**PROFORMA FOR ETHICAL REVIEW**

**(A) RESEARCH RELATED INFORMATION**

1. **Type of review requested**:

Exemption from review Expedited review Full committee review

2. **Overview of research**

1. Lay summary (within 300 words)- *Summarize in the simplest possible way such that a person with no knowledge of the subject can easily understand it*
2. Type of study:

Basic Science Clinical Cross sectional

Retrospective Epidemiological/ Case control

Prospective Public-Health Cohort

Qualitative Socio-behavioural Systemic review

Quantitative Biological samples

Mixed method Any other (specify)

3. **Methodology**- *Describe in the simplest possible way such that a layman with no knowledge of the subject can easily understand it*

**(B) PARTICIPANT RELATED INFORMATION**

4. **Recruitment and research participants:**

1. Types of participants in the study

Healthy volunteers Patients Vulnerable patients/ Special groups

Others *(specify)*………………………………………………………………..

1. Will there be vulnerable persons/ special groups involved: Yes No NA

If yes, type of vulnerable persons/ special group involved

Children under 18 years  Pregnant or lactating women. 

Differently abled (Mental/Physical)  Employees/Students/Nurses/ Staff 

Elderly  Economically & socially disadvantaged 

Refugees/Migrants/Homeless  Terminally Ill (stigmatized or rare disease)  Any other *(Specify):*   ………………………………………………

1. Is any of the clinician involved directly in clinical care of vulnerable population included as PI or Co-I, if not justify……………………………………………………………………………………
2. Are there any incentives to the participant? Yes No NA

*If yes; Provide details*……………………………………………………………………………

1. **Benefits and Risks:**
2. Are there any anticipated physical/social/psychological discomforts/ risk to participants?

Yes No 

1. If yes, categorize the level of risk:

Less than Minimal risk  Minimal risk 

Minor increase over minimal risk or Low Risk  More than Minimal Risk or High Risk 

1. What are the potential benefits from the study?

Yes No If yes, Direct Indirect

For the participant    

For the society/community    

For improvement in science    

1. **Informed Consent:**
2. Type of consent planned for:
3. Written Informed consent 
4. Waiver of consent 
5. Consent from LAR 
6. For children <7 yrs parental/LAR consent 
7. Verbal assent from minor (7-12 yrs) along with parental consent 
8. Written Assent from Minor (13-18 yrs) along with parental consent 
9. Other *(specify)* …………………………………………………….. 
10. Participant Information Sheet (PIS) and Informed Consent Form (ICF):

English  Hindi  Gujarati 

1. Are you seeking waiver of consent: Yes No 

If yes, what are the reasons………………………………………………………………….

………………………………………………………………………………………………

1. **Storage and Confidentiality:**
2. Identifying information: Study involves samples/data *(specify)*

Anonymous/Unidentified Anonymized: Reversibly coded Irreversibly coded Identifiable 

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.)

.………………………………………………………………………………………………………

…………………………………………………………………………………………………….…

1. Who will be maintaining the data pertaining to the study?.................................................................
2. How long the data will be stored?…………………………………………………………………..
3. Whether provisions for maintaining confidentially and privacy of the participants have been addressed?............................................................................................................................................
4. Do you propose to use stored samples/data in future studies? Yes No Maybe 

**(C) OTHER ISSUES**

1. **PUBLICATION, BENEFIT SHARING AND IPR ISSUES:**
2. Will the results of the study be reported and disseminated? Yes No 

*If yes,* *specify*. ……………………………………………………………………………

1. Will you inform participants about the results of the study? Yes No 
2. Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? Yes No NA 

*If yes describe in brief (Max 50 words)………………………………………………………………….*

*……………………………………………………………………………………………………………….*

1. Will the results of the study be reported and disseminated? Yes No NA 
2. Is there is any commercial value or a plan to patent/IPR issues. Yes No NA 

*If yes, Please provide details*…………………………………………….……………………

*……………………………………………………………………………………………………………….*

1. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes No 

*If yes, Please provide details*…………………………………………….……………………