BANGLADESH MEDICAL RESEARCH COUNCIL

MOHAKHALI, DHAKA-1212, BANGLADESH
Tel: +8802222298396, Fax: +8802222263820
Email: info@bmrcbd.org; Web: www.bmrcbd.org

DOCUMENTS TO BE SUBMITTED FOR ETHICAL APPROVAL

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

02. Filled-up Ethical Clearance Application Form. (*Annexure - A*)

03. Signature of Principal Investigator (s) & Co-investigator (s) with details address. (*Annexure - A*)

04. Abstract for National Research Ethics Committee (NREC) (*Annexure - B*)

05. BMRC format for Submission of the Proposal for Ethical Approval (*Annexure - C*)

06. Informed consent form (Both Bangla and English) from participant's or from the Parent / legal guardian. (*Annexure - D*)

07. Questionnaire or interview schedule (Both Bangla and English).

08. Procedure for maintaining confidentiality.

09. Budget (*Annexure - E*)

10. Copy of approval from valid scientific review committee (If any).

11. Four (4) copies of all documents to be submitted to Bangladesh Medical Research Council (BMRC).

12. A Soft Copy in CD to be submitted.

13. All Documents should be Submitted in a A-4 Size Data Bank File / Folder.

14. Review and Processing Fee (RPF) for ethical approval:

I. Review and Processing Fee will be determined based on 2% of the total cost of the approved Research Project, but it will not exceed Tk 5,00,000 (5 lacs).

II. At the time of initial submission of proposal, Principal Investigator will have to pay Tk 20000 (Twenty Thousand) to BMRC.

III. In case of Clinical Trial/Drug Research, Principal Investigator will have to pay Tk 50000 (Fifty Thousand) to BMRC at the time of initial submission.

IV. Undergraduate students will have to pay total Tk 2000 (Two Thousand) at the time of the submission of the proposal.

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 Bangladesh Medical Research Council.

VI. For amendment and renewal 50% of the first approval fee will be charged.

ANNEXURE - A

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Application for Ethical Clearance

1. **Principal Investigator(s):**

   Name:

   Qualification:

   Detail Address:

   Mobile: Telephone (Off./Res)

   e-mail:

2. **Co-Investigator(s):**

   Name:

   Qualification:

   Detail Address:

   Mobile: Telephone (Off./Res)

   e-mail:

3. **Place of the Study/Institution(s):**
4. **Title of Study:**
5. **Type of Study:**
6. **Duration of Study:**
7. **Total Cost:**
8. **Funding Agency:**

Circle the appropriate answer to each of the following
(If not Applicable write NA)

1. Source of Population:

(a) ILL Participant Yes No

(b) Non ILL 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 fluids 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 anonymity of subjects Yes No

Note: If the final instrument / questionnaire is not completed prior to review, the following information should be included in the abstract.

1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific question to be asked in the sensitive areas.
3. An indication as to whom the questionnaire will be presented to the committee for review.

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

Signature

Name of the Principal Investigator/Leader/Coordinator

Date:

Name of Co-investigator (S) **Signature:**

1.

2.

3.

4.

5.

**** Include all the Investigator, Co –Investigators.***

ANNEXURE - B

PREPARATION OF AN ABSTRACT
FOR
NATIONAL RESEARCH ETHICS COMMITTEE (NREC)

The Ethical Review Committee will not consider any application which does not include a specific abstract/summary for the committee. The abstract should summarize the purpose of the study, the methods and procedures to be used, by addressing each of the following items. If an item is not applicable, please note accordingly:

1. Describe the requirements in respect of the population and 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. Describe and assess any potential risks - 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, if any, that were considered and why they cannot be used.

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

4. Include a description of the methods for safeguarding confidentiality or protecting anonymity.

5. When there are potential risks to the subject, or the privacy of the individual may be involved, the investigator is required to obtain a signed informed consent from the participant. For minors, informed consent must be obtained from the authorized legal guardian or parent of the subject. 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 should be waived and provide an alternative procedure such as a verbal consent.

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

   (c) If there is a potential risk to the subject 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.

6. 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. Assess the potential benefit to be gained by the individual subject as well as the benefits which may accrue to society in general as a result of the work. Indicate how the benefits may outweigh the risks.

8. Incase of an experimental drugs, provide information about its status of registration for open sale in Bangladesh and in other developed countries.

9. 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.

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

11. If an experimental 'new' drug* is to be used give a statement regarding its sponsorship and the conditions for such sponsorship.

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

The statement to the subject should include information specified in items 2, 3, 4, 5(c) and 7, as well as indicating the approximate time required for participation in the activity.

**** a 'new' drug means one which is not registered for free and open sale in Bangladesh.***

ANNEXURE - C

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 design, 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 :
- **Approval / Forwarding of the Head of Department / Institute / IRB.**
- **Flow Chart:** (Describe sequence of tasks within time frame).
- **Ethical Implications:** (Think very carefully about possible ethical implications and put views. Consult BMRC'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.

ANNEXURE - D

INFORMED CONSENT FORM SHOULD BE WRITTEN IN BENGALI & ENGLISH

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.
- Reimbursements.
- Confidentiality.
- Termination of study participation / Rights to withdraw from participation.
- 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.

ANNEXURE - E

- 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 :