**INDIAN INSTITUE OF TECHNOLOGY ROPAR**

**Office of the Dean of Research and Development**

**Institutional Ethics Committee (Humans)**

**Form No. IEC-101**

**Note:** Use this form to submit a **research proposal involving human participants** to the Institutional Ethics Committee (Humans) / IEC

1. Title of the proposal:
2. Principal investigator (PI):
3. co-PI (if any):
4. Project personnel details:
5. Provide a brief overview of the research project, including its scientific justification (supported by the findings of related animal and human studies), hypothesis, study design, and statistical basis:
6. Describe the role of human subjects, including what will happen to them and the information that will be disclosed to them about the research:
7. Specify the population to be investigated, the inclusion and exclusion criteria, and approximate number of participants:
8. Describe the recruitment process, the details of information that will be presented to potential participants, and any rewards or incentives offered in exchange of participation:
9. Include a copy of the informed consent document (ICD) that will be given to participants, and its translation in relevant languages:
10. Describe any aspect of research/information that will not be shared with participants, and give reasons for the same:
11. Describe the data that will be collected, such as face-to-face interviews, questionnaires, educational assessments, physical measurements, physiological measurements, physiological sample collections, blood samples, etc.
12. Describe steps taken to collect data, and provide survey forms and interview procedures:
13. Describe steps taken to protect the confidentiality of participants:
14. List expected study locations:
15. Explain the actual and possible risks to participants:
16. Please choose the risk category in accordance with definitions given in Guidelines for the Institutional Ethics Committee (Humans):

 Less than minimal risk [ ]

 Minimal risk [ ]

 Greater than minimal risk [ ]

1. Mention possible negative outcomes that can be effectively identified, avoided, or addressed:
2. Outline the definite and possible benefits to participants:
3. Outline ethical concerns of the study and steps to address those concerns:
4. Include application and approval documents, as needed:
5. List funding sources and finances needed for the study:
6. State conflicts of interest, if any
7. A statement describing following:
8. compensation to study participants for their time (including reimbursement for travel and access to healthcare):
9. a description of indemnity arrangements, if any (in the event of injuries related to the study):
10. a description of insurance coverage plans for research participants, if applicable. All significant prior decisions (such as those that resulted in a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether conducted in the same location or elsewhere); and an indication of any protocol modifications made as a result of those decisions. Explain reasons for negative decisions:
11. If results will be published and, if yes, how the confidentiality of participants will be protected while publishing:
12. Any other details that are relevant to the proposal:
13. Date of commencement of study:
14. Date of termination of study:
15. If the proposal/protocol/study involves biological samples, it must be submitted for approval to the Institutional Biosafety Committee (IBSC). Email: ibsc@iitrpr.ac.in. If the proposal has been submitted to the IBSC:

Yes [ ]

No [ ]

**Undertaking by the PI**

I've read the 2017 ICMR Ethical Guidelines for Biomedical Research on Human Participants and Institutional Ethics Committee (Humans) guidelines of IIT ROPAR. [ ]

The proposal being submitted is complete in every way, as per the guidelines of Institutional Ethics Committee (Humans) of IIT ROPAR. [ ]

I pledge to abide by all guidelines for ethical research. [ ]

On IEC approval and initiation of the study, I will:

1. personally monitor the research. [ ]
2. report all serious adverse events to the IEC and any interventions made. [ ]
3. prior to any protocol change, notify the IEC and provide sufficient justifications. [ ]
4. Send any protocol modifications to the IEC for revised approval. [ ]
5. inform the IEC of any new information related to the study. [ ]
6. notify the IEC of any early termination of study along with reasons and summary of data collected until the termination. [ ]
7. update the IEC on any changes to the investigators or sites. [ ]
8. Submit a full report to IEC, after the completion of the study. [ ]

Signature of PI: Name of PI:

Date: Department:

Place: Tel No:

 Email: