GCP Auditing of Research Studies

NJRO-QA-SOP-001

Contents

1. Background/Introduction

The UK Policy Framework for Health & Social Care Research 2017 requires all organisations ensure that legislation applicable to research is followed for sponsored and hosted research projects where care is provided to research participants. The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH FT) uses the annual audit cycle of research projects to help meet this responsibility. The purpose of a Good Clinical Practice (GCP) research audit is to assess compliance with:

- UK policy framework for health and social care research (November 2017)
- Medicines for Human Use (Clinical Trials) Regulation 2004 (SI:1031) incorporating amendments on GCP (SI:1928)
- Medicines Act 1968
- ICH (International Conference on Harmonisation) Good Clinical Practice E6
- ICH General Considerations for clinical studies E8
- HRA Guidance
- Good Practice Quality Guidelines (GxP)
- Newcastle Joint Research Office (NJRO) SOPs
- Study protocol
- Data Protection Act 2018
- General Data Protection Regulation 2016/679
- Joint Protocol Between Newcastle University and Newcastle upon Tyne Hospitals NHS Trust
- NuTH FT Standard Operating Procedures (SOPs), policies and procedures
- Research and Development/ Research Governance Policy
- Research Passport Policy
- Research Sponsorship Policy
- Research Audit Policy

Audit helps to:

- Ensure participant and staff safety
- Assist research teams with meeting their responsibilities under the necessary frameworks and regulations
- Identify trends for further education
- Prepare researchers for audit/inspection by external organisations

2. Purpose

The purpose of this SOP is to describe the process for NuTH FT Research and Development (R&D) GCP auditing of research studies which are sponsored or hosted by NuTH FT.

3. Scope of Document

The SOP covers the selection of studies for audit, conduct and reporting of audits and the process by which corrective and preventative actions are managed.

4. Definitions

AQAM	Assistant Quality Assurance Manager
ATIMP	Advanced Therapy Investigational Medicinal Product
CI	Chief Investigator
CTIMP	Clinical Trials Investigational Medicinal Product
DQAM	Deputy Quality Assurance Manager
GCP	Good Clinical Practice
ISF	Investigator Site File
LPMS	Local Portfolio Management System
NCTU	Newcastle Clinical Trials Unit
NJRO	Newcastle Joint Research Office
PI	Principal Investigator
QAM	Quality Assurance Manager
QMIF	NJRO Quality Management Improvement Forum
RCT	Regulatory Compliance Team
RGT	Research Governance Team
RCM	Regulatory Compliance Manager
RM&GM	Research Management & Governance Manager
TMF	Trial Master File

5. Roles & Responsibilities

This SOP applies to all NuTH FT staff and all personnel working on behalf of NuTH FT involved in research. It is also applicable to all members of the R&D team within the Newcastle Joint Research Office (NJRO) with responsibility for conducting audits.

If a study team receives notification that an external audit or inspection is to take place for a NuTH FT hosted study, they should inform R&D via email to nuth.genericqueries@nhs.net. Any external audit findings and reports should also be forwarded to NJRO Regulatory Compliance Team via the Sponsor Management Inbox (tnu-tr.sponsormanagement@nhs.net) to allow identification of trends, risks and training needs.

It is the responsibility of the GCP Quality Assurance Manager (QAM) or their delegate to draft the annual audit plan.

It is the responsibility of the QAM or their delegate to inform the Deputy Medical Director – Research and Innovation, the Clinical Director of R&D and Head of NJRO if the audit schedule is delayed or there are significant deviations from the annual plan.

It is the responsibility of the Regulatory Compliance Manager (RCM) or Research Management & Governance Manager (RM&GM) to inform the NuTH FT GCP QA team of any amendments to trials that could impact on the audit frequency or type.

6. Procedures

6.1 Selection of Studies

- To generate the annual audit plan, using the Local Portfolio Management System (LPMS), reports will be run to identify those projects which:
    - Received NuTH FT R&D approval in the previous appropriate twelve-month period
    - Those projects that closed or completed within the previous two years
    - Those projects which have been running for > 2 years
    - CTIMP and ATIMP projects
    - Intelligence is also gathered from the Regulatory Compliance, Research Governance, Information teams and Research Matron regarding areas of concern

- On the basis of risk, priority will be given to the following NuTH FT sponsored trials:
    - All Clinical Trials of an Investigational Medicinal Product (CTIMP)
    - All Advanced Therapy Investigational Medicinal Product (ATIMP) trials
    - All randomised surgical trials
    - All medical device trials of non-CE marked devices or CE marked devices that are being used outside the intended use(s) covered by the CE marking

  The risk assessment process is described in NJRO-QA-SOP-005 Risk Assessment of Studies for Inclusion in the Annual Audit Plan

However, the annual audit plan will reflect the breadth of the research portfolio across NuTH FT and Newcastle University therefore it will also include a selection of:

- Commercially sponsored, high risk CTIMP/ATIMP trials
- Trials closed and in follow-up
- Trials completed
- Self-assessment audits
- Vendor audits (internal and external)
- Sponsorship and hosting activities
- Low risk studies e.g., Registry, Questionnaire and PhD projects

Audits undertaken by Clinical Trials Units (CTUs), Trust Tissue and University Biobanks are taken into consideration in facilitating coverage of the research landscape.

The following studies will be excluded from the audit plan:

- Studies which received local approval < 3 months prior to date of LPMS report generated as basis for the Audit Plan and which are yet to recruit (with the exception of NuTH FT sponsored automatically eligible studies or 'For Cause' audits as raised by Compliance, Governance, Informatics or Delivery teams)
- Studies that have been audited/inspected within the previous 12 months unless explicitly required as part of a previously agreed/identified action plan.
- Studies where NuTH FT is a Patient Identification Centre (PIC) only

- The number of studies audited will be a representative sample of the studies approved by NuTH FT R&D over the previous year. In addition to the identified risk-based eligible studies, further studies/ systems or vendors may be selected for audit as deemed necessary by the QAM to ensure representation of all clinical specialities or research teams and platforms.

6.2 Audit Plan

The QAM/delegate will produce a draft Annual Audit Plan listing those studies selected with corresponding planned audit month. The plan will also include the reason for audit e.g. Long running, high risk; Audit type e.g. process, system and whether the audit will be by self-assessment or attended by the QAM/DQAM.

The plan will be submitted to the Deputy Medical Director – Research and Innovation Clinical Director of R&D and the Head of the NJRO for their review. Following confirmation of approval via e-mail from at least two of the three senior staff listed, the Annual Audit Plan will be finalised, and appropriately abbreviated/ full versions issued to the Directors, Head of NJRO, RCT/RM&GT managers and NCTU QAM.

If any significant changes need to be made to or there are significant deviations from the Annual Audit Plan following finalisation, a draft updated plan will be submitted to the Deputy Medical Director –Research and Innovation, Clinical Director of R&D and Head

of NJRO with reason for change(s) explained. The updated Annual Audit Plan (carrying a new date and version number) will then be issued.

The QAM reserves the right to make changes to the plan for minor reasons i.e., to defer an audit date or change the type of audit from self-assessment to visited at the request of the study team without requiring authorisation or re-issue of the audit plan.

6.2.1 Types of Audit

Systems Audits

System audits can be defined as independent examinations of the functionality of complete systems e.g.

Pharmacovigilance
Data Management
Consent
Sponsorship (NJRO and Commercial/External)
Hosting
Governance
Internal Departmental

(For further detail of areas covered within each system please see NJRO-QA-SOP-001 Appendix 1)

System Tests:

System tests e.g., out of hours cover, unblinding and recall processes are incorporated into an Investigator Site File, Trial Specific or System audit of Management systems.

Process Audits

Process audits are defined as independent examinations of specific processes within the systems e.g.

Approvals
Recruitment
Delegation
End of Study and Follow-Up
Publication
Archiving and Facilities
Clinical Trial Reporting

Training Records

Vendor Audits

Vendor Audits are the assessment of internal and external service providers e.g., laboratories and archiving facilities

Trial Specific Audits

Trial Specific Audits are the assessment of all activities across a single trial

Investigator Site Audits

Investigator Site Audits are a trial specific assessment of activities in the clinical setting including review of participant notes as paper copies or within the electronic health record

Multicentre Sites:

Where the study sponsored by NuTH FT is also open at other NHS Trusts, it may be necessary to audit other sites as part of the annual audit plan, or if NuTH FT are notified of any significant concerns (for example, via monitoring, directly by the study team or by host R&D).

Documentation Audits

Documentation audits are a review of trial specific or system documentation e.g.

Standard Operating Procedures
Trial Master Files
Computer system validation protocols
Interim reports
Clinical trial reports

"For Cause" and Requested Audits

It may be necessary to also conduct specific triggered or "for cause" audits where issues have been identified by other means e.g., routine monitoring, concerns voiced by the study team or a report of a serious breach.

Audits may also be requested by a study team, Research Matrons or Regulatory Compliance Team to provide support and advice following the introduction of a new study design a new system or a new Vendor.

If identified at the time of drafting the annual audit plan these will be incorporated into the schedule, otherwise will be conducted in addition to the minimum target.

On receipt of notification by the MHRA of a site inspection or Sponsor audit, the NJRO QA team will review the current status of the study and reserve the right to audit in advance of the inspection date.

6.2.2 Changes to the Annual Audit Plan

The Head of NJRO will be informed if the audit schedule is delayed by one month.

The Deputy Medical Director – Research and Innovation and the Clinical Director of R&D will be informed if the audit schedule is delayed by three months, supported by a formal report describing the reasons for the delays.

The QAM will be informed if there are any changes to studies i.e., recruitment, trial design or risk assessment that could impact on the audit frequency or type for a particular project.

6.3 Conduct and reporting of Audits

6.3.1 Auditing staff

For the majority of audits, a maximum of two members of the NJRO QA Team will be assigned and one will be identified as the lead auditor.

More than two auditors may be assigned to conduct a systems audit depending on the system under audit.

On occasion the NJRO QA auditors may be accompanied by another member of staff as part of a training/information gathering exercise.

If the study is classified as priority i.e. high risk or the audit is for cause, the audit must be led/conducted by someone who has received formal audit training.

For other audits, the audit may be led/conducted by a member of NuTH FT /Newcastle University staff who has received appropriate in-house training.

6.3.2. Audit Notification

The relevant study team must be informed by a member of the GCP QA team of the intention to audit the study.

The Principal Investigator will be contacted via e-mail copying in the following staff as appropriate:

Chief Investigator
Lead research nurse
Trial co-ordinator
Research team lead

Relevant delivery lead
Responsible pharmacy personnel
Trial manager
NCTU QAM
Approximately 6 weeks' notice will be given in order to allow time to prepare for a visited or self-assessment audit, although this notice period may be reduced in the case of “for cause” audits. If the proposed date is not suitable, another date may be negotiated between NJRO QA and the study team.

The audit notification email will include:

The proposed audit date
Information regarding the audit process
The scope of the audit
A copy of the audit tool that will be utilised during the audit (for self-assessment audits only)
A target completion date for self-assessment audit to be returned (when required)

Study teams and trial managers are responsible for providing a suitable location for the audit (preferably a private office), and all of the required documentation as detailed in the audit notification email.

6.3.3 Audit Preparation

Prior to the audit, the audit team will perform a review of the documentation held within the NJRO and the document repository in the LPMS to familiarise themselves with the study and to identify any missing documentation.

If any issues are highlighted from this review these should be discussed with the research team during the audit.

The lead auditor is responsible for:
Creating the audit agenda
Ensuring all relevant parties are informed of the intent to audit
Ensuring preparation of the necessary documentation in order to complete the audit e.g. audit tool, Site Attendance Log, Document Request Log and a list of questions.

6.4 Audit Conduct

Face to face meetings at the start and end of the audit can be held via teleconferencing if required.
A summary of the audit findings will be provided via email in addition to or in lieu of a close out meeting
Questions arising during the audit can be submitted via telephone or e-mail if preferred.
Consideration will be given to remote auditing where access to systems and documentation can be facilitated

6.4.1. Visited Audits

The audit process should include a meeting between the auditor(s) and Principal Investigator (PI) or Trial Manager and Chief Investigator (CI) (for other activities).

NOTE: for Investigator Site File (ISF), if the PI is not available this may in exceptional circumstances be delegated to a sub-investigator. If the PI is unavailable the review of the ISF will take place and any questions will be directed to the PI via e-mail

The meeting should preferably be prior to the start of the audit but may be at another point in the process depending on the availability of key staff.

During this meeting the auditor will explain the scope and objectives of the audit and how these will be achieved. This will include the progress of the trial and identify any areas of concern.

During the audit, the auditor(s) will be checking to ensure that the study is being conducted in accordance with ICH-GCP, ICH General Considerations for Clinical Studies, the UK Policy Framework on Health and Social Care Research and the relevant Legislation.

Initial findings will be recorded on the audit tool and/ or in the audit notes.

Once the review is complete, a closing discussion will be conducted with the study team to discuss the initial findings and any gaps or queries identified during the audit. This will be in the form of a summary email if preferred by study team due to clinical commitments.

An audit certificate will be issued with the summary email to signify that the audit has taken place.

An audit report will be sent to the team with a date for return of the completed action plan.

The completed action plan will be returned to the GCP QAM/DQAM for review.

Once all actions to findings are agreed by the QA team, and the audit reports signed by all parties, the audit will be considered closed.

6.4.2. Self-Assessment Audits

The self-assessment audit tool will be supplied to the study team with the audit notification e-mail. The tool will identify which sections of the audit tool need to be completed i.e., those sections highlighted in grey are not required, only those in white.

The study team will conduct the audit at their convenience within the allocated timeframe and submit the completed audit tool to the QAM/DQAM for review.

An audit certificate will be issued with the summary email to signify that the audit has taken place.

The QAM/DQAM will review the audit tool and compile a report of findings which will be sent to the team with a timeframe for return of an action plan.

The completed action plan will be returned to the GCP QAM/DQAM for review.

Once all actions to findings are agreed by the QA team, and the audit reports signed by all parties, the audit will be considered closed.

Following review of the completed self-assessment tool a visited audit by the GCP QAM or R&D staff will be arranged if necessary.

6.4.3 Supplementary Audits

Audits within CTUs, Trust Tissue and University Biobanks will be conducted by the QAM of each respective area, according to their schedule and SOPs.

Copies of the completed audit reports will be sent to the GCP QAM to support GCP compliance.

If deemed appropriate an audit by the GCP QAM or R&D staff will be arranged.

6.4.4 Audits of Sponsorship, Hosting Activities and NJRO Office Procedures

The Regulatory Compliance or Hosting Team will be notified by e-mail of the intention to audit within a specified month. The e-mail will explain the scope and objectives of the audit and how these will be achieved

The audit team will conduct the audit at their convenience within the stated timeframe

There will not be a formal opening or closing meeting for these audit types

Initial findings will be recorded on the audit tool and/ or in the audit notes

An audit certificate will be issued with the summary email to signify that the audit has taken place.

For audits of Sponsorship and Hosting activities an audit report will be sent to the team. For audits of NJRO Office procedures the report will be sent to the Head of NJRO. The report will contain a date for return of the completed action plan

The completed action plan will be returned to the GCP QAM/DQAM for review.

Once all actions to findings are agreed by the QA team, and the audit reports signed by all parties, the audit will be considered closed.

6.4.5 Audit Findings – Categories of Non-Compliance

Audit findings will be graded (cited as seen at the time of the audit) utilising the criteria listed below (MHRA GCP Compliance Findings October 2018):

6.4.5.1 Critical:

Where evidence exists that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that:

i) the rights, 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 numbers of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure, and/or

Where inappropriate, insufficient, or untimely corrective action has taken place regarding previously reported Major non-compliances (defined below)

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

Immediate corrective action is required for findings categorised as 'critical'. However, it is appreciated that where a critical finding is assigned due to deficiencies within a system e.g., sample tracking, quality management, safety reporting, remedial actions will take time to achieve. In those circumstances evidence of a CAPA plan would be required as soon as practicable.

Examples of critical non-compliances include:

- Major deviation from the approved protocol
- Inclusion in a project of patients/subjects who have not given documented informed consent in line with NHS Research Ethics approval or do not meet the exclusion/inclusion criteria for the research
- Serious deficiencies in documentation held in the investigator file such that compliance with audit standards could not be verified
- Refusal of the lead investigator to cooperate with the audit process.

6.4.5.2 Major:

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

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.

Examples of Major non-compliances include:

- missing study documentation
- minor extensions/amendments to protocol that do not have NHS Research Ethics approval.

These problems/omissions will be followed up by the audit team and wherever possible should be resolved by the investigator within three months.

If a satisfactory conclusion cannot be reached the findings of the audit will be upgraded to 'critical'.

6.4.5.3 Other/Minor:

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.

Other/Minor non-compliances need to be addressed within twelve months

6.4.5.4 Satisfactory:

Complies with standards

6.4.5.5 Recommendations:

Where there is no specific standard but considered to be good practice

6.4.5.6 Observation

Where a process or documentation requires clarity but does not impact on GCP

Note: Where the study team are able to provide evidence to mitigate/negate the finding this will be acknowledged in the audit report but will not change the grading "as found".

6.5. Audit Reporting and Ratification of Critical Findings

6.5.1. Compilation and Issue of Audit Report

The data compiled during the audit will be processed and the audit report prepared by the lead auditor within 6 to 8 weeks of the audit. Where there could be a delay to this timeframe the lead auditor will make this clear at the feedback meeting.

This report will outline the audit findings and grading of non-compliance as they relate to regulatory requirements where applicable, and a list of actions to be completed by the study team

Where Critical findings are identified they will be taken to the NJRO Quality Management Improvement Forum for ratification prior to issuing of the report.

For ISF audits, the audit report will be sent to the PI at NuTH FT via email for review and response; the lead research nurse, trial co-ordinator, research team lead, delivery lead and relevant pharmacy personnel (if applicable) will be copied into this email.

For TMF audits, the audit report will be sent to the CI with the trial manager and as appropriate the CTU QAM copied into the email.

For process audits involving both the ISF and TMF a joint report will be sent to all staff listed above.

6.5.2. Follow Up Actions

It is the responsibility of the CI/PI to ensure action is taken to correct any identified gaps in regulatory compliance.

Any critical, major or other/minor audit findings must be addressed in the time frame specified above.

Where appropriate any major or critical audit findings must be addressed by production of a Corrective and Preventative Action plan (CAPA). The requirement for this will be specified in the verbal feedback at the close-out meeting and annotated in the audit report.

The CAPA plan must include:
Details of the non-compliance
Corrective action taken immediately
Preventative actions, which will be taken to avoid further instances of non-compliance.

The lead auditor, in conjunction with the CI/PI, will agree the actions and timescales for completion.

If any urgent corrective action is required, the auditor or delegate will correspond with the study team during the follow up process to ensure any issues are being satisfactorily addressed.

The CI/PI should return the completed and signed audit report to the NJRO QA team within 28 calendar days of report issue, although if a reasonable request for more time is submitted this may be agreed with the QAM or delegate.

The QAM and DQAM, will review and sign off all returned and completed audit reports. Reports generated by the QAM and DQAM as part of their visited audits will reviewed by each other. This practice provides a review of decisions made by the QA team to ensure consistency. In the absence of the QAM or DQAM the AQAM (CRF), Regulatory Compliance Manager (RCM) or Research Management & Governance Manager (RM&GM), or delegated deputies will review audit reports prior to issue.

Any findings found not to have been addressed satisfactorily will be re-submitted to the CI/PI and followed up until fully addressed. The study may undergo re-audit if the QAM/AQAM (or RCM/RM&GM) decides it is necessary.

Once all Critical and Major findings are addressed, actions identified for Other/Minor observations and the audit report signed by all parties the audit will be considered closed. It is recommended that only the audit certificate, issued at the time the audit is carried out is stored in the ISF/TMF.

If any advice or assistance is required by the investigator in order to resolve any identified actions, the NJRO QA/R&D team will be happy to assist.

Evidence of continued non-compliance or failure to address audit findings will be escalated to the Deputy Medical Director – Research and Innovation and Clinical Director of R&D for resolution.

6.6 Further Reporting of Audit Findings

6.6.1 Urgent Escalation

If the audit process identifies an actual or potential serious breach this must be followed up immediately by the lead auditor (see NJRO-REG-SOP-013: “Notification of Serious Breaches of GCP or the Trial Protocol”).

In addition, the finding must be assessed by the RCM/RM&GM (or QAM) to determine whether or not it constitutes a serious incident (SI). This is defined as an event or incident that resulted in unexpected or avoidable death, or serious harm, to one or more patients, staff, visitors, or members of the public.

If the event has been classed as (or is suspected to be) a SI, the RCM/RGM (or QAM) will inform the Director of Quality and Effectiveness, via the Clinical Governance and Risk Department (CGARD), as soon as possible by telephone. Please refer to NuTH FT “Serious Incidents Reporting and Management Policy” for further information including categories of SIs.

Any serious breaches of GCP or the trial protocol and/or any findings which significantly affect patient or NuTH FT staff safety or wellbeing must also be reported via the Trust’s DATIX system by the RCM/RM&GM (or QAM). The Incident Type should be entered as “Research Incident/Accident”; Reporter’s Directorate/Division listed as “Research Activities” (entries selected from the drop down menus). See also NuTH FT “Managing and Reporting of Accidents and Incidents Policy”.

6.6.2. Summary Reports

Audience	Frequency of Report	Type of Report	Content
Trust Quality Committee	Bi-annual	Written	High level overview of categories of findings and trends
Clinical and Research Governance Meeting	Monthly	Verbal and a written summary	Hot topics Trends Outcomes and actions from trending QMS Status Summary of audit outcomes Risk of failure to deliver the audit plan Annual audit plan status Education and training

Any trends in non-compliance and examples of good practice will also be shared in an anonymised form with the wider research community to promote the conduct of high quality research in NuTH FT.

6.6.3. Quality Assurance Metrics

The RAG status of the audit progress is documented in the plan where Red = 0 to 33%, Amber = 34-66%, Green = 67-100% compliance.

A breakdown of the findings by grade and an analysis of the categories of audit findings are included in the bi-annual reporting. This information will be utilised to identify trends and provide a focus for staff information and training.

7 REFERENCES

7.1 UK Policy Framework for Health and Social Care Research, 2017

7.2 Statutory Instrument 2004/1031: The Medicines for Human Use (Clinical Trials) Regulations 2004

7.3 Statutory Instrument 2006/1928: The Medicine for Human Use (Clinical Trials) Regulations 2006

7.4 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) General considerations for clinical studies

7.5 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice

7.6 NJRO-REG-SOP-013 'Notification of Serious Breaches of GCP or the Trial Protocol'

7.7 NuTH FT – Serious Incidents Reporting and Management Policy

7.8 NuTH FT – Management and Reporting of Accidents and Incidents Policy

7.9 NJRO-QA-SOP-005 'Risk Assessment of Studies for Inclusion in the Annual Audit Plan'

7.10 NJRO-QA-WI-001 'EHR Audit Trail report Generation & Review'

8 APPENDICES

1 – Audit Content

Appendix 1 Audit Content

Audit Type	Audit Content
System	Safety Reporting; Causality and Expectedness Assessment, AE, SAE, SUSAR Reporting and Monitoring Data Management; Data Queries, Data Protection, Integrity and Security, Randomisation, EDC Consent; ICF and PIS Sponsorship; Contracts, NJRO Approval, Oversight (NJRO & Commercial/External), Delegation, Vendors - Assessment, Selection, Technical Agreements, Risk Management, Deviations/Violations, Monitoring, SAEs, Amendment Management Governance; Audit, Data Monitoring and Safety Committees, Trial Steering Committee and Annual Reports Hosting; CoCaC, Contract, Insurance, Monitoring, Risk Assess Management Systems; LPMS, QPulse, RedCap, Research+Me – validation, operation, training Electronic Health Record; Flags, Clinical Notes, Document Store, Scanning Bureau, EHR Audit Trail
Process	Approvals – Regulatory, Insurance, Finance, Amendments Recruitment and Eligibility Delegation logs PI Oversight (Protocols, Interim Reports, Clinical Trial Reports, Correspondence Training (GCP, HTA, Professional Registration, LoA, HRC, HCC) Archiving (Sponsor & Host Process) End of Study, Close Down, Patient Follow-Up, Publication Management of Laboratory Samples and Results
Vendor e.g. CTU, Laboratory, Archiving provision, Translation services, Statistical Analysis	GCP Compliance, Quality Management System, Trial Management (TMF), Facilities and Equipment, Management of Third Party providers, including service and maintenance, Staff Training

Audit Type	Audit Content
Trial Specific	All activities in a single trial
Investigator Site	Completed Informed Consent Forms Case Report Forms (CRFs) and associated source data (including medical records) Electronic Data Capture (EDC) system, if applicable Training records including evidence of NUTH FT R&D SOP review Study-specific SOPs Facilities where the research is conducted (including clinical areas and pharmacy) Charts/records for sample collection; temperature monitoring; sample processing Participant Notes (paper and/or electronic)
Documentation	TMF, Correspondence, Study Documentation
System Tests	24 hour Medical Cover, Emergency Un-blinding, Recall Processes
Tissue	Approvals, Consent, Laboratory Standards, Staff Training, Facilities Monitoring and Management
Radiology	Approvals, Imaging Guidelines, Facilities and Equipment
Medical Devices	Approvals, Safety Oversight and Reporting, Staff Training
Pharmacy	Delegated duties, Procurement, Manufacture, Storage, Dispensing of IMPs, QMS (SOPs, Staff Training), Facilities