APPENDIX B - If change in PI, the new PI must complete. *Please note: PI must be a TriHealth employee, hold a TriHealth leadership position or be credentialed Medical Staff at a TriHealth owned location.*

PRINCIPAL INVESTIGATOR RESPONSIBILITY LIST

The following are the minimum responsibilities of the Principal Investigator. You **MUST initial** each item to indicate that you have carefully read and understand your responsibilities.

___ **1.** Principal Investigator acknowledges and accepts his/her responsibility for **protecting the rights and welfare of human subjects** and for **complying with all applicable regulations**.

___ **2.** Principal Investigator who intends to involve human research subjects will be **responsible for obtaining IRB review and approval PRIOR to the initiation of research**.

___ **3.** Unless otherwise authorized by the IRB, **Principal Investigator is responsible for obtaining and documenting informed consent and authorization** in accord with applicable institutional and federal regulations.

___ **4.** Principal Investigator is responsible for **providing a copy of the IRB-approved and signed informed consent document to each subject at the time of consent**, unless the IRB has specifically waived this requirement, or the study is determined by IRB to be exempt. All original signed consent documents are to be retained by the PI for the period of time required by the federal regulations or as outlined in the contract with the sponsor.

___**5.** Principal Investigator shall be **responsible for promptly reporting proposed changes in previously approved human subject research activities to the IRB**. The **proposed changes may not be initiated without IRB review and approval, except** where necessary to **eliminate apparent immediate hazards** to the subjects.

___ **6.** Principal Investigator will **report to the IRB all Unanticipated Problems Involving Risks to Human Subjects or Others (Unanticipated Problems) that occur within 5 business days**. All Unanticipated Problems that **involve death must be reported within 24 hours**.

___ **7.** Principal Investigator will submit a **progress report at least eight weeks prior to the date at which the IRB has determined continuing review is required for full board review**. If the progress report is not received by the due date, it cannot be guaranteed that a study will be reviewed before the study's approval lapses. If a study is not reviewed prior to the expiration date, new enrollment is suspended and you may not continue with the study for previously enrolled subjects except as approved by the IRB.

___ **8.** Principal Investigator will **report all noncompliance issues that have an adverse effect on the safety or welfare of the subject(s), and/or the data collected and/or are related to breach of confidentiality within 10 business day of discovery**.

___ **9.** Principal Investigator will **disclose any new conflicts of interest that arise during the course of the study** as outlined in the TriHealth Conflict of Interest in Clinical Research Policy.

___ 10. Principal Investigator will **maintain a list of appropriately qualified persons to whom significant clinical trial related duties have been delegated** and will **seek approval from the IRB for any change in Sub-Investigator, Lead Study Coordinator and/or Research Specialist**.

Full Name:

Address:

24-Hour Phone Number:

Email Address:

TriHealth Department:

Resident: ☐ **Yes** ☐ **No**

PI Designated Contact for this Study:

Designated Contact Email Address:

Have you been audited by the FDA or the Office for Human Research Protections (OHRP) in the past 5 years?

☐ **Yes** ☐ **No**

If yes, please provide the name of the Agency and the date of the audit:

Have you:

Had a sponsor, CRO, or an IRB terminate, suspend, impose restrictions or sanctions on a protocol, or refuse to review a protocol? ☐ **Yes** ☐ **No**

Had the FDA or OHRP terminate a study? ☐ **Yes** ☐ **No**

If yes to any of the above, please provide a written explanation and copies of relevant documents.

CERTIFICATION STATEMENT

I will abide by the requirements of TriHealth and the IRB, as per the above Researcher's Responsibilities, Federal and State Regulations, and the agreement with the sponsor in the conduct of the protocol. I have not been disbarred, suspended or restricted by any federal or state agency.

_____ _____

Signature of New Principal Investigator **Date**