Joint Research Management Office Standard Operating Procedure for:			
Researcher Training			
SOP Number:	**34a**	Version Number:	**10.0**
Effective Date:	**4th December 2023**	Review Date:	**4th December 2025**

Authorship & Review:		**Signature and Date:**
Author:	Marie-Claire Good Senior & Governance Manager	Marie-Claire Good Digitally signed by Marie-Claire Good Date: 2023.11.13 11:35:22 Z
Reviewer:	Rebecca Carroll Quality Assurance Manager	Rebecca Carroll Digitally signed by Rebecca Carroll Date: 2023.11.13 11:38:34 Z

Authorisation:		**Signature & Date:**
Name/Position:	Mays Jawad Research Governance Operations Manager	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2023.11.13 14:26:20 Z

Purpose:

To ensure Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) staff are aware of clinical research training requirements and how to book onto the courses provided by the Joint Research Management Office (JRMO).

Scope:

This standard operating procedure (SOP) applies to all Barts Health and Queen Mary staff undertaking medical research. It covers training provided by the JRMO which staff are required to complete in order to commence work on a research study. This includes Good Clinical Practice (GCP) training for Medicines and Healthcare products Regulatory Agency (MHRA) regulated, interventional and all research studies and is a requirement for compliance to the UK Policy Framework for Health and Social Care Research.

The Lead Study Team refers to the key Barts Health/Queen Mary research team members i.e., Barts Health/Queen Mary Chief Investigators (CI), Barts Health/Queen Mary Principal Investigators (PI), Barts Health/Queen Mary study coordinator/manager.

Central Barts Health and Queen Mary mandatory staff training is not included in this SOP.

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Chief Investigator
GCP	Good Clinical Practice
ISF	Investigator Site File
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance

Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure
TMF	Trial Master File

SOP Text:		
	Responsibility	**Activity**
1.	All Lead Study Team	**Attend the appropriate JRMO training courses.** **Studies sponsored by Barts Health or Queen Mary** The JRMO requires the lead study team working on Barts Health/Queen Mary sponsored studies to attend JRMO training unless the GCP & Governance Manager (for all types of studies) waivers attendance based upon evidence of acceptable external training or an agreed external supplier, such as National Institute of Health Research. Such waiver will be logged with the Quality Assurance (QA) Manager for recording on the non-compliance log The JRMO provides several types of GCP courses. Please see the JRMO website for further details **Hosted at Barts Health (externally sponsored studies)** All staff who work on 'hosted' studies i.e., sponsored by organisations other than Barts Health/Queen Mary, should receive GCP (if a MHRA-regulated study) and/or an equivalent training course (if interventional and research studies), prior to commencing work on any study at the Barts Health or Queen Mary site. The type and extent of the clinical research training is at the discretion of the external sponsor. It is the responsibility of the research team to establish with the external sponsor what training they require. Evidence of training should be maintained by each individual staff member in the Barts Health/Queen Mary Investigator Site File (ISF) (and Trial Master File (TMF), if delegated by the sponsor). For guidance *see SOP 45 - Essential documents including TMF*. All staff (as above) are requested to keep themselves up to date with regulatory changes and attend a GCP refresher course every 2 years (mandatory for staff working on MHRA-regulated studies and advisory for staff working on interventional and research studies).
2.	All Researchers (Site, Co-ordination, and central facility staff)	**Individual researchers working on a research study should ensure an up-to-date CV is present in the trial file** (TMF and ISF). It is advised that researchers use the Health Research Authority short CV template to ensure relevant information is captured. It is advised as best practice that individuals sign and date their CVs. For Sponsored MHRA Regulated studies, CVs must be updated at least on a 2 yearly basis or when a new delegated role within the study is undertaken. If the CV has not been changed, then review can be evidenced through signing with name and date on the original. This is considered best practice for all other active research study types.

3.	CI/PI	**Ensure that site personnel are appropriately trained prior to working on a study.** • The CI is responsible for ensuring that all co-ordination personnel have had appropriate* training and an up-to-date CV is present in the TMF prior to commencing work on the study. • The CI should also ensure that at site initiation all site personnel have had appropriate* training prior to activating the site (as per *SOP 46 Site selection, site initiation & site activation*). • The PI must ensure that they themselves have sufficient knowledge and experience to act as the PI for the study. • Evidence of training needs to be filed as per *SOP 45 Essential documentation including TMF*. It is advised that all research personnel maintain a training record (an example template contents page can be found in *Appendix A*). Superseded training documents such as out of date CV must be stored as part of the personnel's training records. When researchers leave, they should take the original copies of training with them, but a copy must be retained by the line manager or equivalent . **See section 4 for description of appropriate training*
4.	All researchers	**All researchers should ensure that they are appropriately trained prior to commencing work on any research study.** Training should be proportionate to the researcher's role within the study team. Appropriate training should be • Topic specific This should include an understanding of the research area or disease. The researcher's level of knowledge should enable them to accurately perform their allocated role. • Study and protocol specific This should include review of protocol, study specific SOPs and manuals, any training in and allocated study producer (e.g., randomisation, unblinding or Case Report Form completion). This can be delivered as part of a site initiation visit but should also be carried out for all new staff. • GCP or equivalent training This should be in place for all staff who have been delegated a task as part of research. GCP training should be logged on the site file's delegation log and update with each refresher course.
5.	All Researchers	**Work in compliance with Barts Health and Queen Mary research polices and the JRMO SOPs**. Staff should maintain a reading log (*Template 1 SOP reading log template*) to show SOPs have been read and understood. All JRMO SOPs are available on the *JRMO website*. Further information and guidance can be provided by the JRMO QA Manager. For established clinical trials groups and /or units with their own SOPs please refer to *SOP 41 JRMO oversight of CTG and study specific SOPs*.

6.	All Staff	**Booking a JRMO training course and issuing of certificates** Dates of courses and booking details are available on the JRMO website under the 'News and Training' tab: *http://jrmo.org.uk/news-and-training/training/* Training certificates are issues within 7 working days of course completion. Certificates will only be issued where delegates have completed the full course. If a module within the course was not attended by the delegate, certificates will not be issued, and this should be discussed with the course administrator. **The JRMO will not re-issue certificates if the original certificate has been lost by the researcher.** It is the delegates' responsibility to keep a copy of their training certificate. Should a certificate be lost by a course delegate, the JRMO will send an email confirming their attendance.

Change control

This section outlines changes from version **9.0** to version **10.0**

Section changed	Summary and description of changes
Scope and Section 1	Clarification on what defines a Lead Study Team

List of appendices

Appendix ref.	Appendix name
Appendix A	Contents of personal training record

List of Templates

Document ref.	Document name
1	SOP reading log template

Appendix A: Contents of personal training record

1. Job description
2. CV
3. Staff Training Record (e.g., attendance at training courses, conferences, and seminars)
4. Certificates of attendance (where applicable)
5. SOP reading log
6. Correspondence (e.g., Registration for courses and payments made)
7. Miscellaneous