SOP TITLE: MONITORING AND QUALITY ASSURANCE

1 PURPOSE

1.1 This procedure establishes the process for Principal Investigators (PIs) and study personnel under the PI's supervision to follow during monitoring, auditing or inspection[1] activities by sponsor representatives, regulatory authorities, or authorized university officials.

1.2 The process begins when the PI or designee is informed of planned monitoring, auditing, or inspection activity.

1.3 The process ends when the monitoring, auditing, or inspection activity and all related follow-up have been completed.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 REQUIREMENTS

3.1 The PI and designated study personnel will arrange, manage, and participate in monitoring, auditing, and inspection activities conducted with sponsor representatives, regulatory authorities, or university officials.

3.2 Types of monitoring visits include pre-study or site qualification, site initiation, routine or intermittent monitoring, and closeout visits. Visit-specific activities will vary according to the sponsor's objectives for the type of visit.

3.3 For investigator-initiated studies, in which the PI is expected to fulfill any and all applicable FDA obligations when serving as sponsor (holder) of an IND or IDE, the PI will ensure the IRB-approved monitoring plan for the study is followed.

3.4 Access to medical records and study source data by non-study personnel is permitted only for the purposes of verifying study data, ensuring protocol compliance, and maintaining participant safety.

3.5 Monitors, auditors, and inspectors are never allowed to access EPIC using an employee's login information. View-only access can be provided to non-study personnel through the UCSD Office of Compliance and Privacy (OCP).

3.6 The PI or designee should be available to meet and/or talk with the monitor, auditor, or inspector during the visit.

4 RESPONSIBILITIES

4.1 The PI is responsible for ensuring that study activities are completed promptly and accurately, including participant visit documentation, study data entry, and regulatory file maintenance.

4.2 The PI or designee is responsible for ensuring that OCP, the Office of Clinical Research, and the IRB offices are notified in the event of an audit or inspection by federal regulatory authorities.

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[1] For FDA inspection, refer to OCR-104 FDA Inspection Checklist for detailed preparatory and visit activities.

4.3 The PI is responsible for ensuring that adequate personnel are available to facilitate monitoring, auditing, and inspection visit activities and to respond to monitor and auditor requests.

5 PROCEDURE

5.1 The PI and/or designated research personnel will prepare for monitoring, auditing, or inspection visits by completing the following activities:

- 5.1.1 Schedule the visit, ensuring that all required personnel are available for the scheduled visit time.
  - 5.1.1.1 If the visit is an audit or inspection by federal regulatory authorities, ensure that UC San Diego OCP, the Office of Clinical Research, the Office of IRB Administration, and the Regulatory Affairs Department are aware of the visit timing.
    - 5.1.1.1.1 Follow procedure guidance provided by OCP to notify the Regulatory Affairs Department and OCP.
- 5.1.2 Request the monitor's, auditor's, or inspector's agenda, if not already provided in, for example, monitoring visit or audit notification letters.
- 5.1.3 Review all regulatory documentation and participant files to be monitored, audited, or inspected to ensure they are complete and available for review.
- 5.1.4 Review participant files for unanticipated problems, adverse events, and/or protocol deviations and confirm that all required reporting to sponsor and IRB has been completed.
- 5.1.5 Review data queries and resolve queries to the extent possible.
- 5.1.6 Review study test article (drug or device) records to verify that test article accountability concurs with the current stock on hand.
  - 5.1.6.1 Confirm that dispensing records for each study participant who received the test article are complete and accurate.
  - 5.1.6.2 Confirm that the test article remains securely stored in accordance with the protocol requirements.
  - 5.1.6.3 Ensure that any associated test article storage documentation (e.g., temperature logs) is available for inspection.
- 5.1.7 Ensure study participant records, including medical records, will be available for review at the time of the visit.
  - 5.1.7.1 Confirm all signed consent forms are on file, and that the correct informed consent form versions have been used.
  - 5.1.7.2 Compile all printed source documentation for completed study participant visits.
- 5.1.8 Prepare any items or questions for discussion with the monitor, auditor, or inspector.

5.2 The PI and/or designated research personnel will perform the following activities during the monitoring, auditing, or inspection visit:

5.2.1 Confirm the monitor, auditor, or inspector credentials.
5.2.2 Ensure the monitor signs the monitoring log for the study, as required.
5.2.3 Provide the monitor with relevant updates on outstanding issues from previous monitoring visit(s), if applicable.
5.2.4 Confirm the monitor has the documents required to conduct the visit.
5.2.5 During the visit, periodically check with the monitor to provide information or additional documents, as needed.
5.2.6 Address any outstanding issues noted by the monitor.

5.3 The PI and/or designated research personnel will perform the following activities following the monitoring, auditing, or inspection visit:
5.3.1 Address any outstanding issues by providing necessary documents or information to the sponsor and/or monitor.
5.3.2 Document resolution of issues in the study files (e.g., with notes to file, copies of faxes or emails sent to sponsor or monitor).
5.3.3 Review the monitor visit letter or audit report with the PI.
5.3.4 Ensure the monitor visit letter or audit report are filed with the study files.
5.3.5 Report relevant issues to the IRB as required.

6 MATERIALS

6.1 OCR-104 FDA Inspection Checklist

7 REFERENCES

7.1 21 CFR 312.50 – General responsibilities of sponsors
7.2 21 CFR 312.56 - Review of ongoing investigations
7.3 21 CFR 312.59 – Disposition of unused supply of investigational drug
7.4 21 CFR 312.60 – General responsibilities of investigators
7.5 21 CFR 312.62 – Investigator recordkeeping and record retention
7.6 21 CFR 312.64 – Investigator reports
7.7 21 CFR 312.66 – Assurance of IRB review
7.8 21 CFR 312.68 – Inspection of investigator's records and reports
7.9 21 CFR 812.140(a) - Investigator records
7.10 ICH E6 Good Clinical Practice
7.11 FDA Inspections of Clinical Investigators