SOP number	**57.003**	Version	**4.0**
Title	**GCRF Internal Audit**		

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
QA Lead	X			
QA Officer	X			
GCRF Internal Audit Pool	X			
GCRF Manager		X		
Education & Quality Lead				X
R&I QA Manager				X
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This Standard Operating Procedure (SOP) describes the process of conducting internal audits in Glasgow Clinical Research Facility (GCRF) from developing audit schedule to closing audit report.

2. Purpose

The purpose of Internal Audit (IA) is to assess GCRF activities have been conducted in compliance with regulations, clinical research SOPs, systems processes, and local policies. Evaluating the effectiveness of the quality management system and provide an opportunity to improve.
All audit findings categorised 3 or 4 (major or critical) should be escalated to R&I Governance following SOP 51.008.

3. Procedures

The type of audit that may be conducted includes:

Audit	Description
GCP	To verify systems are in place to ensure: • The rights and well-being of research participants are protected. • The reported study data is accurate, complete and verifiable from source documents.

	• The conduct of the study is compliant with approved research protocol, governance and regulatory requirements.
Systems	To verify processes, meet regulatory/study/local requirement and are effective and efficient.
Information Systems	• To ensure all systems used to store and report data are fit for purpose. • To verify research data recorded in systems are complete and accurate.
External Audit/Inspection Preparation	To ensure GCRF staff and study documentation are ready for external audit/inspection.

There are various techniques that can be effective during an audit, this list is not exhaustive:

- Interview/discussion
- Documentation review
- Observing
- Data processing
- Data review and verification
- Process testing/pilot.

Finding classifications are:

Category	**Definition**
Critical	• The safety, well-being or confidentiality of participants has been jeopardised or has the potential to be jeopardised. • Reported data are unreliable or absent. • Inappropriate, insufficient or untimely corrective action has taken place regarding major non-compliance. • Lack of adequate documentation available to reconstruct the study or failure to maintain an appropriate Investigator Site File (ISF)
Major	• Significant and unjustified non-compliance with relevant legislation or the principles of GCP. • A number of breaches of legislation or the principles of GCP within one area, indicating systematic quality assurance failure. • A failure to comply with legislative requirements including annual reporting requirements.
Other	• Low risk to participants but requires resolution. • Any other finding that is neither critical nor major.

GCRF Activity Data Audits will be conducted regularly, all findings will be categorised as other however the following sub-categories will be used:

Category	**Definition**
A	Cells will be highlighted red • Activity data unreliable/inconsistent/inaccurate/incomplete and must be updated or query answered immediately.
B	Cells will be highlighted amber • Minor issues with activity data which need to be addressed within a reasonable timeframe.

3.1. Audit Schedule

The Quality Assurance Lead will develop an annual audit schedule, Form 57.003A, detailing planned internal audits for the coming year. For the auditors to remain objective the QA Lead must assign independent auditors to each scheduled audit.

The audit schedule is presented to and discussed at the GCRF GCP Compliance Committee, final version will be authorised by Education & Quality Lead and GCRF Manager/GCP Compliance Chair. The signed schedule will be reviewed annually by Glasgow Health Science Partnership Regulatory Affairs Group (GHSP RAG).

For-cause audits will be added to the annual GCRF Audit Activities report, the QA Lead will record if these have an impact on any planned audits.

3.2. Preparing for the internal audit

3.2.1. The QA Lead will assign an audit number to each of the audits conducted and must be confirmed during the planning stage.
3.2.2. The auditor will complete the audit plan, Form 57.003B, determining the scope, timescale, personnel required, documentation and/or systems required and audit techniques. The auditor must contact the auditee with draft audit plan and to arrange suitable date for all parties, once date confirmed the final audit plan can be signed-off by auditor and auditee.
3.2.3. If access to information systems is required, the auditor must request this from the auditee.
3.2.4. The auditor and QA Lead will develop a version controlled checklist to assist when conducting the audit.
3.2.5. The auditor must book a suitable room to ensure privacy to conduct the audit.
3.2.6. One-week prior the auditor must finalise any requirements with the auditee.

3.3. During the audit

3.3.1. The auditor holds an opening meeting with all relevant personnel, explaining the audit scope and plan.
3.3.2. The auditor may wish to discuss findings and corrective actions with the auditee during the audit, which can be actioned before the end of the audit.
3.3.3. The auditor holds a closing meeting at the end of the audit to discuss observations and CAPAs confirming reasonable timescale for completion.

3.4. Post Audit

3.4.1. The auditor will prepare the audit report, Form 57.003C, detailing scope, findings and observations, actions for auditee and any other recommendations.
3.4.2. The auditor will send the draft report to the QA Lead to review the findings, actions and recommendations, discussing and amending with the auditor.
3.4.3. The final audit report will be sent to the auditee no later than a fortnight after the audit, to complete actions and report within 4 weeks. Once all CAPAs are addressed the auditee must return the report for verification.
3.4.4. The auditor must follow-up on the return of the report if passed the deadline.
3.4.5. The auditor may wish to conduct a follow-up audit or discuss CAPAs with the auditee to confirm CAPAs have been addressed.

3.4.6. Once CAPA accepted by the auditor the audit must be closed, recording date on the final audit report. A Word and PDF copy of the final report must be saved to the appropriate folder on the common drive.

3.5. GCRF GCP Compliance Committee

All audits and non-compliances within the previous quarter will be presented to the GCRF GCP Compliance Committee. Any issues with internal audits and non-compliances can be escalated to the GCP Compliance Committee for review, comment and resolution.

4. Referenced documents

- Form 57.003A – Audit Schedule
- Form 57.003B – GCRF IA Plan
- Form 57.003C – GCRF IA Report Template
- Form 57.003D – Non-compliance and CAPA Report
- GUI 57.003A – GCRF Non-compliance and CAPA Report
- SOP 51.008 – Handling non-compliance with GCP and/or trial protocol in clinical research sponsored, co-sponsored or hosted by NHS GGC

5. Related documents

- SOP 53.005 – Research Audit

6. Document history

Version	Date	Description
1.0	08/08/2017	First release
2.0	20/09/2018	• Change category Minor to Other to come in line with MHRA categorization • Minor administrative changes • Addition of GCRF QA Representative • Remove requirement to escalate Major findings to R&D Governance to come in line with SOP 51.008 only category 3 and above (Serious and Critical) • Addition of Completed IA Programme Report • Addition of escalation to GCRF GCP Compliance Committee
3.0	26/08/2019	• Periodic review – Minor changes
4.0	10/10/2023	Update to SOP template v2.0 Addition of RACI matrix Minor administrative changes