

Institutional Ethics Committee – Biomedical & Health Research (IEC-BMHR)

ICMR-NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS, KOLKATA



PART 1 (To be filled by coordinating PI)

(Annexure 15)

Initial Review Form for Multicentric Research

EC Ref. No. (for office use):

General Instructions:

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

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 <input type="checkbox"/> Expedited Review <input type="checkbox"/> Full Committee Review <input type="checkbox"/>	
(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:	

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

2. FUNDING DETAILS AND BUDGET		
(a)	Total estimated budget for study:	
	At site	In India Globally
(b)	Self-funding <input type="checkbox"/>	Institutional funding <input type="checkbox"/> Funding agency <input type="checkbox"/> <i>(Specify)</i>

SECTION B – RESEARCH-RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study² (within 300 words)

- (b) Type of study:
- | | | |
|---|---|--|
| Basic Sciences <input type="checkbox"/> | Clinical <input type="checkbox"/> | Cross Sectional <input type="checkbox"/> |
| Retrospective <input type="checkbox"/> | Epidemiological/ Public Health <input type="checkbox"/> | Case Control <input type="checkbox"/> |
| Prospective <input type="checkbox"/> | Socio-behavioural <input type="checkbox"/> | Cohort <input type="checkbox"/> |
| Qualitative <input type="checkbox"/> | | Systematic Review <input type="checkbox"/> |
| Quantitative <input type="checkbox"/> | Biological samples/Data <input type="checkbox"/> | |
| Mixed Method <input type="checkbox"/> | Any others <i>(Specify)</i> <input type="checkbox"/> | |

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.](#)

²Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.

³If 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)	<p>Type of participants in the study:</p> <p>Healthy <input type="checkbox"/> Patient <input type="checkbox"/> Vulnerable person/ volunteer <input type="checkbox"/> Special groups <input type="checkbox"/> Others <input type="checkbox"/> <i>(Specify)</i></p> <p>Who will do the recruitment? Participant recruitment methods used:</p> <p>Posters/ leaflets/Letters <input type="checkbox"/> TV/Radio ads/social media/Institution website <input type="checkbox"/> Patients / Family/Friends visiting hospitals <input type="checkbox"/> Telephone <input type="checkbox"/></p> <p>Others <i>(Specify)</i> <input type="checkbox"/></p>
(b)	<p>i. Will there be vulnerable person/special groups involved? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/></p> <p>ii. If yes, type of vulnerable person /special groups</p> <p>Children under 18 yrs. <input type="checkbox"/> Pregnant or lactating women <input type="checkbox"/></p> <p>Differently abled (Mental/Physical) <input type="checkbox"/> Employees/Students/Nurses/ Staff <input type="checkbox"/></p> <p>Elderly <input type="checkbox"/> Institutionalized <input type="checkbox"/></p> <p>Economically and socially disadvantaged <input type="checkbox"/> Refugees/Migrants/Homeless <input type="checkbox"/> Terminally ill (stigmatized or rare diseases) <input type="checkbox"/></p> <p>Any other <i>(Specify)</i>: <input type="checkbox"/></p>
	<p>iii. Provide justification for inclusion/exclusion</p> <p>iv. Are there any additional safeguards to protect research participants?</p>
(c)	<p>Is there any reimbursement to the participant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details</p>
(d)	<p>Are there any incentives to the participant? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details</p>

(e)	Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution? If yes, Monetary <input type="checkbox"/> Non-monetary <input type="checkbox"/> Provide details <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
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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 risk⁴:

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	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
For the society/community	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
For improvement in science	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Please describe how the benefits justify the risks					

(c) Are Adverse Events expected in the study⁵? 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 <input type="checkbox"/> | Verbal/ oral consent <input type="checkbox"/> | Witnessed consent <input type="checkbox"/> | Audio-Video (A/V) consent <input type="checkbox"/> |
| Consent from LAR (If so, specify from whom) <input type="checkbox"/> | For children<7 yrs parental/LAR consent <input type="checkbox"/> | Verbal assent from minor (7-12 yrs) along with parental consent <input type="checkbox"/> | Written Assent from Minor (13-18 yrs) along with parental consent <input type="checkbox"/> |
| Other (specify) <input type="checkbox"/> | | | |

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

⁵The 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 study⁶

- (g) Elements contained in the Participant Information Sheet (PIS) and Informed Consent Form (ICF)

- | | | | | | |
|-------------------------------|--------------------------|----------------------------|--------------------------|--|--------------------------|
| Simple language | <input type="checkbox"/> | Data/ Sample sharing | <input type="checkbox"/> | Compensation for study related injury | <input type="checkbox"/> |
| Risks and discomforts | <input type="checkbox"/> | Need to recontact | | Statement that consent is voluntary | |
| Alternatives to participation | <input type="checkbox"/> | Confidentiality | <input type="checkbox"/> | Commercialization/benefit sharing | <input type="checkbox"/> |
| Right to withdraw | <input type="checkbox"/> | Storage of samples | <input type="checkbox"/> | Statement that study involves research | <input type="checkbox"/> |
| Benefits | <input type="checkbox"/> | return of research results | <input type="checkbox"/> | Use of photographs/ identifying data | <input type="checkbox"/> |
| Purpose and procedure | <input type="checkbox"/> | Payment for participation | <input type="checkbox"/> | Contact information of PI and Member Secretary of EC | <input type="checkbox"/> |
| Others <i>(Specify)</i> | <input type="checkbox"/> | | | | |

8. PAYMENT/COMPENSATION

- (a) Who will bear the costs related to participation and procedures⁷?
 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

⁶Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 54 in Section 5.8

⁷Enclose 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: Irreversibly Identifiable
reversibly coded coded

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 analyzed⁷ 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

⁷For 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
2.	Brief CV of all Investigators	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
4.	Approval of Scientific Committee/ NTF/ Central Advisory Committee/ Any other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
5.	Agreement/MTA / LOA between collaborating partners	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
6.	Insurance policy/certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
7.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
8.	Copy of contract or agreement signed with the sponsor or donor agency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PROPOSAL RELATED						
9.	Copy of the detailed protocol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
10.	Participant Information Sheet (PIS) and Informed Consent Form (ICF)(English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
11.	Assent form for minors (12-18 years) (English and Translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
12.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
13.	Advertisement/material to recruit participants (fliers, posters etc)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
PERMISSION FROM GOVERNING AUTHORITIES						
	Other Registration/ permissions	Required	Not required	Received	Applied dd/mm/yy	EC Remarks
14.	CTRI ⁸	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
15.	HMSC ⁹	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	

16.	Tribal Board	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
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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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Enter date	
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ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

Item	YES	NO	NA	Enclosure no.	EC remarks
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PART 2 (To be filled by S-PI at the Participating Centre)

18.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
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⁸CTRI: Clinical Trial Registry- India, ⁹HMSC: 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 – PARTICIPANT 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 PARTICIPATING CENTER

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

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