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PROGRESS REPORT FORM (FORM 4.2)

IRB Protocol No.

Date Received (D/M/Y):

Protocol Title:

Sponsor:

Principal & Sub
Investigators:

Primary Reviewers:

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

Please check (✓) each of the boxes that pertains to your report.

1. Any change in participant population, recruitment or selection criteria since the last review?

Yes No

(Explain the changes)

2. Any change in the Informed consent process or documentation since the last review?

Yes No

(Explain the changes)

3. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in the study?

Yes No

(Explain the changes)

4. Are there any unsuspected complications or side effects noted since the last review?

Yes No

(Explain the changes)

5. Did any participant withdraw from this study since the last approval?

Yes No

(If Yes, state the number of participants who withdrew and give the reasons for withdrawal.)

6. Any new investigator that has been added to or removed from the study research since the last review?

Yes No

(Pls. submit the name and the CV of the new investigators.)

7. Summary of protocol participants:

____ Accrual ceiling set by IRB

____ New participant accrued since last review

____ Total participant accrued since protocol began _____

8. Total participants excluded since protocol began:

ACCRUAL EXCLUSION

____ None

____ Male

____ Female

9. Are there other new sites that were added or deleted since the last review?

____ Yes ____ No

(Pls. identify the sites and note the addition or deletion.)

10. Impaired Participants

____ None

____ Physically

____ Cognitively

____ Both

11. Deviations from the approved protocol

11. Detailed Description of Progress Report:

INVESTIGATOR'S ATTESTATION

I certify that the information provided in this report is complete and accurate.

Signature Over Printed Name of Principal Investigator

Date

(IRB Use only) Received by:

Signature Over Printed Name

Date

SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER

Type of Review

Expedited Full Board

Reviewer's
Comments:

Final Action:

- () Accepted
- () Request further information
- () Require specific action from researcher
- () Take Note and No Further Action needed
- () Others: _____

Acknowledged by:

_____ Name of Reviewer IRB Member	_____ Signature	_____ Date
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