Plymouth Research and Development

NHS University Hospitals Plymouth NHS Trust

Standard Operating Procedure

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Title:	Audit		
Approver		Document No:	QA3
Name:	Chris Rollinson	Version No:	7.0
Signature:		Effective Date:	Jan-2022
Date:	20-Jan-2022	Review Date:	Jan-2025

1. Purpose

To describe the procedure for auditing research studies which forms part of the Research and Development (R&D) Quality Management System (QMS) to verify compliance with the provisions of the study protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements.

2. Scope

This SOP relates to Trust sponsored studies and internal audit of hosted studies. The preparation of externally-led audit/ inspections are not described here, refer to SOP QA5.

3. Responsibilities

Research Governance Manager (RGM) or as delegated to the Assistant Clinical Trials Manager will organise and conduct audits on behalf of the Trust. RGM will act as the lead auditor.

Auditor is responsible for documenting observations and conclusions, assessing whether requirements are being met, and developing reports incorporating recommendations for change or adherence.

Auditors should ideally be independent to the research team to conduct audits appropriately and qualified by training and experience to conduct audits properly.

Principal Investigator (PI) or department head must facilitate an audit by the Sponsor, ensuing documents are made available and act on any issues identified.

4. Documents needed for this SOP

- CAPA Plan Template
- Audit Report Template

5. Related documents

- Annual Research Governance Programme
- SOP QA5 Externally-led Audit and Regulatory Inspection

6. Acronyms

CAPA: Corrective and Preventative Action

CI: Chief Investigator

GCP: Good Clinical Practice

PI: Principal Investigator

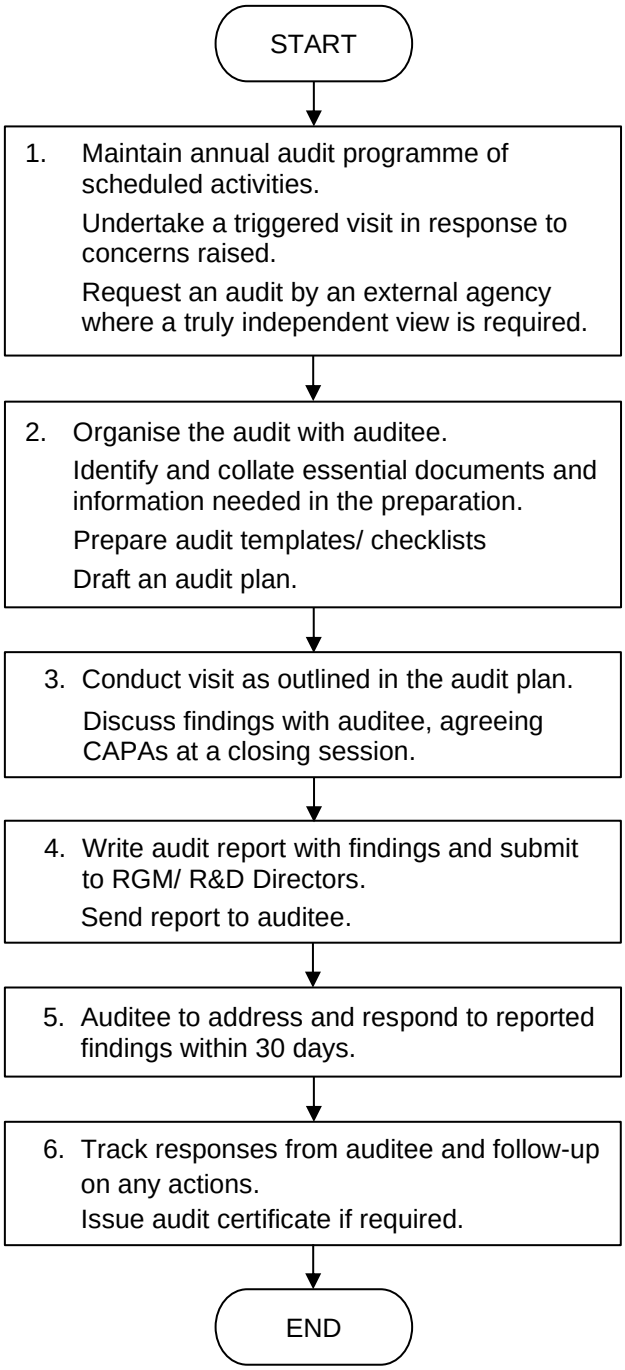
QMS: Quality Management System

R&D: Research and Development

RGM: Research Governance Manager

SOP: Standard Operating Procedure

7. Process map(s)/ flow chart(s)



8. Procedure

Step	Action	Responsibility
1	Maintain an annual audit programme (forms part of the Annual Research Governance Programme) to record scheduled activities over the period of a calendar year. Routine audits may be carried out where required but the Trust will typically only conduct triggered (for cause) audits. Elect a risk based approach ensuing higher risk studies, systems and processes are audited first, where required. Revisions to the audit schedule can be made if concerns are raised, study risk has changed or the study is selected for a regulatory inspection. Undertake a triggered visit in response to concerns raised by R&D personnel, internal or external individuals, departments or agencies at any stage during a study process until data storage ceases. Request, *via* R&D Directors, the Trust to commission an audit by an external agency where an independent view is required.	RGM and Assistant Clinical Trials Manager.
2	Organise the practicalities of the audit (i.e. date, documents to be inspected and required attendees) and communicate them to the auditee with at least one week notice. <u>Note:</u> The Trust reserves the right to perform unannounced audits if deemed appropriate. Identify and collate any essential documentation and information needed in the preparation for the audit in advance from the auditee. Prepare audit templates/ checklists as an aide memoire as appropriate. Draft an audit plan detailing the below points: • Scope and objectives • Timelines • Place and date of audit • Requirements to be audited against • Opening meeting auditees • Groups and areas to be audited (i.e. informed consent procedure, source data and CRFs, IMP records, review of essential documents, audit and monitoring, use of computerised systems, and facilities)	RGM and Assistant Clinical Trials Manager.

Step	Action	Responsibility
	• List staff to be interviewed, including approximate duration • List documents to be made available • Closing meeting • Who will be in receipt of the final report and when. Remain flexible in adjusting the plan where considered appropriate. Send the plan to the auditee in advance of the audit.	
3	Discuss the scope of the audit at an opening meeting. Conduct audit where information is assessed and recorded. Audits can take up to three days depending on the nature of the audit. Applied techniques during the practical audit may include: • Interviewing • Reading documents and reviewing manuals • Studying records and reading reports • Analysing data • Observing activity and documenting observations • Examining conditions • Confirming interview evidence Findings identified during the audit shall be discussed with the auditee(s), agreeing Corrective and Preventative Actions (CAPA) at a closing session.	RGM and Assistant Clinical Trials Manager.
4	Develop a summary using the audit report template and make preliminary recommendations to assist with research conduct, list gaps in compliance with supporting evidence, cross-reference with regulatory requirements and guidance. Grade findings listed using the criteria in Appendix 1. Submit report to RGM and/ or R&D Directors for review and approval. Send report to auditees following approval.	RGM and Assistant Clinical Trials Manager.
5	Address and respond to reported findings within one calendar month unless otherwise agreed.	Auditees
6	Track responses from auditees and follow-up on any actions as appropriate. Issue an audit certificate if required on completion of all findings.	RGM and Assistant Clinical Trials Manager.

9. Changes from last revision

SOP template change.

Appendix 1: Grading criteria and definitions for audit findings

Grade	Definition
Critical	a) Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that: i. the safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or ii. the clinical trial data are unreliable and/or iii. there are a number of Major non-compliances (defined in (d) and (e)) across areas of responsibility, indicating a systematic quality assurance failure, and/or b) Where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances (defined in (d) and (e)) c) Where provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the Regulations
Major	d) A non-critical finding where evidence exists that a significant and unjustified departure from applicable legislative requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or e) Where evidence exists that a number of departures from applicable legislative requirements and/or established GCP guidelines have occurred within a single area of responsibility, indicating a systematic quality assurance failure
Other	f) Where evidence exists that a departure from applicable legislative requirements and/or established GCP guidelines and/or procedural requirement and/or good clinical practice has occurred, but it is neither Critical nor Major.