# Research Audits Guidance
# For Auditors

## Contents



## Purpose

Audits are conducted in order to:

- Improve data quality,
- Protect the reputation of the researcher, Barts Health, and Queen Mary,
- Protect current and future funding opportunities,
- Measure compliance with regulatory requirements, Barts Health, and Queen Mary policies,
- Improve research performance,
- Prepare potential auditees for external audits and inspections.

Audits can be of (but are not restricted to):

- Study essential documentation,
- Sites,
- Clinical facilities,
- Sponsors,
- Laboratories,
- Databases,
- Investigational Medicinal Products (IMPs),
- Studies,
- Systems,
- External vendors.

## Role of the auditor

The primary role of the auditor is to review evidence of research practice and compare it to the appropriate quality standards (e.g. current legislation, GCP, UK Policy Framework for Health and Social Care Research, etc). The auditor is responsible for:

- Proposing an audit schedule,

- Reviewing documents and practices surrounding the research being audited,
- Documenting observations,
- Assessing whether requirements are being met,
- Developing reports documenting assessments, conclusions, and recommendations for change,
- Writing and safeguarding audit records and reports,
- Liaising with the Sponsor Oversight Group (SOG) to ensure awareness of significant findings and trends (JRMO Clinical Research Auditor only).

## Audit notification and plan

The auditor notifies the auditee(s) of upcoming audits, ideally at least 4 weeks in advance, and liaises with them to determine a mutually acceptable time (and location, including whether some or all of the audit will be held remotely with the auditor remaining off site). Unwarranted delays in arranging audits will be escalated. Once a time and date is agreed, the auditor provides an audit plan.

The plan includes:

- Details regarding when and where the audit will take place,
- The outline of scope and objectives of the audit,
- The requirements and standards against which the research will be audited,
- Notification of whether the auditor will be accompanied by an observer,
- A proposed schedule for the audit interviews, visits, tours, and document review,
- A list of groups and areas to be audited,
- A list of documents and records to be reviewed,
- A list of people whose functions will be audited.

The auditees are responsible for arranging meetings and suitable spaces for the auditor (usually meeting rooms for interviews and meetings, and either desk space or a room for document review). They are also responsible for arranging electronic access to documentation; access should be confirmed in advance of any portions of the audit being conducted remotely.

## Opening meeting

Once the audit starts the audit, an opening meeting takes place to introduce the auditor to the auditees and areas to be audited. During this meeting the auditor:

- Defines scope, objectives, and schedule,
- Explains how the audit will be carried out,
- Confirms that the team are ready to support the audit process.

## During the audit

The auditor is responsible for

- Reviewing documents,
- Reviewing data capture methods (e.g. databases),
- Observing study activities,
- Examining physical conditions and facilities,
- Documenting observations,

- Meeting key individuals for interviews
- Developing conclusions.

Some or all of the audit may be held remotely if it is possible to perform the above duties off site. This will be arranged with the auditees prior to the audit (see Audit notification and plan).

The auditor lists the findings (non-compliances with the specified requirements) supported by the observed evidence (or lack thereof) and limitations of the audit (including documents and areas outside of the scope of, or not reviewed during, the audit).

If deemed necessary the auditor may extend the audit. In such instances, the auditor would inform the lead auditee as soon as possible and would return to finish the audit as soon as reasonably possible.

## Discussing results and conclusions

The auditor is responsible for chairing a closing meeting between the primary stakeholders to discuss the main findings.

## Grading definitions for findings

Findings are categorised as critical, major, or other. These categories and definitions are based on the Medicines and Healthcare products Regulatory Agency (MHRA) inspection categories and definitions and are used for all audits.

**Critical**

- Where evidence exists that significant and unjustified departure(s) from applicable requirements have occurred with evidence that:
    - The rights, safety, or well-being or confidentiality of research participants either has been or has significant potential to be jeopardised, and/or
    - The research data are unreliable, and/or
    - There are a number of Major non-compliances across areas of responsibility, indicating a systematic QA failure, and/or
- Where inappropriate, insufficient, or untimely corrective action has taken place regarding previously reported Major non-compliances
- Where provision of the study documentation is not readily available or accessible, or incomplete to such an extent that it cannot form the basis of an audit and therefore impedes or obstructs the auditor(s) in verifying compliance.

**Major**

- A non-critical finding where evidence exists that a significant and unjustified departure from applicable requirements has occurred that may not have developed into a critical issue, but may have the potential to do so unless addressed, and/or
- Where evidence exists that a number of departures from applicable requirements have occurred within a single area of responsibility, indicating a systematic QA failure.

**Other**

- Where evidence exists that a departure from applicable requirements has occurred, but it is neither Critical nor Major.

## Audit report

The auditor is responsible for writing a formal report to document their observations, conclusions, findings, and recommendations. The audit report is sent to the relevant individuals as per SOP.

The report includes:

- A review of the evidence observed by the auditor,
- Any conclusions drawn from the audit,
- An assessment of how well requirements have been met,
- A list of all identified findings identified by the auditor,
- Recommendations for changes in practice to conform to all requirements,
- A timescale for corrective and preventative actions (CAPAs) to be proposed by the auditees to address the findings.

## Auditees response to the report

The auditee should identify actions to correct and prevent recurrence of findings. The auditees can work with the JRMO GCP and Governance managers to address the CAPA findings. Timelines for completion should also be assigned to each action.

The CAPA plan proposed by the auditees is submitted to and reviewed by the auditor to ensure the actions fully address the findings. Once these actions have been agreed and completed, the auditor issues an audit certificate (which documents that an audit has taken place and what it covered).

## Confidentiality

Audit reports are confidential documents which should not be shared outside of the institutions involved in the audit. Please refer to SOP 22.

## More information

For more information and questions about the audit process, please contact the JRMO's Clinical Research Auditor, GCP and Governance Managers, and / or Research Governance Operations Manager (contact details for these individuals can be found on the JRMO's website).