Standard Operating Procedure (SOP)
Auditing of Studies Sponsored by St George's

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Author:	Stefanie Chan	**Title:**	Clinical Research Auditor
Approved by:	Subhir Bedi	**Date:**	17/10/2023
Signature of Authorisor	DocuSigned by: Subhir Bedi 9812BED48A124BB...		

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SOP Chronology

SOP Version Number:	Reason for Change:	Author:
V1.0	Original version.	Lucy H H Parker
V2.0	Updated Logo and Trust Name	Fran Mautadin
V3.0	CORRECTED Audit findings definitions in line with RQA and MHRA findings definitions	Debs Rolfe
V4.0	Updated to reflect new Clinical Research Auditor role in JRES. Updated procedure for selection of studies for audit. Addition of Associated JRES documents table. Administrative changes to text in all sections and amendment of JREO to JRES.	Stefanie Chan

Associated JRES documents

SOPs	WPDs	Docs	LOGs
	JRESWPD0023 General Research Definitions	JRESDOC0088 Audit Report Template JRESDOC0131 Self-Audit Form	

Contents

1. Background

The quality management of the clinical trials/studies is the responsibility of the Sponsor and this includes the implementation of an audit programme. The Sponsor is obligated to ensure that their trials/studies are conducted in accordance with the relevant legislation, policies, guidance and Sponsor Standard Operating Procedures (SOPs).

The purpose of a research audit is to:

- Ensure participant and staff safety.
- Assist researchers in complying with regulatory requirements and local policies.
- Improve research systems and data quality.
- Help prepare researchers for external audits or inspections.

- Demonstrate robust research processes to external funders and industry.

An audit involves collecting evidence of research practice and comparing it against the requirements of Good Clinical Practice (GCP), local policies, SOPs and the applicable UK regulations and guidance.

Audits for studies sponsored by St George's will be conducted according to an Audit Programme which will be developed and implemented by the JRES. Audits may also be conducted if a researcher requests an audit of their study or if the JRES has concerns about the conduct of a study and its compliance with regulatory or local requirements.

The JRES will conduct audits of specific research processes (for example, Informed Consent, maintenance of the Investigator Site File, SAE reporting) across selected sponsored studies and across the main research groups and departments within SGUL and SGHFT.

Studies hosted by St George's (but not sponsored) may also be subject to auditing, for example, auditing the upload of the relevant R&D files on EDGE.

2. Joint Research and Enterprise Office (JRES) Policy

All JRES SOPs will be produced and approved in accordance with the JRES SOP on SOPs and must be used in conjunction with local NHS Trust and St George's policies and procedures.

The JRES acts as the representative of both St George's University of London (SGUL) and St George's University Hospitals NHS Foundation Trust (SGHT). St George's will be the official name used on all SOPs to represent either institution acting as Sponsor.

3. Scope

This Standard Operating Procedure (SOP) outlines the audit process and procedures of the JRES, acting on behalf of St George's, University of London and St George's University Hospitals NHS Foundation Trust.

This SOP does not cover the actual process of auditing or the associated audit documents for the auditor.

4. Definitions

For general research management related acronyms used in this SOP, refer to General Research Definitions Working Practice Document (JRESWPD0023).

Audit: the 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, sponsor SOPs, GCP, and applicable regulatory requirements. (ICH-GCP).

CAPA: a formal plan of Corrective and Preventative Action. Implementation of a CAPA plan after the conduct of an audit is necessary to eliminate present and potential causes of non-conformity and prevent re-occurrence or future occurrence.

5. Responsibilities

This SOP is to be followed by the JRES governance team, Chief Investigator (CI) and Principal Investigator (PI) of the study selected for audit and their study teams.

The Clinical Research Auditor at the JRES is responsible for:

- Developing the Audit Programme in conjunction with the Research Development and Governance Manager (RDGM).
- Informing the relevant CI/PI and research team of an intention to audit.
- Arranging a mutually convenient date and location for the audit, ensuring that the relevant study team members will be available.
- Developing the Audit Plan for each audit.
- Liaising with the CI/PI and research team regarding the audit procedure, the areas to be audited and the documents and processes to be reviewed.
- Preparing all documentation required for auditing.
- Conducting audits according to the Audit Programme.
- Preparing and distributing an Audit Report following each audit.
- Following up on any CAPA implemented as a result of the audit.

6. Procedure

6.1 Audit Programme

The JRES will develop an annual Audit Programme for all sponsored studies and trials on a quarterly basis:

Q1: April – June

Q2: July – September

Q3: October – December

Q4: January – March

The following will be considered when selecting studies for audit:

- The risk of the study.
- The complexity of the study.
- The experience of the PI/study team.
- The number of participants recruited to date.
- The inclusion of minors into research
- Findings from previous audits, remote auditing forms or monitoring visits.
- Any concerns about the conduct of a study.

The main priority is to focus on auditing sponsored high risk non-CTIMP studies. The studies will be selected based on the risk factors mentioned above. The aim is to rotate through the different clinical specialities and audit at least once every two years (dependent on availability of resources).

For multi-centre, low risk studies, the auditor will send out a self-audit form (please see JRESDOC0131) for sites to complete. The completed form should be returned to the JRES Clinical Research Auditor within 4 weeks of receipt. The Auditor will review the self-audit form and if any major issues are identified, they will arrange to audit the site or the whole study.

The following studies will normally be excluded from auditing:

- Sponsored CTIMPs (as these are routinely monitored by the JRES)

- CTIMPs and non-CTIMPs which are externally/commercially sponsored, unless concerns have been raised about the conduct of these studies at St George's
- Studies that have not started recruiting yet

6.2 Auditor Qualifications

The Auditor is part of the JRES Governance Team and is independent to each research team. S/he will be qualified by training and experience to conduct audits correctly.

6.3 Audit Plan

Once a study has been selected, the auditor will send out a notification email to the PI and research team informing them that their study has been selected for a routine audit. Approximately 2 weeks' notice will be given to allow the study team time to prepare the relevant documents.

An audit plan will be developed by the Clinical Research Auditor and agreed with the researcher involved prior to the audit.
The formal plan should:

- Define the scope and objectives for the audit.
- Provide timelines for the conduct of the audit.
- Identify where and when the audit will take place.
- Identify the requirements to be audited against.
- Identify the areas, documents and records to be reviewed.
- List the responsible people whose functions will be audited.
- Clarify who will get the final report and when it will be ready.

6.4 Audit Process

The process will start with the Auditor explaining the scope and objectives of the audit and how it will be carried out. Some examples of audit activities are:

- Interviewing researchers.
- Reading documents.
- Reviewing site files.
- Reviewing informed consent forms.

- Reviewing training records.
- Reviewing Case Report Forms and medical notes.
- Reviewing manuals.
- Studying records.
- Reading reports.
- Analysing data.
- Observing activity.
- Examining conditions.
- Confirming interview evidence.
- Documenting observations.

Once the audit is completed, the auditor will go through the findings with the study personnel and PI if present, and to inform them that a formal report will be provided. A response to the audit findings should be provided within 1 calendar month of receipt of the audit report.

6.5 Audit Findings

Once the audit has been completed, the Auditor will write up a report with the audit findings and recommendations to correct the findings. This should:

- List any gaps in compliance with any supporting evidence. /
- Cross-reference with the relevant protocol/regulatory /local requirements.

For the purposes of the report, there will be three categories of findings. These are Critical, Major and Other.

- **Critical**: weakness of, or non-compliance with, a control process which, if not resolved **will cause harm** to patients or data integrity and/or company reputation that requires the immediate notification and attention of senior management and clear timelines for resolution For example:
    - Where evidence exists that the safety, wellbeing, rights or confidentiality of study subjects has been (or had a significant potential to be) jeopardised.
    - Where reason has been found to cast serious doubt upon the accuracy and/or credibility of study data.
    - Where approval for the study has not been sought from one or more regulatory agency/body or granted from one or more regulatory

agency/body (e.g. Ethics Committee, MHRA) but the study has commenced regardless.
    - Where following study approval, significant amendments have been made to the study protocol or documentation but no new request for approval has been submitted.

- **Major:** weakness of or non-compliance with a control process which, if not resolved **has the potential to cause harm** to patients or data integrity and/or company reputation that requires the immediate notification and attention of senior management and clear timelines for resolution. For example:
    - Where there has been a significant unjustified departure from GCP, e.g. failure to provide participants with a copy of their Informed Consent Form or Participant Information Sheet.
    - Where procedures not covered/included on the consent form are being performed or where new procedures have been introduced into the study protocol but where participants who had consented prior to their introduction have not been asked to re-consent.
- **Other:** weakness of, or non-compliance with, a control process that currently **causes no harm** to patients or data integrity and/or company reputation that requires resolution. For example:
    - No definite document management/organisation processes are in place at site / no ISF exists.
    - Where there has been failure by study staff to inform the relevant authorities of amendments to start and stop dates or study specific documents.

6.6 Audit Results

If the audit reveals a number of areas that need improvement, the Auditor will arrange a meeting with the relevant research staff to discuss the recommendations or gaps in compliance. A CAPA plan should be developed and implemented, as agreed with the PI/research team, to address the gaps in compliance and to prevent re-occurrence.

If an audit reveals critical findings or significant major findings the auditor should escalate to the RDGM/HRGD.

6.7 Final Audit Report

Over the following two weeks from the initial audit, the Auditor will review the gathered information and compile a final audit report, which will be disseminated to the PI. If the study is sponsored by an organisation other than St George's, the Sponsor will be offered a copy of the audit report.

The report will include:

- A review of the evidence collected.
- A discussion of any conclusions drawn from the audit.
- A list of identified gaps in compliance.
- An assessment of how well regulatory requirements have been met.
- Recommendations for change in practice to conform to the regulations / the agreed CAPA plan.

6.8 Follow-up Actions

It is the Chief Investigator's (for studies sponsored by St George's) or Principal Investigator's (for studies hosted by St George's) responsibility to ensure action is taken to correct any identified gaps in regulation compliance. If any advice or assistance is required, the CI/PI should contact the Auditor, who will be able to help with this. The Chief/Principal Investigator of the study is expected to respond to the audit report within 1 calendar month and corrective actions made in a timely manner.

6.9 Research Governance Committee (RGC)

The RGC of St George's will be informed of the results of the audits undertaken since the last RGC meeting. If multiple audits have revealed similar findings, the RGC will be informed as to what corrective and preventative plans have been made and implemented.

7. References

UK Policy Framework for Health and Social Care Research

ICH-GCP

http://www.ct-toolkit.ac.uk/routemap/audit/

8. Appendices

None.