COMREC PROGRESS REPORT FORM

COMREC Use Only
Type of Review: _____

The College of Medicine Research and Ethics Committee
College of Medicine, Private Bag 360, Chichiri

Progress Report

1. Title of Study

2. COMREC #

3. Start Date ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

4. COMREC Expiration Date ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

5. Anticipated End Date ☐☐/☐☐☐/☐☐☐☐ (D D / M M M / Y Y Y Y)

6. Principal Investigator

7. Co-Investigator(s)

8. Host Department

9. Phone No: Email:

10. Student Investigator(s)

11. Name of sponsor[1]

12. Name of funder[2]:

13. Amount of funding *(please indicate the currency)*:

14. Amount of CoM overhead fees CoM (10%) in the original approved budget:

15. Amount of overhead fees paid to CoM (10%)

16. Amount of CoM overhead fees outstanding (if any)

17. If CoM overhead fees are outstanding, provide an explanation why the fee is outstanding in the space below;

[1] A Sponsor is either an individual, organization or other legal entity which takes responsibility for initiating, managing and/or financing a study.

[2] A funder is an institution, organization or company that simply provides funding, but does not take up the responsibility of initiating or managing the study.

EXECUTIVE SUMMARY OF THE PROJECT

In the space below, provide a brief summary of the progress and results obtained to date (Please explain any changes made or are being planned for approval as indicated in C4).

A. Project Status: (Since last approval, check one category only.)

1. Enrollment Has Not Begun* ☐
2. Actively Enrolling Participants* ☐
3. Enrollment Completed, Contact with Participants Ongoing ☐
4. Contact with Participants Completed, Analyzing Identifiable Data Analysis Only ☐
5. Analyzing Identifiable Data (Samples or Data) Only ☐
6. Analyzing Unidentifiable Data; Data Do Not Contain Identifiers or Linkage to the Data if this is a Program Project, check here ☐
7. complete Section E., sign the Progress Report and attach a ☐
8. completed List of Associated Projects ☐

If enrollment has not begun or you are actively enrolling participants, attach a copy of the consent document used or to be used.

B. Number of Participants enrolled, Records Reviewed or Samples Analyzed:

What is the total sample size?

1. Since last renewal:

# of males		# of females	
# of adults		# of children	

2. Since original approval:

# of males		# of females	
# of adults		# of children	

C. **(*Answer Questions 1 through 7 based on information since last review. Attach a memo explaining "Yes" answers to questions 1 through 6.)***

	Yes	No	N/A
1. Have any participants withdrawn voluntarily or been withdrawn from the study?	☐	☐	☐
2. Have any unexpected side effects, complications, or findings been noted that have not been reported to the Committee?	☐	☐	☐

	Yes	No	N/A
3. Have there been any changes to the protocol (participant population, recruitment, study procedures, sample size or consent process) that have not been reviewed and approved by the Committee?	☐	☐	☐
4. Are you requesting any changes to the project (change in investigators, subject population, recruitment, study procedures, sample size or consent process)?	☐	☐	☐
5. Have there been any significant new findings which may relate to the participants' willingness to continue participation in the study?	☐	☐	☐
6. Has any new information appeared in the literature or been discovered from the study results that would affect the risk-benefit assessment of the project?	☐	☐	☐
7. Has a Data Safety and Monitoring Board been established for this project? If yes, provide a status report from the DSMB.	☐	☐	☐
8. Do any of the participating faculty (or their immediate family, staff or students) have a financial interest (royalty, equity or consulting) in the sponsor and/or products used in this project?	☐	☐	☐
Has this been reported to the COMREC previously?	☐	☐	

D. As Investigators indicate your assessment of the progress of this study

As expected ☐

Not as expected ☐

Above expectation ☐

E. Funding Status: ***(select one)***

Awarded ☐

Pending ☐

Project **not** funded ☐

If awarded or pending, provide the following information:

			/				/				
	D	D		M	M	M		Y	Y	Y	Y

Signature of Principal Investigator Date

*****SEE BELOW FOR INVESTIGATOR RESPONSIBILITIES*****

Investigator Responsibilities

- Changes, amendments, or addenda made to the protocol or the informed consent process must be submitted to the COMREC for review and approval prior to initiating the change. This includes changes in investigator(s), sample size, population, research site, subject compensation, etc.

- Incarcerated individuals may not be included in the study unless the study has been approved by the COMREC for inclusion of prisoners.

- The COMREC protocol number should be cited in all correspondence.

- Adverse events should be reported promptly to the COMREC.

- Significant new information that may affect the risk: benefit ratio must be submitted promptly to the COMREC.

- Only consent/assent documents with a valid approval date may be presented to the participants.

- Signed consent forms for all participants enrolled in the study must be retained on file.

- All active research projects must be reviewed and re-approved by the COMREC prior to the project's expiration date.

- The Principal Investigator is responsible for submitting progress reports by the project's current submission date.

- The Principal Investigator is responsible for keeping the Co-Investigator(s) and Student Investigator(s) informed of the status of the project.

RETURN THIS FORM AND SUPPORTING DOCUMENT(S) TO:
College of Medicine Research and Ethics Committee, Mahatma Gandhi Road

COMREC USE ONLY:

Project Re-approved for Period _____ to _____

Project Reclassified as Exempt Status; Continuing Review No Longer Required

_____ _____

Chair/Administrator, COMREC **Date and Stamp**