Ethics Review Committee

Standard Operating Procedures (SOPs)

Version 1

Bangladesh Bioethics Society

1085/1 Malibagh Chowdhury Para, Dhaka-1219, Bangladesh.
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This Standard Operating Procedures (SOP) has been developed in compliance with international guidelines, including the Declaration of Helsinki, CIOMS, WHO and ICH-Good Clinical Practice with the complement of existing local laws and regulations to carrying out biomedical and behavioral research on human participants for ensuring ethical research. Compliance with these guidelines helps the researchers to work efficiently for ensuring the dignity, rights, safety, and well-being of research participants and promote credibility of the results of the research.

Checklist for submitting a protocol for ethical approval

01. Forwarding letter to Chairman, Ethics Research Committee (ERC) of Bangladesh Bioethics Society (BBS).

02. Application shall be submitted as per proforma of ERC of BBS. Application Form shall be signed by the Principal Investigator (PI) / Co-investigators / Collaborators.

03. Abstract with a brief description of all ethical issue to the study.

04. Summary of study proposal.

05. Informed consent form for patient or guardian shall be submitted in the Bangla/ English. (In case of verbal inform consent, a reason for taking verbal inform consent needs explanation).

06. Questionnaire or data schedule (Both Bangla and English) shall be submitted along with protocol.

07. 10 sets of hard copy of the project need to be submitted for review.

08. A soft copy of all material of the project / protocol needs to be submitted.

09. Writing format: 12 Font, 1.5 space, New Time Roman or Arial, in a A-4 size paper.

10. CV of Principal Investigator, all Co-investigators.

11. All relevant documents shall be forwarded along with Application Form to the Members/Secretary of the ERC at 1085/1 Malibagh Chowdhury Para, Dhaka-1219, Bangladesh.

12. Review and Processing Fee (RPF) for ethical approval.

Notification of Ethical Clearance

1. Notification of decision for Ethical clearance within 14 days after following review.

2. Ethical clearance shall be issued not more then three months after the submission of research proposal.

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Review Process: All research protocol shall be peer reviewed.

Exemption from Peer Review:

Research proposal from under graduate students of any University / Medical College / Institution and submitted through proper channel (recommendation from Head of institution / Department / Supervisor or approval from local IRB) may be given exemption from the peer review with a condition that there is no intervention, no physical or psychological risk of distress or injury to the subjects. Chairman and Member Secretary of ERC can give an ethical approval of this proposal and notify to next ERC meeting about the exemption with reasons.

Expedite review:

Expedited Review shall be given by Chairperson and Member Secretary when research without involve any intervention or resubmitted protocol with due corrections or follow up research with no physical or psychological risk of distress or injury to the subjects. The expedited proposal with justification for expedition shall be placed in the next ERC meeting.

Full review:

Research involving human except the above mention criteria shall be reviewed by full ERC.

Terms and conditions for Researcher:

- Report shall be submitted periodically / at the end of the study as mentioned.
- Protocol deviation, if any, should be informed to ERC with adequate justifications.
- Any amendment to the protocol shall be resubmitted for renewed approval.
- Any change of investigators / place of study need to be approved by ERC.
- Any new information related to the study shall be communicated to ERC.
- Safety and confidentiality of participant shall be maintained.
- In Clinical Trial, formation of Data Safety and Monitoring Board (DSMB) is mandatory.
- All Serious Adverse Events (SAEs) and Adverse Events (AEs) should be addressed with proper medical care.

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Annexure 1

Project Proforma

1. Title of study

2. Name & Address of Principal Investigator(s):

3. Name and Address of Co-Investigator(s):

4. Place of the Study/Institution(s):

5. Type of Study:

6. Duration of Study:

7. Total Cost:

8. Funding Agency:

I / We agree to obtain approval of the IRB of BBS for my/our study. I/We am/are ready to change our protocol as per suggestions of the committee needed to protection human rights.

Principal investigator Other investigator(S)

Leader/ Coordinator

Institution Head

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Annexure 2

Questionnaire

Please encircle the appropriate answer to each of the following *(If not Applicable write NA)*

1. What level of study is this?

(a) Undergraduate thesis/dissertation /project	Yes	No
(b) Graduate thesis/dissertation/project	Yes	No
(c) Post graduate thesis/dissertation/Research	Yes	No
(d) Funded Research	Yes	No
(e) Clinical Research	Yes	No

2. Source of Population:

(a) Competence Participant	Yes	No
(b) Non non competence Participant	Yes	No
(c) Minors or persons under guardianship	Yes	No

2. Does the study involve?

(a) Physical risks to the subjects	Yes	No
(b) Social Risks	Yes	No
(c) Psychological Risks to subjects	Yes	No
(d) Discomfort to Subjects	Yes	No
(e) Invasion of the body	Yes	No
(f) Invasion of Privacy	Yes	No
(g) Disclosure of Information damaging to Subject or others	Yes	No

3. Does the study involve?

(a) Use of records, (Hospital, medical, Death, birth or other)	Yes	No
(b) Use of fetal tissue or abortus	Yes	No
(c) Use of organs or body fluid	Yes	No

4. Are subjects clearly informed about?

(a) Nature and purposes of study	Yes	No
(b) Procedures to be followed including alternatives used	Yes	No
(c) Physical risks	Yes	No
(d) Private questions	Yes	No
(e) Invasion of the Body	Yes	No
(f) Benefits to be Derived	Yes	No
(g) Right to refuse to participate or to withdraw from study	Yes	No
(h) Confidential handling of data	Yes	No
(i) Compensation where there are risks or loss of working time or privacy is involved in any particular procedure	Yes	No

5. Will signed consent form/verbal consent be required?

(a) From Subjects	Yes	No
(b) From parent or guardian (if subjects are minors)	Yes	No

6. Will precautions be taken to protect subjects Yes No

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Annexure 3

Preparation of an Abstract

The Ethical Review Committee will not consider any application which does not include a specific abstract for the committee. The abstract should summarize the purpose of the study and procedures addressing each of the following items. If an item is not applicable, please note accordingly. Abstract should be within 1-2 pages (1 page preferred).

1. **Selection of Subject:** Describe the requirements in respect of the population. Explain the rationale for using population of special groups such as children, Incompetent person or groups whose ability to give voluntary informed consent is questionable.

2. **Risk and Benefit:** Describe and assess any potential risks e.g. physical, psychological, social, legal or other and assess the likelihood and seriousness of such risks. If methods of research create potential risks, describe other methods. Explain why they cannot be used. If there is any potential benefit, please mention it. Asses the potential benefit to be gained by the individual participant as well as benefit which many accrue to society in general as a result of the work. Indicate how the benefits may outweigh the risks.

3. **Safeguard:** Describe procedures for protecting against or minimizing potential risks and assessment of their likely effectiveness.

4. **Procedure of maintaining confidentiality**: Describe the methods for safeguarding confidentiality or protecting anonymity.

5. **Procedure of maintaining archiving and dissimilation of data**: Include a description of the methods for how data will archive and result will be dissimilated.

6. **Procedure of inform consent:** When research with human participants, the investigator is required to obtain a signed written informed consent from the participant. For minors, informed consent must be obtained from the authorized legal guardian or parent of the participants. Describe consent procedures to be followed including how and where informed consent will be obtained.

   (a) If signed consent will not be obtained, explain why this requirement will be waived and provide an alternative procedure such as a verbal consent.

   (b) If information is to be withheld from a participant, justify this course of action.

   (c) If there is a potential risk to the participant or privacy of the individual or loss of work time is involved in any particular procedure, include a statement in the consent form stating whether any compensation will be available.

   (d) If it is verbal inform consent, the reason for taking verbal inform consent needs explanation but it will be accepted only in special situation where written consent is impossible to take.

6. **Interview:** If the study involves an interview, describe where and in what context the interview will take place. State approximate length of time required for the interview.

7. **Experimental drugs: a)** In case of an experimental drug, provide information about its status of

registration for open sale in Bangladesh and in other developed countries.

b) For experimental 'new' drugs which are not registered in Bangladesh provide full information about the toxicity studies carried out in animals or human volunteers. Published papers on this regard shall be annexed.

c) If an experimental 'new' drug is to be used give a statement regarding its sponsorship and the conditions for such sponsorship. A new drug means one which is not registrared for the free and open sale in Bangladesh.

10. **Placebo:** If placebo is to be used justify its uses and why the study cannot be done without its use.

12. **Use of Record:** State if the activity requires the use of records (hospital, medical, birth, death or other) for organs, tissues, body fluids, the fetus or the abortus.

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Annexure 4

Summary: Brief description of whole project including introduction, aim & objectives, methodology, out come. It should be within 1-3 pages.

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Annexure 5

Format for submission of a research proposal for ethical approval

- **Project Title :**
- **Introduction:** 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 matter. Cite relevant literature and refer to related studies done in our country or elsewhere.
- **Methodology:** Describe the design of the study 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. 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:
    - Facilities Available :
    - Additional Facilities Required :
- **Flow Chart:** Describe sequence of tasks within time frame.
- **Ethical Implications:** Think very carefully about possible ethical implications and put views.
- **References:** Vancouver style to be followed. e.g. Author(s) name. Title. Can Med Assoc J 1995; 152(9): 1459-1465.

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Annexure 6

Informed consent form: Informed consent form shall be written in Bengali & English. It should be one or one & half page length.

Consent form shall be included:

- Interviewer details.
- Purpose of the Study.
- Types of participation of the study respondents.
- Duration, Procedures of the study and participant's involvement.
- Potential benefits.
- Risks, hazards and discomforts.
- Compensation.
- Confidentiality.
- Rights to withdraw from participation.
- One copy of IC form shall give to the participant
- Name of the participant.
- Signature/Thumb print of the participants.
- Name of the witness.
- Signature of the witness.
- Name of the interviewer.
- Signature of the interviewer.
- In case of Minor Signature of the Parent / Legal Guardian.
- Duplicate copy of Inform Consent shall be give to participant.

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Annexure 7

- 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*:

*Miscellaneous shall not exceeded the 5% of the total budget

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Annexure 8

Review and Processing Fee (RPF) for ethical approval

1. Undergraduate students shall have to pay total 2,000 TK at the time of the submission of the proposal.

2. Graduate students shall have to pay total 3,000 TK at the time of the submission of the proposal for Master thesis below BDTK 2, 00,000.

3. a) Review and Processing fees shall be determined based on 2.5% of the total cost of the approved Research Project above the amount of BDTK 2, 00,000.

b) At the time of initial submission of proposal, Principal Investigator shall pay to BBS bank account which is nonrefundable.

4. For amendment and renewal, 5% of the first approval fee will be charged.

Bank account:

Bangladesh Bioethics Society,

Janata Bank Ltd,

Hotel Sheraton Branch,

Dhaka, Bangladesh,

Ac/No : 34048649

SWIFT: JANBBDDH.