**GUIDELINES FOR PROPOSAL SUBMISSION TO ARMMANs**

**SCIENTIFIC REVIEW BOARD (SRB) AND**

**ETHICS REVIEW BOARD (AERB)**

**(Draft for discussion)**

**Template for proposal submission to ARMMANs SCIENTIFIC REVIEW BAORD (SRB) AND ETHICS REVIEW BOARD (AERB)**

**(Draft for discussion)**

Whilst we are rigorously making efforts to improve the lives and health of vulnerable groups, we need to understand that the research undertaken by us, with however benevolent a rationale and approach, has the potential to cause harm. Research teams should attempt to anticipate harms, take steps to prevent them and make attempts to mitigate them should they arise during the course of their work. We are also very close to our work; and an external review by resource persons can help us get a different; an objective perspective on aspects we may have missed, particularly in the context of science and ethics. It also adds credibility to the work being done.

ARMMAN has systems in place for such external reviews for all research studies: ARMMANs Scientific Review Board (SRB) and ARMMANs Ethics Review Board (ERB). According to the National Ethical Guidelines for Biomedical and Health Research involving Human Participants, 2017; the ERB is responsible for ethical as well as scientific review of submitted proposals. The ARMMAN ERB is registered with the Department of Health Research, Ministry of Health and Family Welfare.

**The purpose of this document**

ARMMAN has large teams across their research departments. Many of them may be new to the processes and the requirements of the various components of their work. It is encouraged, and ideal, for seniors to handhold their team and have relevant discussions around SRB and AERB submissions. The present document serves to simplify the submissions made, and it is hoped that this would also act as a primer to relevant discussions regarding the submissions. It will also enable well timed and standardised style of submissions made and contribute towards facilitating the reviews as well.

Moreover, ARMMANs research and programmes content and strategies are inextricably linked; we have to ensure, to the best of our abilities, that research we do is needs based and scientifically and ethically sound. Enhancing the quality of our work, in this manner, is a crucial step to be able to better address the issues faced by millions of underprivileged.

Important points to be noted:

1. All research should undergo peer review (by the SRB and the Impact and advocacy team) as well as ethics clearance by the AERB.
2. Retrospective / post – facto clearance is not possible.

**For SRB review:**

1. Submission of proposals to the AERB secretariat, addressed to the chairperson of SRB, minimum of 50 days prior to the date of the scheduled AERB review meeting at [aerb@armman.org](mailto:aerb@armman.org).
2. Please prepare your proposals along the following guidelines for submission.
3. Please also submit the comprehensive set of tools prepared for the study.

**RESEARCH PROPOSAL GUIDELINES**

(Written in Times New Roman, font size 12 with one-inch margins and 1.15 spacing)

1. General Information on front page
2. Name of the study
3. Core team of investigators with brief profiles.
4. Project summary (200-300 words)

Should appear on the first page, below the General Information.

Should be an abridged version of the protocol, but yet give a complete picture and describe all the core components.

Accordingly, should include the rationale, objectives, methods, target or study population, expected outcomes, and so on.

1. Rationale and background information (750 – 1000 words)

This should answer the question, “Why does this study need to be undertaken?”, “Why is the question pertinent?”, “What is the magnitude of the problem?”.

It should clearly state the problem statement and its possible solutions that you seek to look at. This should be supported by crisp and relevant literature review. All facts and figures should be referenced. Multiple and relevant references strengthen the rationale and background, and are therefore encouraged. It also indicates the depth of literature review that has been undertaken by the research team.

Where you also seek to source your rationale in the work done by ARMMAN (besides the review undertaken above), it is encouraged to be done from published work or available reports and referenced accordingly. Make sure these study reports are already with the AERB (submitted as required at the end of a reviewed study) or if it pertains to a past study or programme related work not reviewed by AERB (unpublished work/study), then make sure the report is shared as an attachment to the AERB submission and referenced accordingly. Where such reports do not exist, give rationale for the same and alternatively internal project review reports or annual reports should be shared and referenced giving accurate details of date etc.[[1]](#footnote-0)

Positioning the study in external literature review and within ARMMANs programme needs; helps not only get a clearer picture, but also strengthen the rationale. It can add clarity to the research problem, refine your research methodology and even help contextualise the findings.

Please also note that ARMMAN researchers are required to follow the APA (American Psychological Association) standardised citation style.

1. Study goals and objectives (150 – 200 words)

The aim or goal or research question of a study is a broad, yet a clear statement, that defines the overall purpose of the study. It answers the question of why the study is being conducted, what is being investigated or what the researcher hopes to achieve.

Objectives are drawn from the goals and are specific. How does the study seek to answer the research question is listed as objectives.

1. Study design (500 – 750 words)

How are you going to achieve the objectives and hence the goal?

Thus follows: what is the study design, the sampling, how the sample size was arrived at, inclusion and exclusion criteria, study setting / context and so on. It is important to also state the expected duration of the study.

1. Methodology (500 – 750 words)

Methodology helps understand research from the start to the end.

This section should clearly state the methodology to be used, what is to be measured, how this will be done, procedure and tools for data collection, and so on.

1. The intervention (500 – 750 words)

Please share, in brief, the components of the intervention. Where, within this, is the research study for which approval has been sought is placed should be stated clearly.

1. Safety and Ethical considerations (500 – 1000 words)

It is important that all possible safety and ethical considerations that could possibly arise be discussed in detail amongst all team members, just like all other components of the study. Make sure ethical considerations are not just ticked off by making statements such as, “all efforts will be made to protect confidentiality.” Please refer to the AERB SOPs and the National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR, 2017) guidelines to help operationalize aspects of adverse events reporting and ethics in research respectively and other aspects around ethics and safety. Thus, for example, taking interviews of a woman who has just delivered has serious ethical concerns. There has to be a strong rationale behind including them in the study. What follows then are the special ethical considerations and systems put in place to ensure the research is ethically and safely conducted.

From an ethics perspective, every study submitted should present clarity and address the following:

* The rationale and purpose of the study, which is very important to address the question of essentiality;
* a sound informed consent process wherein the right to autonomy and voluntariness are ensured;
* review of efforts made towards anticipating possible harms and risks across the spectrum of the research study; and strategies in place to protect the participants from these; and possible mechanisms to mitigate eventualities;
* potential benefits;
* what methods have been devised to protect and ensure privacy, confidentiality and anonymity of research participants;
* plans for dissemination of research results, plans to build upon evidence generated and how might the results be shared with participants of research; are in place.
* Funding from which the study is designed.

1. Analysis and data management (300 – 500 words)

The proposal should clearly state how the data will be collected and managed. This should cover all aspects from data handling to coding. Also state methods to be used for analysis, statistical analysis to be done and the relevant details therein. Thus, in case of a quantitative study, make sure you note the level of significance used, software to be used, what will be done in case of missing data, etc.

How is the data being collected going to be used? (250 – 300 words)

Oftentimes, as noted earlier, ARMMAN conducts research as per its programme needs. However, we owe it to science to ensure that the work we do is available in the public domain. This makes it available for other researchers and programme planners to help plan their study or intervention or policy better; just as we used available studies to do our literature review to strengthen various aspects of our study. Thus, publication of study results in peer review journals is recommended and encouraged. At the very least, study reports should be uploaded on the ARMMAN website.

1. Authorship (250 – 300 words)

The Standard Operating Procedures (SOP) of the AERB and the National Ethical Guidelines for Biomedical and Health Research involving Human Participants (ICMR, 2017), follow the guidelines laid down by the International Committee of Medical Journal Editors on Authorship (ICMJE). Accordingly, “Authorship confers credit and has important academic, social, and financial implications. Authorship also implies responsibility and accountability for published work” (“Why Authorship matters?” [www.icjme.org](http://www.icjme.org)). The ICJME lays down specific criteria for contribution to be credited as an author. These can be accessed on <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>. It is important that the roles of each team member is clarified beforehand on the basis on these criteria. During the course of the study, roles can change and teams work through complementary expertise. There needs to be a discussion around these in the context of authorship criteria as well. Also see “Authorship Guidelines for Research Teams at ARMMAN” to operationalize this section. For access to the authorship guidelines, please contact the secretariat.

References

ICMR (2017): National Ethical Guidelines for Biomedical and Health Research involving Human Participants, Indian Council of Medical Resrearch (ICMR) <https://main.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf>

International Committee of Medical Journal Editors on Authorship (ICMJE). “Why authorship matters?” <https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>.

1. According to the SOPs, all research teams are required to submit yearly reports and / or study reports to the AERB.

   ARMMAN also encourages research and programme teams to have their work published in peer reviewed journals. It is also an excellent strategy to prepare detailed stand-alone research studies that can be put out in the public domain through our website. Inhouse peer review prior for all reports and papers prior to publication is an absolute necessity to ensure academic and scientific rigour. The Office of the Chief Impact Officer should be approached for the same. [↑](#footnote-ref-0)