Our Vision
To provide every patient with the care we want for those we love the most

SOP 705 Quality Control & Quality Assurance

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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1. Contents

2. Definitions of Terms Used / Glossary

CI	Chief Investigator
GCP	Good Clinical Practice
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
IMP	Investigational Medicinal Product
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
R&D	Research and Development
SI	Statutory Instrument
SOP	Standard Operating Procedure
TMF	Trial Master File

3. Objectives

To provide a clear overview of the Quality Management System (QMS) for research trials in line with ICH GCP E6 / SI 2004/1041

4. Scope

Quality Assurance (QA) refers to all those planned and systematic actions that are established to ensure that a trial is performed and the data generated, documented (recorded) and reported in compliance with the principles of Good Clinical Practice (GCP) and the applicable regulatory requirements (ICH GCP Section 1.46).

Quality Control (QC) refers to the set of operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial related activities have been fulfilled (ICH GCP Section 1.47).

QA and QC activities involve monitoring and auditing against the trial protocol and SOP's.

The sponsoring organisation is responsible for implementing and maintaining the QMS and robust QC systems with written standard operating procedures to ensure that trials are conducted and data is generated, documented, recorded and reported in compliance with the protocol and GCP regulatory requirements. Quality control should be applied to each stage of data handling

See **SOP 003 Research & Development Annual Audit Plan, SOP 330 Monitoring Clinical Trials of an Investigational Medicinal Product and Device Trials** and **SOP 710 Audit and Inspection** for more detailed information regarding these processes.

5. Purpose

This SOP describes the process for Quality Control (QC) and Quality Assurance (QA) systems for trials where NNUH or UEA acts as the sponsoring organisation.

6. Audit and Monitoring

6.1 Audit

An audit is a tool used to fulfil the Quality Assurance (QA) requirements of GCP

- Designed to assess and assure the reliability and integrity of a trial's quality control systems and is a way of measuring performance against recognised standards
- A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, SOP's and GCP requirements

The purpose of auditing is to:

- Assure the sponsor of participant and staff safety

- Assure that data integrity has been, and is being maintained
- Assure the sponsor that the study is being conducted in compliance with the protocol, SOP's, GCP and relevant legislation
- Assure the sponsor of, and demonstrate to external funders and industry that robust research processes are in place and are being followed
- Assist researchers with compliance to regulatory requirements and Trust and University SOP's and policies
- Improve research systems
- Prepare researchers for external audit processes

See **SOP 003 Research & Development Annual Audit Plan**

6.2 Monitoring

Monitoring is an ongoing integral part of the QC of a clinical trial and is designed to verify the quality of the study

- Defined as the act of overseeing the progress of a clinical trial and ensuring that it is conducted, recorded and reported in accordance with the protocol, SOP's, GCP and the applicable regulatory requirements (ICH GCP section 1.8).
- It fulfils the sponsor oversight role for the study.

The purpose of monitoring is to verify that:

- The rights and wellbeing of human subjects are protected
- The reported trial data are accurate, complete and verifiable from source documents
- The conduct of the trial is in compliance with the currently approved protocol and amendments, with GCP, and with the applicable regulatory requirements

See **SOP 330 Monitoring Clinical Trials of an Investigational Medicinal Product and Device Trials**

7. Training Requirements

In order that all research is undertaken to appropriate standards; all staff involved in research must undertake GCP and study specific training. It is advised that training is updated every two years or following introduction of new/revised legislation and evidence of current training should be kept in individual training records and the Trial Master File

(TMF). See **SOP 002 Good Clinical Practice (GCP) Training** and **SOP 505 Training Requirements, Creating and Maintaining Training Records.**

8. Documentation

Essential documentation for a clinical trial consists of those documents which individually and collectively permit evaluation of the trial and the quality of the data produced.

They serve to demonstrate compliance of the investigator, sponsor and monitor with the standards of GCP and with all applicable regulatory requirements, (ICH GCP section 8). The Trial Master File (TMF) must be established at the beginning of a trial and is the key repository of its essential documentation. See **SOP 305 Creating and Maintaining the Trial Master File or Investigators Site File**.

9. Responsibilities

9.1 Auditors and monitors

- An auditor must be qualified by training and experience to conduct audits properly. An auditor's qualifications should be documented (ICH GCP 5.19.2).
- The auditor will be independent to the research team / research systems to conduct audits appropriately
- The monitor's qualifications will be documented
- The monitor shall be familiar with the Investigational Medicinal Product (IMP) and or device, the protocol, information sheet and consent form (ICH GCP 5.18.2), as well SOPs, GCP and applicable regulatory requirements
- Anyone assisting in undertaking monitoring or auditing must be appropriately trained, and shall have the scientific and / or clinical knowledge needed to monitor or audit the trial adequately

9.2 Extent of Monitoring and Auditing

- Monitoring requirements are decided by the Monitor, Chief Investigator (CI) and Sponsor
- Provide assurance that the trial is conducted and documented correctly
- A monitoring plan will be created for each study by the Monitor in conjunction with the CI and Sponsor
- For details on how monitoring is carried out please refer to **SOP 330 Monitoring Clinical Trials of an Investigational Medicinal Product and Device Trials**

- An annual audit plan will be created using a risk based approach; with the focus on Sponsored regulated CTIMP/Device Trials.

- For cause audits may triggered where there are breaches to GCP, Protocol or SOP

For further details on types and scope of Audits please see **SOP 710 Audit and Inspection** and **SOP 003 Research & Development Annual Audit Plan**

9.3 Training

All research team members are responsible for undertaking relevant training, ensuring training is kept up to date and where necessary filing evidence of training in the TMF. See **SOP 505 Training Requirements and Creating and Maintaining Training Records**.

9.4 Documentation

All research team members are responsible for the maintenance and completion of trial documentation in accordance with the protocol and GCP standards. Refer to **SOP 865 Study Specific Document Management**.

10. References and Related Documents

References
ICH GCP E6 / SI 2004/1041 - International Conference on the Harmonisation of Good Clinical Practice

SOP No.	**SOP Title**
SOP 002	Good Clinical Practice (GCP) Training
SOP 003	Audit Programme
SOP 305	Creating and Maintaining the Trial Master File or Investigators Site File.
SOP 330	Monitoring of Clinical Trials
SOP 505	Training Requirements, Creating and Maintaining Training Records.
SOP 710	Audit and Inspection
SOP 865	Study Specific Document Management.

11. Approval

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12. Reason for new version and Training Implication

This SOP replaces the previous version number V1.5

Changes made	
Reason	• New layout • Reworded throughout
Training Implication	**Yes**
Actions required	• Matrix to be updated • Familiarisation with new layout