Directorate of Research & Development and Resource Mobilization (DRDRM)

**Office of the Director, DRDRM, Goa University**

*Format for submission of proposal to obtain approval from the Institutional Human Ethics Committee (IHEC), Goa University* *for research studies* ***INVOLVING Human Participants***

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**Proposal Title**:

**Principal Investigator(PI)/Guide Details**:

**Co-PI / Co-Guide (if any)**:

**Research Personnel Details:**

1. **Please provide a brief description of the research project including scientific rationale (with the results of previous animal and human studies), hypothesis, study design and statistical basis for the structure of the investigation:**
2. **State the role of human subjects, including what will happen to the participants and what they will be told about the research:**
3. **Describe the population to be studied, inclusion and exclusion criteria, and numbers to be recruited/ selected:**
4. **Describe recruitment / selection procedures, what information will be shared with potential participants, any compensation or incentives that will be provided for participation:**
5. **Attach a copy of the informed consent form (ICF) to be shared with the participants. Please include if possible copies of the form with translation in Konkani / Marathi:**
6. **Describe any features that would not be disclosed to the participants and provide a justification for the same:**
7. **State the type of data to be collected as interviews, face to face interviews, questionnaires:**
8. **Details of Education tests, physical measurements, physiological measurements, physiological sample collections including blood samples, etc.:**
9. **Describe data collection procedures. Please attach questionnaires, interview protocols:**

***Tentative Interview questions:***

1. **Describe procedures for maintaining confidentiality of participants:**
2. **Please list the expected study sites:**
3. **Describe real and potential risks to the participants:**
4. **Please classify the risk category as one of the following based on definitions provided in the Table 2.1 of ICMR\_General\_Ethical\_Issues document under Guidelines of GU-IHEC:** *(less than minimal risk / minimal risk / low risk)*
5. **Please list potentially harmful effects that can be adequately detected, prevented, or treated:**
6. **Describe definite and potential benefits to the participants:**
7. **Describe ethical issues in the study and plans to address these:**
8. **List any regulatory clearances required / obtained and attach application and approval copies of the same:**
9. **List the sources of funding and financial requirements if any for the project:**
10. **Statement of conflicts of interest, if any:**
11. **Are the results to be published? Please note that confidentiality of the participants must be maintained while publishing:**
12. **Start Date of the study: 22. End Date of the study**:

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**Undertaking by the PI / Guide**

I have read the Ethical Guidelines for Biomedical Research on Human Participants, 2017 issued by ICMR and the Guidelines of *Institutional Human Ethics Committee (IHEC)*, Goa University.

The proposal being submitted is complete in all respects as given in the Guidelines for Institute Ethics Committee (IHEC), Goa University.

I agree to comply with all guidelines for ethical research. On IHEC approval and initiation of the study, I will personally monitor the study.

* inform the IHEC of all Serious Adverse Events and the interventions undertaken.
* inform the IHEC of any protocol deviation with adequate justifications, prior to the deviation.
* submit any protocol amendment to IHEC for renewed approval.
* inform the IHEC of any new information related to the study.
* notify the IHEC of any premature termination of study along with reasons and summary of the data obtained until the termination.
* inform the IHEC of any change of investigators / sites.
* submit key findings and a compliance report at the end of study before publishing the results to obtain IHEC approval.

PI / Guide’s Signature:

Date

Place: