**ARMMAN’s ETHICS REVIEW BOARD**

**(LETTER HEAD AND DETAILS)**

**(Form 1)**

**APPLICATION FOR STAGE 1 REVIEW; PRIOR TO DATA COLLECTION**

The research teams and the ERB 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 (ERB). There should be ethical compliance and consistency in conduct of research as well as in ethics review.** Right from the beginning, while planning studies, the research teams should be well versed with ethical guidelines.

It is the responsibility of the ERB 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 conduct of the research, and the ERB in their review should maintain and promote the highest possible ethical and scientific standards.

The submissions by the research team should be complete and be prepared in line with the SOPs and the ethical guidelines.

While overall the ERB 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:

* The rationale and purpose of the study is very important to address the question of essentiality;
* a sound informed consent process (Form 2) wherein the right to autonomy and voluntariness are ensured;
* there has been an effort 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;
* 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.

A **formal letter of request** needs to be sent to the Secretariat addressed to the ERB enlisting the complete list of documents attached and if teams have a special request such as a subject matter expert.

The documents required for a complete submission for **Stage 1 review; Prior to data collection**, are (you can attach this list to the submission being made and tick where relevant). Please number documents submitted in the same serial order as stated below. Example, if an MOU is relevant and shared – tick against it and put it as item number 7 in the list of attachments shared in the mail.

1. Covering letter
2. Brief CVs of core team
3. Completed project submission form (the present one, Form 1 filled by the team)
4. Project proposal with literature review
5. Detailed Research Protocol and tools (including project summary, rationale and background information, goals and objectives, study design and methodology, interview guide or focus group guide or questionnaire – as relevant, an explanation of the content of intervention/s, ethics and safety management plan, data analysis plan, publication and dissemination plan, etc.) (translated versions, where relevant, should be shared as well).
6. Copy of the signed minutes of the Scientific Review Committee
7. Copy / Copies of Memorandums of Understanding in case relevant
8. Copy / copies of ethics approval certificate and comments if any other ethics committee involved
9. Request for subject matter expert/s if required
10. Budget heads and allocation for each (if required, or can be entered in the form as well)
11. Documents relevant to all the components of the Informed Consent Process (Form 2) along with a copy of the information being shared in the Participant Information Format (PIF) in local language and English.
12. Any other document/s that you might find relevant to attach in order to better facilitate the process of review by the ERB and in accordance to the requirements of the submission form; such as permissions from agencies (see I.4), etc. Please number them and add them to the above list.

**ARMMAN’s ETHICS REVIEW BOARD (ERB)**

**(LETTER HEAD AND DETAILS)**

**(Form 1)**

**APPLICATION FORM STAGE 1 REVIEW: PRIOR TO DATA COLLECTION**

TITLE OF THE STUDY: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

REVIEW REQUESTED:

|  |  |
| --- | --- |
| REGULAR FULL COMMITTEE REVIEW |  |
| EXPEDITED REVIEW |  |

**SECTION I**

1. A. NAME OF THE PRINCIPAL INVESTIGATOR with AFFILIATION:

B. NAME OF THE CO – PRINCIPAL INVESTIGATOR with AFFILIATION:

(All ERB correspondence will be sent to the PI and Co-PI)

C. IF PI AND / OR CO – PI NOT FROM ARMMAN, CITE REASONS:

D. BESIDES THE PI AND CO-PI, WHO ARE THE OTHER CORE MEMBERS OF THE RESEARCH STUDY? STATE WITH AFFILIATIONS.

1. A. IS THIS A MULTICENTRIC STUDY? YES / NO

B. HAS THERE BEEN ANY OTHER ETHICAL REVIEW? YES / NO

IF YES, PLEASE SHARE CERTIFICATE AND FEEDBACK AS ATTACHMENTS.

1. HOW HAS THE RESEARCH TEAM / THOSE ASSOCIATED WITH THE STUDY FOR SPECIFIC PURPOSES / OR FOR ANY WORK THAT HAS BEEN OUTSOURCED; BEEN TRAINED FOR THE PURPOSE OF THE STUDY? WHAT SPECIFIC ETHICS RELATED GUIDANCE HAS BEEN PROVIDED TO THEM FOR THEIR FIELDWORK AND AFTER?
2. A. DOES THE STUDY REQUIRE ANY PERMISSIONS FROM AGENCIES? YES / NO

B. STATE FROM WHICH AGENCIES / GOVERNMENT DEPARTMENTS / HOSPITAL (SPECIFY) (AND ATTACH A COPY OF PERMISSION):

1. A. IS THIS A COLLABORATIVE STUDY? YES / NO

IF YES, NAME/S OF COLLABORATORS:

B. IS THERE A MEMORANDUM OF UNDERSTANDING (MOU) SIGNED WITH COLLABORATORS? YES / NO

IF NO, PLEASE SHARE WHY NOT:

C. IF YES, ATTACH A COPY OF THE MOU AND SHARE IN BRIEF THE ROLES AND RESPONSIBILITIES OF EACH COLLABORATOR:

1. HOW IS THIS PROJECT FUNDED? SHARE THE TOTAL BUDGET, BUDGET HEADS OR ATTACH A COPY OF THE BUDGET.
2. YOU HAVE ATTACHED A COPY OF THE COMMENTS AND SIGNED MINUTES OF THE SCIENTIFIC REVIEW COMMITTEE FOR YOUR PROJECT. ARE THERE ANY RECOMMENDATIONS OF THE COMMITTEE THAT HAVE NOT BEEN IMPLEMENTED? PLEASE STATE ONLY THOSE HERE ALONG WITH YOUR REASONS.

**SECTION II**

1. A. WHAT IS THE KIND OF STUDY PROPOSED (SOCIAL SCIENCE RESEARCH, IMPLEMENTATION RESEARCH, RANDOMISED CONTROL TRIAL, CLUSTER RANDOMISED CONTROL TRIAL, RETROSPECTIVE, QUALITATIVE, QUANTITATIVE, MIXED METHOD, ETC)?

B. SHARE THE RATIONALE FOR THE STUDY AND WHAT NEW INFORMATION / KNOWLEDGE DO YOU THINK THE STUDY WILL CONTRIBUTE?

C. DURATION OF THE STUDY AND PHASES / STAGES IF RELEVANT:

1. A. IN CASE OF IMPLEMENTATION RESEARCH SHARE THE ROLES PLAYED BY VARIOUS STAKEHOLDERS, INCLUDING PARTICIPANTS:

B. INFORMED CONSENT TO BE SOUGHT FROM WHO ALL? (PLEASE MAKE SURE YOU HAVE UNDERSTOOD THE INFORMED CONSENT PROCESS AND FILLED AND ATTACHED THE RELEVANT FORM 2 TO BE SUBMITTED ALONG WITH THE PRESENT APPLICATION).

C. i. WHAT ARE THE RISKS AND BENEFITS THAT YOU ANTICIPATE AS A RESULT OF THE STUDY?

ii. HOW ARE THESE BALANCED FOR ALL STAKEHOLDERS, PARTICULARLY IF IT INVOLVES RANDOMISATION?

1. A. PLEASE STATE THE METHOD/S OF DATA COLLECTION TO BE USED IN THE STUDY:

|  |  |  |  |
| --- | --- | --- | --- |
| FOCUS GROUPS |  | INTERVIEWS |  |
| QUESTIONNAIRE / SURVEY |  | OBSERVATIONS |  |
| CASE HISTORIES / ORAL HISTORIES |  | EXISTING DOCUMENTS AND RECORDS |  |
| ANY OTHER: | | | |

B. IF ANY OF THE ABOVE ARE TO BE RECORDED BY ANY AUDIO / VISUAL DEVICE, PLEASE SHARE RATIONALE. ALSO SHARE STRATEGIES TO PROTECT THE INFORMATION THUS RECORDED:

1. WHAT IS THE TOTAL SAMPLE SIZE AND SAMPLING PLAN ACROSS THE CATEGORIES OF PARTICIPANTS (INCLUDING CRITERIA USED FOR SATURATION IN CASE QUALITATIVE)?
2. ARE THE PARTICIPANTS GOING TO BE GIVEN COMPENSATION / INCENTIVES TO PARTICIPATE? YES / NO

IF YES, ARE THESE MONETORY / NON – MONETORY?

SHARE DETAILS AND JUSTIFY.

1. A. WHO ARE THE STUDY PARTICIPANTS AND THE RATIONALE BEHIND DOING THE STUDY WITH THIS SPECIFIC GROUP/S?

GIVE JUSTIFICATION FOR THE INCLUSION AND EXCLUSION CRITERIA.

B. IF THE PARTICIPANTS BELONG TO VULNERABLE GROUPS WHAT PRECAUTIONS HAVE BEEN TAKEN?

**SECTION III**

1. A. PLEASE STATE WHETHER –

|  |  |
| --- | --- |
| YOU HAVE SUBMITTED DOCUMENTS RELEVANT TO THE INFORMED CONSENT PROCESS |  |
| REQUESTING WAIVER OF CONSENT |  |

B. FOR THE INFORMED CONSENT PROCESS, PLEASE ENTER THE INFORMATION THAT HAS BEEN COVERED ACROSS THE INFORMED CONSENT PROCESS (A, B AND C)[[1]](#footnote-1):

|  |  |
| --- | --- |
| STEPS | TICK WHERE RELEVANT |
| PARTICIPANT INFORMATION FORMAT | PARTICIPANT INFORMATION SHEET/ RECORDED AUDIO MESSAGE / RECORDED VIDEO MESSAGE / ANY OTHER PLEASE SPECIFIY: |
| MODE OF SHARING: ONE ON ONE / THROUGH WHAT’S APP / THROUGH CALLS FROM CALL CENTRE / ANY OTHER PLEASE SPECIFY: |
| ORAL COMMUNICATION AND SHARING ABOUT THE STUDY | TRANSLATED IN LOCAL LANGUAGE / S: YES / NO  LANGUAGES TRANSLATED INTO: |
| CONFIRMATION OF CONSENT | ORAL / WRITTEN INFORMED CONSENT FORM / TECHNOLOGY ENABLED (PLEASE SPECIFY): |

C.INFORMATION COVERED IN THE INFORMED CONSENT PROCESS (A AND B) ABOVE (PLEASE TICK):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| It is a research study |  | Title, purpose |  | How it will be conducted? |  |
| Kind of data to be collected |  | Method of data collection |  | Number of interviews / meets |  |
| Expected duration of participation |  | Expected duration of the study |  | Anticipated benefits |  |
| Anticipated risks / discomfort |  | Participation voluntary and autonomous |  | Right to withdraw |  |
| Anonymity and confidentiality |  | Immediate use of data |  | Long term / future use of data |  |
| Any payment / reimbursement |  | How results will be shared with them |  | Contact information about ARMMAN and ERB |  |

1. IF ANY INFORMATION NOT SHARED / WITHHELD, PLEASE EXPLAIN:

1. IS INFORMED CONSENT BEEN SOUGHT FROM ANYONE BESIDES THE STUDY PARTICIPANT (GATEKEEPER/FAMILY MEMBER)? IF YES, PLEASE MENTION FROM WHOM ELSE AND RATIONALE. UNDER THE CIRCUMSTANCES, WHAT PLAN DO YOU HAVE IN PLACE TO ENSURE VOLUNARINESS AND AUTONOMY OF THE PARTICIPANTS BEING APPROACHED FOR THE STUDY?
2. IF SOMEONE ELSE IS GIVING CONSENT ON BEHALF OF THE STUDY PARTICIPANT PLEASE JUSTIFY AND STATE FROM WHOM (PARENT / LEGALLY AUTHORISED RESPRESENTATIVE – LAR / ANY OTHER). WHAT STEPS WILL BE TAKEN TO PROTECT THE RIGHTS OF THE PARTICIPANT UNDER THE CIRCUMSTANCES?
3. IF REQUESTING WAIVER OF CONSENT SHARE RATIONALE. HOW DO YOU PLAN TO PROTECT AND PROMOTE THE RIGHTS OF THE PARTICIPANTS UNDER THE CIRCUMSTANCES?
4. IN CASE OF RESEARCH USING ARTIFICIAL INTELLIGENCE (AI) –
5. PLEASE STATE THE RATIONALE FOR THE USE OF AI AND HOW IS IT BEING PLANNED TO BE USED?
6. HOW WILL DATA BE STORED, SHARED AND USED BY THE MULTIPLE STAKEHOLDERS AND MENTION THE STAKEHOLDERS. UNDER THE CIRCUMSTANCES, WHAT ARE THE ETHICAL ISSUES ADDRESSED IN THE CONTEXT OF PRIVACY, CONFIDENTIALITY AND ANONYMITY OF PARTICIPANTS AND DATA PERTAINING TO THEM?
7. WHAT SYSTEMS HAVE BEEN PUT IN PLACE TO ENSURE THAT DATA SETS AND PROCESSES THAT ARE BEING USED TO MAKE ALGORITHMS HAVE BEEN REVIEWED AND BIASES ADDRESSED?
8. WHAT ARE THE SYSTEMS IN PLACE TO ENSURE THAT THE DATA GENERATED IS ALSO FREE OF BIASES?
9. HOW WILL PARTICIPANTS OF RESEARCH BE USED TO “HUMANIZE” THE RESEARCH AND ENSURE A CONTEXT TO THE STUDY AND SUBSEQUENT ANALYSIS?

**SECTON IV**

1. WHO ARE THE STUDY PARTICIPANTS AND THE RATIONALE BEHIND DOING THE STUDY WITH THIS SPECIFIC GROUP / S?

GIVE JUSTIFICATION FOR THE INCLUSION AND EXCLUSION CRITERIA.

1. IF THE PARTICIPANTS BELONG TO VULNERABLE GROUPS (SEE SOPs SECTION VIII) WHAT PRECAUTIONS HAVE BEEN TAKEN?
2. WHAT IS THE STUDY SETTING (AT PARTICPANTS HOME / AT A HOSPITAL WARD / ANY OTHER)? WHAT STEPS ARE GOING TO BE TAKEN TO ENSURE PRIVACY AT THE TIME OF ADMINISTRATION OF THE TOOL?
3. WHAT SOCIO – CULTURAL NORMS HAVE BEEN TAKEN INTO CONSIDERATION WHILST PLANNING THE STUDY? HOW HAVE THESE BEEN INCORPORATED INTO THE PROTOCOL?
4. A. WHAT ARE THE POTENTIAL RISKS INVOLVED IN THIS STUDY (PHYSICAL/SOCIAL/PSYCHOLOGICAL/ANY KIND OF DISCOMFORT/FINANCIAL/ANY OTHER) (IF ADDESSED IN 9, PLEASE ADD CROSS REFERNCE)?

B. WHAT STEPS WILL BE TAKEN TO MITIGATE THESE RISKS?

C. WHAT ARE THE POTENTIAL BENEFITS OF THE STUDY (DIRECTLY TO THE PARTICIPANTS / TO THE COMMUNITY WHERE THE STUDY IS BEING DONE / TO THE SOCIETY / TO SCIENCE? PLEASE SHARE DETAILS.

D. HOW DO YOU THINK ARE POTENTIAL RISKS BALANCED AGAINST POTENTIAL BENEFITS?

**SECTION V**

1. A. PLEASE SHARE THE DATA ANALYSIS PLAN. WHAT STEPS ARE GOING TO BE TAKEN TO PROTECT CONFIDENTIAL INFORMATION AND FOR ANONYMITY OF RESEARCH PARTICIPANTS?

B. HOW IS THE DATA THUS GENERATED GOING TO BE USED (IMMEDIATE AND FUTURE USE)?

C. HOW IS THE DATA GOING TO BE STORED? FROM THE POINT OF COLLECTION TO ANALYSIS AND FUTURE USE:

**SECTION VI**

1. DESCRIBE IN BRIEF THE DISSEMINATION / PUBLICATION PLANS FOR THE FINDINGS OF THE STUDY TO THE PARTICIPANTS AND TO THE LARGER COMMUNITY OF RESEARCHERS AND POLICY MAKERS.
2. HAVE YOU IDENTIFIED A WAY FORWARD IF YOU FIND THAT THE INTERVENTION STUDIED / OUTCOME OF THE STUDY WAS POSTIVE? PLEASE SHARE IN THE CONTEXT OF THE PARTICIPANTS OF RESEARCH AS WELL AS IN THE LARGER CONTEXT (EXAMPLE, CONTINUE PROVISION OF INTERVENTION TO THE STUDY PARTICIPANTS, LEVERAGING THE SAME, ADVOCACY ETC. DO MENTION HOW IT MIGHT BE DONE INCLUDING PRACTICAL ASPECTS SUCH AS FUNDING).
3. IS THERE ANY OTHER INFORMATION REGARDING THE STUDY THAT YOU MIGHT WANT TO ADD?

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Signature of the PI Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Co – PI Date

1. Please refer to FORM 2 [↑](#footnote-ref-1)