



INSTITUTIONAL ETHICS COMMITTEE (IEC)

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

Annexure 4

AX 04/SOP 05-A/V 7

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.

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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

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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: