Guidance for Completing a Supervisory Plan for Clinical Research

This document serves as a guide to assist Principal Investigtors (PI) with completing the **Supervisory Plan for Clinical Research (Plan)**.

Each investigator should develop a Plan specific to the research being conducted documenting the way in which s/he will provide oversight and supervision for clinical research for which s/he serves as the PI. Supervision and oversight is required when any research related task is delegated to anyone on the research team regardless of experience.

Each section of the Plan should be addressed. If the section is not applicable to the research, N/A should be written in that section. Once completed and signed/dated by the PI, the Plan should be filed with the regulatory documents for the research. The Plan should be made available to any internal reviewer.

Examples of processes and procedures are provided below for each section of the Supervisory Plan to assist with the development of the specific Plan.

**Section 1: Routine Meetings with Staff**

* During the enrollment period of this research, team meetings will occur each week. Once enrollment is completed, meetings will occur monthly, unless otherwise indicated [e.g., discussion of an unanticipated problem].
* Meetings will be held in-person or by teleconferencing and attendance will be taken.
* Minutes will be taken during each meeting, documenting the progress of the trial, any adverse events that have occurred, new information from the sponsor inclusive of information that should be relayed to research participants.

**Section 2: Routine Meetings with Monitors**

* This section is not applicable as there is no sponsor for this research.

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

* Review any internal audits with the reviewers to discuss problems discovered.
* Provide the reviewers with CAPAs (if required) or completed Action Items within 30 days of the receipt of the internal report.

**Section 4: Performance of Delegated Research Tasks**

* Complete the Delegation Log within 1 week when new research staff are added. My initials and date on the log will serve as documentation that the tasks are delegated appropriately.
* Collection of CVs/licenses/certifications of the research staff will occur prior to the initiation of the research to document their qualifications to perform the tasks.
* If training on a specific task is required, I will observe the performance of the task and document adequacy (e.g., personally supervise the consent process for X subjects; personally supervise phlebotomy draws for X subjects)

**Section 5: Consent Process**

* Research staff will document the consent process for each participant using the Informed Consent Process Documentation template found on OCTs website.
* Participants will be provided with new information that may impact their willingness to continue participating in the research once IRB approval is received except when necessary to eliminate an immediate hazard.

**Section 6: Source Data**

* All data relevant to the research will be located (state where the source documentation will be located)
* Data will be reviewed on a quarterly basis and compared to the case report forms to confirm accuracy and timely entry. Documentation of this activity will be included in the regulatory file.

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

* See above.

**Section 8: Data Queries and Discrepancies**

* Queries will be resolved within 7 business days.
* Time will be scheduled to discuss and follow up on queries and discrepancies.
* Documentation of this activity will be included in the regulatory files.

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

* All events deemed reportable to either the sponsor or the IRB will be made according to the timeframes indicated in the protocol or SOPs.
* During the routine meetings (See Section 1), discussion of adverse events, outstanding issues, protocol compliance will be included and documented in the meeting minutes. The minutes will be included in the regulatory files.

**Section 10: Medical and Ethical Issues**

* Each member of the research team will document they have read and understood the University’s Research Code of Conduct and Standards.

**Section 11: Compliance with HIPAA**

* Only the minimal amount of Protected Health Information will be viewed to determine eligibility for the trial. A log will be maintained to document eligibility: met criteria, did not meet criteria and which element of inclusion or exclusion was not met, whether or not eligible subject enrolled.
* Each participant will have a signed HIPAA authorization included in their research file and will be scanned into their electronic medical record.