Institutional Review Board
Bangladesh Medical University

IRB Project Addendum Form

Section A: General Information

1. **Principal Investigator (PI):**
    - Name:
    - Title:
    - Institution/Department:
    - Email:
    - Phone Number:
2. **IRB Protocol Number:**
3. **Project Title:**

4. **Principal Investigator:**

5. **Original Approval Date:**
    - [MM/DD/YYYY]
6. Have the protocol activities been started? ☐ No ☐ Yes
7. **Actual start date:**
    - [MM/DD/YYYY]
8. **Planned/expected end date:**
    - [MM/DD/YYYY]

If yes, current status of implementation of the research protocol
(Check all boxes that are applicable):

☐ Continuing enrolment of the study participants
☐ Enrollment closed but follow-up or data analysis are ongoing
☐ Ongoing laboratory testing
☐ Study activities only involve data analysis or manuscript writing

☐ Others, please specify:

Indicate if this is the first addendum proposal to the research protocol? ☐Yes ☐ No

If No, Part II of the form to be completed

PART-II: Particulars of previously approved addendum of the research Protocol

Number	Description of approved addendum of the research protocol	Approval dates
		IRB

PART-III: Particulars of proposed addendum

Proposed changes affects: (check all boxes that are applicable)

☐ Investigator(s)
☐ Study objective(s)
☐ Research procedure(s)
☐ Number of participants to be enrolled
☐ Age and/or sex group of the study participants or addition of special group(s) e.g. pregnant women, malnourished children
☐ Eligibility (inclusion and/or exclusion) criteria
☐ Intervention (drug/vaccine formulation or dosing) or devise
☐ Collection of biological samples (type, number, amount, etc)
☐ Consent process
☐ Consent forms
☐ Study instrument (questionnaire, FGD guidelines etc.)
☐ Study sites
☐ Compensation for participation in research (e.g. increasing/decreasing the amount)
☐ Data Collection/analysis
☐ Budget
☐ Others, specify:

A. Provide itemized description of the proposed changes with **justifications**.

1.
2.
3.
4.

B. Please respond to the following:

a) Is the request based on any new finding(s)?

☐ Yes ☐ No

If yes, describe the significance of the finding(s) (e.g. new adverse event) available during the course of research, or information concerning requested change(s) that may influence study participants' willingness to continue participation. In such events, the PI shall modify the consent form(s) and apply that for re-consenting of participants already enrolled in the study.

b) Will the requested change(s) alter/likely to alter the scientific validity of the study?

☐ Yes ☐ No

If yes, explain in detail

c) Do any of the proposed change(s) alter the risk (physical, psychological and sociological) /or benefit to the study participants?

☐ Yes ☐ No

If yes, explain in detail:

d) If answer to the question # (c) is 'YES', will the enrolled participants be willing to remain in the study;

☐ Yes ☐ No

If yes, describe how this will be done and mention if the study participants need to be informed or re-consented.

e) Do the proposed change(s) affect any other service benefits?

☐ Yes ☐ No

If yes, explain in detail:

f) Any other relevant information, which might not have been covered above:

Section C: Changes in the Study

1. **Are there any changes to the original protocol, study population, or procedures?**
    - No
    - Yes (If yes, please describe the changes below or attach an updated protocol.)

2. **Have there been any adverse events, unanticipated problems, or deviations from the protocol?**
    - No
    - Yes (If yes, please describe and include the date of the IRB report.

Section F: Ethical Considerations

1. **Have all participants been informed of the extended timeline?**
    - Yes
    - No (If no, explain why.)

2. **Do the extension activities involve new risks to participants?**
    - No
    - Yes (If yes, please describe the risks and the mitigation plan.)

3. **Is there a deviation in the consent process?**
    - No
    - Yes (If yes, please attach updated consent documents.)
4.

Was there any protocol deviation:	
a) In enrolling the participants? If Yes, provide reasons for deviation:	Yes ☐ No ☐ NA ☐
b) In sample collection procedures? If Yes, please provide reason(s)	Yes ☐ No ☐ NA ☐
c) In intervention process? If Yes, please provide reason(s)	Yes ☐ No ☐ NA ☐
5. Was any unanticipated problem(s) encountered involving risks to the participant(s)? If Yes, please describe	Yes ☐ No ☐ NA ☐
6. Was there any adverse event associated with the study? If Yes, state the number of SAE	Yes ☐ No ☐ NA ☐
7. Did any enrolled participant(s) withdraw from the study because of the adverse event(s)? If Yes, please briefly describe	Yes ☐ No ☐ NA ☐
8. Whether the control group was provided with medical care as specified in the protocol? If No, please provide reason(s)	Yes ☐ No ☐ NA ☐

9. Is the confidentiality of the information collected being maintained? If No, please provide the reason(s)	Yes ☐ No ☐ NA ☐
10. Any other remarks	

Section F: Supporting Documents

- Attach the following documents, if applicable:
  - Updated Protocol (if changes are made)0.
  - Revised Consent Forms (if changes are made)
  - Recruitment Materials
  - Any Additional Supporting Information

Section G: Certification

I understand that I cannot initiate any change in the approved research protocol until my requested change(s) is/are approved by all relevant Committees.

_____ Date:

Signature of the Principal Investigator

Date:

Principal Investigator Signature:
[Signature]
Date: [MM/DD/YYYY]

Section 8: For IRB Use Only

IRB Review Outcome:

- Approved
- Conditionally Approved
- Denied

Reviewer Comments (if applicable):
[Comments or instructions for revisions]

IRB Chair/Authorized Official Signature:
[Signature]
Date: [MM/DD/YYYY]