Continuing Review Form

INSTRUCTIONS TO THE PRINCIPAL INVESTIGATOR: *Ethical clearance or approval is typically granted for a period of one year. The deadline for submission for continuing review is indicated in the Study Protocol Approval Letter. For ethical clearance or approval approaching the one-year expiry date and requiring a renewal or extension, it is advisable to submit this form 60 days prior to expiry date. Obtain an electronic copy of this form and encode all information required in the space provided. Print the form then date and sign this form before submission.*

UPCHE REC CODE:		
STUDY PROTOCOL TITLE:		
APPROVAL DATE:		
PRINCIPAL INVESTIGATOR:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE:		
STUDY SITE ADDRESS:		
SPONSOR:		
SUBMISSION DATE: (to be filled out by UPCHE REC) <mm/dd/yyyy>		

1. START DATE:

1.1. Date of research site initialization: <mm/dd/yyyy>

1.2. Explanation, if not yet initialized as of date of this submission: <reason/s>

2. ACTION REQUESTED:

2.1. ☐ Renewal: New participant accrual to continue

2.2. ☐ Renewal: Enrolled participant follow up only

2.3. ☐ Early Termination: Study protocol discontinued ahead of study indicated duration

2.4. ☐ Other (specify):

3. HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL?

3.1. ☐ No

3.2. ☐ Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)

4. **SUMMARY OF STUDY PROTOCOL PARTICIPANTS**:

• Accrual ceiling set by the REC	<number>
• New participants accrued since last review/approval	<number>
• Total participants accrued since study protocol began	<number>

5. ACCRUAL EXCLUSIONS

5.1. ☐ None

5.2. ☐ Male

5.3. ☐ Female

5.4. ☐ Other (specify):

6. IMPAIRED PARTICIPANTS

6.1. ☐ None

6.2. ☐ Physically

6.3. ☐ Cognitively

6.4. ☐ Both

7. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW/APPROVAL?

7.1. ☐ No
7.2. ☐ Yes (Explain changes and indicate date(s) of Study Protocol Amendment Submission(s))

8. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document
8.1. ☐ No
8.2. ☐ Yes (Explain changes and indicate date(s) of Study Protocol Amendment Submission(s))

9. HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE COMMITTEE'S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?
9.1. ☐ No
9.2. ☐ Yes **(**Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable**)**

10. HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?
10.1. ☐ No
10.2. ☐ Yes (Summarize and indicate date(s) of SAE/RNE/SUSAR report submission(s))

11. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?
11.1.☐ No
11.2.☐ Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)

12. HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL
12.1. ☐ No
12.2. ☐ Yes (Describe use and indicate date/s of Study Protocol Deviation/Non-Compliance/Violation Report Submission/s)

13. HAVE ANY INVESTIGATORS BEEN ADDED OR REMOVED SINCE LAST REVIEW/ APPROVAL?
13.1. ☐ No
13.2. ☐ Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted to the UPCHE REC)

14. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR REMOVED SINCE THE LAST REVIEW/ APPROVAL?
14.1. ☐ No
14.2. ☐ Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)

15. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?
15.1. ☐ No
15.2. ☐ Yes (Append a statement of disclosure)

16. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL?
16.1. ☐ NONE:
16.2. ☐ DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
16.3. ☐ ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)

17. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis. 17.1. ☐ No **17.2.** ☐ Yes **(**Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
18. PROGRESS STATUS (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete) 18.1. <Component 1><Provide description as needed> **18.2.** <Add components as necessary>

SIGNATURE OF PRINCIPAL INVESTIGATOR:	**For students, SIGNATURE OF THESIS ADVISER:**
DATE SIGNED:	**DATE SIGNED:**

For UPCHE REC use only:

Type of Review:			
	Expedited Review		Full Review
Comments of Primary Reviewer (i.e., compliance with the approved protocol, effect on patient well-being and safety and overall assessment of risks against benefits in the conduct of study)			
Recommendation(s)			
RECOMMENDED ACTION: ☐ Approval with no further action ☐ Request information (specify) ☐ Recommend further action (specify)			
REVIEWER (Scientist or Non-scientist) Date:		Signature Name Position	