Internal Audit of Clinical Research Projects	
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Author Name: Lyndsay McDade Title: Senior Clinical Research Governance Manager Signature: ON FILE Date: 04/10/2021	**Approver** Name: Kay Currie Title: Associate Dean - Research Signature: ON FILE Date: 04/10/2021

Document History

Version	Description of Update	Date Effective
1.0	First Release	26/02/2021
2.0	Section 4.7.1 - Inclusion of remote audit processes.	04/10/2021

1. Purpose

1.1 To document the procedure for preparation, implementation and follow up of internal audit procedures for clinical research projects.

2. Scope

2.1 GCU SHLS staff members involved in clinical research.

3. Responsibilities

3.1 The Sponsor of clinical research is responsible for implementing quality systems including the development of an audit plan for sponsored research.

3.2 The SCRGM is responsible for creating, implementing and conducting audits of clinical research projects sponsored by GCU.

3.3 SHLS staff members undertaking clinical research are responsible for taking part in audits of their research projects. This includes providing access to requested documentation and responding to any outcomes of audit inspections.

4. Procedures

4.1 Definitions

4.1.1 Audit is designed to assess and assure the reliability and integrity of sponsor's trial systems against all written standards.

4.2 Audit Schedule

4.2.1 The SCRGM shall maintain an audit schedule of all ongoing clinical research projects within SHLS.

4.3 Pre Audit Procedures

4.3.1 At study set up the SCRGM will discuss with the PI the requirements for routine audits of their project. The scope of the audit and number of audits for the project will be determined by a risk assessment (SHLS-F-008A) conducted by the SCRGM in agreement with the PI. The research team will provide the IRAS form and protocol to the SCRGM to allow for the completion of the risk assessment document.

4.3.2 One month before an audit research teams will be notified that the SCRGM intends to conduct a review. The date and time will be agreed in advance between the SCRGM and research team.

4.3.3 Prior to the audit, the SCRGM will complete an audit scope document tailored to the research project to be reviewed. The plan shall:

- Define scope and objectives for audit
- Provide timelines for audit conduct
- Identify where and when the audit will take place
- Identify requirements to be audited against
- Identify groups and areas to be audited
- List documents and records to be reviewed

4.4 During Audit

4.4.1 During an audit the SCRGM shall review:

- Consent process
- Subject safety or rights
- Data integrity
- Compliance with sponsorship procedures
- Compliance with GCP and regulations
- Adherence to the protocol
- REC submission process
- Approved documents
- Management of protocol amendments
- Compliance with GDPR requirements
- Any other area not noted above that would allow for a complete audit of the research project

4.4.2 During the audit if the SCRGM identifies any findings which may require an urgent response the research team will be notified immediately. If the SCRGM has concerns regarding poor quality and/or fraud in a research project this will be escalated to the appropriate staff member.

4.5 Categorisation of Findings

4.5.1 Findings will be categorised and sent to the research team to review and resolve any issues highlighted during the audit.

4.5.2 Findings shall be categorised into the following:

Minor/Other (1)	Minor/ Other findings are issues arising that have little impact on the trials data integrity and/or safety and rights of the participant. Example of a minor finding: • A lack of document management/ organisation processes.
Major (2)	Major findings are issues that have the potential to have an effect on data integrity or risk the safety and rights of participants. Examples of major findings: • A significant, unjustified departure from GCP • Failure to comply with regulatory requirements
Critical (3)	Critical defines a finding that has serious potential to directly undermine the integrity of the study. Examples of critical findings: • Where there is evidence that safety, wellbeing, rights or confidentiality of participants has been (or may be) jeopardised. • Where there is serious reason to doubt the data credibility/accuracy of the study • Where changes have been made to study procedures with no approval from external bodies e.g. consent forms that have not been approved by NHS REC.

4.6 Post Audit Follow Up

4.6.1 The SCRGM will provide a follow up letter and action resolution document if required.

4.6.2 The research team will have one month to provide a completed response to any minor/major actions.

4.6.3 Critical actions must be dealt with as a matter of urgency. This will be followed up by the SCRGM.

4.7 Remote Audit

4.7.1 Where appropriate audit can be done remotely (SHLS-F-008B). An audit list will be sent to the research team to complete with a request of completion within one month. The auditor shall be provided temporary access to project files through OneDrive. A member of the research team may also be asked to discuss the audit through a video call with the SCGRM.

4.7.2 Remote audit paperwork will be reviewed by the SCRGM and any issues shall be followed up as per 4.5 and 4.6.

4.8 Changes to the Audit Schedule

4.8.1 Audits may take place out with the initially agreed schedule where required. Reasons for an unscheduled audit may be (but are not limited to):

- An amendment to the research project that increases the risk of the study
- A request from sponsor
- A request from the study team

5. Referenced and Related Documents

- SHLS-F-008A: Audit Risk Assessment
- SHLS-F-008B: Clinical Research Remote Audit

6. Abbreviations and Definitions

GCU - Glasgow Caledonian University
SCRGM – Senior Clinical Research Governance Manager
SHLS - School of Health and Life Sciences
SOP – Standard Operating Procedure