अखिल भारतीय आयुर्विज्ञान संस्थान राजकोट, गुजरात 360006
All India Institute of Medical Sciences, Rajkot, Gujarat 360006
Institute of National Importance under PMSSY, MoHFW
Government of India www.aiimsrajkot.edu.in

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**

a) 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*

b) 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:**

a) Types of participants in the study

Healthy volunteers ☐ Patients ☐ Vulnerable patients/ Special groups ☐

Others ☐ *(specify)*……..

b) 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):* ☐	……

c) Is any of the clinician involved directly in clinical care of vulnerable population included as PI or Co-I, if not justify…… ☐ ☐ ☐

d) Are there any incentives to the participant? Yes No NA

If yes; Provide details……

5. **Benefits and Risks:**

a) Are there any anticipated physical/social/psychological discomforts/ risk to participants?
Yes ☐ No ☐

b) 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 ☐

c) 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	☐	☐		☐	☐

6. **Informed Consent:**

a) Type of consent planned for:

i) Written Informed consent ☐

ii) Waiver of consent ☐

iii) Consent from LAR ☐

iv) For children <7 yrs parental/LAR consent ☐

v) Verbal assent from minor (7-12 yrs) along with parental consent ☐

vi) Written Assent from Minor (13-18 yrs) along with parental consent ☐

vii) Other *(specify)* …….. ☐

b) Participant Information Sheet (PIS) and Informed Consent Form (ICF):

English ☐ Hindi ☐ Gujarati ☐

c) Are you seeking waiver of consent: Yes ☐ No ☐

If yes, what are the reasons…….

……

7. **Storage and Confidentiality:**

a) 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.)

……

……

b) Who will be maintaining the data pertaining to the study?.....

c) How long the data will be stored? ……..

d) Whether provisions for maintaining confidentially and privacy of the participants have been addressed?.....

e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐

(C) OTHER ISSUES

8. **PUBLICATION, BENEFIT SHARING AND IPR ISSUES:**

a) Will the results of the study be reported and disseminated? Yes ☐ No ☐
If yes, specify. ……

b) Will you inform participants about the results of the study? Yes ☐ No ☐

c) 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)……
……

d) Will the results of the study be reported and disseminated? Yes ☐ No ☐ NA ☐

e) Is there is any commercial value or a plan to patent/IPR issues. Yes ☐ No ☐ NA ☐
If yes, Please provide details……
……

f) 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……