Heading of the Upload Title

Ethical Review Committee Guidelines for Conducting Research Involving Humans and Animals of Mawlana Bhashani Science and Technology University (MBSTU), Bangladesh

Attachment-1

INFORMED CONSENT FORM SHOULD BE WRITTEN IN BENGALI & ENGLISH

1.	Name of the participant:	
2.	Age of the participant:	
3.	Name of the interviewer:	
4.	Interviewer details:	
5.	Purpose of the Study:	
6.	Types of participation of the study respondents:	
7.	Duration, Procedures of the study and participant's involvement:	
8.	Potential benefits:	
9.	Risks, hazards and discomforts:	
10.	Reimbursements:	
11.	Confidentiality:	
12.	Termination of study participation / Rights to withdraw from participation:	
13.	Signature/Thumb print of the participants:	
14.	Name of the witness:	
15.	Signature of the witness:	
16.	Signature of the interviewer:	
17.	In case of Minor Signature of the Parent / Legal Guardian. (For age group 0 – 10 years and aged 11-17 year):	

*Duplicate copy of Inform Consent shall be given to participant.

Attachment-2

Curriculum vitae form for Investigators

(Use separate sheet if necessary)

Give biographical data in the following table for key personnel including the Principal Investigator. Use a photocopy of this page for each investigator.

(Note: Biography of the external Investigators may, however, be submitted in the format as convenient to them)

1 Name:

2 Present Position:

3 Educational background:

(last degree and diploma & training relevant to the present research proposal)

4 List of ongoing research protocols

(start and end dates; and percentage of time)

4.1. As Principal Investigator

Project name	Starting date	End date	Percentage of time

4.2. As Co-Principal Investigator

Project name	Starting date	End date	Percentage of time

4.3. As Co-Investigator

Project name	Starting date	End date	Percentage of time

5 Publications

Types of publications	Numbers
a. Original scientific papers in peer-review journals	
b. Peer reviewed articles and book chapters	
c. Papers in conference proceedings	
d. Letters, editorials, annotations, and abstracts in peer-reviewed journals	
e. Working papers	
f. Monographs	

6 Five recent publications including publications relevant to the present research protocol

1)
2)
3)
4)
5)

Attachment -3

(Ethical Clearance Application Form)

Project Number: (Office will fill up) | P | R | - | 0 | 9 | 0 | 0 | 0 |

ETHICAL REVIEW COMMITTEE, MBSTU

Date:

Principal Investigator :

Trainee Investigator (if any): Yes ☐ No ☐

Student Investigator (if any): Yes ☐ No ☐

Project Title:

Project Status:

☐ New Study

☐ Secondary data analysis (Skip 2, 4 & 5)

☐ Others (please specify)

Check the appropriate box to answer to each of the following (If Not Applicable write NA)

		Yes	No
1	Source of population:		
(a)	Ill participants	☐	☐
(b)	Non-ill participants	☐	☐
(c)	Minor or persons under guardianship	☐	☐
(d)	Others _____	☐	☐
2	Does the study involve:		
(a)	Physical risk to the participants	☐	☐
(b)	Social risk to the participants	☐	☐
(c)	Psychological risks to participants	☐	☐
(d)	Discomfort to participants	☐	☐
(e)	Invasion of participants' privacy	☐	☐
(f)	Disclosure of information damaging to participants or others	☐	☐
3.	Does the study involve:		
(a)	Use of records (hospital, medical, death or other)	☐	☐
(b)	Use of fetal tissue or abortus	☐	☐
(c)	Use of organs or body fluids	☐	☐
(d)	Use of stored biological specimens	☐	☐
(e)	Use of already collected data	☐	☐
4.	Are participants clearly informed about:		
(a)	Nature and purposes of the study	☒	☐
(b)	Procedures to be followed including alternatives used	☒	☐
(c)	Physical risk	☒	☐
(d)	Sensitive questions	☒	☐
(e)	Benefits to be derived	☒	☐
(f)	Right to refuse to participate or to withdraw from the study	☒	☐
(g)	Confidential handling of data	☒	☐
(h)	Compensation and/or treatment where there are risks or privacy is involved in any particular procedure	☒	☐

		Yes	No
5.	Will informed consent be obtained from		
(a)	Study participants	☐	☐
(b)	Parent or guardian or next to kin (if study participants are minor and/or under guardianship)	☐	☐
(c)	Participant aged 11 – 17 years (Assent)	☐	☐
6.	Will precautions be taken to protect anonymity of study participants	☐	☐

7. Check documents being submitted herewith to Committee:

☐ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual research protocol)

Research protocol should include:

☐ Abstract Summary

☐ Consent form for study participants

☐ Consent form for parent or guardian or next to kin

☐ Assent form for participant under guardianship

☐ Questionnaire*

* If the final instrument is not ready at the time of submission of the protocol for review by the ERC, the following information should be included in the abstract summary.

1 Issues to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.

2 The final questionnaire must be approved by the committee before its use.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of study participants before making such changes.

Principal Investigator _____ Trainee investigator _____ Student investigator _____

Attachment -4

Format for submission of a research proposal for ethical approval

• **Project Title :**
• **Summary :**
• **Introduction:** (Introduce the subject. Provide full background information. Cite literatures that are specific to the topic of the research proposal. Information should be completed to prove that the research proposal is based on a sound scientific footing.)
• **Objectives:** (List the general and specific objectives of the proposed study and state clearly the question that is being posed or the hypothesis being tested.)
• **Rationale:** (Describe the relevance of the proposed study to national health priorities and relationship of the objectives to existing scientific knowledge on the subject. Cite relevant literature and refer to related studies done in our country or elsewhere.)
• **Methodology:** (Describe the design of the study and methodology in sufficient detail to enable assessment of how they will contribute towards achievement of the stated objectives and to permit proper appraisal of the budget. Plan for data analysis should be included if relevant and important. This section should contain details of the research methods. Enough detail should be given to evaluate whether the methods are already tested and feasible. The following scheme is suggested: Factors in study (variables), Study Population, Sampling, Statistical basis of the sample size, Procedures, Methods of Data Collection, Pretesting, Data Interpretation, Statistical Analysis (Correlation, Significance Test, Coefficient of Variation, Evaluation Methods, wherever applicable).
• **Utilization of Results:** (Describe in brief how you perceive that the results from this study may contribute to health development of the Country.)
• **Facilities :** (Resources, equipment, chemicals, subjects (human, animal) etc. required for the study):
o Facilities Available :
o Additional Facilities Required :

• **Approval / Forwarding of the Chairman of Department / Institute / Research cell.**

• **Flow Chart:** (Describe sequence of tasks within time frame).
• **Ethical Implications:** (Think very carefully about possible ethical implications and put views. Consult ERC's Guidelines for Ethical Review of Projects involving Human Subjects).
• **References:** Vancouver style to be followed. e.g.- Can Med Assoc J 1995; 152(9): 1459-1465.

Attachment-5

Total Budget.

Detailed Budget:

1. Personnel Cost: (Professional Scientific Staff, Technical & Other Staff. Please mention percentage of time to be devoted by each personnel to this Project).
2. Field Expenses/Laboratory Cost:
3. Supplies and Materials (Items & quantity to be specified):
4. Patient Cost (If applicable):
5. Travel Cost (Internal travel cost only) :
6. Transportation of Goods :
7. Office Stationery (Items & quantity to be specified):
8. Data Processing/Computer Charges (If applicable) :
9. Printing and Reproduction :
10. Contractual Services (Other than manpower):
11. Miscellaneous :

Information

Review and Processing Fee (RPF) for ethical approval:

i. At the time of initial submission of proposal, Principal Investigator will have to pay 500.00 BDT to ERC.
ii. Review and Processing Fee will be determined based on 2% of the total cost of the approved Research Project, but minimum fee is 5000.00 BDT and maximum 20000.00 BDT..
iii. Non funded research project for degree purpose, Applicant will have to pay total 500.00 BDT at the time of the submission of the proposal.
iv. For amendment and renewal 50% of the first approval fee will be charged.
v. Total Fee will be paid by the Principal Investigator after ethical approval (at the time of receiving approval letter) by an Account Payee Cheque in favor of ERC.
vi. Review and Processing Fee for outside of MBSTU will be determined based on 2% of the total cost of the approved Research Project, but minimum fee is 5000.00 BDT and maximum 30000.00 BDT.

ERC may, with the approval of the academic council and regent board of the Mawlana Bhashani Science and Technology University, Tangail, Bangladesh levy a schedule of review fees for different types of protocols. The schedule of fees must be approved by the ERC from time to time as required.

Check list

Mawlana Bhashani Science and Technology University
Tangail-1902, Bangladesh
Tel.: **Fax:**
E-mail: **www.mbstu.ac.bd**

Documents to be submitted for ethical approval

01. Cover Letter to Chairperson for Ethical Clearance by Principal Investigator.

02. Filled-up Ethical Clearance Application Form (Attachment 3).
03. Signature of Principal Investigator (s) & Co-investigator (s) with details address (Attachment 2) (CV).

04. ERC format for Submission of the Proposal for Ethical Approval (*Attachment - 4*)
05. Informed consent form (Both Bangla and English) from participant's or from the Parent / legal guardian (*Attachment-1*).
06. Questionnaire or interview schedule (Both Bangla and English).
07. Procedure for maintaining confidentiality.
08. Budget (*Attachment-5)*
09. A Soft copy of proposal to be send to the committee.
10. All Documents should be submitted in a A-4 Size Data Bank File / Folder.
11. Review and Processing Fee (RPF) for ethical approval (Bank Draft in favor of ERC**)**
12. Fee for the initial submission of research project proposal (Bank Draft in favor of ERC). Ethical Review Committee (Account No. : 6030101003352, Sonali Bank Ltd, MBSTU Branch, Tangail-1902, Bangladesh)