchers should put in place special measures to protect vulnerable participants. Even if participants are at a more than average level of minimal risk (physical, social, psychological, any kind of discomfort, financial, any other) in their everyday lives, researchers’ duty toward preventing risk remains high. **These measures are important to review.**

IX.C. Vulnerable persons may not be in a position to make autonomous or voluntary decisions due to self or external factors such as poverty, an expectation of benefits, etc. Thus, for instance, pregnant women, especially in patriarchal situations or in poor rural communities, would be considered vulnerable, and therefore researchers need to formulate ways to **promote their autonomy and voluntariness.**

IX.D. The ERB is responsible for reviewing research with vulnerable populations by doing a thorough **assessment of autonomy and voluntariness** (for instance, by looking out for undue inducement, making sure the informed consent process was adapted and made multilayered – if consent from the husband had to be taken to involve the wife in the study, then consent from the wife should be taken individually in private).

IX.E. Further, there may be reduced autonomy as a result of the circumstances of vulnerable participants, and the study may therefore involve taking consent/permission from a proxy or gatekeepers (such as the community head, tribal leaders, the Dean of a hospital and so on). However, this does not negate taking consent from the participant and following **the informed consent process** (information sharing; comprehension and competence; and autonomy and voluntariness) (Refer to ICMR, 2017 for details and refer to Form 2).

IX.F. The entire process of consent should be **documented** on paper and/or in the form of a recording (audio or video where applicable). The documentation should also mention those present at the time consent was given (member(s) of the research team and participant). The **privacy of the participant at the time of taking consent and doing research** is of paramount importance, and the ERB should ensure that the team has evolved mechanisms to ensure the same.

IX.G. Thus, it is important to ensure that measures are undertaken to **protect autonomy and protect participants from undue risk or burden of research.**

IX.H. **Clear justification** needs to be provided for the inclusion of vulnerable participants along with a clear statement on the **special measures taken for their protection and welfare**.

IX.I. The benefits and risks of research should be distributed fairly.

IX.J. The ERB should keep themselves **updated** on the latest guidelines and regulations involving vulnerable populations.

IX.K. The protocol and the ERB submission forms shared by the team should include **measures to gauge protection of and sensitivity towards vulnerable participants**. This would include, but is not limited to, measures put in place in the proposal, study protocol, informed consent information sheet and form, etc. to safeguard their rights and interests.

IX.L. While ERB members are required to **guide** researchers, researchers too can get in touch with ERB members and seek help to design such appropriate research protocols, informed consent processes, etc.

IX.M. No participant who has declined to participate in the study should be deprived of the benefits, direct or indirect, as a result of the research.

IX.N. In case there is a control arm in the research study, all efforts should be made to share the positive benefits of the study with the control group.

X. Special Section: Using Artificial Intelligence

Tools, methods, and technologies used in big data and artificial intelligence (AI) are already being used to improve health services, health systems, and policies. The scope of use of such data and AI is very relevant and useful and such use is here to stay. It is pertinent therefore that the ERB and research team anticipate and address the ethical issues that can arise in studies using AI.

X.A. The **benefits of using an AI system for research should be clear and documented** by the research team.

X.B. The ethical aspects of such studies concern the **ethical collection, analysis, and sharing of health data**. This includes but is not limited to:

- The **nature and scope of the informed consent** sought (broad vs dynamic with the option of opting out of the app or discontinuing use of the app/software without consequences) and **how such consent will be facilitated using technology** without compromising on the informed consent process (Form 2)
- **Right to decline** and how it can be implemented in the scenario of big data and AI
- Level and **scope of privacy and confidentiality** that can be ensured
- **Risk of harm and type of harm**
- **Programmer's biases and values** are important to address as well as issues of biased data as these could drive the algorithm. Biases and/or discrimination in algorithms can affect the collection and analysis of data. Thus, for instance, the data that is used to train AI is essentially what currently is available. Consider data on pregnant women. Now, if in this data, if unwed pregnant women are excluded from an algorithm, then their experiences will be excluded from the analysis and/or from benefits. The algorithm may also not consider the "human factor" or the contexts of women – such as why a woman might not be able to go for 4 antenatal care visits. By excluding women with less than 3 or 4 antenatal visits in the

data, we would be actually excluding the most powerless or those who need the services and relevant information the most. Moreover, because of the speed of AI and data size, the harm that can be done due to biased coding is multiplied

- **Challenges to ownership, sharing of data and forms in which data is shared and how it is used** (for instance, how will the technology partner use the data and what are the rights of that partner over the data?)
- **Security, reliability of data, and its appropriate use**
- **Issues with decision-making based on data analysed based on probabilities**
- Research teams and ERB need to recognise the stakeholders and identify the **ethical duties of the various stakeholders involved** including government and software developers and number crunchers

X.C. Research teams and the ERB should ensure that a **humanistic approach** is used when developing AI systems to ensure that human values drive development and use of the system to promote the rights and dignity of those affected by it. Aspects of gender sensitivity and cultural values should be considered while building and using such systems to make them fair.

X.D. Human insight can play a large role and therefore even **research participants** can help humanise these numbers. Their help could be involved in the analysis.

X.E. The AI systems must be **robust and transparent**; thus, what has gone into making the AI system should be made known and data sets and processes should be documented, making the results and outcomes explainable.

X.F. When reviewing a proposal that is seeking to use AI for research, an external expert on AI who understands the ethics of such research should be present during the meeting.

X.G. It is critical to **learn from international research and ARMMAN's own experience** in research using AI to continually and effectively balance the needs of science and ethics.

XI. Information on the ARMMAN Website

XI.A. Names and emails of both external members and the Secretariat are to be shared on the website of ARMMAN along with the ARMMAN office address.

XI.B. It should also have the SOPs and forms to be filled by the research teams.

XI.C. The biennial reports and the review/audit reports should be uploaded to the website.

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