Institutional Human Ethics Committee
Indian Institute of Technology Bhubaneswar
Argul, Jatni, 752050
Email: ihec@iitbbs.ac.in

Research Proposal For Initial Review by IHEC of IIT Bhubaneswar
(Form to be filled by the Principal Investigator)

For Official Use of IHEC			
Internal Proposal No.			
Date of Submission			
Broad Classification of the Submitted Proposal			
A.	Basic Sciences (BS)	D.	Social Sciences (SS)
B.	Medical Sciences (MS)	E.	Medical Devices (MD)
C.	Data Sciences (DS)	F.	Others (OT)

Information Related to the Proposal

1. Title of the proposal:

2. Name/Designation/Email/Contact details of the Principal Investigator (PI):

3. Name/Designation/Email/Contact details of the Co-Investigator (Co-PI):

4. Duration of the project / study:

5. Details of the IIT Laboratory where the research would be carried out:

6. Brief CV of the PI and Co-PIs (should contain 5 recent publications and relevant experience in the proposed field of research, ≤ 5 pages)**:**

7. Details of the collaborators (if any):

8. If the collaborators belong to other institutes, indicate whether there is an MoU with the partnering institute:

Institutional Human Ethics Committee
Indian Institute of Technology Bhubaneswar
Argul, Jatni, 752050
Email: ihec@iitbbs.ac.in

9. IHEC/IEC clearance from the collaborating/partnering institute: Attached/Not attached (Give reason if not attached)

10. Funding source (Please tick the applicable option):

Institute Funding	☐	Private Funding	☐
Govt. of India Funding	☐	Self-Funding	☐
International Funding	☐	Others	☐

11. Details of source of funding, address and contact information:

12. Total estimated budget (₹):

13. Technical Details of the Research Proposal:
    - i Background and motivation of the study (limit 500 words)
    - ii Main objectives (mention in bullet points)
    - iii Methodology and technical approaches in brief
    - iv Justify the need of human participants for the proposed study
    - v Sample size of the study (collected/recruited)
    - vi Justification for the sample size for the study (explain the statistical relevance etc.)

14. Research Participants Recruitment Details:
    - i Name of the Institute/Organization where the human participants will be recruited
    - ii Inclusion and exclusion criteria for the selection of participants
    - iii Will participant from both sexes be recruited?
    - iv Type of participants in the study

Healthy volunteer	☐	Patient	☐
Vulnerable persons or special group	☐	Others	☐

    - v. Does the study involve any vulnerable persons/special group participants?

Children under 18 years	☐
Pregnant or Lactating women	☐
Differently abled (mental/physical)	☐
Economically or socially disadvantaged	☐

    - vi. Expected “benefits” to volunteer/participants

vii. Usefulness of the project / trial
viii. Whether the research participants will be provided “wage compensation”?

15. Details of the Biological Fluids/Samples/Data of Human Origin:

i. Indicate the type of sample, including size/volume to be used in the study

Sample Type	Size/Volume	Biosafety level
Urine		
Blood		
Secretions (Saliva, Tears)		
Spinal fluid		
Hair		
Tissues (specify)		
Others (specify)		

ii. Purpose of the biological samples:
iii. Coding and decoding plan of the biological samples:
iv. Clearly describe how the samples will be obtained:
v. Samples obtained outside of IIT BBS should also be accompanied with ethical clearance documents
vi. Are the collected samples for bio-banking / future research? (time period cannot be beyond the end date of the study)
vii. If yes, how the samples will be stored for future use (appropriate consent form should be enclosed for storing sample for future use)
viii. Provide details about the hospital and disposal methods (for use of tissues, organs or body fluids)
ix. Does the study involve the use of autopsy data?
x. Provide the details on plan of containment and waste disposal for use of pre-existing/stored/leftover/bio hazardous samples
xi. Does the study involve use of genetically modified organism (GMO)/animals/stem cells? (If yes, attach the clearance from the appropriate regulatory body)

xii. Does the study involve the use of clinical information/medical imaging (Ultrasound, CT scan, MRI, EEG, ECG, etc) data / demographic details?

xiii. Is there a plan to share the samples with others (not connected with the proposal) outside IIT BBS (if yes, then appropriate consent form should be enclosed)

xiv. Will the research proposal be submitted to any Ministry Screening Committee for international collaboration

xv. Is there a plan to send the collected samples to abroad? (If yes, then mention the reasons and also submit the clearance from appropriate ministry)

xvi. Please state whether this proposal has been submitted to the Institutional Biosafety Committee (IBSC): Yes/No

Please note that all studies that involve biological samples must be sent to the IBSC for review (Email: ibsc@iitbbs.ac.in) and necessary approval.

16. Privacy and Confidentiality Detail:

i. Does the study involve direct identifiers / indirect identifiers / completely anonymized / delinked?

ii. Elaborate the approaches undertaken for maintaining the confidential handling of data

iii. Is the data going to be shared with a third party? If yes, attach the Data sharing and Data management policy agreement

iv. Explain all anticipated “risks” associated with the project and the efforts that can be made to minimize the “risks”

v. Explain how the confidentiality of personal information/identity of the research participants will be maintained while publishing the results or commercializing the product.

17. Conflict of interest (if any) statement:

18. Details of the Informed Consent:

i. Describe the Informed consent process to be followed in the study

Signed Consent ☐
Audio-Video Consent ☐
Others (specify) ☐

ii. List of languages in which translations of Informed consent form and Participant information sheet have been made and will be used in the study

Hindi ☐
English ☐
Local Language ☐

iii. Copy of translated Informed consent form (ICF) attached: Yes / No
(If not attached, please justify)

iv. Copy of Participant information sheet (PIS) attached: Yes / No
(If not attached, please justify)

Institutional Human Ethics Committee
Indian Institute of Technology Bhubaneswar
Argul, Jatni, 752050
Email: ihec@iitbbs.ac.in

UNDERTAKING BY THE PI

I/We hereby declare that the information given in the IEC application form for the project titled _____, including the related documents submitted by me/us are true to the best of my/our knowledge and belief.

I/We undertake that we/I shall comply with Indian Council for Medical Research's (ICMR) "National Ethical Guidelines for Biomedical and Health Research Involving Human Participants", including the Ethical Guidelines for Application of Artificial Intelligence In Biomedical Research and Healthcare.

We are/I am aware that these guidelines are in accordance with Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules, 1945, as amended, guidelines therein in Schedule Y, Drugs and Clinical Trial Rules, 2019, Medical Devices Rules 2019 as amended, Indian Good Clinical Practices Guidelines, 2001 and World Health Organization's Standard and Operational Guidelines for Ethics Review of Health-Related Research on Human Participants.

We/I agree to comply with all guidelines for ethical research and upon receiving the approval for the same from the IIT BBS-Institutional Human Ethics Committee (IITBBS-IHEC) and subsequent initiation of the study, we/I will

i. Personally monitor the study.
ii. Inform IHEC of any protocol deviation with adequate justifications, prior to the deviation. In addition, We/I will submit any amended protocol to IHEC for renewed approval.
iii. Inform the IHEC of any new information or observed adverse events noticed during the project related to the study.
iv. Notify the IHEC of any premature termination of study with reasons, along with summary of the data obtained until the termination.
v. Inform IHEC of any change of investigators / sites.
vi. Submit continuing review report annually.
vii. Submit a final report at the end of study.

Name of the Principal Investigator :

Signature with Seal :

Date :

Name of Co-Principal Investigator :

Signature & Seal :

Date :