Institutional Review Board
Bangabandhu Sheikh Mujib Medical University

Project Extension Request Form

Section 1: General Information

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

4. **Co-investigator:**

5. **Original Approval Date:**
    - [MM/DD/YYYY]
6. **Actual start date:**
    - [MM/DD/YYYY]
7. **Planned/expected end date:**
    - [MM/DD/YYYY]
8. **Requested Extension Period:**
    - From: [MM/DD/YYYY]
    - To: [MM/DD/YYYY]
9. **Was/were any proposal(s) for addendum to/modification of the protocol submitted inthe preceeding in 12 months?**
    - No
    - Yes (if yes, addensum approval date)

Section 2: Reason for Extension

1. **Justification for Extension (Brief Description):**
    - Explain the reasons for the extension (e.g., recruitment delays, additional data collection, data analysis, unforeseen circumstances, etc.).

2. **Progress Summary:**
    - Provide a brief update on the progress made to date, including milestones achieved and the current status of the project.

Section 3: 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 4: Current and Future Activities

1. **Describe the Activities to be Conducted During the Extension Period:**
    - Detail the specific activities planned (e.g., continued recruitment, follow-up with participants, additional data collection).

2. **Anticipated Outcomes During the Extension Period:**
    - State the expected results or milestones to be achieved during the requested extension.

3. Do you have any information from this study or from other studies that significantly changes the risk/benefit ratio for the participants enrolled in this study or likely to affect the consent of prospective participants? Yes ☐ No ☐

   If yes, Describe in detail.

4. Total number of study participants approved in the protocol:
5. Number of participants enrolled till date :
6. If the enrolment target was not achieved, please give reasons:

Section 5: 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 6: Supporting Documents

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

Section 7: Certification

I certify that the information provided in this form is accurate and complete to the best of my knowledge. I acknowledge that any changes to the study protocol during the extension period must be reported to and approved by the IRB.

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]