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SOP 003 Research & Development Annual Audit Schedule

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	R&D, Audit, Audit Schedule, Audit Plan
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To be reviewed before: This document remains current after this date but will be under review	27th July 2026 (3 years, unless legislation or process changes)
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Version No:	2
Description of changes:	Addition of escalation process. Aligned definitions with SOP 210. Added requirements for recording non-compliances. Clarification to Process Based Audit Clarification re audit conduct. Clarification of "audit plan" and "audit schedule" Addition of NCTU audit plan information

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

1. Contents

2. Definitions of Terms Used / Glossary

CAPA	Corrective Action Preventive Action
GCP	Good Clinical Practice
ISF	Investigator Site File
JRGC	Joint Research Governance Committee
NNUH	Norfolk and Norwich University Hospital
QMS	Quality Management System
R&D	Research and Development
SOP	Standard Operating Procedure
TMF	Trial Master File
UEA	University of East Anglia

3. Objectives

This SOP is intended to assess compliance with Good Clinical Practice (GCP) ICH E6 GCP, SI 2004/1031, demonstrating a robust Quality Management System (QMS).

4. Scope

This SOP describes the Research Governance Annual Audit Schedule for joint research activities involving the UEA and NNUH.

5. Purpose

Each year the scope of the annual audit schedule will be assessed by the NNUH Research Governance Coordinator and the Research Services Manager.

Audits will be scheduled, conducted, reported and followed up as defined by the schedule.

6. Rules

The annual audit review will take place in February +/- two months

7. Procedure NNUH

The R&D team at NNUH will conduct the audit schedule assessment and will advise the Joint Research Governance Committee (JRGC) of the audit schedule for the year. The audit schedule will run from April to March each year.

Any audit outstanding from the previous year will be assessed to see if the audit is still of higher priority before being carried over to the next years audit schedule. If, after the assessment, the audit priority is downgraded then it will not be carried forward to the next year.

Once agreed, the plan will be actioned for the year to provide a proposed schedule for all audits and inspections. See **SOP 003 Appendix 1 Audit Plan Template.**

The audit plan is not restrictive and may be adapted at any time to meet GCP regulatory requirements or if there are any concerns or serious issues which may require a for cause audit and Corrective Action Preventive Action (CAPA) investigation.

8. Scope of Audit schedule

Annual Facility Inspection Programme

- Facilities to be inspected will be determined during the annual assessment of facilities used in the conduct of research studies
- R&D will provide 30 days' notice of the audit and will issue an audit plan to the facility management which will cover the scope of the audit.
- The audit will be conducted according to the plan and will follow a checklist for guidance to the auditors.

Study Specific Audit
• Risk based approach for NNUH sponsored regulated studies is in place • R&D will perform an audit of approximately 10% of the regulated NNUH sponsored studies • Risk of Low / Medium / High will be applied to each study at the point of making decision about Sponsorship. • Focus of the audit will be for the highest risk studies (in particular CTIMP / Device studies)

Process Based Audits
• During planning, an assessment will be made whether any research processes / procedures will be audited.

For Cause Audit
• Additional audits may be required on an ad-hoc basis • These may be due to a major non-compliance being identified, a serious breach, study misconduct or triggered by an external sponsor or regulatory audit • For such audits a CAPA will be initiated to determine the root cause, corrective and preventative action

9. Audit Conduct and Reporting

Advance notification of all audits will be advised and the schedule agreed.

Audit plans will be issued prior to the agreed scheduled date of the audit, unless it is a for cause audit which may need to be carried out immediately with no notice.

All audits will include:
• An opening meeting to carry out introductions and discuss the scope • Audit activities to cover scope of a particular audit. • A close out meeting to discuss the findings and possible upgrading of findings • A date for issue of the audit report. This will be agreed at the close out meeting

A Summary of the audit will be reported to JRGC at audit completion.

Once all responses to audit findings are received and accepted by R&D an audit certificate will be issued.

10. Classification of audit findings

The grading of all findings will be discussed at the closing meeting and before the audit report is issued.

Category	Implication	Action
Critical / serious	• is a significant and unjustified departure from the protocol, SOP or GCP • which **is** likely to effect to a **significant** degree the safety or physical or mental integrity of the trial participant or the scientific value of the trial • Serious Breach assessment and reporting is required as described in section 5 & 6	• Immediate cessation of all study activities until findings have been resolved. • CAPA investigation will be required.
Major	• is a significant and unjustified departure from the protocol, SOP or GCP • that may not have developed into a **critical** issue but may have the **potential** to do so unless addressed • Where there are a number of instances of minor non-compliance within a single area of responsibility, this indicates **a systemic quality assurance failure** and so should be collectively treated as major non-compliance	• A corrective action, preventive action investigation (CAPA) should be undertaken and reported by the CI/PI • Findings are required to be investigated and resolved within 2-3 months. • A follow-up audit may be required
Minor / other findings	• Retrospective departures or deviations from the protocol which will not have an effect on the safety of the trial subjects or the outcome of the study • which is neither critical or major and so **not** likely to effect to a significant degree the safety or physical or mental integrity of the trial participant or the scientific value of the trial	• Findings are required to be resolved by the next audit (12 months)

Any noncompliance identified during Audit needs to be recorded and reported in accordance with SOP 210 Managing protocol and Regulatory non–compliance including serious breaches.

Upgrading of Findings

⬇	**Minor / Other** • If there are numerous minor / other findings which can be attributed to a failure following SOPs or protocol deviations which do not demonstrate a robust quality management system or deviate from regulatory requirements then multiple findings may be grouped together and upgraded to a major finding
⬇	**Major** • If actions are not resolved in the timeframe stated or by the next audit then they may be upgraded to a critical finding
⬇	**Critical** • If there is a major breach of GCP these will be assigned as a critical finding • This will result in cessation of all study activities followed by a CAPA investigation

Escalation

It is the responsibility of the Investigator to engage with the auditor and respond to any actions and non-compliances arising from audit in a timely and proactive manner.

If any actions or non-compliance are not resolved satisfactorily or in a timely manner the Research Services Manager and Research Governance Coordinator will be informed of the concerns and a meeting between the Investigator, Monitor and Research Governance Co-ordinator will be organised with the aim of addressing any issues.

If actions are still not resolved the Research Governance Coordinator will escalate these to the Joint Research Governance Committee for action.

11. Audit Reports and Certificates

Audit Reports
• Audit reports are confidential documents and shall not be made public, therefore they must not be added to the TMF / ISF • They must not be shared with external sponsors • Audit report findings will be made available for discussion at JRGC meetings

Audit Certificates
• The audit certificate provides evidence that an audit has taken place • The certificate shall be added to the TMF / ISF and retained in R&D records on the S:Drive in the audit folder, unless it is study specific, when it will be saved in the Research Project folder. • See **SOP 003 Appendix 2 Audit Certificate Template**

12. Procedure UEA

The audit plan for UEA sponsored studies will be described in Faculty working practices.

13. Procedure NCTU

The audit plan for NCTU studies is described in NCTU_Q_WPD_5 Audit Plan.

14. References and Related Documents

References
ICH GCP E6 / SI 2004/1041

SOP No.	SOP Title
SOP 001	Production, Review, Approval and Control of SOPs Related to Research Activities
SOP 003 App 1	Audit Plan Template
SOP 003 App 2	Audit Certificate Template

15. Approval

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Date	28 July 2023 | 2:26 BST

16. Reason for new version and Training Implication

This SOP replaces the previous version number V1.0

Changes made	
Reason	• New layout • Revision in procedure
Training Implication	**Yes**
Actions required	• Additional training may be required

Research and Development Audit Schedule 20xx / 20xx

Study Audits

R&D / IRAS Number	Investigator	Title	Audit Scope	Date of audit	Notification letter date	Audit Status

Other Audits

Scope	Date of audit	Notification letter date	Audit Status

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Certificate of Audit Completion

Audit commenced: xx/xx/xxxx

to certify that the audit has been completed for:

[Audit/Study Name]

Completed on: XX/XX/XXXX

Signature of Research & Development Auditor