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**Annexure 06/SOP-06/V2.1**

**For Socio-Behavioural and Public Health Research**

**(Additional information to be provided with application form)**

SMVMCH-EC Ref. No. (for office use) :

Title of study:

Principal Investigator (Name, Designation and Affiliation):

1. Data Collection method used in the study

Focus group Questionnaire/ Survey Observation

Interviews Documents and records Ethnographies / oral

Other (specify) 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

1. Type of informed consent used in the study.

Individual consent Gate-keeper consent Community consent

Others (specify)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.
2. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified. (e.g.: suicide or infanticide) Yes No NA
3. Are cultural norms / Social considerations / Sensitivities taken into account while designing the study and participants recruitment? Yes No
4. Is there a use of an interpreter? If yes, describe the selection process. Yes No NA
5. Describe any preparatory work or site preparedness for the study Yes No NA
6. I. Type of risk related to procedures involved in the study

Invasive Potentially harmful Emotionally disturbing Involving disclosure

Describe the risk minimization strategies.

II. Justify reasons if individual harm is overriding societal benefit. Yes No NA

III. Describe how do societal benefits outweigh individual harm.

1. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale deception. Yes No
2. 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.

Signature of PI with date: