Humber Health Partnership

Audit SOP

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This page details the version history and the main changes made for each new version.

Version Log		
Version number and date	**Author**	**Details of significant changes**
Version 1	**L Cox**	**New SOP**

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Please note for definitions of acronyms refer to Appendix 1 of Management of SOPs. Refer to Appendix 2 of Management of SOPs for the standards to which clinical trials that investigate the safety and/or efficacy of a medicinal product are conducted.

All the HUTH R&D GCP SOPs are available at:
https://www.hey.nhs.uk/research/researchers/gcp-sops-for-hey-sponsored-ctimps/

1 Purpose

This SOP describes the processes for the planning, conduct, reporting, and closure of audit activities conducted under the Sponsor responsibilities of Hull University Teaching Hospitals NHS Trust (HUTH) / Humber Health Partnership (HHP).
This includes:

- Internal audits
- Sponsor oversight audits of third parties
- Self-assessment audits
- Preparation for regulatory inspections
- This SOP ensures compliance with:
- MHRA regulatory requirements
- HRA expectations for sponsor oversight
- ICH GCP E6(R3) principles of risk-based quality management

2 Scope

This SOP applies to:

- All studies sponsored or co-sponsored by HUTH/HHP
- All research staff involved in sponsor oversight, QA, and study conduct
- All third parties undertaking trial-related duties

3 Definitions

- **Audit:** A systematic, independent, and documented process for obtaining evidence and evaluating it objectively.
- **CAPA:** Corrective and Preventive Action plan developed in response to audit findings.
- **For-cause audit:** An audit triggered by identified risks, issues, or potential non-compliance. **Self-assessment audit:** Structured self-review conducted by study teams.

4 Roles and Responsibilities

4.1 *Sponsor Oversight Group*

- Approves the audit programme and any updates
- Reviews risk-based decisions relating to audit frequency and type
- Determines need for for-cause audits

4.2 *R&D QA Team*

- Develops and maintains the audit programme
- Conducts or coordinates audits
- Reviews self-assessment outputs
- Ensures CAPA follow-up and closure

4.3 *Independent Auditors*

- Must be appropriately qualified and independent of the activity audited
- Conduct audits in accordance with this SOP and regulatory requirements
- Produce audit reports

4.4 *Study Teams*

- Participate in audits and self-assessments
- Implement CAPA actions within agreed timelines

5 Types of Audit

5.1 Regulatory Inspection (MHRA)

- Inspections conducted by the MHRA at a time determined by the regulator
  - Focus on:
  - Sponsor systems and processes
  - Application of GCP in CTIMPs

5.2 Sponsor Audit of Third Parties

Independent audits are conducted to ensure compliance with:

- Protocol
- SOPs
- GCP
- Applicable regulatory requirements

Examples of third parties:

- Clinical Trials Units (CTUs)
- Laboratories
- Pharmaceutical manufacturers
- Randomisation services

5.3 Internal QA Audits

Conducted independently from routine monitoring activities.

Types include:

- System audits (full system functionality)
- Process audits (specific processes)
- Investigator site audits
- Documentation audits
- For-cause audits
- Self-assessment audits

6. Audit Programme and Risk Based Approach

6.1 General Principles

The audit programme shall be reviewed annually

Audit frequency shall be risk-based, considering:

- Study complexity
- IMP risk profile
- Vendor criticality
- Previous findings

7. Audit Processes

The standard audit lifecycle is as follows:

1. Audit scheduling
2. Preparation
3. Audit conduct

4. Audit report
5. CAPA development
6. Audit closure

7.1 Audit Planning
- Audit scope, objectives, and timelines are defined
- Appropriate auditor is selected
- Relevant documentation is requested

7.2 Audit Conduct
Conducted in accordance with GCP and internal SOPs
Includes:
- Document review
- Interviews
- Process evaluation

7.3 Audit Reporting
- Findings categorised (e.g. critical, major, minor)
- Report issued to relevant stakeholders

7.4 CAPA Management
- CAPA plans developed for all findings
- Timelines agreed and tracked
- Effectiveness checks performed

7.5 Audit Closure
Closure occurs when:
- All CAPAs are implemented
- Effectiveness is demonstrated
- Audit certificate may be issued

8. Self-Assessment Audits
- Checklists issued to study teams
- Reviewed by QA team
- Actions followed until resolution
- Certification issued upon satisfactory completion

9. Governance and Oversight
All audit programmes must be approved by the Sponsor Oversight Group
Audit outcomes feed into:
- Sponsor oversight reporting
- Quality management systems
- Continuous improvement activities

10. Documentation and Record Keeping

Audit plans, reports, and CAPAs must be retained in accordance with:

- Sponsor TMF requirements
- Regulatory retention requirements

11. Escalation and For-Cause Audits

For-cause audits may be triggered by:

- Serious breaches
- Monitoring concerns
- Stakeholder concerns

12. Training

All staff involved in audits must:

- Be appropriately trained in GCP
- Be trained on this SOP

13. Implementation

Implementation must also include training and inclusive of quality-by-design, proportionality, risk-based decision-making, and data governance. Continuous improvement activities must be undertaken to evaluate the effectiveness of version control processes and ensure ongoing compliance with R3 expectations.

Appendix 1 – Audit Frequency Programme

Audit Type	Frequency	Approach
MHRA Inspection	As required by MHRA	External regulatory process
Sponsor audits (CTU)	Prior to trial + periodic (risk-based)	Based on study duration and risk
Sponsor audits (other vendors)	At least once or as required	Triggered based on risk/issues
Internal QA audits	At least annually	Determined by Sponsor Oversight Group
External Audits of Service Providers (e.g. Restore, Sealed Envelope)	At least annually	All new Service providers not already audited and then based on risks/issues.
Self-assessment audits	6–12 monthly or one-off	Based on study risk