GRAMEEN CALEDONIAN COLLEGE OF NURSING

House-06, Main Road, Diabari Dokhin, Turag, Dhaka-1230
Mobile No.: +8801749194796
Email: info@gccn.ac.bd; Website: www.gccn.ac.bd

1. Documents to be submitted for institutional review board (IRB) approval:
   a. Cover Letter to Chairman for Ethical Clearance by Principal Investigator (PI)/Student. (*Annexure - A*)
   b. Filled-up IRB Application Form. (*Annexure - B*)
   c. Abstract (Proposed study summary) for IRB (*Annexure - C*)
   d. Research Proposal (IRB of GCCN format) for Ethical Approval *(Annexure - D)*
   e. Informed consent form (Both Bangla and English) *(Annexure - E)*
   f. Questionnaire or interview schedule (Both Bangla and English). *(Annexure - F)*
   g. Budget *(Annexure - G)*
   h. Copy of approval from a valid scientific review committee (If any).
2. Five (5) copies of all documents are to be submitted to the IRB of GCCN.
3. All Documents of each copy should be submitted with a binding file.
4. IRB fees (BDT):

Review Type	**Internal Applicants (GCCN Investigator/ Students)**	**External Applicants**	
		National (Investigator/ Students)	**International (Investigator/ Students)**
Full Board Review	10,000/- (Regular) 15,000/- (Fast track)	20,000/- (Regular) 25,000/- (Fast track)	30,000/- (Regular) 35,000/- (Fast track)
Expedited Review	7000/-	15000/-	20,000/-
Exempt Review	4000/-	7000/-	10,000/-
Amendments / Continuing Reviews	3000/-	5000/-	7,000/-

5. Timeline for the IRB review:
   Feedback: 2-3 weeks of submission (regular); 1 week (fast track)
   Final approval: 30 days (regular); 15 days (fast track) upon receiving the revised proposal
6. Fees for Conducting study in GCCN:

Internal Applicants (GCCN Investigator/ Students)	**External Applicants**	
	National (Investigator/ Students)	**International (Investigator/ Students)**
BDT 2,500/- TK and per subject: BDT 50Tk/-	BDT 5,000/- TK and per subject: BDT 70 Tk/-	BDT 10,000/- TK and per subject: BDT 100 Tk/-

7. For details please contact:
   - **GCCN Office**
     Phone- +8801749194796
     Email- info@gccn.ac.bd
   - **Ms. Sajia Afrin**
     Sr. Administrative Officer
     Phone- +8801717529406
     Email: gccn.sajia@gmail.com

IRB APPLICATION

Title Name

Submitted By:

Principal Investigator (PI)

……..

……..

Student

Name of Student: .....

ID. No. .....

Session: …….

Batch: …….

Course: …….

Name of Institute/College: ……

Date of Submission:

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Application for Ethical Clearance

Date:
To,
Chairperson
Institutional Review Board (IRB)
Grameen Caledonian College of Nursing
House-06, Main Road, Diabari Dokhin, Turag, Dhaka-1230

Subject: Application for the approval of Institutional Review Board (IRB).

Respected Sir/Madam,
I am writing to formally request ethical approval for my research proposal titled **"----------**
----------"

1. **Researcher Information: (Principal Investigator/Student)**
   - Principal Investigator (PI)/Name of Student:

   - Student ID. No.----------, Session: ----------, Batch: ----------,
     Course: ----------, Major:----------,
     Name of Institute/College:----------
   - Contact information: Email: ----------, Mobile No.: ----------
2. **Expected Date of Examination: …….**
3. **Guide/Supervisor/Advisor: ……..**
4. **Co-Supervisor/Advisor: …….**
5. **Project Overview:**
   a. **Title:** ……..
   b. **Objective:** ……
   c. **Methodology (Specially, research approach, study design, sample, type of questionnaire):** …….
   d. **Place of Study:** ……
6. **Ethical Considerations:**
   a. **Informed Consent Procedure:** ……
   b. **Confidentiality:** …….
   c. **Risk Assessment and Protection:** …….

d. **Benefit to Participants and Society:** ……

7. **Data Handling and Storage: …….**
   a. **Data Collection:** ……..
   b. **Data Storage:** ……
   c. **Data Disposal:** ……...
8. **Timeline:**
   a. **Start Date:** …….
   b. **End Date:** …….
9. **Budget:**
   a. **Funding Source:** …….
   b. **Budget Overview:** …….
10. **Funding Agency (If applicable):** ……
11. **Findings:** ……
12. **Approval Request:**
    a. I affirm my commitment to adhere to ethical guidelines and seek approval to commence this research.
    b. I am open to any recommendations or modifications suggested by the IRB to ensure ethical standards are met.

So, I therefore pray and hope that you would be kind enough to approve the ethics for this study and oblige thereby. I also appreciate your time and consideration. Please feel free to contact me if further information is needed.

Thank you for your attention to this matter.

Sincerely,

Principal Investigator (PI): Signature: Name: ……. ……. …… **Student:** Name of Student: ……. ID. No. ..... Session: …… Batch: …… Course: ……. Name of Institute/College: ……	**Name of Supervisor/Guide:** **Name of Co-Investigator/Guide with signature:** 1. …… 2. …… 3. ……..

SELF-CHECKLIST

Put tick sign (✓) appropriate answers against each of the following statement

(If not applicable, please write NA)

1. Source of Population:

(a) Patients ☐ Yes ☐ No

(b) Healthy Subjects ☐ Yes ☐ No

(c) Minors or person 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 ☐ 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 foetal tissues 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 alternative used ☐ Yes ☐ No

(c) Physical risks ☐ Yes ☐ No

(d) Private questions ☐ Yes ☐ No

(e) Mental risks ☐ 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) Compensations: (where there are risks or loss of working time or privacy is involved in any particular procedure) ☐ Yes ☐ No

5. Signed consent form will be obtained:

(a) From Subjects(If adult) ☐ Yes ☐ No

(b) From parent or guardian (if subjects are minor) ☐ Yes ☐ No

6. Will precautions be taken to protect anonymity of subjects? ☐ Yes ☐ No

Name of Principal Investigator (PI)/ Student with signature: ……..	**Name of Co-Investigator/Guide with signature:** 1. …….. 2. …… 3. ……

Annexure - C: Study Summary (Abstract)

Title:

Name of Principal investigator/Student: ……

Name of Co-investigator/Supervisor: ……

Background:……

……Aim:……

……Methods:……

……Conclusion:…….

P**otential benefits from findings:** ……...

Additional information briefly (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. In case 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*

Note: 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.

Annexure – D: Format for Submission of a Research Proposal

Title Page: *Includes the title of the research proposal, the researcher's name, institutional affiliation, department, and submission date.* (***Research Title will be according to the specialty of MSN course, and 12 to 15 words as APA style*)

CHAPTER – 01: INTRODUCTION

Introduction: *Provides an introduction to the research topic, including background information, rationale for the study, significance of the research, and an overview of the proposed research questions or hypotheses.*

1.1. Introduction

1.2. Background: *Contextualize the issue with relevant data or references.*

1.3. Problem Statement: *Clearly describe the issue to be addressed.*

1.4. Justification of the Study/Significance of the Study: (*Discusses the potential significance and contributions of the proposed research to the field of study, academic knowledge, policy, or practice. It explains why the research is important and how it fills gaps or addresses key questions in the literature***.)** *Explain why this study is important (practical, academic, or policy relevance.*

1.5. Research Question/Hypothesis: *List the specific research questions or hypotheses (quantitative).*

1.6. Objectives of the Study – General Objective and Specific Objectives *(Clearly state the research objectives or hypotheses that the study aims to investigate. Objectives should be specific, measurable, achievable, relevant, and time-bound (SMART).)*

1.7. Operational Definition

1.8. Variables

1.9. Assumption (optional**)**

1.10. Delimitation (optional**) (***The characteristics that limit the scope (define the boundaries of the inquiry***)**

1.11. Conceptual Framework: *A conceptual framework is a group of concepts and a set of propositions that spell out the relationship between them. The conceptual framework plays several interrelated roles in the progress of science.*

CHAPTER – 02: LITERATURE REVIEW

Literature Review*:* *Summarizes and synthesizes existing research and scholarly literature (from broader to narrower) relevant to the research topic. It identifies gaps or controversies in the literature that the proposed study aims to address and provides theoretical or conceptual frameworks guiding the research. APA style will be followed for citation in text.*

CHAPTER- 03: RESEARCH METHODOLOGY

Research Methodology: *Describes the research design, methods, and procedures that will be used to conduct the study. This section includes details on the research approach (qualitative, quantitative, or mixed methods), data collection methods (e.g., surveys, interviews, experiments), sampling strategy, data analysis techniques, and any ethical considerations.*

3.1. Research Approach

3.2. Study Design

3.3. Study Setting *(Describe the study area, e.g., location, number of population)*

3.4. Study Period

3.5.Study Population *(Those who are the population in the study)*

3.6.Sample Size *(Sample size will be estimated by calculation (Formula) or software, e.g., G power)*

3.7. Sampling Technique

3.8. Criteria for Sample Collection (Inclusion Criteria and Exclusion Criteria)

3.9. Data Collection Tools *(It includes describing tools or instruments used in the study, and the instrument scoring or measuring system) N.B. Tools in English and Bangla must be needed for IRB*

3.10. Validity and Reliability/ Trustworthiness (For Qualitative): *Content Validity of instruments by 3 or 5 experts. Cronbach's alpha, or other tested the reliability of the instruments.*

3.11. Translation Process (If language translation in the tool is needed for the study), *e.g., Back translation method*

3.12. Data Collection Procedure/Methods *(Describe the procedure)*

3.13. Data Processing

3.14. Data Analysis *(Describe statistical or thematic analysis (For Qualitative))*

3.15. Data Presentation

3.16. Ethical Consideration: *Approval, consent, confidentiality, risk, benefit*

3.17. Pilot Study / Pre-Test: *A pilot study tests the entire research process, while a pre-test focuses on a specific research instrument. A pilot study helps determine if the research is feasible and worthwhile, while a pre-test ensures the instrument is reliable and valid.*

4. Expected Outcome (Optional)

REFERENCES

References: *APA style will be followed for citation in text and references. Lists all sources cited in the research proposal using a consistent citation style (e.g., APA style). This section ensures proper attribution of sources and allows readers to access the referenced literature for further reading.*

APPENDICES

Appendices: *Optional section where supplementary material such as research instruments (e.g., survey questionnaires, interview guides), consent forms, or additional documentation are included. Appendices provide additional detail or support for the proposal but are not included in the main body of the document.*

- **Appendix-1: Informed Consent**
- **Appendix-2: Questionnaire**
- **List of Experts for Content Validity** *(At least 3 experts (one Internal and two external)*
- **Appendix-3: Proposed Budget** *(If applicable, outlines the anticipated budget required to conduct the research, including costs for materials, equipment, participant compensation, travel, and any other expenses. It demonstrates financial planning and resource allocation for the project.)*
- **Appendix-4: Gantt Chart/Timeline** *(Provides a proposed timeline or schedule for completing the various stages of the research project, including data collection, analysis, and writing up the results. It helps demonstrate feasibility and realistic expectations for the project's timeline.)*

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 given to participant.

Annexure-F: Questionnaire or interview schedule (Both Bangla and English)

1. Total Budget:
2. Detailed Budget:
   a. Personnel Cost: (Professional Scientific Staff, Technical & Other Staff. Please mention percentage of time to be devoted by each personnel to this Project).
   b. Field Expenses/Laboratory Cost:
   c. Supplies and Materials (Items & quantity to be specified):
   d. Patient Cost (If applicable):
   e. Travel Cost (Internal travel cost only):
   f. Transportation of Goods:
   g. Office Stationery (Items & quantity to be specified):
   h. Data Processing/Computer Charges (If applicable) :
   i. Printing and Reproduction:
   j. Contractual Services (Other than manpower):
   k. Miscellaneous:

OFFICE USE ONLY

Date received		Date PI\Student notified
Date checked and accepted		Date of change notification
Date(s) of committee review		

Is the consent requirement waived?	----YES	----NO	----N/A
Is documentation of the consent process waived?	----YES	----NO	----N/A
Is demographic information collected with cultural sensitivity?	----YES	----NO	----N/A

Is the research proposal exempt from Full Board Review?	Yes ---------- No - - - - - - - - Revisions required:	Remarks
Detail any revisions or additional information required		
Name of reviewer(s):		Date: