

Annexure 4



(Annexure 11)

Application Form for Socio-Behavioural and Public Health Research

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Data collection method used in the study

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|---------------------------|--------------------------|-----------------------|--------------------------|----------------------|--------------------------|
| Focus group | <input type="checkbox"/> | Questionnaire/Survey | <input type="checkbox"/> | Observation | <input type="checkbox"/> |
| Interviews | <input type="checkbox"/> | Documents and records | <input type="checkbox"/> | Ethnographies/Oral | <input type="checkbox"/> |
| Others (<i>Specify</i>) | <input type="checkbox"/> | | | history/Case studies | |

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes No

2. Type of informed consent used in the study.

- | | | | | | |
|--------------------|--------------------------|------------------------|--------------------------|-------------------|--------------------------|
| Individual consent | <input type="checkbox"/> | Gate-keeper consent | <input type="checkbox"/> | Community consent | <input type="checkbox"/> |
| Others | <input type="checkbox"/> | <i>(specify)</i> | | | |

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.

4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified.(e.g.:

Suicide or infanticide) Yes No NA

5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment?

Yes No

6. Is there a use of an interpreter? If yes, describe the selection process.

Yes No NA

7. Describe any preparatory work or site preparedness for the study

Yes No NA

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8. I. Type of risk related to procedures involved in the study

Invasive Potentially harmful Emotionally disturbing Involving disclosure

Describe the risk minimization strategies.

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II. Justify reasons if individual harm is overriding societal benefit.

Yes No NA

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III. Describe how do societal benefits outweigh individual harm.

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9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception.

Yes No

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10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

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Signature of PI:

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