

Joint Research Management Office Standard Operating Procedure for:

Researcher Training

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Purpose:

To outline the clinical research training requirements for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) staff, and to describe how to access Joint Research Management Office (JRMO) delivered training.

Scope:

This Standard Operating Procedure (SOP) applies to all Barts Health and Queen Mary staff involved in the design, set-up, management, conduct, analysis, or oversight of medical research.

It sets out the training requirements provided or recognised by the JRMO that must be completed before individuals undertake research activities, and where refresher training is required.

Good Clinical Practice (GCP) training is required for Medicines and Healthcare products Regulatory Agency (MHRA) regulated, interventional, and observational research studies in line with the UK Policy Framework for Health and Social Care Research.

This SOP does not apply to staff whose activities do not go beyond their routine clinical responsibilities as determined by the Sponsor.

For the purpose of this SOP, the "Lead Study Team" refers to Barts Health/Queen Mary Coordinating Investigators (CIs), Principal Investigators (PI), and study coordinators/managers employed by or working on behalf of Barts Health or Queen Mary.

This SOP does not cover central corporate training requirements for Barts Health and Queen Mary mandatory staff, which are managed separately.

Abbreviations:

Barts Health	Barts Health NHS Trust
CI	Coordinating Investigator
GCP	Good Clinical Practice
ILF	Investigator Location File

JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute of Health Research
PI	Principal Investigator
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. Staff must attend the appropriate JRMO training courses relevant to their role and the type of research activity undertaken. <u>Studies sponsored by Barts Health or Queen Mary</u> Members of the lead study team working on Barts Health/Queen Mary sponsored studies must attend JRMO provided training unless attendance is formally waived by the GCP & Governance Manager. A waiver may be granted where there is evidence of acceptable external training or use of an agreed external supplier, such as the National Institute of Health Research (NIHR). The JRMO provides two types of GCP courses: • Implementation of GCP at Barts Health and Queen Mary. • GCP refresher (for people who have previously completed GCP training), Completion of a Transcelerate accredited GCP course (such as the NIHR course) is mandatory prior to attending the <i>Implementation of GCP at Barts Health and Queen Mary course</i>, for individuals who have not previously received GCP training. All Barts Health and Queen Mary staff who have not previously completed GCP training and who will work on clinical research sponsored by Barts Health or Queen Mary must complete the <i>Implementation of GCP at Barts Health and Queen Mary course</i>. It is recommended that staff new to the organisations also attend this course. Please see the JRMO website for further details. <u>Externally Sponsored Hosted studies at Barts Health or Queen Mary</u> All staff working on studies sponsored by organisations other than Barts Health/Queen Mary must complete GCP training prior to working on any study at a Barts Health or Queen Mary location. External sponsors determine their own training requirements; research teams must confirm and comply with those requirements before study activity begins.

		<u>Refresher Training and Records</u> GCP refresher training within 3 years of last GCP training is mandatory for MHRA regulated studies and recommended for all other research studies. All staff must keep up to date with regulatory changes. Staff must retain evidence of training in the Investigator Location File (ILF) and where applicable, the Trial Master File (TMF).
2.	All Researchers (Location, Co-ordination, and central facility staff)	Researchers must maintain an up-to-date CV in the TMF / ILF. Using the Health Research Authority short CV template is recommended. Individuals should sign and date their CVs. For sponsored MHRA regulated studies, CVs must be updated at least every 3 years or when a new delegated study role 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 best practice for all other research study types.
3.	CI/PI	Ensure that site personnel are appropriately trained prior to undertaking study -related activities. The CI must ensure: • All co-ordination personnel have completed appropriate* training and that it is documented in the TMF prior to commencing work on the study. • At initiation, all site personnel have completed appropriate* training (as per SOP 46 Site selection, site initiation & site activation). In line with SOP 45 (Essential documentation including TMF), maintain and file training records (including GCP) in the ILF/TMF for all delegated staff for the duration of a study, see appendix A for template. Retain all superseded training documents (e.g. outdated CVs) and allow departing researchers to take original training documents provided that a copy is retained in ILF/TMF. <i>*See section 4 for description of appropriate training.</i>
4.	All researchers	All researchers must be appropriately trained prior to commencing any research activity. Research Specific Training should be proportionate to the researcher's role. Appropriate training should be • Topic specific understanding sufficient to perform their role. • Study and protocol specific training, including review of approved protocol, study specific SOPs and manuals, and any training in study specific procedures (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 ad hoc for new staff or Protocol updates. • GCP or equivalent training for all staff delegated tasks beyond their routine duties, at a level proportionate to their roles and responsibilities.

6.	All Staff	Booking a JRMO training course and issuing of certificates Dates of courses and booking details are available on the JRMO website: https://www.jrmo.org.uk/news-and-training/research-governance-training/ Training certificates are issued within 7 working days of course completion. Certificates will only be issued where delegates have completed the full course. The JRMO will not re-issue certificates if the original certificate has been lost by the researcher. Should a certificate be lost by a course delegate, the JRMO will send an email confirming their attendance.
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Change control

This section outlines changes from version **10.0** to version **11.0**

Section changed	Summary and description of changes
Scope	Clarification on the definition of the lead study team
Section 1	Update to JRMO delivered GCP courses
Section 1 and 2	Timeline change for updating GCP training and CV renewal
Throughout	Updated terminology in line with ICH E6 R3

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