



## INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth G. S. Medical College and KEM Hospital, Mumbai.

### Annexure 4

#### AX 04/SOP 05-A/V 7.1

### Application Form for Socio-Behavioural and Public Health Research

Principal Investigator (Name, Designation & Affiliation): .....

IEC No. of the Project: .....

Study Title: .....

1. Data collection method used in the study

Focus Group  Questionnaire/Survey  Observation

Interviews  Documents and records  Ethnographies/Oral history/Case Studies

Others (Specify)  .....

If it is an interview, will there be audio-video recording of participants interview? Yes  No

If yes, justify the reasons and storage strategies .....

2. Type of informed consent used in the study.

Individual consent  Gate-keeper consent  Community consent

Others (Specify)  .....

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



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6. Is there a use of an interpreter? If yes, describe the selection process. Yes  No  NA

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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 disclosures

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? Yes  No

If yes, provide details and rationale for deception.

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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 Principal Investigator (PI) with Date: .....