Annexure 15- Initial Review Form for Multicentric Research

Yenepoya Ethics Committee-3(YEC-3)

EC Ref. No. *(for office use):*

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable. Attach additional sheets if required
b) For submission to Designated Ethics Committee and to be shared with PIs at Participating Centres

PART 1 (To be filled by coordinating PI)

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Institute under which Designated Ethics Committee is constituted:

(b) Name of the Ethics Committee:

(c) Name of Coordinating Principal Investigator:

(d) Designation and Qualification:

(e) Department/Division: (e) Date of Submission: Click here to enter a date.

(f) Address for communication *(include email and mobile no.)*

(f) Type of review requested[1]**:**

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

(g) Title of the study:

Acronym/ Short title, (If any):

(h) Protocol number (If any): Version number: Date: Click here to enter a date.

(i) Number of studies where applicant is a:

i) Principal Investigator at time of submission: ii) Co-Investigator at time of submission:

(j) Duration of the study:

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for study:

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review*

At site In India Globally

(b) Self-funding ☐ Institutional funding ☐ Funding agency ☐
(Specify)

SECTION B – RESEARCH-RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study[2] (within 300 words)

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐			Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

4. METHODOLOGY

(a) Sample size/ No. of Participants (*as applicable)*

At site In India Globally

Control group Study Group

Justification for the sample size chosen (*100 words*); In case of qualitative study, mention the criteria used for selection

(b) Is there an external laboratory/ outsourcing involved for investigations?[3] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review	☐	Review by Sponsor/Funder	☐	Review within PI's institution	☐
Review within multi-centre research group	☐	No Review	☐		

Date of review: Click here to enter a date.

[2] *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*
[3] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.*

Comments of Scientific Committee, if any (100 words)

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable person/ Special groups ☐ 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 person/special groups involved? Yes ☑ No ☐ NA ☐

ii. If yes, type of vulnerable person /special groups

Children under 18 yrs. ☐ 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

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

(c) Is there any reimbursement to the participant? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ Provide details

(d) Are there any incentives to the participant? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ Provide details

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?

If yes, Monetary ☐ Non-monetary ☐ Provide details Yes ☐ No ☐

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[4]:

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

(c) Are Adverse Events expected in the study[5]? Yes ☐ No ☐ NA ☐

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

If Yes, Specify

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8. Yes ☐ No ☐

(b) Version number and date of Participant Information Sheet (PIS):

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

(c) Type of consent planned for:

Signed consent	☐	Verbal/ oral consent	☐	Witnessed consent	☐	Audio-Video (A/V) consent	☐
Consent from LAR (If so, specify from whom)	☐	For children<7 yrs parental/LAR consent	☐	Verbal assent from minor (7-12 yrs) along with parental consent	☐	Written Assent from Minor (13-18 yrs) along with parental consent	☐

Other *(specify)* ☐

[4] *For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1*

[5] *The term adverse events in this regard encompass both serious and non-serious adverse events.*

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other *(Specify)* ☐

Any tools to be used

(e) Participant Information Sheet (PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ other ☐ (*specify*)

List the languages in which translations were done

If translation has not been done, please justify

(f) Provide details of Consent requirement for previously stored samples if used in the study[6]

(g) 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	☐	Contact information of PI and Member Secretary of EC	☐
Others*(Specify)*	☐				

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[7]?

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

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

If yes, then who will provide the treatment?

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

Sponsor ☐ Institution/ Corpus funds ☐ Project grants ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ NA ☐

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[6] *Information on re-consent requiremnts can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Particpants 2017, Page 54 in Section 5.8*

[7] *Enclose undertaking from PI confirming the same*

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, Specify Yes ☐ No ☐ NA ☐

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.)

(b) Who will be maintaining the data pertaining to the study?

(c) Where will the data be analyzed[7] 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?

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 ☐ NA ☐

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(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 ☐

(d) Is there any plan for post research benefit sharing with participants? If yes, specify
Yes ☐ No ☐ NA ☐

(e) Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details

Yes ☐ No ☐ NA ☐

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

[7] *For example, a data entry room, a protected computer etc.*

SECTION E: CHECKLIST FOR COORDINATING PI

11. CHECKLIST

S.No	Items	Yes	No	NA	Enclosure No.	EC Remarks
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4.	Approval of Scientific Committee/ NTF/ Central Advisory Committee/ Any other	☐	☐	☐		
5.	Agreement/MTA / LOA between collaborating partners	☐	☐	☐		
6.	Insurance policy/certificate	☐	☐	☐		
7.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
8.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
PROPOSAL RELATED						
9.	Copy of the detailed protocol	☐	☐	☐		
10.	Participant Information Sheet (PIS) and Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
11.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
12.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
13.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**	**EC Remarks**
14.	CTRI[8]	☐	☐	☐	Enter date	
15.	HMSC[9]	☐	☐	☐	Enter date	

16.	Tribal Board	☐	☐	☐	Enter date	

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable. Attach additional sheets if required
b) For submission to Participating Ethics Committee (PEC) and to be shared with coordinating PI

17.	Any Other	☐	☐	☐	Enter date	

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY						
	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**

PART 2 (To be filled by S-PI at the Participating Centre)

18.		☐	☐	☐		

[8]*CTRI: Clinical Trial Registry- India,* [9]*HMSC: Health Ministry's Screening Committee*

1. ADMINISTRATIVE DETAILS

a) Name of the institute under which PEC is constituted:

SECTION A - BASIC INFORMATION

b) Name of the Ethics Committee:

c) Name of Site Principal Investigator:

d) Designation/ Qualification: e) Department/ Division:

f) Address for communication (include mobile no. and email address):

g) Expected duration of the study**:** Estimated budget at the participating site:

SECTION B - RESEARCH INFORMATION

1. OVERVIEW OF RESEARCH

a) Briefly describe the role of the participating center in the study (*50-100 words*):

b) Briefly mention local changes made in protocol, if any:

c) Type of review requested**:**

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

SECTION C – PARTICPANT RELATED INFORMATION

1. PATIENT RECRUITMENT AND RESEARCH PATIENTS

a) Number of participants to be recruited at site:

b) Site specific/ community concerns, if any

c) Briefly mention local changes in Recruitment/ Advocacy material:

d) Copy of the Local Recruitment/ Advocacy material: Yes ☐ No ☐

2. INFORMED CONSENT

a) Who will obtain the informed consent?

S-PI/Co-S-PI ☐ Nurse/Counselor ☐ Research Staff ☐ Other *(Specify)* ☐

Any tools to be used

b) Language/s ICD is translated in:

c) Version number and date of the Participant Informed Sheet (PIS) :

d) Version number and date of the Informed Consent form (ICF) :

e) Copy of the Local ICD translations enclosed: Yes ☐ No ☐

f) Back translation of the ICD in English with the translation certificate Yes ☐ No ☐

g) Changes made in informed consent form (ICF), if any:

h) Copy of the audio / visual transcript for consent enclosed, if any: Yes ☐ No ☐

3. DATA AND STORAGE

i) Brief details on data collection, storage, sharing, transfer, if any?

SECTION D – OTHER ISSUES

a) Do you have any additional information to add in support of the application, which is not included elsewhere in the form? If yes, provide the details. Yes ☐ No ☐

SECTION E – CHECKLIST FOR S-PI AT PARTICPATING CENTER

1. CHECKLIST

Sr.No	Items	Yes	No	NA	EnclosureNo.	EC Remarks
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	☐	☐	☐		
2.	Brief CV of Site Principal Investigator / other site Co-PI	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of investigator in last 3 years	☐	☐	☐		
4.	Agreement between collaborating partners	☐	☐	☐		
5.	MTA between collaborating partners	☐	☐	☐		
6.	Insurance policy/certificate	☐	☐	☐		
PROPOSAL RELATED						

7.	Copy of the modified protocol	☐	☐	☐		
8.	Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated)	☐	☐	☐		
9.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
10.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
11.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		
12.	Any other relevant information/documents related to the study	☐	☐	☐		