Clinical Research Enterprise (CRE)

Standard Operating Procedures

Sponsor Audits

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Version: 1.0

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Approval:

Approved By	Date
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Revision History:

Version	Effective Date	Description

Purpose

The purpose of this SOP is to describe the process for sponsor audits. Sponsor companies conduct periodic audits of clinical sites to identify and correct problems which might create difficulty in the event of an FDA audit.

References

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Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

This SOP is meant to be followed without deviation.

I. Notification

a. When the sponsor company sends notification of an audit, the Research Nurse Manager, Clinical Trial Manager, Clinical Trial Administrator PI, and Study Coordinator are notified immediately.

b. The date is scheduled with the auditor after the Research Nurse Manager, Clinical Trial Manager, Clinical Trial Administrator, and Study Coordinator have discussed the dates.

II. Preparation

a. The PI, Research Nurse Manager, Clinical Trial Manager, Clinical Trial Administrator, and Study Coordinator work together to prepare the source documents, CRFs, and regulatory files as requested by the auditor.

III. The Audit

a. The auditor is given space to review the documents. The Study Coordinator and

Clinical Trial Administrator are on hand to answer questions. The Research Nurse Manager, Clinical Trial Manager, Clinical Trial Administrator, and Study Coordinator will be present and available for questions the entire audit.

b. At the conclusion of the audit, the auditor will meet with the PI, Research Nurse Manager, Clinical Trial Administrator and the Study Coordinator. The final report will be sent to the IRB for review.

c. Issues that are identified or arise as a result of the audit will be addressed accordingly and corrective actions will be implemented as necessary.

Training