

# Monno Medical College

Monno City, Gilondo, Manikganj, BANGLADESH

Tel: +880.....

Email: ....., Web adresse: [www.monnomch.edu.bd](http://www.monnomch.edu.bd)

## **CHECK LIST FOR SUBMISSION OF PROJECT PROFORMA**

**01. Project Proforma:** *must contain the Umbrella proposal, Proposal Summary, Informed consent form for subjects/parent/legal guardian, Procedure for maintaining confidentiality, Questionnaire or Data Collection Sheet from **Part-A to H***

**02.** Procedure for maintaining confidentiality.

**03.** Two (2) 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.

# Monno Medical College

Monno City, Gilondo, Manikganj, BANGLADESH

Tel: +880.....

Email: ....., Web adresse: [www.monnomch.edu.bd](http://www.monnomch.edu.bd)

## Project Proforma

### PART - A

1. Project Title:
2. Name & Designation of Principal Investigator(s): *Detail curriculum vitae be annexed*
3. Name & Designation of 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. Duration:
6. Date of Commencement:
7. Date of Completion:
8. Total Cost :
9. Date of Submission :
10. Signature of Principal Investigator(s) :
11. Signature of Co-Investigator(s) :
12. Endorsement of the Department Head :
  - Name and Signature :
  - Designation :
  - Official Seal :

# **PART - B**

## **PRINCIPAL INVESTIGATOR(S) INFORMATION SHEET**

1. Name, Designation, Official Address with telephone & Email
2. Academic Background:
3. Field of Specialty:
4. (a) Research Experience:  
(b) Other Experiences:
  - 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:** *WRITE THE SUMMARY OF THE PROPOSAL WITHIN 600 WORDS*

## **PART - D**

**1. INTRODUCTION:** *Write here the background of the disease with the citations mentioning the information based on the title of the study within 1500 words*

**2. OBJECTIVES:** *Write the general and specific objectives of the proposed study*

**3. RATIONALE:** *Write here the reason of performing the study in your own language without any citations/references within 600 words*

**4. METHODOLOGY:** *Write in Details mentioning*

- *Study Design*
- *Study Period*
- *Study Place*
- *Study Population*
- *Sample Size*
- *Sample Size Calculation*
- *Sampling Technique*
- *Important Variables*
- *Selection Criteria*
  - *Inclusion Criteria*
  - *Exclusion Criteria*
- *Operational Definition*
- *Study Procedure*
- *Data Collection procedure*
- *Quality Control of Data*
- *Statistical Analysis*
- *Ethical Consideration*
- *Time Frame/Gann's Chart*

**5. Available FACILITIES** *like Resources, equipment, chemicals, subjects (human, animal) etc. required to perform this study*

**6. APPROVAL OF THE HEAD OF THE DEPARTMENT**

**7. FLOW CHART:** *Describe sequence of tasks*

**8. REFERENCES:** *Write in Vancouvers style as mentioned in Google Scholar*

# **PART - E**

## **BUDGET**

### **I. Total Budget:**

### **II. Detailed Budget:**

1. Personnel Cost: *Not more than 20% of total budget*
2. Field Expenses/Laboratory Cost: *According to need, no limit of total budget*
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  
Miscellaneous (*Not exceeding 2.5% of the total budget. Items & quantity to be specified*)

**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
-----	----

## **PART-H (ANNEXURE)**

### **Write an Informed Consent Form**

**Guideline for Informed Consent Form** (Consent Form should be include 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.

# ANNEXURE I:

## INFORMED CONSENT FORM (Bangla) Adult Participants (Sample)

**Title of the study:**

**Research investigator:**

### অবহিতক্রমে সম্মতিপত্র

এই সম্মতিপত্রের উদ্দেশ্য হলো আপনাকে প্রয়োজনীয় তথ্য প্রদান করা, যে তথ্যগুলো আপনাকে সিদ্ধান্ত নিতে সাহায্য করবে, আপনি এই গবেষণায় অংশগ্রহণ করবেন কিনা?

**উদ্দেশ্য পদ্ধতি:** আপনি যদি এই গবেষণায় অংশগ্রহণ করতে সম্মত থাকেন তাহলে গবেষণায় নিয়োজিত ব্যক্তি সে সম্পর্কিত কিছু প্রশ্ন আপনাকে করবেন।

**গবেষণার ঝুঁকি:** এছাড়া এই গবেষণায় আপনাকে কিছু প্রশ্ন জিজ্ঞাসা করা হবে। কিছু কিছু প্রশ্ন আপনাকে বিব্রত করতে পারে অথবা আপনাকে মানসিক ভাবে দুর্বল করতে পারে। এই ক্ষেত্রে আপনার ভয় পাওয়ার কোন কারণ নাই। আমাদের গবেষণা দলে একজন মানসিক রোগ বিশেষজ্ঞ আছেন যিনি এই ধরনের সমস্যা সুন্দর ভাবে সমাধান করতে পারবেন। তদুপরি এই গবেষণা প্রধান গবেষক একজন রেজিস্ট্রার্ড চিকিৎসক।

**গবেষণায় অংশগ্রহণের সুবিধাদি:** এই গবেষণায় অংশগ্রহণে আপনি ব্যক্তিগত ভাবে লাভবান হবেন না, কিন্তু সমাজের একটি গুরুত্বপূর্ণ ইস্যুতে আপনার মতামত সামষ্টিকভাবে আপনাকে লাভবান করবে।

**বিকল্প:** এই গবেষণায় অংশগ্রহণ করা কিংবা না করা আপনার ব্যক্তিগত সিদ্ধান্ত বা অংশ গ্রহণ করার পর যে কোন সময় আপনি নিজেকে গবেষণা থেকে সরিয়ে নিতে পারেন।

**খরচ:** এই গবেষণায় অংশগ্রহণের জন্য আপনার কোন খরচ নাই বা আপনাকে কোন টাকা পয়সা দেয়া হবে না।

**গোপনীয়তা:** গবেষণা চলাকালীন ও পরবর্তীতে সকল তথ্য কঠোর ভাবে গোপন রাখা হবে। পরবর্তীতে ফলোআপ ও অনুসরণ প্রক্রিয়ার জন্য আপনাকে একটি আইডি নম্বর দেওয়া হবে। আপনার আইডি নম্বর সম্বলিত সবধরনের কাগজপত্র অফিসের ফাইলিং কেবিনেটে তালাবদ্ধ থাকবে এবং গবেষণার পরীক্ষক ব্যতীত কারো কাছে প্রকাশ করা হবে না। ফলে আপনার কোন তথ্য অন্য কেউ জানতে পারবে না।

**স্বৈচ্ছামূলক অংশগ্রহণ:** এই গবেষণায় আপনার অংশগ্রহণ সম্পূর্ণ স্বৈচ্ছামূলক। আপনি গবেষণায় অংশ গ্রহণে অস্বীকৃতি জানাতে পারেন অথবা গবেষণা চলাকালীন যে কোন সময় গবেষণা থেকে নিজেকে প্রত্যাহার করে নিতে পারেন। এই ফরমে স্বাক্ষর করলে আপনার আইনগত কোন অধিকার খর্ব হবে না।

**প্রশ্নাবলী:** যদি আপনার কোন প্রশ্ন থাকে তবে দয়া করে জিজ্ঞাসা করুন। আমরা তার উত্তর প্রদান করার যথাসাধ্য চেষ্টা করবো। যদি ভবিষ্যতে আপনার অতিরিক্ত কোন প্রশ্ন থাকে তাহলে গবেষণারত ব্যক্তির সাথে যোগাযোগ করতে পারেন।

**সম্মতির স্বীকারোক্তি:** আমি গবেষণায় নিয়োজিত গবেষক-এর সাথে এই গবেষণা নিয়ে আলোচনায় সন্তুষ্টি প্রকাশ করছি। আমি এটা বুঝেছি যে গবেষণায় অংশ গ্রহণ স্বৈচ্ছামূলক এবং আমি যে কোন সময় কোন বাধ্যবাধকতা ছাড়াই গবেষণা থেকে নিজেকে বিরত রাখতে পারি। আমি উপরোক্ত শর্তগুলো পড়ি/ আমার সম্মুখে পঠিত হয়েছে এবং স্বৈচ্ছায় গবেষণায় অংশগ্রহণ করতে সম্মতি জ্ঞাপন করছি।

সাক্ষাৎকার গ্রহণকারীর স্বাক্ষর:

অংশগ্রহণকারীর স্বাক্ষর:

স্বাক্ষীর স্বাক্ষর

তারিখ:

তারিখ:

তারিখ:

## **ANNEXURE II:**

### **INFORMED CONSENT FORM (English) Adult Participants (Sample)**

**Protocol Title:**

**Research investigator:**

**Name and address of the organization:**

**Part I: Information sheet**

Good morning/afternoon/assalamualaikum, I am Dr. .... In this research, I will talk with some adult patients and will ask them some question. You have been randomly selected for this study. Before going to the interview session, I would like to explain you the purpose of our study. After knowing the detail of the research you can agree or disagree to participate the research. You may take some more time to make your decision and feel free to consult with anyone regarding this issue. If you have any questions you can ask them to me or any other researchers of our team.

**Purpose:** The objectives are to evaluate the effectiveness of nosocomial infections (NIs) control educational module in improving nurses' knowledge and practice

**Time required:** Your participation in this study will be for 30 to 45 minutes.

**Risks and discomforts:** There is no social risk in this study. If any emotional problem will arise, our team members will be able to handle the issue. All questions will be related to (1) demographic data such as age, gender, previous in-service training course related to infection control measures, and previous working experience with patients having nosocomial infections, (2) a knowledge scale, with 30 items to elicit nurses' knowledge about nosocomial infections control measures and (3) practice scale. You must know that you will have the freedom not to respond these questions or you can refuse to take part in the interview. You should not give us any explanation for not responding to any questions, or refusing to take part in the interview.

**Benefits :** You will get direct benefit from this study. Furthermore, the patients, society as a whole may get benefit from the result of this study. The finding of this study may help to formulate policy to take preventive measure against nosocomial infections.

**Payment for participation:** No payment will be made for your involvement in this study.

**Confidentiality:** We will not share any information about you outside the research team. We will use a specific number instead of your name to hide your identity. All information collected from you will be kept under key and lock. Nobody other than researchers of this team will have any access to this information.

**Sharing of research findings:** At the end of the study, we will share our research findings with the participants and with the community. We will publish our research findings in order that other interested people may learn from our study.

**Participation and withdrawal:** Your participation in this study is fully voluntary and you are free to decide not to participate. Even after taking the decision to take part in this research you can withdraw yourself at any time without giving any explanation.

**Questions about the study:** If you have any question regarding the research, please feel free to ask me.

**Your rights as a Participant:** This research has been reviewed and approved by the IRB of BMRC. If you have any questions about how you are being treated by the study team or your rights as a participant, you may contact with us.

**Part II: Consent form for participation in research**

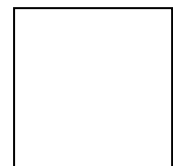
I.....being over the age of 18 years hereby consent to participating, as requested, in the interview for the research on ‘.....’

1. I have read/listen carefully the information provided by the researcher
2. I understand the research procedure and possible risk/discomfort related to the research
3. I agree to participate.
4. I am aware that I should retain a copy of the information sheet and Consent Form for future reference.
5. I understand that:
  - I will not get any financial benefit from taking part in this research or I will not receive any payment.
  - I am free to withdraw from the research at any time and will have the freedom not to respond to answer particular questions.
  - My identity will not be disclosed and no one can identify me. All of my information will remain confidential.

Participant’s name and

Signature.....Date.....

Thumb print for participant (in case of illiterate person)



I certify that I have explained the study to the participant and consider that s/he understands what is involved. I confirm that consent has been given by the participant freely and voluntarily.

**Researcher’s name**.....

**Researcher’s signature**..... **Date**.....

**Name of witness:**

**Signature of witness:**

## **ANNEXURE III:**

### ***Questionnaire/Data Collection Sheets/Case Record Form (CRF)***

*Write a Questionnaire (Both Bangli and English) of the Research Project*

- A. Particulars of the patients/Patient's or Participant's Profiles
- B. Socio-Demographic Characteristics
- C. Clinical profiles
- D. Diagnostic Tests
- E. Treatment/Management of Patients
- F. Outcome measures

## **ANNEXURE IV:**

**Procedure for Maintaining Confidentiality:** By following under-mentioned steps confidentiality will be maintained:

- Research data will be coded.
- Data will be stored in locked cabinets.
- Only research personnel will be allowed to access the data.
- The collected information will be used only for research purpose
- Social, financial and legal risk will be minimized during data collection.
- For safeguarding confidentiality and protecting anonymity each of the participants will be given a special identification no.
- An informed consent form will be developed which contains details about the aim and objectives of the study, procedure of the study, benefit and risk of participation and also the principal investigator's identity.
- A questionnaire will be prepared which requires a short interview about 30-45 minutes.
- An informed written consent will be taken.