ARMMAN’S ETHICS REVIEW BOARD (ERB)

(Letter head and details)

**Informed Consent Process (Section A and B) and**

**Form 2 (Section C)**

Informed consent is an integral and indispensable part of any research with human participants. It protects the participants autonomy and stresses on voluntariness regarding willingness to participate in a study.

**The informed consent process has three critical components –**

1. **Providing information** to the participants about the study in a format which they can keep or store. This is usually done in the form of sharing printed information also referred to as the “*Participant Information Sheet (PIS)*”. As ARMMAN makes extensive use of technology for research, the format in which this information is shared can be adapted to the needs of the project. Thus, for ARMMAN’s specific purpose, this component can be referred to as **Participant Information Format** (PIF).

The PIF can be in a form that may be required to facilitate the consent process – thus besides a printed sheet, such information can also be shared as a recorded audio or video message (simple and in a language that they understand).

The **purpose** of a PIF is to provide all relevant information regarding the study that a potential participant needs in order to make an **informed decision** about whether to participate or not in the study; and that this information has been given in a manner so that the participant has a copy (either a PIS or the relevant recording as per the requirement of the study) has been shared and available with them.

1. Researchers need to ask if participants have **read** the information **shared / listened** to the voice message / or accessed any other information format that was shared by the research team; and if they have understood the shared information. Researchers need to ensure that the information shared has been **comprehended** by the potential participants. It is therefore essential that the **information is also explained orally**, in simple words in a language they understand. Even medical terminology should be simplified. They should also be encouraged to ask questions and seek clarifications about the study.
2. The **signing of informed consent form** or any other mode of seeking **confirmed consent** using technology where needed (example, as used by ARMMAN; by replying “yes” to a message leading to confirmation of participation).

(A)

Based on the ICMR guidelines (1997), a Participant Information Sheet (shared on ARMMAN letter head) (in case of ARMMAN, it could be the relevant Participant Information Format); and consent seeking **should cover the following elements** in simple local language that the participants of research can comprehend. Whilst it is important that the information shared is comprehensive, care should be taken to not make it too lengthy and time consuming such that it defeats the purpose of “informing” the participants as they might not go through it in full -

1. Statement mentioning that it is a research study that the participant has been approached for.
2. Title of the study, purpose of the study and how it will be conducted to be explained in simple steps (i.e., explanation of the methodology with specific points where their participation is requested).
3. The kind of data to be collected and how it will be collected (interviews, FGDs, etc.). How will these be recorded should be explicitly mentioned.
4. Expected duration of the participation and frequency of contact (example, pre and post – test and at the time of sharing of data and information at the end of the study).
5. Anticipated / expected benefits to the participant, community or others that might reasonably be expected as an outcome of research.
6. Any foreseeable risks (Physical/social/psychological/discomfort/ financial/any other) to the participants resulting from participation in the study (example, they may need to take out time from their schedule specifically for the purpose and the assurance that this will be done as per their convenience).
7. Communication regarding voluntariness and autonomy regarding participation in the study and to right to withdraw from the study at any time without loss of potential benefits to which the participant would otherwise be entitled by being part of the target population or is already receiving as a result of a previous engagement in a connected study.
8. Extent to which confidentiality of records can be maintained, the limits

to which the researcher would be able to safeguard confidentiality and the anticipated consequences of breach of confidentiality.

1. Immediate use of data / information collected and form in which data / information will be shared with others (example, anonymous with no identifiable markers, or just aggregate data, etc.). Any anticipated future use of data or information thus collected (publications / secondary research / advocacy / etc.).
2. Payment/reimbursement for participation and incidental expenses, if any, depending on the type of study.
3. Possibility of any compensation if any injury / harm anticipated as a result of participation (loss in wages, loss of job, etc.).
4. Post – research plan and benefit sharing. Communication of outcomes of study to the participants, publication plans and assurance of anonymity. If any identifiable information requires to be used (such as a photograph), written consent for the same to be sought, even of faces or other identifiable markers to be blurred.
5. The identity of the research team and ERB members (Principal Investigator, Co – Principal Investigator; and Chairperson and Member Secretary of the ERB) with contact numbers with addresses. ARMMAN office email and phone numbers can be

the ones shared. The participants should be informed that they can contact the ERB members in case of any issue.

(B)

**ARMMAN letter head**

(letter head and details)

(Sample template, can be adapted to specific needs and language)

(**Oral communication** – after PIS or information in any other format has been shared)

Hello, my name is, (name and designation of researcher taking consent), and I work for ARMMAN. ARMMAN’s work focusses on the well - being of pregnant women, new mothers, infants and children in the first five years of their life. If you want more information about our work, you can visit our website [https://ARMMAN.org/](https://armman.org/) (OR share a brochure).

Today I am here as I am doing research with my team on a study titled, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Detailed information about the study has been shared with you via a what’s app voice message / pamphlet / (state mode of sharing participant information format). Have you read the sheet / heard the voice message?

(If no) – please take the time to do so. I will wait here / come back / call back another day (as relevant). Can you tell me when I can come back / call you back (as relevant)?

(If yes) - I am here / talking to you personally; to help you understand the study and how your participation can help us (**share the details of the study orally as shared in the PIF in simple local language**).

(Continue) You can take time to make your decision and you can speak to anyone you feel comfortable with about the study. Is there anything that I have shared with you that you would like to understand better? Can you please share that with me so that I can clarify your doubts?

(The researcher should also ask questions to ensure that the potential participant has understood the details. These could be, “Can you tell me what this study is about?” or “Why we have approached you to participate?”, “Do you know you can say no to participation or withdraw at any stage?” and so on).

This study has been reviewed by the ARMMAN Ethics Review Board who are helping us do the study in the best way possible. Their Names and numbers are (Chairperson and Member secretary). Feel free to contact them if you have any problems while participating in the study. Share how you will ensure privacy (at the time of the interview), confidentiality (of information) and their identity (anonymity).

(If potential participant agrees to participate, inform them that they would like to confirm participation using the informed consent form or they should reply on technology enabled confirmation of consent).

(C)

**(Form 2)**

**INFORMED CONSENT FORM (ICF)**

(a copy remains with the participant and one with ARMMAN)

Name of participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(name to be given an identification number to protect anonymity and confidentiality or omit if not needed. Can be replaced with phone number).

Name of study:

I have understood the study as explained to me and I have also heard on the audio / video message / read on the pamphlet/\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(state the participant information format used to share information about the study with the participants). I voluntarily agree to participate in this study for the said duration. I understand that I can withdraw my participation at any point without consequences and understand the potential risks and benefits along with extent of confidentiality possible to be given and future anonymous use of data thus generated as part of this study for research purposes for the benefit of more people and for science in general (read it out if required).

Name of the Organization: ARMMAN

Address and phone numbers: Details

Name of the Principal Investigator:

Name of the Co – Principal Investigator:

Signature of Participant \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*If illiterate,* take witness signature:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Name of witness\_\_\_\_\_\_\_\_\_\_\_\_Thumb print of participant

Signature of witness \_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Statement by the researcher taking consent -

I have shared the information about the study in a Participant Information Format and I have shared the same orally to the potential participant, and to the best of my ability made sure that the participant understands what is the study is about and her role as a participant. I confirm that the participant was given an opportunity to ask questions about the study, and that these were answered to the best of my ability. I confirm that the individual has not been coerced directly or indirectly into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Name of Researcher/person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Researcher /person taking the consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_