### DOCUMENTS TO BE SUBMITTED FOR ETHICAL APPROVAL

01. Cover letter from the Principal Investigator to the Director, requesting ethical clearance.
02. Completed Application for Ethical Clearance (Annexure A).
03. Signatures of the Principal Investigator(s) and Co-Investigator(s), with their detailed addresses (Annexure A).
04. Abstract for the Ethical Review Committee (ERC) (Annexure B).
05. Research proposal in the Society's prescribed format (Annexure C).
06. Informed consent form, in both Bangla and English, for the participant or the parent / legal guardian (Annexure D).
07. Questionnaire or interview schedule, in both Bangla and English.
08. Procedure for maintaining confidentiality.
09. Budget (Annexure E).
10. Copy of valid approval from a scientific review committee, if any.
11. Four (4) copies of all documents, to be submitted to Bangladesh Academy of Clinical Research Society.
12. A soft copy of all documents on CD.
13. All documents should be submitted in an 'A4' size data bank file / folder.
14. Review and Processing Fee (RPF) for ethical approval:
    - I. The fee is 2% of the total cost of the approved research project, up to a maximum of Tk 5,00,000 (5 lakh).
    - II. At initial submission of the proposal, the Principal Investigator must pay Tk 20,000 (twenty thousand) to the Society.
    - III. For clinical trials and drug research, the Principal Investigator must pay Tk 50,000 (fifty thousand) to the Society at initial submission.
    - IV. Undergraduate students must pay a total of Tk 2,000 (two thousand) when submitting the proposal.
    - V. The total fee must be paid by the Principal Investigator after ethical approval, on receipt of the approval letter, by account payee cheque in favor of Bangladesh Academy of Clinical Research Society.
    - VI. For amendment and renewal, 50% of the original approval fee will be charged.

## ANNEXURE – A

| Application for Ethical Clearance | | |
|---|---|---|
| **1. Principal Investigator(s):** | | |
| Name | | Qualification |
| Detailed address | | |
| Mobile | Telephone (office / residence) | E-mail |
| **2. Co-Investigator(s):** | | |
| Name | | Qualification |
| Detailed address | | |
| Mobile | Telephone (office / residence) | E-mail |
| 3. Place of study / institution(s) | | |
| 4. Title of study | | |
| 5. Type of study | | |
| 6. Duration of study | 7. Total cost (Tk.) | |
| 8. Funding agency | | |

| Ethical Checklist | | | |
|---|---|---|---|
| ☑ *Tick the appropriate answer to each of the following (if not applicable, choose N/A).* | | | |
| **Item** | **Yes** | **No** | **N/A** |
| **1. Source of population:** | | | |
| (a) Ill participants | ☐ | ☐ | ☐ |
| (b) Non-ill participants | ☐ | ☐ | ☐ |
| (c) Minors or persons under guardianship | ☐ | ☐ | ☐ |
| **2. Does the study involve any of the following?** | | | |
| (a) Physical risks to subjects | ☐ | ☐ | ☐ |
| (d) Social risks | ☐ | ☐ | ☐ |
| (e) Psychological risks to subjects | ☐ | ☐ | ☐ |
| (f) Discomfort to subjects | ☐ | ☐ | ☐ |
| (g) Invasion of the body | ☐ | ☐ | ☐ |
| (h) Invasion of privacy | ☐ | ☐ | ☐ |
| (i) Disclosure of information damaging to subjects or others | ☐ | ☐ | ☐ |

| ☑ *Tick the appropriate answer to each of the following (if not applicable, choose N/A).* | | | |
|---|---|---|---|
| **Item** | **Yes** | **No** | **N/A** |
| **3. Does the study involve any of the following?** | | | |
| (a) Use of records (hospital, medical, death, birth or other) | ☐ | ☐ | ☐ |
| (b) Use of fetal tissue or abortus | ☐ | ☐ | ☐ |
| (c) Use of organs or body fluids | ☐ | ☐ | ☐ |
| **4. Are subjects clearly informed about the following?** | | | |
| (a) Nature and purposes of the study | ☐ | ☐ | ☐ |
| (b) Procedures to be followed, including any alternatives | ☐ | ☐ | ☐ |
| (c) Physical risks | ☐ | ☐ | ☐ |
| (d) Private questions | ☐ | ☐ | ☐ |
| (e) Invasion of the body | ☐ | ☐ | ☐ |
| (f) Benefits to be derived | ☐ | ☐ | ☐ |
| (g) Right to refuse to participate or to withdraw from the study | ☐ | ☐ | ☐ |
| (h) Confidential handling of data | ☐ | ☐ | ☐ |
| (i) Compensation where there are risks, or loss of working time or privacy, in any particular procedure | ☐ | ☐ | ☐ |
| **5. Will signed or verbal consent be required?** | | | |
| (a) From subjects | ☐ | ☐ | ☐ |
| (b) From the parent or guardian (if the subjects are minors) | ☐ | ☐ | ☐ |
| **6. Will precautions be taken to protect the anonymity of subjects?** | ☐ | ☐ | ☐ |

## Declaration and Signatures

**Note:** If the final questionnaire or interview instrument is not ready before the review, the abstract must include the following:
1. A description of the areas covered by the questionnaire or interview that could be considered sensitive or an invasion of privacy.
2. Examples of the specific questions to be asked in the sensitive areas.
3. An indication of when the final questionnaire will be presented to the committee for review.

**We agree to obtain the approval of the Ethical Review Committee before making any change to the methodology or any change affecting the rights and welfare of participants.**

| Name of the Principal Investigator / Leader / Coordinator | Signature | Date |
|---|---|---|
| | | |

| **Name of Co-Investigator(s)** | **Signature** |
|---|---|
| 1. | |
| 2. | |
| 3. | |
| 4. | |
| 5. | |

** Include all investigators and co-investigators.*

## ANNEXURE – B

| Preparation of an Abstract for Ethical Review Committee (ERC) | |
|---|---|
| The Ethical Review Committee will not consider any application that does not include an abstract prepared for the committee. The abstract should summarize the purpose of the study and the methods and procedures to be used, addressing each of the following items. If an item is not applicable, write N/A. | |
| **1.** | Describe the study population requirements. Explain the rationale for including special groups, such as children, persons lacking capacity, or groups whose ability to give voluntary informed consent is in question. |
| **2.** | Describe any potential risks (physical, psychological, social, legal or other) and assess their likelihood and seriousness. If the research methods create potential risks, describe any alternative methods that were considered and explain why they cannot be used. |
| **3.** | Describe the procedures for preventing or minimizing potential risks, and assess how effective they are likely to be. |
| **4.** | Describe the methods for safeguarding confidentiality or protecting anonymity. |
| **5.** | Where there are potential risks to the subject, or the individual's privacy may be affected, the investigator must obtain signed informed consent from the participant. For minors, consent must be obtained from the authorized legal guardian or parent. Describe the consent procedures to be followed, including how and where consent will be obtained.<br>(a) If signed consent will not be obtained, explain why this requirement should be waived and describe an alternative, such as verbal consent.<br>(b) If any information is to be withheld from a subject, justify this.<br>(c) If any procedure poses a potential risk to the subject, a risk to privacy, or loss of work time, state in the consent form whether any compensation will be available. |
| **6.** | If the study involves interviews, describe where and in what context they will take place, and state the approximate time each will take. |
| **7.** | Assess the potential benefit to the individual subject, and the benefits that may accrue to society in general as a result of the work. Indicate how the benefits outweigh the risks. |
| **8.** | For an experimental drug, state its registration status for open sale in Bangladesh and in other developed countries. |
| **9.** | For experimental 'new' drugs* not registered in Bangladesh, provide full details of toxicity studies carried out in animals or human volunteers. Attach any published papers on this. |
| **10.** | If a placebo is to be used, justify its use and explain why the study cannot be done without it. |
| **11.** | If an experimental 'new' drug* is to be used, state who is sponsoring it and the conditions of the sponsorship. |
| **12.** | State whether the study requires the use of records (hospital, medical, birth, death or other), organs, tissues, body fluids, a fetus or abortus. |
| The statement to the subject should include the information specified in items 2, 3, 4, 5(c) and 7, and the approximate time required for participation. | |

** A 'new' drug is one that 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<br>Introduce the subject and provide full background information. Cite literature specific to the topic of the proposal. The information should be sufficient to show that the proposal rests on a sound scientific basis. | |
| Objectives<br>List the general and specific objectives of the study and state clearly the research question or the hypothesis being tested. | |
| Rationale<br>Describe the relevance of the study to national health priorities and how its objectives relate to existing scientific knowledge on the subject. Cite relevant literature and refer to related studies done in Bangladesh or elsewhere. | |
| Methodology<br>Describe the study design and methodology in enough detail to show how they will achieve the stated objectives and to allow the budget to be properly appraised. Include a plan for data analysis where relevant. Give enough detail on the research methods to show that they are tested and feasible. The following scheme is suggested: variables, study design, study population, sampling, statistical basis of the sample size, procedures, methods of data collection, pretesting, data interpretation, and statistical analysis (correlation, significance tests, coefficient of variation, evaluation methods, wherever applicable). | |
| Utilization of results<br>Briefly describe how the results of this study may contribute to the country's health development. | |
| Facilities<br>Resources, equipment, chemicals, subjects (human or animal), etc. required for the study. | |
| Facilities available | Additional facilities required |
| Approval / forwarding by the Head of Department / Institute / IRB | Signature and date |
| Flow chart<br>Describe the sequence of tasks within the time frame. | |
| Ethical implications<br>Consider carefully the possible ethical implications and state your views. Consult the Society's Guidelines for Ethical Review of Projects Involving Human Subjects. | |
| References<br>Follow the Vancouver style, e.g. Can Med Assoc J 1995; 152(9): 1459-1465. | |

**ANNEXURE – D**

| Informed Consent Form | |
|---|---|
| *The informed consent form must be written in both Bangla and English, and must include:* | |
| ☐ Interviewer details | ☐ Purpose of the study |
| ☐ Nature of participation of the study respondents | ☐ Duration and procedures of the study, and the participant's involvement |
| ☐ Potential benefits | ☐ Risks, hazards and discomforts |
| ☐ Reimbursements | ☐ Confidentiality |
| ☐ Termination of participation / right to withdraw from the study | ☐ Name of the participant |
| ☐ Signature / thumb print of the participant | ☐ Name of the witness |
| ☐ Signature of the witness | ☐ Name of the interviewer |
| ☐ Signature of the interviewer | ☐ For a minor, signature of the parent / legal guardian |
| ☐ A duplicate copy of the consent form must be given to the participant. | |

## ANNEXURE – E

| Budget | | | |
|---|---|---|---|
| Total budget (Tk.) | | | |
| **Detailed budget:** | | | |
| **No.** | **Budget head** | **Details** | **Amount (Tk.)** |
| 1 | Personnel cost<br>*Professional scientific staff, technical and other staff. Please state the percentage of time each person will devote to this project.* | | |
| 2 | Field expenses / laboratory cost | | |
| 3 | Supplies and materials<br>*Specify items and quantity.* | | |
| 4 | Patient cost<br>*If applicable.* | | |
| 5 | Travel cost<br>*Internal travel only.* | | |
| 6 | Transportation of goods | | |
| 7 | Office stationery<br>*Specify items and quantity.* | | |
| 8 | Data processing / computer charges<br>*If applicable.* | | |
| 9 | Printing and reproduction | | |
| 10 | Contractual services<br>*Excluding manpower.* | | |
| 11 | Miscellaneous | | |