



**Procedure Name:** Quality Audits  
**Effective Date:** March 2, 2010  
**Revision:** 01  
**Initiating Department:** Office of Clinical Trials  
**Procedure Number:** QA-004, Rev 0  
**Application:** Office of Clinical Trials  
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**OBJECTIVE:**

Establish the requirement for and the frequency of internal quality audits of the University of North Texas Health Science Center (UNTHSC), Office of Clinical Trials (OCT) Quality System.

**SCOPE:**

The OCT Quality System has been established to ensure compliance with the regulatory requirements for conducting human clinical research under 21 CFR 312, CFR 812, ICH E-6 and/or other regulatory requirements that may be applicable to individual studies. Certain policies and procedures have been established to ensure regulatory compliance. This procedure details the internal quality audits to be conducted to assure that the requirements in key UNTHSC policies and procedures are followed.

**RESPONSIBILITY:**

Quality Assurance (QA) is responsible for conducting the quality audits described in this procedure.

Quality Assurance is responsible for writing an audit report detailing the results of the audit and providing the written audit report to the OCT senior management.

OCT senior management is responsible for reviewing the results of the quality audits and ensuring that significant deviations from requirements are addressed through the Corrective and Preventative Action (CAPA) procedure.

**PROCEDURES:**

QA will:

- 1.0 Schedule Quality Audit as needed at the frequency described in Table 1 for internal audits of the OCT Quality System.
- 2.0 Create an audit plan following the requirements established in Appendix 1.

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- 3.0 Conduct the audit as scheduled, documenting findings for later inclusion in the audit report. Note that no one audits his/her own work.
- 4.0 Write an audit report, following the requirements established in Appendix 2, review, sign and date.
- 5.0 Forward the signed audit report to the designated member of Senior Management.
- 6.0 If appropriate (i.e., findings of significant observations/deviations from established quality requirements), assure that a CAPA plan is created per the requirements of the CAPA Procedure. If a CAPA is not required, assure that any corrective actions are documented and filed with the audit report.

Senior Management will:

- 7.0 Review the audit plan and report assuring that the requirements established in the audit plan were met and the results are documented in the audit plan. Assure that any corrective and remedial actions were accomplished as described in their respective plans.

**REVISION HISTORY**

Rev	DCO	Description of Change	Approved by
1	08-004	Edited for clarity	MVWB

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**APPENDIX 1**  
**Audit Plan Requirements**

Audit plans are customized for each audit, but each audit will be governed by a written audit plan. Prescribed elements of an audit plan are detailed below:

1. Cover page – Subject of audit, location if applicable, audit contact if applicable, auditor and date(s)
2. Introduction – Describe the rationale for conducting the audit – e.g. the relevance or criticality of the auditee’s process/procedure to the OCT’s Quality System.
3. Audit Standards – Specify the established, documented standard(s) and/or requirement(s) that the auditee is being audited against. In most cases, this will be a CFR or ICH reference, protocol requirements, or a requirement from an internal policy/procedure. All audit observations must be tied to a formally documented requirement (see Audit Reports in Appendix 2).
4. Audit Plan and if applicable schedule. Outline the areas that will be reviewed during the audit. When conducting an external audit, assure that time is reserved at the beginning of the audit to review the audit plan with the auditee. Time also should be reserved at the end of the audit for a close-out to review initial audit observations with the auditee.

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**APPENDIX 2**  
**Requirements for Audit Reports**

Each audit will be documented in a written audit report. Audit reports may be customized for each audit, but certain prescribed elements should be present in all audit reports. These are detailed below.

1. Cover page – Subject of audit, location if applicable, audit contact if applicable, auditor and date(s) the audit was conducted
2. Introduction – Describe the rationale for conducting the audit – e.g. the relevance or criticality of the auditee’s process/procedure to the OCT’s Quality System. Note that this should be copied from the Audit Plan
3. Audit Standards – Copy this section from the Audit Plan. Assure that the standards against which the auditee was audited are specified. In most cases, this will be a CFR, ISO, or ICH reference or a requirement from an internal SOP or other quality document. All audit observations must be tied to a formally documented requirement. While comments regarding variances from “industry best practices” based on the auditor’s experience or opinion are useful and may be included in the audit report, they must be identified as such and are not to be presented as formal audit observations. Audit observations should resemble US FDA 483 reports i.e. specific, detailed observations of failure to meet established and published requirements.
4. Executive Summary: Prepare a brief summary of the audit findings (both positive and negative). Keep the summary brief – it is intended for management and is supported by the detailed observations discussed below.
5. Detailed Audit Observations – As discussed in “Standards”, observations are made of a failure to conform to a documented requirement. Thus every observation in an audit report should be linked to a specific quality requirement. In the audit report, observations may be categorized by system, classification (Critical/Major/Minor) or by other means as the discretion of the auditor.
6. Audit findings classified as “Critical”, “Major” or “Minor”. The definitions of these terms are:
  - Critical:** a divergence from an established requirement that has the potential to impact the health or safety of a clinical subject. Critical observations may also have the potential to independently cause significant regulatory issues such as a failure to obtain Informed Consent. Critical observations would almost certainly to be cited by a regulatory authority and could result in significant compliance action. Critical observations warrant immediate remediation – generally utilizing a CAPA plan
  - Major:** a divergence from an established requirement that indicates a significant failing of the quality system. It may have a potential negative impact on data

integrity BUT does not have the potential to directly impact the health/safety of a clinical subject. Major observations typically include failure to follow significant procedural requirements. Note that a pattern of Major findings suggests a failure of the quality system and a lack of control that could be result in significant negative impacts on a clinical study. Major observations require a formal remediation plan such as a CAPA.

**Minor:** a divergence from administrative requirements that, while requiring correction, is not likely to have significant regulatory impact. Minor observations may be remediated without a CAPA plan, although their correction should be documented.

7. Recommendations: Where applicable, detail any suggested corrective actions for the observations cited above. This also the section to discuss divergence from “best practices” or opportunities for improvement. Note that this section is optional and may not appear in every audit report.
8. References: Add any references that may have been cited in the body of the report. Also indicate (if known) if a CAPA or other remediation plan has been created.

## AUDIT PLAN

Internal quality audits in the UNTHSC's Office of Clinical Trials will be conducted to ensure compliance with the regulatory requirements for clinical research.

The frequency of audits shown in Table 1 refers to internal audits of the Office of Clinical Trials Quality System:

- Documentation change control- annually
- Document history file-annually
- CAPA plans- semi-annually
- Training files-annually

The frequency of audits shown in Table 2 refers to audits of individual clinical studies. These will be divided in two categories:

1. Protocol Specific Internal Audits: 10% of all new protocols for the current fiscal year will be audited 2 times a year.
2. Coordinator Specific Internal Audits: 5% of all participating subjects/records from coordinators will be audited once a year.

Criteria for auditing individual clinical studies:

- Protocol violations and deviations
- Consent process documentation
- IRB documentation and approvals
- Data integrity/verify CRFs against source

Each audit will be followed by the audit report.

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**TABLE 1 – INTERNAL AUDITS – TOPICS and FREQUENCY**

Topic	Frequency
Documentation Change Control	Annually
Document History File	Annually
CAPA Plans – conformance to plan	Semi-annually (twice a year)
Training files	Annually
Individual Clinical Studies	As directed by the OCT Management

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**TABLE 2- INTERNAL AUDIT CALENDAR**

Criteria	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
Protocol Violations and Deviations	PS						PS				CRCS	
Consent Process Documentation	PS						PS				CRCS	
IRB Documentation and Approvals	PS						PS				CRCS	
Data Integrity/Verify CRFs Against Source	PS						PS				CRCS	

- PS-Protocol Specific
- CRCS- Clinical Research Coordinator Specific
- The audit schedule is subject to change based on available resources and identified need
- No one audits his/her own work

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