### SOP No.: 801  Compliance and Monitoring Visits

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This SOP pertains to: All personnel involved in human subject research within the Memorial Healthcare System.

Responsibility for executing this SOP: Investigator Designated Research Personnel, and assigned monitor.

Approved By (Sign & Date):
- Senior Vice President & Chief Medical Officer, MHS
- Chief Medical Research Officer, OHR

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1 **PURPOSE**

This procedure describes the process to follow for initiating or otherwise participating in internal compliance and monitoring visits to assess adherence with applicable regulatory requirements and guidelines for conducting human subject research within the Memorial Healthcare System.

2 **GENERAL INSTRUCTIONS AND RESPONSIBILITES**

   a) The OHR is responsible for securing a trained and qualified Monitor/Auditor to conduct periodic internal audits of clinical or other research related programs, for reviewing the audit report with the Investigator and their designees, and for participating in the development of a corrective action plan (when applicable).

      i. The Monitor/Auditor may perform scheduled/unscheduled/for-cause/study closeout visits for any studies deemed necessary while being conducted at MHS.

      ii. Any member of staff may request that a compliance review be done on one of their studies should they require assistance/clarification/review of a particular circumstance.

      iii. Compliance reviews will be scheduled on an as-needed basis and done in order of priority and risk assessment.

   b) The Investigator and their study personnel are responsible for fully cooperating with all Monitoring and Compliance Visit requests from any authorized party.

   c) The Monitor/Auditor is responsible for preparing the site notification of the internal Monitoring and Compliance Visit, conducting it according to applicable standard operating procedures and regulatory requirements, reviewing his/her observations in a monitoring report, and reviewing and submitting that report to the Investigator and the OHR.
d) The Investigator is responsible for maintaining a record of Monitoring and Compliance Visit dates, for maintaining monitoring reports and corrective action plans, and for implementing corrective actions for any objectionable or otherwise non-compliant monitoring observations.

e) The OHR will maintain all internal monitoring reports in a confidential file; copies should not be included in the Study Master File.

3 SPECIFIC PROCEEDURES

3.1 Internal Monitoring and Compliance Visits

a) The OHR should ensure that Investigator initiated studies are periodically monitored.

b) When a Monitoring and Compliance visit is scheduled, the Investigator should ensure that all requested study personnel are available on that date to participate in the visit.

c) The Investigator may request the Monitoring and Compliance officer prepare and provide to him/her with a monitoring schedule and/or monitoring plan to ascertain the scope of the program that is to be monitored.

d) A meeting of all study personnel should be held prior to the Monitoring and Compliance visit to ensure that all necessary documentation is available for the visit and/or a confirmatory email sent to remind study personnel what will be required of them during the visit.

e) The Investigator should request a verbal summary of all relevant visit observations from the Monitor and review those findings at the completion of the visit.

f) The Investigator should request and receive a complete Monitoring and Compliance visit report (or post-visit letter) from the Monitor as soon as possible after the visit is completed (Reference SOP 504, Attachment A, Monitoring Visit Report).

g) The Monitoring and Compliance visit report will be reviewed by the Chief Medical Research Officer for the OHR prior to being distributed to the Investigator and relevant staff, if appropriate.

h) The Investigator will develop a plan for the implementation of corrective actions and process improvements arising from objectionable visit observations, with consultation from the OHR.

i) The Investigator and his research team will implement those corrective actions and improvements within a mutually agreed upon time period.

j) The Investigator will maintain a record of Internal Monitoring and Compliance Visit dates (Reference SOP 401, Attachment B Site Visit Log) and a copy of the procedure used for conducting those visits (Attachment E, Monitoring Plan) for viewing by the FDA, if requested.

k) The Investigator will maintain a file of Monitoring and Compliance visit reports and their follow-up corrective action plans in a clearly labeled “Confidential Quality Assurance” file.

l) Internal Monitoring and Compliance visit results (reports, corrective action plans) are NOT provided to the FDA, and the FDA personnel are NOT entitled to request them.

m) The Investigator will consult with the OHR concerning requests from outside auditors for internal Monitoring and Compliance visit reports and corrective action plans.
3.2 External Monitoring by the Sponsor

a) All efforts should be made to accommodate monitors representing the sponsor in their review of the clinical research records (space permitting) (Reference SOP 504, Routine Monitoring Visit).

b) The Principal Investigator, Research Specialist, Regulatory Coordinator and Pharmacy representative should be notified of the potential date of the visit, and their availability confirmed prior to booking the monitor visit for a specific date.

c) Upon arrival, the monitor will be accompanied to a designated area for chart review and provided with login access through the Administrative Assistant/IT Dept via EpicCare link.

d) Scheduled meetings with the relevant site research personnel will be accommodated as necessary to discuss the results of the monitoring visit.

e) The monitor is expected to provide the Principal Investigator with a complete report or letter documenting the findings from the visit and the expected date of resolution.

f) The Principal Investigator and/or designee is required to respond to the report/letter by the designated time noted in the letter documenting what findings have been resolved, and the corrective action plan (where applicable).

3.3 External Audits by Third Parties

a) If contacted by an external authority such as the FDA (Reference SOP 802, FDA Inspections), NIH, pharmaceutical sponsors etc. to schedule an audit, the investigator will inform the OHR and the IRB of record, and may request that an OHR representative be available. The investigator should also immediately notify all relevant parties, including but not limited to, Chief Medical Research Officer for OHR, Monitoring and Compliance Officer, Department Directors, Investigational Drug Services, Medical Records/Health Information Management personnel, Research Nurses, Regulatory team, etc.

b) If an external Auditor has direct access to any subject source data or source documents, he/she must be reminded to respect the confidentiality of that information, and not be permitted to make copies of any information that has subject identifiers on it.

c) If a written response to the Audit is requested, it should be prepared and submitted to the auditing authority as soon as possible after the audit.

d) The Investigator or designee will draft the audit response, circulate it for review and approval to the OHR, and other institutional officials (e.g. legal) to be determined, and retain a copy of the response in the appropriate file.

4 REFERENCES TO OTHER APPLICABLE SOPS

- 103 Investigator Responsibility and Delegation of Responsibility
- 106 Vendor Selection
- 401 Initiation Visit
- 504 Routine Monitoring Visit
Investigator Standard Operating Procedures

- 802 FDA Inspections

5. ATTACHMENTS
   A. CTN Best Practices Audit Checklist
   B. CTNBP Monitoring Visit Checklist
   C. CTNBP Study File Organization
   D. CTSU Audit Education Slides
   E. Monitoring Plan

6. APPLICABLE REGULATIONS AND GUIDELINES
   - General Responsibilities of Sponsors (21 CFR 312.50)
   - General Responsibilities of Investigators (21 CFR 312.60)
   - General Responsibilities of Sponsors (21 CFR 812.40)
   - General Responsibilities of Investigators (21 CFR 812.100)
   - Specific Responsibilities of Investigators (21 CFR 812.110)
   - The Principles of ICH GCP (ICH E6, Section 2.10)
   - Investigators’ Qualifications and Agreements (ICH E6, Section 5.1)
   - Quality Assurance and Quality Control (ICH E6, Section 5.1)
   - Record Access (ICH E6, Section 5.15)
   - Audit (ICH E6, Section 5.19)
   - Noncompliance (ICH E6, Section 5.20)