Clinical Research Enterprise (CRE)

Standard Operating Procedures

Internal Audit

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Purpose

The purpose of this SOP is to describe the policy for internal Audit (Quality Assurance) conducted on all clinical research studies.

References

- Appendix

Scope

This SOP applies to all members of the CRE staff.

Allowable Exceptions

I. Internal Audit

a. Each month, at least two research studies will be selected randomly to undergo an internal quality assurance review.

b. Subject charts and regulatory records will be selected at random for review.

II. Documentation

a. Subject charts and regulatory records will be reviewed and results will be recorded according to each QA checklist, respectively. The Clinical Trial Manager will review all regulatory records. The Research Nurse Manager or designee will review subject charts.

b. Each QA checklist will be signed and dated by the reviewer.

III. Reports and Issues

a. The formal report and the QA checklist will be filed within the CRE.

b. Any issues that need to be addressed will be done so in a timely manner.

Training