BANGLADESH MEDICAL RESEARCH COUNCIL (BMRC)

Mohakhali, Dhaka, Bangladesh

Standard Operating Procedures (SOPs)

National Research Ethics Committee (NREC)

Standard Operating Procedures (SOPs) for Ethical approval

The objective of this SOP is to achieve effective functioning of the National Research Ethics Committee (NREC) (Annexure-F) so that a quality and consistent ethical review mechanism for conducting research studies involving human subjects and biomedical research is in place.

All research projects for ethical approval should be submitted in the prescribed Application Form which is available in BMRC office and in the website (www.bmrcbd.org). It is requested to go through the instruction before preparing the Research proposal for submission.

Research proposal submitted to Bangladesh Medical Research Council (BMRC) for ethical approval should be methodologically sound and scholarly standard and approved by valid scientific review committee. If the proposal is not approved by any valid Scientific Review Committee than it should be approved by the Scientific Review Committee of BMRC before submission to NREC. Principal Investigator will be informed at time of any comments/queries arisen. NREC will be give the final Ethical Approval after considering the justification given / points addressed on the ethical issues of the research proposal.

Scientific Review Committee will justify the research proposal is of good scientific quality, scientific value, validity and feasibility of the protocol and cited relevant scientific literature (if any) on of proposed research as well as ethical issues by peer review process.

The NREC will conduct meeting in every 2 (two) months. The frequency of meetings may increased depending on the number of applications. All decisions will be communicated to the Principal Investigator in writing.

All relevant documents should be enclosed with Application Form. Required number of copies of the proposal (soft & hard copy) along with the formal application / letter and documents in prescribed format (all must be duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators) should be forwarded to the Members/Secretary of the NREC.

Chairperson's Review and Expedited Review:

Expedited Review will be given when the research proposal is approved by valid Scientific Review Committee – as methodologically sound, without any intervention and risk of distress or injury, physical or psychological to the subjects. The expedited proposal with justification for expedition should be placed in the next NREC meeting.

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, risk of distress or injury, physical or psychological to the subjects. Chairman of NREC can give an ethical approval of this proposal in condition that the proposal must submit in the next NREC meeting.

Terms and conditions for Post approval completion of research:

- Reports should be submitted at intervals prescribe by NREC for review.
- Report should be submitted periodically & at the end of the study.
- In Clinical Trial, formation of Data Safety and Monitoring Board (DSMB) is mandatory.
- At least 2 (two) members shall be included from NREC during formation of DSMB.
- All Serious Adverse Events (SAEs) and Adverse Events (AEs) should be addressed with proper medical care.
- Protocol deviation, if any, should be informed with adequate justifications.
- Any amendment to the protocol should be resubmitted for renewed approval.
- Any new information related to the study should be communicated to NREC.
- Change of investigators / place of study need to be approved by NREC.
- Safety and confidentiality of participant shall be maintain.

BANGLADESH MEDICAL RESEARCH COUNCIL

MOHAKHALI, DHAKA-1212, BANGLADESH

Tel: 8819311, 8828396, Fax: 880-2-8828820

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

BANGLADESH MEDICAL RESEARCH COUNCIL

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Tel: 8819311, 8828396, Fax: 880-2-8828820
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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 Yes No
under guardianship

2. Does the study involve?

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

3. Does the study involve?

(a) Use of records, Yes No
(Hospital, medical, Death, birth or other)

(b) Use of fetal tissue Yes No
Or abortus
(c) Use of organs or Yes No
Body fluids

4.Are subjects clearly informed about?

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

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

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

6. Will precautions be Yes No
taken to protect
anonymity of subjects

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 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 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 :

ANNEXURE - F

NATIONAL RESEARCH ETHICS COMMITTEE (NREC)

Bangladesh Medical Research Council (BMRC) is the Secretariat for the National Research Ethics Committee (NREC). According to BMRC Policy each and every Project Proposal approved by the Scientific Review Committee must get ethical approval before funding. Scientific validity should be approved by a valid Scientific Review Committee before submission of a research project to NREC.

The Ethics Review Committee of BMRC was established in 1979. The Committee consists of 9-13 Members (Lawyer, Female Representative, Religious Leader, Research Methodologist / Bio-statistician are obligatory as member) including chairman and member secretary. The Committee is formed by the Council under Guidelines for formation of Ethics Review Committee for tenure of 3 Years. The NREC is multidisciplinary and multi-sectorial in composition and an independent Body.

The Committee is registered in OHRP as an official IRB (lRB No. 0001494) and has FWA (#00006444). Usually every year the Ethics Review Committee evaluates around 100 Research Proposals. The Committee meets every month. The Committee has given ethical approvals to investigators of numerous International Agencies and Academic Institutions (e.g. WHO, UNICEF, UNFPA, Harvard, Johns Hopkins, Columbia, Cambridge Universities, Intl. NGOs etc.)

• The NREC provides approval for:

- BMRC Funded Research Projects (Internal/Intramural)
- Projects funded by Organizations (National and International) other than BMRC (External/Extramural), including multicentric collaborative studies.
- Research studies leading to Postgraduate Degrees (Specifically PhDs).

• The Chairperson will conduct all meetings of the NREC. In absence of the Chairperson, members of the NREC will elect a chairperson who will conduct the meeting.

• The NREC will conduct meeting in every 2 (two) months. The agenda should not be so loaded that sufficient time is not available for discussion. The frequency of meetings may increase depending on the number of applications.

• Member Secretary is responsible for organizing the meetings, maintaining the records and communication in all concerned. The Notice of the meeting should be issued at least 7 (seven) days before the meeting.

• Minutes of the previous meeting should be confirmed. Proceeding of the meetings should be confidential and maintained in a standard format.

• The proceedings of the meeting should be prepared within 3 working days after the meeting.

• All decisions will be communicated in writing to the Principal Investigator.

• NREC should have following documentation:

- Copy of all study protocols with enclosed documents, progress reports, and Serious Adverse Effect (SAEs).

- Minutes of all meetings.

- Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

- Copy of all correspondence with members, researchers and other regulatory bodies.

- Final report of the approved projects.

- All documents should be archived.

• **Updating NREC members:**

-All relevant new guidelines should be brought to the attention of the members.

- Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

GUIDELINES ON RESEARCH ETHICS AS PER NATIONAL HEALTH RESEARCH STRATEGIES:

- The National Research Ethics Committee (NREC) will set standards, advice the Departments and the Ministry of Health & Family Welfare on the management of research ethics for Bangladesh and arbitrate on matters of Ethics.
- The NREC will be responsible to review all clinical trials of both non registered medicinal substances in Bangladesh and new indication of already registered medicinal substances.
- Research issues having religious or social sensitivity should be approved by NREC
- International collaborative research involving Bangladeshi population will have to get ethical approval by the NREC, while the administrative approval shall be given by the Government

Registration of Health Research as per National Health Research Strategy:

BMRC has developed a Registration Form for registration of research studies. BMRC is developing electronic submission system for health research registration. There is a specific section in this system for Clinical Trial Registry.

- Any health research to be conducted in Bangladesh has to be registered with the BMRC.
- The Clinical Trials Protocol should be reviewed and approved by the NREC.
- Clinical Trials should be registered in the Clinical Trial Registry in the BMRC.
- Clinical Trials be well monitored.
- Clinical Trials should be conducted following ethical standard (Social or Scientific Value, Scientific Validity, Fair Subject Selection, Favorable Risk-Benefit Ratio, Independent Review, Informed Consent & Respect for Potential and Enrolled Subjects)

Clinical Trial

- The NREC conducts post-approval monitoring of Clinical Trial.
- It is mandatory to form Data Safety Monitoring Board (DSMB) for conducting Clinical Trial.
- At least 2 (two) members shall be included from NREC during formation of DSMB.
- Principal Investigator should report Serious Adverse Events (SAE) as well as Adverse Events (AE) to the NREC.
- Approval is given subject to several conditions.