Annexure 1

AX 01/SOP 05-A/V 7

Application Form for Initial Review for all types of trials.

General Instructions:

a. Tick one or more as applicable. Mark NA if not applicable.
b. Attach additional sheets if required.
c. May select more than one option.
d. Signature of HODs of all collaborative departments is mandatory.

SECTION A- BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

IEC No. of the Project:		**Submission Date:**			
a. Type of review requested:					
Exemption from Review		**Expedited Review**		**Full Committee Review**	

b. Title of the Study:

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Acronym/Short Title (If Any): .....

c. Protocol Number (If Any): ..... **Version number with date:** .....

d. Details of Investigators:

	Name	**Designation & Qualifications**	**Department & Institution**
Principal Investigator			
Co-Investigator-1			
Co-Investigator-2			
Co-Investigator-3			
Co-Investigator-4			

e. Duration of the Study: .....

f. Number of study visits: .....

2. FUNDING DETAILS AND BUDGET

a. Total estimated budget for site: .....

b. Self-Funding ☐ **Institutional Funding** ☐ **Funding Agency *(Specify)*** ☐

c. Research fund will be deposited in: DJST ☐ **DDF** ☐ **Research Society** ☐ **MRU** ☐

Other ☐ **If other, please specify** ……

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SECTION B- RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

a. Lay Summary (Within 300 words): ……

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b. Type of study:

Basic Sciences ☐	Clinical ☐	Academic Clinical Trial ☐
Retrospective ☐	Epidemiological/Public Health ☐	Cross Sectional ☐
Prospective ☐	Socio-behavioural ☐	Cohort ☐
Qualitative ☐	Biological samples ☐	Systematic Review ☐
Quantitative ☐	Regulatory Clinical Trial ☐	
Mixed Method ☐	Any Other *(Specify)* ☐	

4. METHODOLOGY

a. Sample size/number of participants

KEMH …… India …… Global ……..

Control Group …… Study Group ……

Justification for the sample size chosen (100 words); In Case of Qualitative study, mention the criteria used for saturation ……

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b. Clinical: Single Centre ☐ Multicentre ☐

If Multicentre,

No. of Centres in India …….. No. of Centres Globally ……

c. Is there an external laboratory/outsourcing involved for Investigators? Yes ☐ No ☐ NA ☐

SECTION C- PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a. Type of participants in the study:

Healthy Volunteers ☐ Patient ☐ Others ☐ ***(Specify)***……

Who will do the recruitment? ……

Participant recruitment methods used:

Posters/Leaflets/Letters ☐ TV/Radio ads/social media/Institution website ☐

Patients/Family/Friends visiting hospitals ☐ Telephone ☐ Others ☐ (***Specify)***

……

b. i. Will there be vulnerable persons/special groups involved? Yes ☐ No ☐ NA ☐

ii. If Yes, type of vulnerable persons/special groups

Children under 18 years	☐	Pregnant or Lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and Socially Disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally Ill (Stigmatized or Rare Diseases)	☐		
Any Other (Specify)	☐	……	

iii. Provide justification for Inclusion/Exclusion ……

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iv. Are there any additional safeguards to protect research participants? ……

……

c. Is there any reimbursement to the participants? Yes ☐ No ☐

If Yes, Monetary ☐ Non-monetary ☐ Provide details

……

6. BENEFITS AND RISKS

a. i. Are there any anticipated physical/social/psychological discomforts/risk to participants?

Yes ☐ No ☐

If Yes, categorized the level of risk:

Less than Minimal risk	☐	Minimal Risk	☐
Minor increase over minimal risk or low risk	☐	More than minimal risk or High risk	☐

ii. Describe the risk management strategy: ……

……

b. What are the potential benefits from the study?

	Yes	No	If Yes,	Direct	Indirect
For the participant	☐	☐		☐	☐
For the Society/community	☐	☐		☐	☐
For Improvement in science	☐	☐		☐	☐

Please describe how the benefits justify the risks ……..

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c. Are Adverse events expected in the study? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify ……

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7. INFORMED CONSENT

a. Version number and date of Participant Information Sheet (PIS): ……..

Version number and date of Informed Consent Form (ICF): ……

b. Type of consent planned for:

Signed Consent ☐ Verbal/Oral Consent ☐ Waiver of Consent ☐ Witnessed consent ☐

Consent from LAR ☐ For children <7 years parental/LAR consent ☐ Verbal assent from minor (7-12 years) along with parental consent ☐ Written assent form minor (13-18 years) along with parental consent ☐

(If so, specify from whom) ……..

Audio-Video (AV) Consent ☐ Others *(Specify)* ☐ ……

c. Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counseller ☐ Research Staff ☐ Others ***(Specify)*** ☐ ……

Any tools to be used ……

d. Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local Language ☐ Others ***(Specify)*** ☐ ……

List the languages in which translations were done ……

If translations has not been done, please justify ……

e. Are you seeking waiver of consent? If yes, what are the reasons. Yes ☐ No ☐

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f. Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

Simple language ☐	Data/Sample sharing ☐	Compensation for study related injury ☐
Risks and discomforts ☐	Need to recontact ☐	Statement that consent is voluntary ☐
Alternatives to participation ☐	Confidentiality ☐	Commercialization/Benefit sharing ☐
Right to Withdraw ☐	Storage of samples ☐	Statement that study involves research ☐
Benefits ☐	Return of research results ☐	Use of photographs/ identifying data ☐
Purpose and Procedure ☐	Payment for participation ☐	Sponsor contact information ☐
Others ***(Specify)*** ☐	……	

8. PAYMENT/COMPENSATION

a. Who will bear the costs related to participation and procedures?

PI ☐ Institution ☐ Sponsor ☐ Other agencies *(Specify)* ☐

……

b. Is there a provision for free treatment of research related injuries? Yes ☐ No ☐

If yes, then who will provide the treatment? ……

c. Is there a provision for compensation of research related SAE? If Yes, specify. Yes ☐ No ☐

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

9. STORAGE AND CONFIDENTIALITY

a. Identifying Information: Study Involves samples/data ***(Specify)***:

Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited/data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

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b. Who will be maintaining the data pertaining to the study? ……

c. Where will the data be analyzed and by whom? ……

d. For how long will the data be stored? ……

e. Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

If yes, explain how you might use stored material/data in the future? ……

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SECTION D- OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

a. Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐

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b. Will you inform participants about the results of the study? Yes ☐ No ☐

c. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes, describe in brief (Max 50 words) Yes ☐ No ☐ NA ☐

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d. Is there any plan for post research benefit sharing with participants? Yes ☐ No ☐

If yes, specify ……..

……..

e. Is there any commercial value or a plan to patent/IPR issues? Yes ☐ No ☐

If yes, please provide details ……

f. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes ☐ No ☐

If yes, please provide details ……

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SECTION E- DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)	
☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.

☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. …… 2. ……

Name of Principal Investigator (PI) **Signature with date**	**Name of Co-Investigator (Co-I)-5** **Signature with date**
Name of Co-Investigator (Co-I)-1 **Signature with date**	**Name of Co-Investigator (Co-I)-6** **Signature with date**
Name of Co-Investigator (Co-I)-2 **Signature with date**	**Name of Co-Investigator (Co-I)-7** **Signature with date**
Name of Co-Investigator (Co-I)-3 **Signature with date**	**Name of Co-Investigator (Co-I)-8** **Signature with date**
Name of Co-Investigator (Co-I)-4 **Signature with date**	**Name of Co-Investigator (Co-I)-9** **Signature with date**

12. CHECKLIST

Sr. No.	Items	Yes	No	NA	Enclosure No.	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover Letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of Investigators in the last 3 years.	☐	☐	☐		
4.	EC clearance of other centres	☐	☐	☐		
5.	Agreement between collaborating partners	☐	☐	☐		
6.	MTA between collaborating partners	☐	☐	☐		
7.	Insurance policy/certificate	☐	☐	☐		
8.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
9.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
10.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (Whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
11.	Copy of the detailed protocol	☐	☐	☐		
12.	Investigators Brochure (If applicable for drug/biologicals/device trails)	☐	☐	☐		
13.	Participants Information Sheet (PIS) and Participant Informed Consent Form (ICF) (English and translated) (Hindi & Marathi mandatory)	☐	☐	☐		
14.	Assent form for minors (12-18 years) (English and translated) Hindi & Marathi mandatory	☐	☐	☐		

15.	Proforma/Questionnaire/Case Record Forms (CRF)/Interview Guides/Guides for Focused Group Discussion (FGDs) (English and translated)	☐	☐	☐		
16.	Advertisement/material to recruit participants (Filters, posters, etc.)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other Permissions	**Required**	**Not Required**	**Received**	**Applied DD/MM/ Year**	**EC Remarks**
17.	CTRI	☐	☐	☐		
18.	DCGI	☐	☐	☐		
19.	HMSC	☐	☐	☐		
20.	RCGM	☐	☐	☐		
21.	GEAC	☐	☐	☐		
22.	BARC	☐	☐	☐		
23.	Tribal Board	☐	☐	☐		
24.	Others ***(Specify)***	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	**Yes**	**No**	**NA**	**Enclosure no.**	**EC Remark**
25.						
26.						