University of North Texas Health Science Center

Office for the Protection of Human Subjects

PROGRESS REPORT

As a condition of project approval, the Institutional Review Board (IRB) provides for the Continuing Review (or Final Report) of all research projects involving the use of human subjects **at least** annually, or more frequently, appropriate to the degree of risk. The responses submitted to the requested information will provide the basis for continued approval of your project. Please answer all questions. **Do not leave items blank** (if not applicable, mark N/A). Please note that INCOMPLETE or INACCURATE Reports (attachments missing, incomplete forms, faulty data entries, illegible writing, etc.) will be returned without review and may delay continuing approval or result in protocol suspension or termination.

OPHS-IRB Protocol Project # _____ ☐ **CONTINUING REVIEW** or ☐ **FINAL REPORT**

Principal Investigator: _____

Contact Person and Phone # (if different from P.I.) _____

Department: _____ Telephone: _____

Project Title: _____

Sponsor Protocol Number: _____

Federal regulations require that all documentation for projects involving human subjects be submitted in a timely manner, even if the project has been completed. Failure to comply with this request will result in revocation of approval and a delay in the processing of future IRB applications.

STATUS OF THE PROJECT:

_____ Actively Enrolling new subjects

_____ Enrollment complete, but research intervention continues

_____ Enrollment and research intervention complete, subject follow-up continues

_____ Enrollment, research intervention, subject follow-up complete, data analysis only continues

_____ Project NOT YET STARTED (list reason and date expected to begin) _____

_____ Project ON HOLD (list reason and date expected to resume) _____

_____ Project COMPLETED / CLOSED (list date completed/closed) _____

_____ Project terminated before completion (list date and reason project terminated) _____

_____ Project has not been and will not be conducted (list reason project not pursued) _____

AMENDMENTS/MODIFICATIONS TO PROJECT:

Have there been **ANY** changes or modifications to the protocol since the most recent review of the project? ***This includes amendments, revised investigator's brochures, safety addendums, and sponsor-requested changes to the informed consent, etc.***

No ☐ There are NO changes, modifications or amendments to the protocol since the last review.

Yes ☐ If Yes, attach a brief summary of any changes that have been made to the project since you last reported on this study (list amendment number, if applicable, and date of IRB approval of revisions):

_____

Subject Enrollment:

Maximum Number of Subjects Approved by the IRB	
Date FIRST subject signed informed consent (month/year)	
Date MOST RECENT subject signed informed consent (month/year)	
Total number of subjects reported previously *	
Number of new subjects **	
Total number of subjects reported to date	

**if this is the first progress report for your study just place a zero in this blank.*

***this will be the number of new subjects since your last progress report. If this is the first progress report since your study was initially approved, then report the total number of subjects enrolled to date.*

	*Total Number of Subjects to Date **
Undergoing Research Protocol	
Follow-Up Data Collection *Only*	
Completed BOTH Study and Follow-Up	
Lost to Follow-Up	
Withdrawn by PI (incl. Screen Failures)	
Subjects who Withdrew from Study	
Deaths **	

** Of the total number of subjects you have reported; please provide information in order to capture the status of the study participants. The numbers in these boxes should add up and equal the total number of subjects enrolled to date.*

*** Note that DEATHS must be reported to the IRB Immediately*

Please answer the following questions (if applicable):

Reasons subjects were Withdrawn by Investigator (DURING THIS REPORTING PERIOD):

_____

_____

Reasons Subjects Withdrew from study (their decision) DURING THIS REPORTING PERIOD:

_____

_____

Of all subjects who signed informed consent, how many were:

	Total Number to Date
Male	
Female	

Of all subjects who signed informed consent, how many were:

	Total Number to Date
African-American (Black)	
American Indian / Native American	
Asian	
Caucasian (White)	
Hispanic (Latino)	
Native Hawaiian / Pacific Islander	
Other or Unknown	

Federal regulations require that women and minorities be included in all studies unless there is a valid scientific reason for not doing so. If no women or minorities are included in the above numbers, have you instituted a procedure to recruit female and minority subjects? Explain: _____

CONSENT DOCUMENT STATEMENT:

Was informed consent obtained on all human subjects? Yes ☐ No ☐ If response is No, explain:

_____

Copies of the executed consent forms are maintained at _____

Briefly describe any problems you have encountered in obtaining and documenting informed consent from participants: _____

SERIOUS ADVERSE EVENTS:

Did any serious adverse events (SAEs) occur since you last reported on this study? Yes ☐ No ☑

If yes, indicate number of the following: **On-site** SAEs _____ **Off site** SAEs _____

Was an IRB Form 3a or 3b completed for each SAE? Yes ☐ No ☐

Was it necessary to modify the consent form as a result of the SAE reports? Yes ☐ No ☐

If yes, date of IRB approval of revised consent: _____

Based on your knowledge of adverse events for this study, do you feel there is a significant increase in risks to subjects? Yes ☐ No ☐ If yes, explain: _____

If your protocol described safeguards which were designed to avoid risks or detect complications, were these safeguards adequate? Yes ☐ No ☐ If no, explain: _____

COMPLAINTS:

Were any **complaints** from subjects registered about this study since you last reported on this study?
Yes ☐ No ☐ If yes, explain: _____
_____

DATA SAFETY MONITORING BOARD (DSMB) REPORT:

For some protocols, a DSMB is required. All DSMB reports **MUST** be submitted to the IRB within 10 working days of receipt. If your study requires a DSMB, please indicate the date of the most recent DSMB Meeting/Report: _____

*****attach a copy of this DSMB Report to this document***

RISK/BENEFIT ASSESSMENT:

Has anything occurred since **initial** IRB review and approval which may have altered the risk/benefit relationship? Yes ☐ No ☐ If the answer is yes, provide your current assessment of the risk/benefit relationship of the research based upon the results obtained, on-site and off site SAEs, and other factors:

Has any new literature or findings been reported since you last reported on this study which would significantly impact the design of this study or the risks associated with this study? Yes ☐ No ☐ If response is yes, attach a summary of these findings.

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PRINCIPAL INVESTIGATOR ASSURANCES:

In accordance with federal regulations, it is necessary for all individuals identified as "key personnel" to complete an *updated and current* Conflict of Interest Disclosure at the beginning and during continuing review for each research project involving human subjects. The form can be completed on-line, then printed and must be signed by EACH individual listed as "key personnel" on the protocol. Web location for this form is **http://research.hsc.unt.edu/documents/Conflict_of_Interest.pdf**

As a condition of continuing approval, the Principal Investigator certifies that the above research project and protocol has been and will be conducted in full compliance with all federal regulations and UNTHSC policies governing human subject research. Further, the Principal Investigator asserts that the information in this Report is accurate. The Principal Investigator also notes that any changes in the research activity, research proposal and consent forms must be approved by the IRB prior to implementation, and that all serious adverse events must be reported to the IRB. The Principal Investigator states that any new literature or findings that would significantly impact this study or risk associated with this study have been duly noted and reported to the IRB. The Principal Investigator also assures that all key personnel associated with the project have successfully completed educational training in the protection of human research subjects, and that all key personnel have completed and signed Conflict of Interest Disclosures relevant to this research project.

_____ _____
Principal Investigator Date

_____ _____
Clinical Trial Coordinator (if applicable) Date

ATTACHMENTS REQUIRED:

THIS Original Signed Progress Report, plus:

- ONE Copy of a ***NEW*** *(updated) CO*NFLICT OF INTEREST FORM for EACH OF THE KEY PERSONNEL LISTED FOR THIS PROTOCOL

  NOTE: If this is a Close-Out or Final Report, no Conflict of Interest forms are required.

- **Refer to Cover Memo for Type and Number of Hard-Copies of additional documents needed (Consent Forms, Protocol Synopsis, etc.)**