SOP number	**57.008**	Version	**3.0**
Title	**External Audit and Inspection**		

Prepared by Signature	Eilidh Wright Date
Approved by Signature	Lynn Prentice Date
Released by Signature	Julie Brittenden Date

SOP category	57 NHS GG&C Clinical Research Facility – Administration

Staff category

Staff Category	**R**	**A**	**C**	**I**
Nursing	X			
Administration	X			
Principal Investigator	X			
Clinical Research Fellow	X			
Site Clinical Trials Pharmacy	X			
Clinical Research Imaging Facility (CRIF)	X			
GCRF Manager		X		
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

2. Purpose

The purpose of this SOP is to describe the process when preparing and hosting an external audit or regulatory inspection (Medicines & Healthcare products Regulatory Agency (MHRA) or Food and Drug Administration (FDA) or European Medicines Agency (EMA)).

3. Procedures

Audits and inspections are the systematic and independent examination of research activities conducted during or after study completion.

3.1. Notification

The External Auditor/Regulatory Authority may contact the Principal Investigator (PI) directly to inform an audit/inspection is to take place at a suggested date. The PI must inform GCRF Research Nurse Manager and QA Lead immediately. QA Lead/Representative must inform GCRF GCP Compliance Committee and GG&C R&I Governance.

Form 57.008A External Audit/Inspection Checklist should be used when notified of an external audit/inspection.

3.2. Preparing

The external auditors/inspectors will review the following areas during the audit/inspection:

- Essential Documents – Investigator Site File and if applicable including Pharmacy, ensuring all documents approved by REC, R&I and if applicable MHRA.
- Trial Team – Current delegation/responsibilities log with all members of the study team documented with delegated tasks and trained appropriately.
- Source data – All records (paper CRF, eCRF or worksheets) are accurate, complete and legible.
- Participants – Informed Consent process as per SOP 17.012 and subsequent visits documented as per SOP 57.005.
- Protocol – all tasks conducted as per study protocol.

QA Lead/Representative and/or GCRF Internal Audit Pool will assist the PI and study team when preparing for an external audit/inspection ensuring all study documentation is up-to-date and inspection ready for auditors/inspectors:

- MHRA, REC, R&I approvals and all relevant correspondence are filed.
- Current approved protocol available along with superseded versions with signature and date.
- Current approved supporting documents available along with superseded versions i.e. Participant Information Sheet (PIS), Consent Form, Questionnaires, Diary.
- Current Investigator Brochure/Summary of Product Characteristics along with superseded versions.
- Completed participant Consent Forms including previous versions.
- Study personnel – CVs and GCP certificates (up-to-date signed within last 2 years).
- Up-to-date delegation log, detailing all members of the study team delegated tasks.
- Training log for detailing training for each member for the study team.
- Participant screening and recruitment logs are up-to-date.
- Study team is familiar and confident about their areas of responsibility.
- Study team can provide up-to-date and accurate information and/or documentation in a timely manner.

To help prepare, the study team can request the assistance of GCRF Education and Quality Team to provide mock audit/inspection interviews and assign a suitable scribe during the inspection, Form 57.008C to be used when scribing. Form 57.008D Document Tracker must be used to track documents requested by auditor/inspector.

An external audit/inspection plan will be provided detailing scope of audit/inspection, dates/times of document review and potential interviews. It must be agreed who will meet and greet the auditor/inspector i.e. PI, Lead Study Nurse and/or QA Lead/Representative.

It is crucial that all members of the study team expected to attend the audit/inspection are given sufficient notice to prepare and rearrange other commitments. If there are issues with dates requested by external auditor/inspector (PI annual leave, clinical commitments) the auditor/inspector may be contacted to request further dates; however this should be within 3/4 weeks of the original dates requested.

Suitable venue must be booked; this must include interview room, document review room, waiting room for study team and war room for QA team. Photocopying facilities must be available along with access to computer systems. Refreshments should be arranged and provided for the auditor/inspectors.

An email must be circulated to notify all GCRF staff of impending audit/inspection and to ensure all areas are tidy and given dates/times of facility tours.

3.3. During the external audit/inspection

On arrival

- The auditors/inspectors identification must be requested.
- The audit/inspection coordinator along with PI if available must meet and greet the auditors/inspectors, provide orientation and house-keeping of the venue.

Documents may be requested throughout the audit/inspection, if no form is provided by the external audit/inspector Form 57.008B Document Request must be used to coordinate and record the documents requested.

All documents submitted to the inspectors must be quality control check for accuracy and completeness. It must be made clear to auditors/inspectors whether documents provided are copies (COPY stamp) or the original.

At the end of each day the study team must ensure that any information and/or documents requested have been provided.

Close-out

- At the end of the audit/inspection a close-out meeting will take place and verbal feedback of the findings will be provided.

3.4. External audit/inspection report and site response

A report will be provided giving further detail of each finding. The study team must respond to each finding with corrective and preventative action plan. The Education and Quality Team can provide assistance with responses. The response must be provided within the agreed timeframe or within 4 weeks of receipt. A summary of the report and responses must be provided to the GCRF GCP Compliance Committee and GG&C R&I Governance.

4. Referenced documents

- Form 57.008A – External Audit/Inspection Notification Checklist
- Form 57.008B – External Audit/Inspection Document Request
- Form 57.008C – External Audit/Inspection Scribe Template
- Form 57.008D – External Audit/Inspection Document Tracker
- Form 57.008E – External Audit/Inspection CAPA Tracker
- SOP 17.012 – Informed Consent
- SOP 57.005 – Hosted Study Documentation and Data Management

5. Related documents

- SOP 57.003 – GCRF Internal Audit

6. Document history

Version	Date	Description
1.0	11/12/2018	First release
2.0	26/08/2019	Minor changes, removal of specific interview advice
3.0	17/11/2023	Update to SOP template v2.0 Addition of RACI matrix Minor additions including QC check of documents Addition of Form 57.008E