Joint Research Management Office Standard Operating Procedure for:			
JRMO Audits			
SOP Number:	**22**	Version Number:	**7.0**
Effective Date:	**15th March 2022**	Review Date:	**15th March 2025**

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Purpose:

As a sponsor, vendor or host organisation, Barts Health NHS Trust (Barts Health)/Queen Mary University of London (Queen Mary) has a responsibility to audit research practice and assure adherence to current legislation and guidelines. The length and detail of the audit will depend on the complexity and regulatory requirements of the studies or the service provided.

This Standard Operating Procedure (SOP) describes the audit procedure for clinical research activity (including regulated, interventional and research studies) sponsored by Barts Health or Queen Mary, or for which these institutions are acting as vendors, host sites or participant identification centres (PICs). This SOP specifically describes the processes for auditing studies to assess compliance with the United Kingdom (UK) Policy Framework for Health and Social Care Research (Oct 2017) and / or the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, the Data Protection Act 2018, the UK Research Integrity Office Code of Practice for Research, GCP guidelines, the research protocol, and Barts Health / Queen Mary policies and research SOPs. It also details processes for documenting observations and conclusions, assessing whether requirements are being met, developing reports including recommendations for change or adherence, ensuring appropriate and proportional Corrective and Preventative Actions (CAPAs) are proposed to address all findings, and safeguarding audit documents, records and reports.

Scope:

This SOP is applicable to all Joint Research Management Office (JRMO) staff performing clinical research audits (whether scheduled or for cause), and non-JRMO parties acting on the JRMO's behalf to perform audit activity.

This SOP is also applicable to all research personnel whose studies are subject to an audit. Research activity covered by the SOP does not include clinical audits, service evaluations, product development, animal research, or laboratory work that does not involve human tissue (which is considered "relevant material" by the Human Tissue Authority (HTA)).

This SOP also covers audits of facilities, systems and vendors who support research activity sponsored by Barts Health / Queen Mary.

This SOP should be considered best practice for all Queen Mary and Barts Health sponsored and hosted research and can be applied proportionately to other types of research that do not fall within the scope above.

For more detailed information, please see Associated Guidance Documents 1 and 2: Research Audits Guidance for auditees and auditors respectively.

Abbreviations:

Barts Health	Barts Health NHS Trust
CAPA	Corrective and Preventative Action
CI	Chief Investigator
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HTA	Human Tissue Authority
ISF	Investigator Site File
JCRB	Joint Clinical Research Board
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Authority
PI	Principal Investigator
PIC	Participant Identification Centre
QA	Quality Assurance
Queen Mary	Queen Mary University of London
RG	Research Governance
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
TMF	Trial Master File
UK	United Kingdom

Definitions:

Audit:	"*A 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, analyzed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).*" – GCP definition.
Auditee(s):	The person or people being audited, usually the research study team.
Auditor:	The person conducting the audit. They must be suitably trained and qualified.

Relevant SOPs:

- SOP 33 Research Misconduct
- SOP 34b JRMO staff training and induction

SOP Text:		
	Responsibility	**Activity**
1.	Research Governance Operations Manager	**Auditor Selection** Auditors must be suitably qualified by education, training, and experience. For JRMO auditors, this must be recorded according to the JRMO training matrix (see SOP 34b). JRMO Clinical Research Auditors must be independent of the research study team being audited. Non-JRMO auditors (e.g. Clinical Trials Unit Auditors and independent external contractors) must be suitably experienced and trained and must provide evidence of this to the JRMO Clinical Research Auditor, who will file this accordingly.
2.	Research Governance Operations Manager, JRMO Clinical Research Auditor	**Scheduled and For-Cause Audits** An audit schedule will be proposed annually by the JRMO Clinical Research Auditor in agreement with the Research Governance Operations Manager and will be approved by the Sponsor Oversight Group (SOG). Subsequent changes to the schedule will be approved by the SOG. Research teams may, on occasion, request an audit of their research, and where deemed appropriate by the Research Governance Operations Manager these will be added to the audit schedule. The extent and nature of audits will be proportional to the JRMO portfolio of research activity. Where research studies are considered to have higher risk factors (e.g. using novel interventions, working with vulnerable populations, inexperienced study team, lone investigators, international study, complex study design, new vendors etc.) they are more likely to be included in the audit schedule. Some research will be selected entirely at random.
3.	Auditor, SOG, Research Governance Operations Manager	**Unscheduled/for cause audits** When the JRMO is made aware of any concern associated with any sponsored or hosted research, a for-cause audit may be added to the audit schedule and notified to SOG. In the event of an alert against a particular study or researcher from a member of the public, a patient, or a staff member who wishes to remain anonymous, the JRMO will follow the Barts Health Whistle-blower Policy and the JRMO Research Misconduct Policy as appropriate. The alert will be discussed by the SOG members and an investigation following SOP 33 (Research misconduct allegations) may be completed before a decision will be made to undertake a for-cause audit.
4.	Auditor	**Notification of audit** The auditor will notify the auditee(s) of their intention to audit. For scheduled audits, the auditor should give as much notice as reasonably possible (ideally four weeks) to ensure a mutually convenient time can be agreed. The auditor is not required to provide any notice for for-cause audits.

		Where possible the auditor will notify the auditee(s) whether any co-auditors or observers will accompany the lead auditor.
5.	Auditee(s)	**Expectations from Auditees** The auditee(s) will be responsible for ensuring there are suitable facilities for the audit (space for the auditor to review documentation and interview relevant individuals for on-site visits) and that the required individuals are available for the audit, and for ensuring that all the relevant documentation and electronic systems are available and accessible.
6.	Auditor, auditee(s)	**Remote audits** Depending on the scope of the audit and if records are held electronically and it is possible for the auditee(s) to grant the auditor direct access (e.g. granting permission to shared drives), the audit (or part thereof) may be held remotely with the auditor remaining offsite.
7.	Auditor, auditee(s)	**The Audit Visit** The auditor will introduce the audit with an opening meeting with key auditees. During the audit, the auditor will review relevant documentation and speak with appropriate individuals to ascertain the level of compliance of the research activity. At the end of the audit, the auditor will hold a close out meeting at which the key auditee(s) must be present (in person or remotely). For audits of the coordinating aspects of a study (e.g. the Trial Master File (TMF)) the Chief Investigator (CI) must be present, and for audits of sites the Principal Investigator (PI) must be present. The GCP and Governance Managers and/or Research Governance Operations Manager will be invited to attend this meeting, although their attendance is optional. The auditor will provide a summary of significant findings during the close out meeting and explain how the audit report should be addressed, the timelines for completion, and escalation process.
8.	Auditor, Research Governance Operations Manager	**Audit Report** The auditor will write a report. which will detail all findings of non-compliance with the standards listed in the audit plan. The audit report (and its contents) should be treated confidentially and should not be shared outside of Queen Mary or Barts Health without approval from the Research Governance Operations Manager. Audit Findings Findings will be classed as critical, major, or other. Definitions of these classifications can be found in Associated Document 2. The report will detail findings, as well as any observations and recommendations which will be in an advisory capacity to support best research practice and prevent non-compliance(s) in the future. The audit report will be reviewed by the Research Governance Operations Manager or designee.

		The auditor will send the finalised report to the auditee(s), the auditee's Unit Director (for Clinical Trials Units), Clinical Board Research Lead, Speciality Signatory, or Head of Institute (as appropriate), the Research Governance Operations Manager, GCP and Governance Managers, and JRMO Clinical Trial Monitor (if applicable). Where the lead auditee is a Head of Institute the report will be sent to the Vice Principal, and where the lead auditee is a Clinical Board Research Lead the report will be sent to the Group Chief Medical Officer. The audit report may also be distributed outside of Barts Health / Queen Mary where appropriate (e.g. to the sponsor when the audit is of a hosted site, or to the study team using a vendor when the audit is of a vendor). This will be determined by the Research Governance Operations Manager on a case-by-case basis. The audit report will be distributed within six weeks of the audit close out meeting, wherever possible.
9.	Auditor, SOG, Research Governance Operations Manager	**Audit Escalation** The Research Governance Operations Manager and/or auditor may escalate issues to the SOG (and/or research sponsor for hosted research) if the findings are serious, if suitable Corrective and Preventative Actions (CAPAs) are not proposed to address the findings, if insufficient action is taken to address findings, or if the study team fails to engage with the audit in a timely manner. The SOG, in turn, may escalate issues to the Joint Clinical Research Board (JCRB). If there is no resolution, these bodies will decide whether it is necessary to further escalate issues to the Chief Executive or the Vice Principal (depending if the study is Barts Health or Queen Mary sponsored / hosted).
10.	Auditee(s), Auditor	**CAPAs** The auditee(s) will propose CAPAs to address each finding. For MHRA regulated research, these must be discussed with the JRMO GCP and Governance Managers, who will review the proposed CAPAs and advise whether they are considered to be sufficient to address the audit findings. The CAPA plan will be sent to the auditor within the given timeframe (typically six weeks, unless there are immediate concerns that must be addressed more quickly). The timeframe given may be shorter or longer in the case of extenuating circumstances. The auditor will confirm whether the CAPAs are adequate. If any CAPAs are considered inadequate, the auditor will work with the study team until all CAPAs are resolved/actioned and when the audit is considered closed and the auditor will issue the audit certificate. If it is not possible to reach an agreement regarding the appropriate CAPAs or there is a delay in implementing the actions agreed, the issue may be escalated (please see part 9 above).
11.	Auditor, Auditee (s)	**Issue Certificate** The auditee(s) must ensure that a copy of the audit certificate is filed alongside all the documentation that was audited, as evidence that an audit took place. The auditor is responsible for ensuring that all documentation associated with the audit (including the audit plan, relevant notes, the report, CAPA plan, audit certificate, and associated correspondence) are retained by the JRMO.

12.	Auditor, Research Governance Operations Manager, SOG, JCRB	**Review of Findings** Critical and major findings as well as any trends from other findings will be reported to the SOG. The JCRB will receive the minutes of the SOG, including information surrounding audits where escalation is required. Audit findings will not be logged on the JRMO Non-Compliance log.

Change control

This section outlines changes from version 6.0 to version 7.0

Section changed	Summary and description of changes
All	Spelling, punctuation, and grammar corrections throughout. Updated job titles where appropriate. Removed references to the General Data Protection Act (GDPR).
Associated Documents	Guidance documents separated for auditors and auditees.
Associated Documents	Removal of AD1 Audit report template

List of appendices

There are no appendices associated with this SOP.

List of associated documents

Document ref.	Document name
1	Research audits guidance (auditees)
2	Research audits guidance (auditors)