CHITTAGONG MEDICAL UNIVERSITY

BITID BUILDING, FOUZDERHAT, CHATTOGRAM, BANGLADESH

Tel: 0244075146, Fax: 0255165104

Email: registrar@cmu.edu.bd, **Web:** **www.cmu.edu.bd**

CHECK LIST FOR SUBMISSION OF PROJECT PROFORMA

01. **Cover Letter addressing to Vice-Chancellor 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. **Four (4) copies of Project Proposal including all mention documents and a soft copy in CD needs to be submitted along with A-4 size Data Bank File / Folder.**

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Project Proforma (PP)

Health, Population and Nutrition Sector Development Programme
[HPNSDP]
Research & Development

Proposals should be submitted in 4 (four) copies

PART - A

1. Project Title :

2. Principal Investigator(s) : (Detail curriculum vitae be annexed)

3. Co-investigator(s) : (A copy of the curriculum vitae and list of publications in respect of each collaborating investigator be annexed).

4. Place of the 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(s) :

13. Signature of Co -Investigator(s) :

14. Endorsement of the Institute Head :

Name and Signature :

Designation :

Official Seal :

PART - B

PRINCIPAL INVESTIGATOR(S) 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. MET HODOLOGY :

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).

5. UTILIZATION OF RESULTS :

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):

6.1. Facilities Available :

6.2. 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 CMU's Guidelines for Ethical Review of Projects involving Human Subjects).

10. REFERENCES: (Vancouvers style to be followed. Please consult Can Med Assoc J 1995; 152(9): 1459 -1465)

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

PART - E

BUDGET

I. Total Budget :

II. 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 * :

12. Miscellaneous (Not exceeding 2.5% of the total budget. Items & quantity to be specified):

PART-F

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Application for Ethical Clearance

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

- **Check documents being submitted herewith to committee:**

  - ❑ Umbrella proposal
  - ❑ Proposal Summary
  - ❑ Abstract for Ethical Review Committee as per attachment (Obligatory)
  - ❑ Informed consent form for subjects
  - ❑ Informed consent form for parent or 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 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.

Principal Investigator/ Leader/ Coordinator Other Investigators

PART-G

Write an Abstract For National Research Ethics Committee (NREC)

Guideline For Preparation of an Abstract for 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 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 risk s - 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 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 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 f or 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 beinclude the following points)**:**

Consent Form should be in both Bangali & English.

- Interviewer 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 it's preservation if any.
- 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.

PART-I

Write a Questionnaire or interview schedule (Both Bangali and English) of the Research Project .

Guidelines for Research Grants under Health, Population and Nutrition Sector Development Programme (HPNSDP)
Research & Development

1. Four (4) copies of Project Proforma (PP) to be submitted to Chittagong Medical University (CMU)

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 CMU 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 Scientific Review Committee of CMU.

7. Research Projects involving human subjects shall be reviewed by the Ethical Review Committee of CMU.

8. The duration of a research proposal may not generally exceed one year. However, in exceptional cases, extension may be granted by the Scientific Review Committee of CMU.

9. The total cost of a Project shall not normally exceed Tk. 2.00 (two) lakhs for a duration of one year.

10. 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.

11. Information on the progress of activities in respect of the Research Protocol and financial statement shall be supplied to CMU through structured proforma on a quarterly basis.

12. 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.

13. Results of the Research shall neither be published in any Journal nor be presented in any seminar/ symposium without prior written permission from the Council.

14. The investigator whose contribution is maximum for the conduction of the study shall be the PI and principal author for publication(s), while others shall be co -investigator(s) or co -authors.

15. The author(s) should acknowledge the support of CMU in all publications emanating from the research programme.

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

17. Fund will be released on the basis of a Contractual Agreement between the PI and CMU.

18. The approved research protocol should be implemented in accordance with regulations/ rules/ conditions/ circulars of Bangladesh Govt., CMU and Donor Agency as and when it may be applicable.

19. The Chittagong Medical University reserves the right of accepting or rejecting any Project Proposal.