Principal Investigator Supervisory Plan for Clinical Research

The overall conduct and supervision of clinical research is the responsibility of the Principal Investigator (PI). The development of a Supervisory Plan is key in documenting PI oversight, supervision, and ongoing involvement with the trial. This plan should be developed in accordance with the responsibilities set forth in the following regulations as applicable:

 21 CFR 312 (investigational drugs and biologics [IND] studies)

 21 CFR 812 (investigational device exemptions [IDE] studies)

 21 CFR 50 and 56 (protection of human subjects and institutional review boards)

 21 CFR 54 (financial disclosure)

 45 CFR 46 (protection of human subjects – for those studies not regulated by FDA)

 45 CFR 160 and 164 (HIPAA)

 FDA Form 1572

 ICH GCP E6 (R2) Section 4 (investigator)

The following sections should be completed (as applicable) by the PI, signed and dated, and filed with the regulatory documents for the research. It should be made available for any internal reviewer of this research (**Note: Review of this document by persons outside of UNC is not required)**. This form does not require review by the IRB.

**Section 1: Routine Meetings with Staff**

(Describe the manner and frequency in which trial progress, adverse events, and updates to the protocol and other research related information will be communicated among the research team. The meetings may take place in person, via teleconference, or web conferencing. The frequency of the meetings should be dependent upon the stage or nature of the research.)

**Section 2: Routine Meetings with Monitors**

(Describe the manner in which you will interact with sponsor monitors. Enter N/A if not applicable.)

**Section 3: Correction and Documentation of Problems**

(Describe the process for the ***timely*** correction and documentation of problems identified by research staff, outside monitors or auditors, or other parties involved in the conduct of the research.)

**Section 4: Delegation of Research Tasks and Review of Performance**

(Describe the procedure for documenting or reviewing the performance of delegated tasks in a ***satisfactory*** and ***timely*** manger [e.g., observation of the performance of selected assessments or independent verification by repeating selected assignments].)

**Section 5: Consent Process**

(Describe the process for ensuring that the consent process is being conducted in accordance with 21 CFR 50 or 45 CFR 46 and that study subjects understand the nature of their participation and the risks.)

**Section 6: Source Data**

(Describe the procedure for ensuring that source data [e.g., clinical findings, observations, or other activities necessary for the reconstruction and evaluation of the research] are accurate, contemporaneous, and original.)

**Section 7: Case Report Forms (CRFs)**

(Describe the procedure for ensuring that information in source documents is accurately captured on the case report forms.)

**Section 8: Data Queries and Discrepancies**

(Describe the procedure for resolving data queries and discrepancies identified by the sponsor monitors or others involved with data management.)

**Section 9: Protocol Compliance and Event Reporting**

(Describe the process for identifying adverse events, unanticipated problems, deviations from the protocol, non-compliance with applicable regulations [i.e., federal, state, institutional] and reporting of those events to the IRB of record, CRO or sponsor as applicable)

**Section 10: Medical and Ethical Issues**

(Describe the procedure for addressing medical and ethical issues arising during the course of the research in a ***timely*** manner.)

Section 11: **Compliance with HIPAA**

(Describe the process for ensuring compliance with HIPAA. If not applicable, enter N/A in this section with an explanation [i.e., no PHI will be viewed or collected].)

**Section 12: Institutional Responsibilities**

As the PI for this research, I am aware that it is my responsibility to:

* follow all applicable University policies and procedures for conducting clinical research, including but not limited to Investigational Drug Services, Investigational Device policy, and the Office of Human Research Ethics SOPs. **(Delete any that are not applicable to the research.)**
* ensure all research staff have completed the applicable training to include Human Subjects Protection, HIPAA, Good Clinical Practices and Conflict of Interest.

As indicated by my signature below, this document represents my plan to oversee and supervise this research.

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Signature of Principal Investigator Date

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Printed Name of Investigator

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Signature of Department Chair or Designee Date

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Printed Name of Department Chair or Designee (if Designee include title)