

ASSAM DON BOSCO UNIVERSITY

Tapesia Gardens, Kamarkuchi, Sonapur - 782 402, Assam, INDIA

Ref. No. F 44/JJ/21-019

Date: 6th November 2021

NOTIFICATION: INSTITUTIONAL HUMAN ETHICS COMMITTEE

The Vice Chancellor, on the recommendation of the 'Research Integrity and Ethics Review Board' of the University, is pleased to constitute Institutional Human Ethics Committee of Assam Don Bosco University as given below:

Chairperson cum Convenor

Dr. Jacob Islary, Asst. Professor, Department of Social Work, ADBU

Members

- 1. Dr Marie Martinho Nympha, Asst. Professor, Department of Social Work, ADBU
- 2. Dr. Chandita Baruah, Head and Asst. Professor, Department of Psychology, ADBU
- 3. Dr. Biju Mani Das, Head and Asst. Professor, Department of Commerce, ADBU

Legal Expert

Adv. Ujjwal Das, Lawyer at High Court, Guwahati and Supreme Court of India

Layperson/ Community Representative

Shri. Ramesh Chandra Das, President, Panchayat Cluster, Dimoria

Medical Expert

Dr. Aparup Sharma, Nemcare Hospital, Guwahati

Institutional Human Ethics Committee is constituted with the purpose of ensuring that research in the University is conducted adhering to appropriate ethical, legal and professional frameworks, obligations and standards and of supporting a research environment that is underpinned by a culture of integrity, good governance and best practices. The terms of reference of the Committee shall be the Assam Don Bosco University Policy Document on Research Integrity and Ethics.

Tenure of the members shall be three years. Quorum shall be 3 out of 7 members including Chairperson.

The recommendations of the Committee shall be subject to approval by the Vice Chancellor, and where needed, the Vice Chancellor may refer them for review to Research Integrity and Ethics Review Board.

Registrar

Assam Don Bosco University Tapesia Gardens, Sonapur Assam-782402, INDIA. SONAPUR ASSAM-782402 INDIA

Annexure 1

Summary Outline of Institutional Human Ethical Committee, Assam Don Bosco University for Review of Research involving Human subjects

- 1. The basic four principles of *respect for persons* (*autonomy*), *beneficence*, *non-maleficence and justice* shall guide the research to protect the dignity, rights, safety andwell-being of research participants.
- 2. The expanded principles based on the four basic principles that shall guide the research process are
 - i) Principle of Essentiality
 - ii) Principle of Professional Competence
 - iii) Principle of Voluntariness
 - iv) Principle of Maximization of Benefit
 - v) Principle of Non-exploitation
 - vi) Principle of Institutional Arrangements
 - vii) Principle of Social Responsibility
 - viii) Principle of Transparency & Accountability
 - ix) Principle of Ensuring Privacy & Confidentiality
 - x) Principle of Totality of Responsibility
 - xi) Principle of Risk Minimization
 - xii) Principle of Environmental Protection
- 3. The below mentioned general ethics issues shall be assessed by the Committee
 - i) Benefit-risk assessment (on four levels)
 - i. Less than minimal (Probability of harm or discomfort is nil or not expected).
 - ii. *Minimal risk*(Probability of harm or discomfort anticipated in the research is not greater thanencountered in routine life activities/ serious harm or adverse event is unlikely).
 - iii. Minor increase over minimal risk or Low risk (Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. Such research should have a social value. Social risks, psychological harm and discomfort may also fall in this category).
 - iv. More than Minimal/high risk (Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk or interventional study).
 - ii) Privacy Confidentiality
 - iii) Distributive Justice
 - iv) Payment for Participants
 - v) Conflict of Interest
 - vi) Community Engagement

- vii) Post Research Access nd Benefit sharing
- viii) Storage of Datasets/Information
- ix) Collaboration in Research
- x) Public Concern (Health) and Social Behavioral Research
- xi) Role of Agencies/Sponsors and Governance of Research
- xii) Biosafety measures in case of involvement of Laboratories and Hospitals
- 4. Ethical Review Procedure (meetings could be in person or virtual in keeping with COVID-19 Protocol)
 - i) Application by the researcher (cover letter and research proposal submission)
 - ii) Acknowledgement by the Chairperson/Member Secretary) of the submission and allocation of a Reference Number.
 - iii) Circulation of the copies of the proposal to all the Committee Members (with record in a log book/receipt note) for individual review and feedback.
 - iv) Submission of the individual feedback to the Chairperson of the Committee.
 - v) The Committee may seat for prior discussion if needed
 - vi) Sitting of the Committee Members with a quorum to review the proposal along with the Applicant (Principal Investigator or with Research Team) documented by Chairperson/Member Secretary.
 - vii) Only Committee Members meeting post-meeting the research applicant.
 - viii) Clearance/Revision/Rejection of the Ethical Clearance Application in writing.
- 5. Ethical issues to Consider in the Review Protocol
 - i) Social values
 - ii) Scientific design and conduct of study
 - iii) Review of informed consent process
 - iv) Benefit-risk assessment
 - v) Selection and recruitment of participants
 - vi) Qualification & adequacy of study sites
 - vii) Payment for participation
 - viii) Disclosure of conflict of interest
 - ix) Community considerations
 - x) Protection of privacy and confidentiality
 - xi) Plans for medical management and compensation for study related injury

Note: Research during pandemic times – could be categorized into three categories and reviewed accordingly

- a) New research directly related to COVID-19
- b) Ongoing non-COVID research
- c) New non-COVID research

- 6. Informed consent (in print/writing, electronic, parental/adult consent in children)
- 7. Vulnerability checks
 - i) Socio-cultural, linguistic, gender, sexual orientations, politically disadvantaged
 - ii) Those incapable of giving informed consent children, persons with mental illness, illiterate, language constrains
 - iii) Situational vulnerabilities victims of injustice, survivors of injustice and disasters, and those needing psycho-social support

Adapted from ICMR, India