Master Copy

Research Cell

COMMUNITY BASED MEDICAL COLLEGE & HOSPITAL

Mymensingh, Bangladesh | Established 1995

CHECK LIST FOR SUBMISSION OF PROJECT PROFORMA (PP)

01. Cover Letter addressing to director by principal Investigator

02. Project proforma

Part-A

Part-B

Part-C

Part-D

Part-E

Part-F

Part-G Part-H

Part-I

03. Procedure for maintaining confidentiality.

04. One (01) copy of project proposal (Master copy) including all mentioned documents and a soft copy in CD to be submitted along with A-4 size Data Bank File/Folder.

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Project proforma (PP)

Revenue Research Grants

Proposal Should be Submitted in 4 (four) copies

PART – A

1. project title:
2. Principal Investigator: A copy of the curriculum vitae and list of publications be annexed 3. Co-investigator(s)
4. Place of study / Institution (s):
5. Sponsoring/Collaborating Agencies:
6. Duration:
7. Date of commencement:
8. Date of completion:
9. Total cost:

10.Other Support for Proposed Research:

(1) Is this research project being supported by any other source? Yes No

(2) Has an application for funding of this project been submitted to any other organization(s)? Yes No

If "Yes" to 10(1) or 10(2) above, please indicate the organization(s) and amount of funds.

11. Date of Submission :
12. Signature of Principal Investigator :
13. Signature of Co- Investigator(s) :
14. Endorsement of the Institute Head :

Name and Signature :

Designation :

Official Seal :

PART –B

PRINCIPAL INVESTIGATOR INFORMATION SHEET

1. (i) Name:

   (ii) Designation:

   (iii) Official Address with telephone:

   (iv) Present Residential Address with telephone:

2. Academic Background:

   Degree University Field Year

3. Field of Specialty:

4. (a) Research Experience:

   (b) Other Experience: Teaching:

   Administration:

   Others:

5. Percentage of time to be devoted to this Project:

6. Number of Scientific publications:
   (Please attach a list of your Publications)

signature of Principal Investigator

PART-C

1. PROJECT TITLE:

2. SUMMARY:

PART –D

1. INTRODUCTION:

Introduce the subject. Provide full background information. Cite literatures that are specific to the topic of the research proposal. Information should be complete enough to prove that the research proposal is based on a sound scientific footing.

2. 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.

3. 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

4. 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 evolute 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, Statical Analysis (Correction, significance Test, coefficient of variation, Evaluation Methods, Wherever applicable).

5. IMPECT OF RESEARCH:

Describe in brief how you perceive that the results from this study may contribute to health development of the country.

6. FACILITIES (Resources, equipment, chemicals, subjects human, animal etc. required for the study):

1.1 . Facilities Available:
1.2 . Additional Facilities Required:

7. APPROVAL OF THE HEAD OF THE DEPARTMENT/INSTITUTE:

8. FLOW CHART (Describe sequence of tasks within time frame).

9. ETHICAL IMPLICATIONS (Think very carefully about possible ethical implications and put views. consult **IERB'S** Guidelines for Ethical Review of Projects involving Human Subjects).

10. REFERENCES: Vancouver style to be followed

Note: All Citations should be referenced in the reference section/ bibliography.

PART-E

BUDGET

I. **Total Budget**:

II. **Detailed Budget:**

1. Personal 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 (Item & quantity to be specified)
8. Data processing / Computer Charges (If applicable)
9. Printing and Reproduction:
10. Contractual Services: Other than manpower
11. Administrative Overhead: 15% of the total project cost will be taken by **Research Cell of CBMCB.**
12. Miscellaneous: Not exceeding 2.5% of the total budget. Items & quantity to be specified

PART-F

COMMUNITY BASED MEDICAL COLLEGE & HOSPITAL

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Application for Ethical Clearance

1. **Principal Investigator:** Please mention the detail address

2. **Co-Investigator(s):** Please mention the detail address

3. **Place of the study/ Institution(s):**

4. **Title of Study:**

5. **Type of Study:**

6. **Duration:**

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 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 subjects Yes No

(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 body Yes No

(f) Benefits to be derived Yes No

(g) Right to refuse Yes No
To participate or
To withdraw from study

(h) Confidential handling of data
Yes No

(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 taken to protect anonymity of subjects Yes No

☐Check documents being submitted herewith to the IERB of CBMCB:

- ☐ Umbrella Proposal
- ☐ Proposal Summary
- ☐ Abstract for IERB as per attachment (Obligatory)
- ☐ Informed consent form for subjects
- ☐ Informed consent form for parent guardian
- ☐ Verbal consent form for subjects
- ☐ Procedure for maintaining confidentiality
- ☐ Questionnaire or interview schedule*

* 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 questions 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 National Research Ethics committee for any changes involving the rights and welfare of subjects or any changes of the Methodology before making any such changes.

PART-G

Write an Abstract for Institutional Ethical Review Board of CBMCB (IERB)

Guideline for Preparation of an Abstract for IERB:

The Research Ethical 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 write "N/A" and explain the reason behind it.

1. Describe the requirements in respect of the subject population and explain the rational 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 likehood 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 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's is to be withheld from a subject, justify this course of action.

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

PART-H

Write an Informed Consent Form

Guideline for Informed Consent Form (Consent Form Should include the following points):

Consent Form should be in both Bengali & English.

- Interviewer's details
- Purpose of the study.
- Types of participation of the study respondents.
- Duration, procedures of the study and participant's involvement.
- Potential benefits.
- Use of sample (e.g.: blood, urine, saliva, tissue etc.) and its preservation if any.
- Risks, hazards and discomforts.
- Reimbursements.
- Termination of study participation / Rights to withdraw form participation.
- Name of the participation.
- 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 the informed consent form should be given to participant.

PART- I

Write a questionnaire or interview schedule (both in Bengali and English)

of the Research project

Guidelines for Research Grants (Revenue)

1. Four (4) copies of project proforma (PP) to be submitted to **Research Cell of CBMCB**.

2. The project proposal should be confined within the priority Research Areas.

3. The research proposal should be developed strictly in accordance with the prescribed format providing detail information on each section/item and be submitted in A4 size offset paper.

4. Recommendation from the Head of the concerned institution/department should be obtained before the research proposals are submitted to **Research Cell** for necessary processing.

5. Research grants shall be provided mainly to conduct Health systems Research, Clinical Research and Basic Medical Research etc.

6. The project proposal will be evaluated by relevant experts through the **Research Cell of CBMCB.**

7. Research projects involving human subjects shall be reviewed by the **IERB of CBMCB.**

8. The duration of a proposal may not generally exceed one year. However, in exceptional cases, extension may be granted by the **Research Cell of CBMCB.**

9. Payment shall be made into a separate Current Account in a Scheduled Bank in the name of the Principal Investigator (PI). Principal Investigator (PI) of the project will operate the Bank Account.

10. Information on the progress of activities in respect of the Research protocol and financial statement shall be supplied to **Research Cell** through structured proforma on a quarterly basis.

11. After completion of the project the PI shall submit a final scientific report along with a statement of expenditure with photocopy of vouchers duly countersigned by the PI. Original vouchers shall be preserved in safe custody by the Principal Investigator for audit.

12. Results of the Research shall neither be published in any journal nor be presented in any seminar/symposium without prior written permission from the **Research Cell**.

13. The investigator whose contribution is maximum for the publication(s), while others shall be co-authors.

14. The author(s) should acknowledge the support of CBMCB in all publications emanating from the research program.

15. The budget of an approved PP may be modified by CBMCB on the basis of advice from relevant experts.

16. Fund will be released on the basis of a Contractual Agreement between the **PI and CBMCB.**

17. The approved research protocol should be implemented in accordance with regulations/rules/conditions/circulars of CBMCB and Donor Agency as and when it may be applicable.

18. **The Research Cell of CBMCB** reserves the right of accepting or rejecting any project proposal.

19. **In Case of any change in address the PI should immediately inform the new address to Research Cell, CBMCB.**