Standard Operating Procedures (SOP) for:			
JRMO Audit			
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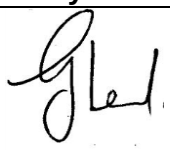
Signature	
Date	**17/09/2013**

Purpose and Objective:
This SOP describes the audit procedure of Barts Health NHS Trust and Queen Mary University of London research activity (BH/QMUL). This SOP specifically describes the processes for selecting those studies for audit that fall under the Department of Health Research Governance Framework for Health and Social Care 2005 (2nd Edition) and/or the Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments; the procedures for carrying out audits; and reporting audit results. This SOP also describes the requirements corrective and preventative action plans. As a sponsor and host organisation under section 3.10 of the Research Governance Framework BH/QMUL has a responsibility for auditing research practice and assuring adherence to current legislation and guidelines.
Scope:
This SOP is applicable to all JRMO staff performing audits or non JRMO parties acting on JRMO's behalf that are performing audit activity, for example: - Clinical Trial Groups within BH/QMUL - Clinical Trial Groups external to BH/QMUL The scope of audit carried out under this SOP is to assess compliance with the requirements of the Research Governance Framework for Health and Social Sciences 2005, the Data Protection Act 1998, the Medicines for Human Use (Clinical Trials) Regulations 2004 and all subsequent amendments, GCP guidelines, Barts Health and Queen Mary University of London research SOP's and Policies. This SOP is related to governance audits only.

SOP Text		
	Responsibility	Activity
1.	JRMO	<u>Selection and role of auditors</u> JRMO auditors will be trained by the R&D Governance Operations Manager as per the JRMO training matrix (as per SOPs 34, 35 & 36).

		Non JRMO auditors will be asked to provide evidence of their training by the RG & GCP manager, who will file this in the JRMO files accordingly (e.g. with audit reports). It is the auditor's primary role to collect evidence of research practice and compare it against the requirements of Good Clinical Practice and Research Governance. The auditor is responsible for documenting observations and conclusions, safeguarding audit documents, records and reports, assessing whether requirements are being met, and developing reports including recommendations for change or adherence. Auditors should be independent to the research project team.
2.	JRMO GCP and RG manager; R&D Governance Operations Manager	The extent and nature of audits will be proportional to the JRMO portfolio of research activity. A schedule will be created by the RG and GCP Manager (s), which is to be approved by the R&D Governance Operations Manager. The R&D Governance Operations Manager will review the schedule periodically. Audits can be but are not restricted to : • Study essential documentation audits • Laboratory audits • Database audits • Investigational Medicinal Product (IMP) audits • Project audits
3.		**Audit Plan:** The RG & GCP manager will schedule the audit at a mutually convenient time, 'ideally' allowing the auditee 4 weeks' notice. This will be in writing and detailing as follows: • Define the 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. • List responsible people whose functions will be audited. • Clarify who will get the final report and when it will be ready.
4.		**During Audit:** The auditor will perform the audit using relevant audit tools (associated document 1). All audits will consist of an open and close out meeting with the auditee (s) present. The auditee (s) should be made aware of a summary of findings during the close out meeting.
5.		**Audit Findings** Findings will be classed as: **Minor**: No significant concerns. **Moderate**: Significant (but not immediate) concerns regarding the safety and well-

		being of trial participants or project integrity. **Major**: Critical and immediate concerns regarding the safety and well-being of trial participants or project integrity. Findings will be categorised into : 1. Essential documents 2. Vendors and subcontractors 3. Informed consent procedures 4. Inclusion and exclusion criteria 5. IMP and non-IMP 6. Laboratory assessment procedures 7. Study procedures 8. Pharmacovigilance 9. Randomisation and cohort allocation 10. Source data 11. Trial equipment 12. Deviations to GCP or protocol 13. CRF and data management, and computer systems 14. Other
6.		**Post Audit:** The audit report should be completed and passed to the auditor's manager (for the JRMO this should be the R&D Governance Operations Manager) for review and comment, prior to dissemination. The auditee should expect the audit report within 3 weeks of an audit being conducted. <u>Findings Review:</u> Depending on the seriousness of audit findings, findings will be escalated, by the R&D Governance Operations Manager, to the Head of Research Resources, Director of RD, Chief Executive or the Warden (Depending if the trial is BH or QM sponsored). The auditee is to follow up on the actions: corrective and preventive until resolved. If the actions have not been carried out in a timely manner, the RG&GCP Manager is to be to be notified, who will if necessary escalate to the Governance Operations Manager. There will be a JRMO centralised log of audit findings – which is to be kept up to date by the JRMO RG & GCP Manager (s). This will be discussed at regular intervals with the RG&GCP manager and R&D Governance Operations Manager.

Associated Documents

Number	Name of document
1	JRMO Audit report and checklist