THE UNIVERISTY OF TULSA
INSTITUTIONAL REVIEW BOARD (IRB)
ANNUAL PROGRESS REPORT FORM

Project Title: **Protocol No.:**

Principal Investigator(s):

Status of the Study (PART A) - Please check only one of the following:

☐ **Completed – please inactivate**. Enrollment and follow up are complete and no further contact with participants/identifiable records/or identifiable biospecimens is anticipated. Only de-identified data is left.

☐ **Active**, continuing to enroll subjects – request one (1) year extension.

☐ **Active**, with conditions **(check all that apply in PART B)** – meet the requirements to request no more annual reviews

☐ **No subjects have been enrolled yet**, under the auspices of The University of Tulsa; **and no additional risks** have been identified – request one (1) year extension.

☐ **No subjects enrolled yet**, under the auspices of The University of Tulsa; but new risks identified that pose greater than minimal risks to subjects. – request one (1) year extension. **Please give a description of the new risks* – (may require Modification Request Form submission).

Status of the Study (PART B)- If Active, *but* with conditions for this site, please check *all* that apply:

☐ Permanently closed to enrollment of new subjects
☐ All subjects have completed all research-related interventions
☐ Research is to remain active only for long-term follow-up of subjects
☐ Research activities are limited only to data analysis that may require contact with records or biospecimens linked to privately identifiable information.

APPROVED STUDY SITE(S): _____

NUMBER OF SUBJECTS ENROLLED THIS YEAR (since last report): _____

NUMBER OF SUBJECTS ENROLLED TO DATE: _____

NUMBER OF SUBJECT WITHDRAWALS TO DATE: _____ (For each please explain why the subject chose to withdraw or why you withdrew the subject from the study.)

1. Synopsis of activities to date. (Include the progress of the study as compared to the hypothesis.)

2. Were any grievances or complaints received about this study? ☐ Yes or ☐ No
   If yes, please explain. (TU IRB Adverse Events/Problems Form should have been submitted)

3. Have unexpected events or complications occurred that may indicate a need for a change in the protocol or consent? ☐ Yes or ☐ No
   If yes, a please explain; include number of events and if they were reported to the IRB (TU IRB Adverse Events/Problems Form should have been submitted).

4. Has information (publications, presentations, etc.) become available since starting this study that indicates a need to modify this study?
   ☐ Yes or ☐ No If yes, please explain.

5. Summarize any anticipated revisions not yet reviewed by IRB. (Approval of this Progress Report does not indicate an approval of such revisions. Any/all revisions must be submitted to the IRB separately for approval on the TU IRB Modification Request Form.)

6. **Please list *ALL PERSONNEL CURRENTLY working* on this protocol:**

_____

_____

_____

Have there been any changes in key personnel? ☐ Yes or ☐ No If yes, please explain.

a.

7. Is there new funding proposed for this activity? ☐ Yes or ☐ No *If yes, send us one complete copy of the proposal and explain if there are any differences between this new proposal and what is approved in this application.

8. Does this protocol need to be updated on clinicaltrials.gov? ☐ Yes or ☐ No

****If you have checked "ACTIVE, continuing to enroll subjects" above:**
a copy of each current consent form and any current recruitment materials must be included with this Progress Report

Principal Investigator (PI) Signature: _____ Date:_____

(an inserted electronic signature or copy of the original signature is allowed)

(As PI, I have read and approve this report and continue to be responsible for ethical standards during the course of this study.)

***If student PI,** Faculty Mentor signature:_____ Date:_____

(an inserted electronic signature or copy of the original signature is allowed)

(As the Faculty Mentor, I have read and approve this report and continue to be responsible for guidance to the student in implementing and assuring ethical standards during the course of this study.)

phone: _____ email address: _____

_____ Date:_____ IRB Action: Approved ☐ Closed ☐ Denied ☐

(IRB Authorized Approval Signature)