বঙ্গবন্ধু শেখ মুজিব মেডিক্যাল বিশ্ববিদ্যালয় **Bangabandhu Sheikh Mujib Medical University** শাহবাগ, ঢাকা-১০০০।	**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 Researcher/ Principal Investigator	:	
05.	Name of Institute	:	
08.	Co-Investigators	:	
09.	Place of Study	:	
10.	Type of study	: (Check all that Apply)	
	☐ Case Control study		☐ Programme (Umbrella Project)
	☐ Clinical Trial (Hospital/Clinic/Field) *		☐ Prophylactic Trial
	☐ Community-based Trial/Intervention		☐ Record Review
	☐ Cross Sectional		☐ Secondary Data Analysis
	☐ Longitudinal Study		☐ Surveillance/Monitoring
	☐ Meta-analysis		☐ Systemic Review
	☐ Health Programme Evaluation/ Quality improvement		☐ Curriculum Evaluation Study
	☐ Randomized Controlled trial		☐ Pilot/Feasibility Study
	☐ Cohort Study (Prospective and retrospective)		☐ Registry-Based Studies
	☐ Surveillance /Monitoring		☐ Outbreak Investigation
	☐ Risk factor analysis		☐ Retrospective Chart Reviews
	☐ Use of existing Databases		☐ Medical wearables and Sensors Study
	☐ Investigational Device Exemption (IDE) Study		☐ Mixed methods research combining qualitative and quantitative
	☐ Other (Specify):……		
11.	Duration of study	:	
12.	**Study Population: Sex, Age, Special Group and Ethnicity**		
	Research Subject: ☐ Human ☐ Animal		**Special Group:** ☐ Pregnant Women ☐ Fetuses

	☐ Microorganism ☐ Other (specify): _____ **Sex** ☐ Male ☐ Female ☐ Transgender **Age:** ☐ 0 – 4 Years ☐ 5 – 10 Years ☐ 11 – 17 Years ☐ 18 – 64 Years ☐ 65+	☐ Prisoners ☐ Destitute ☐ Service Provides ☐ Cognitively Impaired ☐ Expatriates ☐ Immigrants ☐ Refugee ☐ Other (specify): _____ **Ethnicity:** ☐ No ethnic selection (Bangladeshi) ☐ ☐ Other (specify): _____
13.	**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)
	b) Will there be any legally authorized representative (LAR)?	☐ Yes ☐ No ☐ NA
	c) Will there be an impartial witness (If the participant is illiterate)?	☐ Yes ☐ No ☐ NA
	d) In order to participate in research with children, is assent being taken?	☐ Yes ☐ No ☐ NA
	e) For research involving pregnant woman, consideration of risks with potential benefit for the fetus and pregnant women has been properly addressed?	☐ Yes ☐ No ☐ NA
16.	**Proposed Sample Size:** Sub-group (Name of subgroup e.g. Men, Women) and Number	
17	**Study Site:**	
18.	**Collaborating 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 related 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)			
	☐ Greater than minimal risk	☐ No more than minimal risk	☐ Only part of the diagnostic test	
	Explain	Explain	Explain	

22. **Contribution by the Members of the Team:**

Members' Name	Contribution								
	Research Idea/ concept	Study Design	Protocol writing	Respond to Reviewers and documents	Defending at IRB	Developing Data collection Tool(s)	Data collection	Data analysis and interpretation	Manuscript writing
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐

23.	**Dissemination type**	**Response**		**Description (if the response is a yes)**
		No	**Yes**	
	Please provide a detailed description of the dissemination plans, including how the research findings will be shared with stakeholders, specifying them if known, and the methods to be used. Indicate the anticipated type of publication, such as working papers, internal (institutional) publications, international journals, or presentations at international conferences, seminars, workshops, or agencies.			
	Seminar	☐	☐	
	Internal publication	☐	☐	
	Working paper	☐	☐	
	Sharing with GoB (e.g. DGHS/ Ministry, others)	☐	☐	
	Sharing with national NGOs	☐	☐	
	Presentation at international workshop/conference	☐	☐	
	Peer-reviewed publication	☐	☐	
	Sharing with international agencies	☐	☐	
	Policy brief	☐	☐	

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.

Principle Investigator

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
	(a)	Ill participants	☐	☐
	(b)	Non-ill participants	☐	☐
	(c)	Minor or persons under guardianship	☐	☐
	(d)	Others: Pregnant mother	☐	☐

02.	Does the study involve:		Yes	No
	(a)	Physical risk to participants	☐	☐
	(b)	Social risk to participants	☐	☐
	(c)	Psychological risks to participants	☐	☐
	(d)	Discomfort to participants	☐	☐
	(e)	Invasion of participants' privacy	☐	☐
	(f)	Disclosure of information damaging to participants or others	☐	☐

03.	Does the study involve use of		Yes	No
	(a)	Body fluids or organs	☐	☐
	(c)	Records (hospital, medical, death or other)	☐	☐
	(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)	☐	☐	☐

	(e)	Benefits to be derived	☐	☐	☐
	(f)	Right to refuse to participate or to withdraw from the study	☐	☐	☐
	(g)	Confidential handling of data	☐	☐	☐
	(h)	Provision for compensation	☐	☐	☐

05.	Precautions to be taken to protect anonymity of study participants	Yes	No	NA
		☐	☐	☐

06.	The following have been included		Yes	No	NA
	(a)	IRB Project Summary	☐	☐	☐
	(b	Consent form for adult participan	☐	☐	☐
	(c)	Consent form from parent or guardian	☐	☐	☐
	(d)	Assent form	☐	☐	☐
	(e)	Consent form of previous studies	☐	☐	☐
	(f)	MOU	☐	☐	☐
	(h)	Questionnaire/Research instrume	☐	☐	☐

I agree to abide by the approved protocol and shall obtain prior approval of the IRB for any changes in the protocol.

Principal Investigator

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. Principal investigator
    2. Research Protocol title
    3. Proposed start date
    4. Estimated end date
    5. Background information (in brief)- Burden, Knowledge gap, relevance and rationale
    6. Hypothesis to be tested/ Research Question
    7. Objectives
    8. Study design and methodology
    9. Outcome variables/ Outcome measurement

- **Description of the Research project**

1. Background of the project [Establish the scientific validity of the hypothesis by grounding it in the background information of the proposed study and referencing prior research on the topic. Address the relevance of sex, gender, and diversity factors, such as ethnicity and socioeconomic status (SES), and support the discussion with specific references. Critically evaluate the existing body of knowledge, highlighting the questions and gaps that remain unresolved and need to be addressed to meet the proposed objectives. If the subject lacks adequate information, emphasize the necessity of generating new insights to advance understanding in the field.]

2. Study design and methodology

[This research will employ a well-defined design and methodology to achieve its specific aims. The study will adhere to strict laboratory protocols, including the use of personal protective equipment (PPE), aerosol confinement techniques, and, if necessary, BSL2 or BSL3 laboratory facilities for specific procedures. The study population will be clearly defined with inclusion and exclusion criteria, supported by a robust sampling strategy to ensure relevance and representativeness. Primary outcome and exposure variables will be identified and measured using validated data collection tools, with follow-up plans incorporated if applicable. The methodological approach, whether biomedical, social, gender-sensitive, or environmental, will be scientifically justified to ensure validity. Potential limitations and challenges will be acknowledged, with strategies outlined to mitigate them, ensuring the robustness of the research process.]

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

3. 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.]

4. Data storage and record keeping

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

6. Patient / participant confidentiality [Include a description of the methods for safeguarding confidentiality of data and protecting anonymity of the participant.]

7. 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.]

8. Potential risk of the project [Describe any potential physical, psychological, social, legal or other risks and seriousness of such risks. If methods of research create potential risks, describe other methods, if any, that were not considered for specific reasons. Describe procedures for protecting against or minimizing potential risks and an assessment of their likely effectiveness.]

9. 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.]

10. 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]

11. 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