Institutional Review Board (IRB)
National Institute of Neurosciences and Hospital
Sher-E-Bangla Nagar, Agargaon, Dhaka-1207, Bangladesh
Tel:+88-02-9137305; **Fax**:+88-02-9137292
Email: nins_hospital@yahoo.com; **Website:** www.nins.com.bd

Documents to Be Submitted for Ethical Approval

1. Application (Cover Letter) addressing to Chairperson of Institutional Review Board (IRB) of National Institute of Neurosciences & Hospital (NINS&H), Dhaka, Bangladesh for Ethical Clearance by Principal Investigator
2. Filled-up Ethical Clearance Application Form (Annexure - A)
3. Signature of Principal Investigator (s) & Co-investigator (s) with details address. (Annexure – B)
4. Abstract of Research Proposal for Institutional Review Board (IRB) of National Institute of Neurosciences & Hospital, Dhaka, Bangladesh (Annexure - C)
5. Complete the Research Protocol format for Submission of the Proposal for Ethical Approval from Institutional Review Board (IRB) of National Institute of Neurosciences & Hospital (NINS&H), Dhaka (Annexure - D)
6. Written Informed consent form (Both Bangla and English) from participant's or from the Parent / Legal Guardian (Annexure - E)
7. Questionnaire or Case Record Form (CRF) or interview schedule or Data Collection Form (Both Bangla and English) (Annexure - F)
8. Submit the Procedure for maintaining confidentiality (Annexure - G)
9. Proposed Budget according to the Format (Annexure - H)
10. Two (02) copies of all documents to be submitted for Ethical Approval to Institutional Review Board (IRB) of National Institute of Neurosciences & Hospital (NINS&H), Dhaka
11. A MS Word File format should be submitted in CD/DVD or send the File format to Email (ayusuf75@yahoo.com; irb@nins.gov.bd)
12. All Documents should be printed in an A-4 paper in 12 Font Size in Times New Roman font with 1 inch spacing and should be Submitted in a spiral binding with the above mentioned serial of documents addressing the Title of the research Proposal and the name & address of principal investigator
13. Review and Processing Fee (RPF) for ethical approval: 2000/- (two Thousand) BDT

COVER LETTER

To

The Chairperson
Institutional Review Board
National Institute of Neurosciences & Hospital
Sher-E-Bangla Nagar, Dhaka-1207

Subject: Application for Submission of Research Project Proposal for Ethical Clearance from Institutional Review Board

Sir,

With due respect and humble submission, I beg to state that I am Dr. …… working as ……..… in the Department of …… at ……... Here, I am submitting a research project proposal for Ethical Clearance from Institutional Review Board (IRB) of National Institute of Neurosciences & Hospital, Dhaka, Bangladesh which is entitled as "……..". The research project proposal has been prepared according to the instruction of IRB, NINS&H. This research proposal has been submitted for the purpose of thesis/dissertation/only data collection purposes.

Therefore, I will be very grateful to you if you kindly consider my research proposal for Ethical Clearance from Institutional Review Board of National Institute of Neurosciences & Hospital, Dhaka, Bangladesh and oblige me thereby.

Your Sincerely

Date: …….

ANNEXURE - A

Institutional Review Board (IRB)
National Institute of Neurosciences and Hospital
Sher-E-Bangla Nagar, Agargaon, Dhaka-1207, Bangladesh
Tel:+88-02-9137305; **Fax**:+88-02-9137292
Email: nins_hospital@yahoo.com; **Website:** www.nins.com.bd

Application for Ethical Clearance

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

Name:

Qualification:

Detail Address:

Mobile: Telephone (Off./Res)

Email:

2. **Co-Investigator(s):**

Name:

Qualification:

Detail Address:

Mobile: Telephone (Off./Res)

Email:

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:**

IRB of NINS&H

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 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

ANNEXURE - B

Signature of Principal Investigator (S) & Co-Investigator (S) with Details Address

We agree to obtain approval of the Ethical Review Committee of National Institute of Neurosciences & Hospital, Dhaka, Bangladesh 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 Supervisor/Co-investigator(S) **Signature:**

1.

2.

3.

4.

5.

**** Include all the Investigator, Co –Investigators.***

ANNEXURE - C

Preparation of an Abstract
For IRB of NINS&H

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 methodology and study 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 - D

Format for Submission of Research Proposal for Ethical Approval

1. **Project Title:**
2. **Protocol Summary:** Briefly described the protocol
3. **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.
4. **Rationale:** Describe the relevance of the proposed study to national health priorities and relationship of the objectives to existing scientific knowledge on the subject. Mention the relevant literature and refer to related studies done in our country or elsewhere.
5. **Research Question/Hypothesis:** If analytic Study, then hypothesis is needed; if descriptive study, research question is needed.
6. **Objectives of the Study:** List the general and specific objectives of the proposed study
7. **Methodology:** 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: Study design, Study Place, Study Period, Study Population, Sample Size, Sample Size Calculation, Sampling technique, Important variables, Selection Criteria (Inclusion & Exclusion Criteria), Operational Definition, Study Procedure, Data Collection, Ethical Clearance, Statistical Analysis, Time Frame.
8. **Utilization of Results:** Describe in brief how you perceive that the results from this study may contribute to health development of the Country.
9. **Facilities:** Resources, equipment, chemicals, subjects (human, animal) etc. required for the study
    - Facilities Available:
    - Additional Facilities Required:
10. **Approval/Forwarding of the Head of Department / Institute / IRB**
11. **Flow Chart:** Describe sequence of tasks
12. **References:** Vancouver style in Google Scholar should be followed.

ANNEXURE - E

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

INFORMED CONSENT FORM (Bangla)

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 দূর্বল 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।

স্বেচ্ছামূলক অংশগ্রহণ:

এই গবেষণায় আপনার অংশগ্রহণ সম্পূর্ণ স্বেচ্ছামূলক। 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 সাথেএই গবেষণা নিয়ে আলোচনায় সন্তুষ্টি প্রকাশ করছি । আমি এটা বুঝেছি যে গবেষণায় অংশ গ্রহণ স্বেচ্ছামূলক এবং আমি যে কোন সময় কোন বাধ্যবাধকতা ছাড়াই গবেষণা থেকে নিজেকে বিরত রাখতে পারি । আমি উপরোক্ত শর্তগুলো পড়িছে/ আমার সম্মুখে পঠিত হয়েছে এবং স্বেচ্ছায় গবেষণায় অংশগ্রহণ করতে সম্মতি জ্ঞাপন করছি ।

সাক্ষাৎকার গ্রহণকারীর স্বাক্ষর:	অংশগ্রহণকারীর স্বাক্ষর:	স্বাক্ষীর স্বাক্ষর
তারিখ:	তারিখ:	তারিখ:

ANNEXURE – E

Informed Consent Form (English) for adult participation in research (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:

<u>ANNEXURE</u> - F

Questionnaire/Case Record Form/
Data Collection Sheet

[*Write down the variables according to the objectives of the Study*]

ANNEXURE - G

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.

ANNEXURE – H

Proposed Budget

- 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 - H

Sample of Proposed Budget

Name of the Project/Protocol:						
Budget Period:						
Name of the Implementing PI:						
Particulars		**Month Rate (BDT)**	**# of Staff**	**% Time**	**# of Month**	**Total Cost**
Personnel:	Principal Investigator			0%	10	
	Co-Principal Investigator			10%	10	
	Study Nurse/ Data Collector			100%	6	
	Medical Technologist			100%	6	
	Study Physician			100%	5	
	Statistician			100%	2	
	Admin Officer/ project manager			100%	6	
	Support staff			100%	6	
	Total project personnel					
	Subtotal					
Travel and Perdiem		**Rate**		**No.**		
	Local Transport including hiring vehicle					
	Perdiem and Lodging					
	Subtotal					
Supplies:	Sample collect supplies					
	PPE for Sample collection					
	Sample test CS/					
Supplies - Lab Equipment						
	Office Supplies/stationaries					
	Laptop/ Computer					
	Paper					
	Printer					
	Key Lab equipment					
	Subtotal					
Others	Data Collector training					
	Workshop / Seminar at project hospital and Central level					
	Communication (Phone bill, Courier, postage etc.)					
	Study finding dissemination l					
	Printing and photocopy					
	Miscellaneous					
	Subtotal					
Total Project Direct Cost						
	Overhead/Admin cost @15%					
Total Budget:						