বঙ্গবন্ধু শেখ মুজিব মেডিক্যাল বিশ্ববিদ্যালয় **Bangabandhu Sheikh Mujib Medical University** kvnevM, XvKv-1000|	**IRB APPLICATION FORM**

RESEARCH PROTOCOL **Number: Version No.** **Version date:**	**FOR OFFICE USE ONLY**			
	IRB Meeting:	☐ Yes	☐ No	Date: 23-Dec-2024
	IRB Approval:	☐ Yes	☐ No	Date:
		☐ Yes	☐ No	Date:
		☐ Yes	☐ No	Date:

Institutional Review Board (I.R.B) Application Form

01.	Title of the study	:
02.	Name of the student	:
03.	Address of the student	:
04.	Contact number	:
05.	Email	:
06.	Name of Institute	:
07.	Is this research in fulfillment of a degree?	☐ Yes ☐No
08.	Degree Registered for	:
09.	Guide's Name	:
10.	Guide's Email address	:
11.	Guide's Institute	:
12.	Co-Investigators	:
13.	Place of Study	:
14.	Type of study	: (Check all that Apply)

☐ Case Control study	☐ Longitudinal study
☐ Randomized Controlled trial	☐ Observation Clinical Study
☐ Clinical Trial (Phase I, II, III, IV)	☐ Meta-Analysis and systemic Reviews
☐ Community Based Trial	☐ Secondary Data Analysis
☐ Cross Sectional	☐ Surveillance /Monitoring
☐ Cohort Study (Prospective and retrospective)	☐ Mixed methods research combining qualitative and quantitative
☐ Health Programmed Evaluation/ Quality Improvement	☐ Outbreak investigation
	☐ Risk factor analysis
☐ Systemic Review	☐ Retrospective Chart Reviews
☐ Pilot/Feasibility Study	☐ Use of existing Databases
☐ Registry-Based Studies	☐ Medical wearables and Sensors Study
☐ Curriculum Evaluation Study	☐ Investigational Device Exemption (IDE) Study
☐ Teaching Methodologies Study	☐ Others……..

	☐ Interventional studies (non-clinical trials): behavior, educational, psychological, lifestyle modifications	

15.	Duration of study	:
16.	Proposed start date of the project	:
17.	Proposed end date of the project	:
18.	Total cost	:
19.	Funding Agency (lf Applicable)	:

14.	**Study Population: Sex, Age, Special Group and Ethnicity**	
	Research Subject: ☐ Human ☐ Animal ☐ Microorganism ☐ Other (specify): _____ **Sex** ☐ Male ☐ Female ☐ Transgender **Age:** ☐ 0 – 4 Years ☐ 5 – 10 Years ☐ 11 – 17 Years ☐ 18 – 64 Years ☐ 65+	**Special Group:** ☐ Pregnant Women ☐ Fetuses ☐ Prisoners ☐ Destitute ☐ Service Provides ☐ Cognitively Impaired ☐ Expatriates ☐ Immigrants ☐ Refugee ☐ Other (specify): _____ **Ethnicity:** ☐ No ethnic selection (Bangladeshi) ☐ ☐ Other (specify): _____
15.	**Consent Process: (Check all that apply)** ☐ Written ☐ Oral ☐ Audio ☐ Video ☐ None	**Language:** ☐ Bangla ☐ English ☐ Other (specify): _____
	a) Will study tools/questionnaire be used for this protocol?	☐ Yes ☐ No ☐ NA (If yes, tools/ questionnaire must be attached)
16.	**Proposed Sample Size:** Sub-group (Name of subgroup e.g. Men, Women) and Number	
17	**Study Site:**	
18.	**Collaborating Department/Institute (s):** Please provide full official address **Institution/ Department # 1**	

Name	
Contact person	
Department	
Institution	
Directorate (in case of GoB i.e. DGHS)	
Ministry	

	Other:			
	Collaborating Institute (s): Please provide full official address **Institution/ Department # 2**			
	Name			
	Contact person			
	Department			
	Institution			
	Directorate (in case of GoB i.e. DGHS)			
	Ministry			
19.	**Determination of Risk: Does the Research Involve** (Check all that apply)			
	☐ Human exposure to radioactive agents? ☐ Fetal tissue or abortus? ☐ Investigational new device? Specify: _____ ☐ Existing data available from Department?	☐ Human exposure to infectious agents? ☐ Investigational new drugs? ☐ Existing data available via public archives/ sources? ☐ Pathological or diagnostic clinical specimen only? ☐ Observation of public behavior? ☐ New treatment regime?		
19.	Will the data be recorded in a way that allows study participants to be identified either directly or through information linked to them?		☐ Yes	☐ No
	Does the research address sensitive topics relate to the study participants' sexual behavior, alcohol consumption, or illegal activities such as drug use?		☐ Yes	☐ No
20.	Does the study involve any biohazards materials/agents' microorganisms of risk group 2, 3, or 4?		☐ Yes	☐ No
	Biological Specimen use		☐ Yes	☐ No
	Will the biological specimen be stored for future use?		☐ Yes	☐ No
	If the response is 'yes', how long the specimens will be preserved?			
	Will the specimens be shipped to other country/ countries? If yes, name of institution(s) and country/countries.		☐ Yes	☐ No
	Who will be the custodian of the specimen at BSMMU?			
	Who will be the custodian of the specimen when shipped outside Bangladesh?			
	Who will be the owner(s) of the specimens?			
	Will the consent be obtained from the study participants for use of the preserved specimen for other initiative(s) unrelated to this study, without their re-consent?		☐ Yes	☐ No
	Has a MoU been signed with regards to collection, storage, use and ownership of specimen?		☐ Yes	☐ No
21.	**Do you consider this research?** (Check one and give justification)			
	☐ Greater than minimal risk	☐ No more than minimal risk	☐ Only part of the diagnostic test	
23.	**Funding:**	☐ Yes	☐ No	

	Is the protocol fully funded?		
	If the answer is yes, please provide sponsor's name		
	Is the protocol partially funded?	☐ Yes	☐ No
	If the answer is yes, please provide sponsor's name	1.	
		2.	
	If fund has not been identified:		
	Is the proposal being submitted for funding?	☐ Yes	☐ No
	If yes, name of the funding agency		
24.	**Conflict of interest:** Do any of the participating investigators and/or member(s) of their immediate families have an equity relationship (e.g. stockholder) with the sponsor of the project or manufacturer and/or owner of the test product or device to be studied or serve as a consultant to any of the above?		
	☐ No	☐ Yes ((please submit a written statement of disclosure to the BSMMU)	

I hereby certify that the information provided is true, complete, and accurate to the best of my knowledge. I understand that any false, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties. I accept responsibility for the scientific integrity of the project and commit to submitting the necessary progress reports, including updating protocol details, if this application results in a grant award.

We agree to obtain approval of the Institutional Review Board of BSMMU for any changes involving the rights and welfare of subjects or any changes of the Methodology before making any such changes.

…….
Student/Researcher

Comments of Reviewer 1	Comments of Reviewer 2
☐ Can be accepted	☐ Can be accepted
☐ Can be accepted with minor corrections	☐ Can be accepted with minor corrections
☐ Can be accepted with major corrections	☐ Can be accepted with major corrections
☐ Reject and rewrite the Protocol	☐ Reject and rewrite the Protocol
Name and signature	Name and signature
Date:	Date:
Seal	Seal

Put Tick sign (√) against appropriate answers to each of the following statement

(If not Applicable, please write N/A)

Protocol Number:								Version No.; Version date:
Principal Investigator								

Protocol Title:

01.	Study population:		Yes	No		(e)	Benefits to be derived	☐	☐	☐
	(a)	Ill participants	☐	☐		(f)	Right to refuse to participate or to withdraw from the study	☐	☐	☐
	(b)	Non-ill participants	☐	☐						
	(c)	Minor or persons under guardianship	☐	☐		(g)	Confidential handling of data	☐	☐	☐
	(d)	Others: Pregnant mother	☐	☐		(h)	Provision for compensation	☐	☐	☐
02.	Does the study involve:		Yes	No	05.	Precautions to be taken to protect anonymity of study participants		Yes	No	NA
	(a)	Physical risk to participants	☐	☐				☐	☐	☐
	(b)	Social risk to participants	☐	☐						
	(c)	Psychological risks to participants	☐	☐	06.	The following have been included		Yes	No	NA
	(d)	Discomfort to participants	☐	☐		(a)	IRB Project Summary	☐	☐	☐
	(e)	Invasion of participants' privacy	☐	☐		(b	Consent form for adult participan	☐	☐	☐
	(f)	Disclosure of information damaging to participants or others	☐	☐		(c)	Consent form from parent or guardian	☐	☐	☐
						(d)	Assent form	☐	☐	☐
03.	Does the study involve use of		Yes	No		(e)	Consent form of previous studies	☐	☐	☐
	(a)	Body fluids or organs	☐	☐		(f)	MOU	☐	☐	☐
	(c)	Records (hospital, medical, death or other)	☐	☐		(h)	Questionnaire/Research instrume	☐	☐	☐
	(d)	Stored biological specimens	☐	☐						
	(e)	Data from Previous study	☐	☐						
04.	Informed written consent/assent be obtained from:		Yes	No	NA					
	(a)	Adult participants	☐	☐	☐					
	(b)	Parent or guardian or next to kin (if participants are <11 years of age/or under guardianship)	☐	☐	☐					
	(c)	Participants aged 11-17 years (Assent)	☐	☐	☐					

I declare that:

- I undertake to abide by the ethical principles underlying the Declaration of Helsinki (1964, as amended) and good practice guidelines on the proper conduct of research.
- I agree to conduct my project on the basis set out in this form, and to consult my Guide if making any subsequent changes – especially any that would affect the information given with respect to ethics approval.
- I undertake to adhere to all conditions set out by review bodies in giving approval and will not start the project until all required approvals are in place

- I agree to comply with the relevant safety requirements
- I confirm that there are no conflicts of interest that preclude my participation in the project

---
Student

I declare that:

- I agree that the information submitted in this application is a reasonable summary of the proposed project.
- I agree that this form correctly indicates whether or not ethics approval will be required.
- I confirm that there are no conflicts of interest that preclude my role as supervisor for this project.

Guide/Supervisor

INSTRUCTIONS FOR PREPARATION OF AN PROTOCOL FOR THE INSTITUTIONAL REVIEW BOARD (IRB), BSMMU

Check documents being submitted here with to Board (Total eight copies should be submitted):

- **IRB Application form**
- **List of abbreviation**
- **Abstract**
    1. Background information (in brief)- Burden, Knowledge gap, relevance and rationale
    2. Hypothesis to be tested/ Research Question
    3. Objectives
    4. Study design and methodology
    5. Outcome variables/ Outcome measurement
- **Description of the Research project**

1. Background of the project [Give an outline of the proposed project, including background to the proposal. Sufficient detail must be given to allow the Committee to make an informed decision without reference to other documents.]

2. Rationale of the study [State the intended value of the project, detailing why the topic is of interest or relevance.]

3. Study design and methodology

[Specify the procedures/methodology to be conducted during the project. For literature reviews, include details on search strategy, search terms, inclusion and exclusion criteria. Specify numbers, with scientific justification for sample size, age, gender, source and method of recruiting participants for the research project.]

a) Study duration
b) Study site/s
c) Study population
d) Selection Criteria
e) Sample size calculation [State the assumptions clearly, including those related to the study population and data reliability. Specify the desired power (e.g., 80%) and precision level (e.g., 0.05 significance level). Describe the optimal conditions necessary to achieve the required sample size, such as accessibility to a large population, low dropout rates, and efficient sampling strategies.]
f) Patient enrollment and data collection
g) Study procedure
h) Sample collection procedure
i) Method details (lab procedure/ other methods applied- in details)
j) Follow up of the enrolled patients (if any planned)
k) Operational definition
l) Data safety monitoring Plan (DSMP) if required
m) Study flow chart

4. Data Analysis [Outline the data analysis plans, including a detailed strategy for stratifying results by sex, gender, and diversity factors such as ethnicity and socioeconomic status. Specify whether the investigators will perform the analysis or if it will be outsourced to other professionals. Clearly state the statistical software packages to be used (e.g., SPSS, R, or STATA). If the study is blinded, explain when the blinding code will be opened. For clinical trials, mention whether interim data analysis will be conducted to guide decisions on the study's future course. Ensure all procedures align with the study objectives and ethical standards.]

5. Data storage and record keeping [State how your data will be stored and what will be done with it at the end of the project.]

6. Ethical Assurance for Protection of Human rights [Describe the procedures to ensure privacy of the participants]

7. Patient / participant confidentiality [Include a description of the methods for safeguarding confidentiality of data and protecting anonymity of the participant. Specify how confidentiality will be maintained with respect to the data collected. When small numbers are involved, indicate how possible identification of individuals will be avoided. Where data will be anonymized, specify how this will be done.]

8. Use of animal (if applicable) [Describe if and the type and species of animals to be used in the study. Justify with reasons the use of particular animal species in the research and the compliance of the animal ethical guidelines for conducting the proposed procedures.]

9. Potential risk of the project [State the potential discomfort, distress or hazards that research participants may be exposed to (these may be physical, biological and/or psychological). What precautions are being taken to control and modify these? Include information on hazardous substances that will be used or produced, and the steps being taken to reduce risks.]

10. Collaborative arrangement [Describe if this study involves any scientific, administrative, fiscal, or programmatic arrangements with other national or international organizations or individuals. Indicate the nature and extent of collaboration and include a letter of agreement between the applicant or his/her organization and the collaborating organization.]

11. Literature cited [Identify all cited references to published literature in the text by number in parentheses. List all cited references sequentially as they appear in the text. For unpublished references, provide complete information in the text and do not include them in the list of Literature Cited. There is no page limit for this section, however, exercise judgment in assessing the "standard" length]

12. Detailed budget and budget justification. [Please provide one-page statement justifying the budgeted amount for each major item, including the use of human resources, major equipment, and laboratory services]

Appendix 1: Information sheet for participation (English and Bangla)
Appendix 2: Consent for participants/ assents
Appendix 3: Questionnaire (English)/ Case record form
Appendix 4: Questionnaire (Bangla)
Appendix 5: SOP /Laboratory manuals

Proposed Bugdet format

Total Budget	
Study title	
Student/ Resident Name	
Supervisor's Name	
Start Date	
Duration	

	12-month project			
Costs	**Unit Cost**	**Unit (of cost)**	**Quantity**	**Total**
Equipment				
Subtotal				
Consumables/ Laboratory test related cost				
		per sample		
		per sample		
		per sample		
Subtotal				
Travel and subsistence				
		per site		
		per night		
		per visit to Bangkok		
Subtotal				
Training and meetings				
		per staff member		
		per participants		
Subtotal				
Miscellaneous				
Photocopy and printing				
Subtotal				
TOTAL COSTS				
Overhead cost (10% of total direct cost)				
TOTAL COSTS (including direct and indirect cost)				