Goa University
Institutional Human Ethics Committee(IHEC)

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Checklist for Screening Research Proposals by IHEC sub-committee, DRDRM before forwarding to IHEC Committee, Goa University

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Researchers who are planning a research project that will involve Human Participants need to use the following checklist when preparing their research proposal or application for ethical approval.

This checklist is prepared keeping in mind the ICMR 2017 guidelines for research involving Human Participants.

The Checklist ensures to identify whether a full application for ethical approval needs to be submitted to IHEC. The principal investigator or, where the principal investigator is a student, the supervisor, is responsible for exercising appropriate professional judgment in this review.

A. Project Details	
Project title/ PhD student Research Title	
B. Applicant Details	
Name of researcher (applicant)	
Designation	
Contact address	
Email	
Telephone	
C. Research Ethics Initial Checklist	
Please answer each question from C.1 to C.7 by typing YES / NO/NA :	
In cases where the answer is YES /NA, the justification/clarifications should be provided in the Research Proposal seeking IHEC Approval.	
C.1 Social Value: Does the outcome of this research have any social value such as addressing the health problems of the society?	
C.2 Scientific Design & Conduct of the Study: Does this research involve sound scientific method.	
C.3 Benefit-Risk assessment: a) Does this research have any risk to the human persons or the society?	
b) If Yes, Is the benefit accruing from this research justifying the risk inherent in this research?	
C.4 Community Consideration: a) Does the proposed research lead to any stigma or discrimination of the community?	

b) Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?	
c) Will the research take place - 1. within Goa (Yes/No) Are there any additional issues that need to be considered as a result (for example, local customs, local "gatekeepers", political sensitivities)? Provide details in the Research Proposal. 2. Other States of India(Yes/No) Are there any additional issues that need to be considered as a result (for example, local customs, local "gatekeepers", political sensitivities)? Provide details in the Research Proposal. 3. outside India(Yes/No) Are there any additional issues that need to be considered as a result (for example, local customs, local "gatekeepers", political sensitivities)? Provide details in the Research Proposal.	
d) Will the research expose participants to the internet or other visual/vocal methods where respondents may be identified?	
C.5 Risk Considerations:	
a) Of Research team? Is there a possibility that the safety of the researcher may be in question?	
b) Risk factor of Participants addressed (for example - harm, deception, impact of outcomes)?	
c) Is pain or more than mild discomfort likely to result from the study?	
d) Could the study induce psychological stress, discomfort, anxiety or cause harm or negative consequences beyond the risks encountered in normal life?	
e) Will the study involve prolonged or repetitive testing?	
f) Risk factor addressed of the research organizations, project partners, and funders involved?	
g) Might anyone else be put at risk as a consequence of this research?	
C.6 Details and Recruitment of Participants:	
a) Have you considered consent?	
b) Have you considered anonymity and confidentiality?	
c) Can participants opt out?	
d) Does the study involve participants age 16 or above who are unable to give informed consent?	

e) Does the research involve potentially vulnerable groups: children, those with cognitive impairment, or those in unequal relationships? (eg your own students)?	
f) Is the recruitment of the participants' voluntary and is the selection distributed across the population, region or tribe or economic groups?	
g) Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited? (e.g students at school, members of self- help group, residents of nursing home?)	
h) Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (eg covert observation of people in non- public places)	
i) Will the study involve discussion of sensitive topics? (eg sexual activity, drug use, politics)	
j) Are drugs, placebos or other substances (eg food substances, vitamins) to be administered to the study participants?	
k) Will the study involve invasive, intrusive or potentially harmful procedures of any kind?	
l) Will tissue samples (including blood) be obtained from participants?	
m) Will any unequal relationships exist between anyone involved in the recruitment and the potential participants?	
n) Are there any benefits to participants? Or, Will financial recompense be offered to participants?	
o) Is there a need for participants to be de-briefed?	
p) Will the competence of participants to give informed consent determined?	
q) Is there a proper methodology planned for identifying, approaching and recruiting Participants for the research study?	
C.7 Data and Information	
a) Will research involve the sharing of data or confidential information beyond the initial consent given?	
b) Are there any conflicts of interest in undertaking this research (for example, financial reward for outcomes etc.)?	

c) Will you be collecting information through a third party?	
d) If using secondary data, does the consent from the primary data cover further analysis?	
e) Does your information sheet (or equivalent) contain all the information participants need?	
f) Have you considered ethics within your plans for data confidentiality, dissemination/impact?	
g) Are there any direct users for the information output from your planned research ?	
h) Is there a proper plan in place for the time period of retention and disposal of the data collected during the research study?	
i) Does your project need to abide by the Information Technology Act, 2000, as amended by the Information Technology (Amendment) Act, 2008 ?	
j) Does your project need to abide by the Information Technology Act, 2000, as amended by the Right to Information Act, 2005?	
k) Does your project need to abide by the Information Technology Act, 2000, as amended by the Protection of Human Rights Act, 1993?	
l) Does your project need to abide by any other Indian Legislative Act?	

UNDERTAKING

I/We undertake the responsibility to follow the Goa University's code of practice on ethical standards, and also abide by any relevant academic or professional guidelines during the conduct of my/our research study, which includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and usage of data.

In case of any change in the question, design or conduct over the course of the research study, I/We undertake the responsibility to notify the DRDRM office and submit a new application for ethics approval.

Principal Investigator		
Signed:	Date:	
Supervisor or module leader (where appropriate)		
Signed:	Date:	