Checklist for research teams prior to Stage 1 submission (prior to data collection) to ARMMANs Ethics Review Board (AERB)

The research teams and the AERB are required to follow the guidelines laid down by the Indian Council of Medical Research’s **National Ethical Guidelines for Biomedical and Health Research Involving Human Participants** (ICMR, 2017), the World Medical Associations (WMA) the **Declaration of Helsinki** (2013), and the **International Committee of Medical Journal Editors** (ICMJE) guidelines on authorship for publications; as well as the **Standard Operating Procedures (SOPs) of ARMMAN’S Ethics Review Board (AERB).**

It is the responsibility of the AERB to review all health research involving human participants being done by the organization for the purpose of safeguarding participants’ dignity, rights, safety and well – being , especially when they are marginalized, disadvantaged and vulnerable.

The research teams in the planning and conduct of the research, and the AERB in their review; should maintain and promote the highest possible ethical and scientific standards.

While overall the AERB strives to ensure that the study being reviewed promotes and protects this goal; it also reviews each study on specific aspects that operationalize the above. Some of these aspects include:

* The rationale and purpose of the study is very important to address the question of essentiality; and the study protocol to assess soundness of research.
* A concrete plan for informed consent (please see Form 2 to understand the process and prepare relevant documents and plans) wherein the right to autonomy and voluntariness are ensured.
* Effort to be made towards anticipating possible harms and risks across the spectrum of the research study; and there are strategies in place to protect the participants from these. Strategies and resources in place to address any adverse event that may arise during the course of the study.
* 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.

The documents required for a complete submission for **Stage 1 review; Prior to data collection** are:

1. Covering letter: A **formal letter of request** needs to be sent to the Secretariat addressed to the ERB enlisting the complete list of documents attached.
2. Brief CVs of core team.
3. Completed project submission form (Form 1).
4. Detailed Research Protocol and tools (please refer to the proposal submission guidelines).
5. Copy of the signed minutes of the Scientific Review Committee.
6. Copy / Copies of Memorandums of Understanding in case relevant.
7. Copy / copies of ethics approval certificate and comments if any other ethics committee is involved.
8. Request for subject matter expert/s if required with details and rationale.
9. Documents relevant to all the components of the Informed Consent Process (see Form 2) along with a copy of the information being shared in the Participant Information Format (PIF) in local language and English / or share audio file if audio being used to share information with the participants for the purpose of informed consent.
10. Any other document/s that you might find relevant to attach in order to better facilitate the process of review by the AERB and in accordance to the requirements of the submission form; such as permissions from agencies, etc. Please number them and add them to the above list.