Institutional Review Board (IRB)

National Institute of Neurosciences and Hospital

Sher-E-Bangla Nagar, Agargaon, Dhaka-1207, Bangladesh

Email: irb@nins.gov.bd; **Website:** www.nins.gov.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 (As per Given Format)
2. Filled-up Ethical Clearance Application Form (Annexure - A)
3. Signature of Principal Investigator (s) & Co-investigator (s) with details address. (Annexure – B)
4. Summary for 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) Sets 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 and please maintain the above mentioned serial of documents addressing the Title of the research Proposal and the name & address of principal investigator
13. Each Research Protocol 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/Revised Research Project Proposal/Amendment of Research Project Proposal** for Ethical Clearance from Institutional Review Board of NINS&H, Dhaka

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/ Revised Research Project Proposal/ Amendment of Research Project Proposal** for Ethical Clearance from Institutional Review Board (IRB) of National Institute of Neurosciences & Hospital, Dhaka, Bangladesh which is entitled as "…….". This research project proposal has been prepared according to the instruction of IRB of NINS&H, Dhaka. 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 Project Proposal/ Revised Research Project Proposal/ Amendment of Research Project Proposal** for Ethical Clearance from Institutional Review Board of National Institute of Neurosciences & Hospital, Dhaka, Bangladesh and oblige me thereby.

Your Sincerely

Date: …….

Signature
Name:
Designation:
Department:
Institute/Hospital:

ANNEXURE - A

Institutional Review Board (IRB)

National Institute of Neurosciences and Hospital
Sher-E-Bangla Nagar, Agargaon, Dhaka-1207, Bangladesh
Email: irb@nins.gov.bd; **Website:** www.nins.gov.bd

Application for Ethical Clearance

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

Name:
Qualification:
Designation:
Department:
Working Station with Address:
Mobile:
Email:

2. **Supervisor/Guide/Co-Principal Investigator(s):**

Name:
Qualification:
Designation:
Department:
Working Station with Address:
Mobile:
Email:

Name:
Qualification:
Designation:
Department:
Working Station with Address:
Mobile:
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:

Supervisor/Guide/Co- Principal Investigator/Co-investigator(S)

NAME	SIGNATURE
1.	
2.	
3.	
4.	
5.	

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

ANNEXURE - C

Summary of Research Protocol

1. **Project Title:** *Write here the title of the study*
2. **Protocol Summary:** *Briefly described the protocol mentioning background, general objective and methodology in brief, this will be within 400 to 600 words*

ANNEXURE - D

Research Protocol Format

1. **Introduction:** *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 background. Briefly describe on the topics related information, write this section within 900 words*

2. **Rationale:** *Describe the justification of the study without any references in a single paragraph within 600 words in your own words explaining why this study is undertaken*

3. **Research Question/Hypothesis:** *If analytic Study, then hypothesis is needed; if descriptive study, research question is needed. Please mention only Alternate Hypothesis*

4. **Objectives of the Study:**

a. General Objective: *Write in a single sentence*

b. Specific Objectives: *Mention the all-specific objectives to achieve the general objective*

5. **Methodology:** This section should contain details of the research methods. Methodology should contain following sections:

a. Study Design
b. Study Place
c. Study Period
d. Study Population
e. Sample Size
f. Sample Size Calculation
g. Sampling Technique
h. Important Variables
i. Operational Definition
j. Selection Criteria
    - **a. Inclusion Criteria**
    - **b. Exclusion Criteria**

k. Study Procedure: *Write here in details of the research procedure including the socio-demographic characteristics, others variables related to the study, sample collection, clinical examinations, laboratory tests, follow up and outcomes measures according to the variables of intertest.*

l. **Data Collection:** Data will be collected using a semi-structured questionnaire (research instrument) containing all the variables of interest. Appropriate data will be collected by using a preformed data collection sheet. These data will be analyzed statistically by standard procedure to arrive at definitive conclusion in respect of the research question. *Customize these text according to your need of the study*

m. Quality Assurance (Q/A): The researcher will put predetermined Q/C checkpoints at the laboratory for Q/A. Documentation of instruments that will be used in each test and of all reagent lot numbers will be maintained. During the validation process, any variation from the defined standard procedures will be recorded. Monitoring of all variables will be part of the quality assurance (Q/A) and quality improvement programs. For the assurance of quality all data will be taken properly. Datasheets will be re-evaluated regularly by co-guide and guide. Every step of the study will be completed under the proper guidance of a guide and co-guide. After completion of data collection, it will be analyzed with SPSS software properly. *Customize these texts according to your need of the study*

n. Ethical Clearance: The researcher is duly concerned about the ethical issues related to the study. There is minimum physical, psychological, social and legal risk during taking history, physical examination and investigations. Proper safety measures will be taken in every step of the study. According to Helsinki Declaration for Medical Research involving Human Subjects 1964, all the patients will be informed about the study design, the underlying hypothesis and the right of the participants to withdraw themselves from the research at any time, for any reason. Only researcher will be allowed to access the collected data. In this study the following criteria will be followed to ensure maintaining the ethical values.

A. Formal ethical clearance will be taken from the ethical review committee and Institutional Review Board (IRB) of the NINS for conducting the study.
B. Ways of maintaining the Confidentiality of the person and the information will be maintained as well as observed and unauthorized persons do not have any access to the data.
C. Storage procedure and use of collected data will be explained to the patient guardians
D. Explain the Use of collected blood sample
E. Informed written consent will be taken from the subject.
F. Their voluntary consent will be taken by signature/thumb impression.
G. The content of the consent requirements will be as such/ The informed consent was taken from each participant after explaining the following:

1) Explanation of the nature & purpose of the study
2) Explanation of the procedure of data collection and the study.
3) Explanation that they have the right to refuse, accept & withdrawal from the research at any time.

H. The participants don't gain financial benefit from this study.
I. Chance of physical, psychological and social risk
J. Each participant of the present research will be informed about the purpose and the ethical aspects relevant to the research and an informed consent form that has been written in Bangla will be given/read to each individual.
K. After that data will be collected from all participants, 3 ml blood will be collected only from each patient.

Keep these texts related to the ethical consideration for your research proposal

o. Statistical Analysis: All the data will be checked and edited after collection. Then the data will be entered into computer statistical analysis of the results being obtained by using windows-based computer software device with SPSS - 22. Quantitative data will be expressed in mean (+-SD) and median (interquartile range). Qualitative data will be expressed as frequency and percentage. Quantitative data will be compared between groups by Student's t-test and qualitative data will be compared by Pearson's Chi-squared test. The results will be presented in tables and figures. Statistical significance will be set at $p<0.05$ and confidence interval at 95% level.

Customize these texts according to your need of the study

p. Time Frame/Gann's Chart

Tasks	Jan	Feb	Mar	Apr	May	June	Jul	Aug	Sep	Oct	Nov	Dec
Conceptualization												
Literature Review												
Identify Research Gap												
Protocol Preparation												
Data Collection												
Data Analysis												
Report/Thesis Writing												
Draft Submission												
Final Report Submission												
Thesis Defense												

6. **Utilization of Results:** Results will be disseminated in various ways. They will be presented and will be discussed locally at NINS&H and also at a different meeting. These results will also be written up for publication in a journal. The impact of this study will be providing the prospective data to guide management of this disease in Bangladesh. This study results will lead to improve the disease entity.

7. **Facilities:** Resources, equipment, chemicals, subjects (human, animal) etc. required for the study

- Facilities Available:
- Additional Facilities Required:

8. Approval/Forwarding of the Head of Department / Institute / IRB

Signature
Principal/Director/Institute Head

9. Flow Chart: *Describe sequence of tasks*

10. 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)
(For Adult Patient)
(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 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 Patient)

(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/purposively 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: *Write here the general objective of the study*

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 *demographic data, clinical data, investigational data and treatment data*. 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

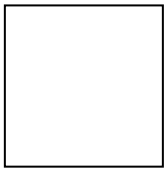
I….....being over the age of 18 years hereby consent to participating, as requested, in the interview for the research on ‘……...

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 - F

Questionnaire/Case Record Form/
Data Collection Sheet

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

Patients Details:

Socio-demographic Characteristics:

Clinical Profiles

Laboratory Tests

Management Profiles

Follow Up and Outcome Measures

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

Name of the Project/Protocol:
Budget Period:
Name of the Implementing PI:
Total Budget

- Detailed Budget:

1. Personnel Cost:

- Principal Investigator
- Co-Principal Investigator
- Study Nurse/ Data Collector
- Medical Technologist
- Study Physician
- Statistician
- Admin Officer/ project manager
- Support staff

Total project personnel

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: