

BANGLADESH MEDICAL RESEARCH COUNCIL
MOHAKHALI, DHAKA-1212, BANGLADESH
Tel: 8819311, 8828396, Fax: 880-2-8828820
Email: info@bmrcbd.org
Web: www.bmrcbd.org

Application for Ethical Clearance

- 1. Principal Investigator(s):**

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

- 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 Subjects | Yes | No |
| (b) Non ILL Subjects | 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.

PREPARATION OF AN ABSTRACT FOR

THE ETHICAL REVIEW COMMITTEE (ERC)

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 subject population and explain the rationale for using population of special groups such as children, 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 can not 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 subject. 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. If experimental drugs will be used 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 subject shall be annexed.
10. If placebo is to be used justify its uses and why the study can not 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.*

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Check documents being submitted herewith to committee:

01. Letter to Director for Ethical Clearance
02. Signature of Principal Investigator (s) & Co-investigator (s) with details address
03. Fill-up BMRC Ethical Clearance Form
04. Abstract for National Research Ethics Committee (NREC)
(see attached guideline)
05. Following instructions should be maintained for proposal:
 - **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):
 - Facilities Available :
 - Additional Facilities Required :
 - **Approval of the Head of the Department/Institute :**
 - **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.

**06. Informed consent form from subjects or from the Parent/guardian.
(Both Bangla and English)**

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

08. Procedure for maintaining confidentiality.

09. Budget

- 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. Administrative Overhead :

10. Four (4) copies of Project Proposal to be submitted to Bangladesh Medical Research Council (BMRC).

11. Soft Copy in CD.

12. A-4 Size Data Bank File (1 Pc).

Note: Review and Processing Fee (RPF) for ethical approval:

- I. Review and Processing Fee will be determined based on the total cost of the approved Research Project.
- II. RPF will be calculated at the rate of 2% of total budget from March, 2012.
- III. The Fee will be paid by the Principal Investigator after approval (before receiving approval letter) by **Account Payee Cheque in favour of Director, Bangladesh Medical Research Council.**
- IV. For amendment and renewal 50% of the approval fee will be charged.