Standard Operating Procedures (SOP) for:			
Researcher Training			
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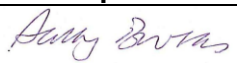
Signature	
Date	**27/4/15**

Purpose and Objective:
To ensure Barts Health NHS Trust (BH)/Queen Mary University of London (QMUL) staff are aware of clinical research training requirements and how to book on the courses provided by the Joint Research Management Office (JRMO).
Scope:
This SOP applies to all QMUL and BH staff undertaking clinical research. This SOP covers **JRMO** training required to commence work on a research project which includes Good Clinical Practice (GCP) training and/or Research Governance Framework (RGF) training. BH and QMUL mandatory staff training is not included.

Abbreviations:	
CI	Chief Investigator
BH	Barts Health NHS Trust
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
QMUL	Queen Mary University of London
PI	Principal Investigator
RGF	Research Governance Framework
SOP	Standard Operating Procedure

Definitions *(if needed):*

Lead Team: refers to the key BH/ QMUL research team members i.e. BH/QMUL CI, BH/QMUL PI, BH research nurse dedicated to the trial, BH/QMUL trial coordinator/manager

Hosted trials: trials or studies which are sponsored by external parties i.e. commercial companies or NHS Trusts or Universities other than QMUL or BH

CTIMPs: Clinical Trial of Investigational Medicinal Products (drug trials)

ATMPs: Advanced-therapy medicinal product

Clinical Investigations: is defined as that segment of clinical research for which an investigator directly interacts with patients in either an outpatient or inpatient setting. This definition excludes studies for which material of human origin is obtained through a third party and for which an investigator has had no direct interaction with the patient.

Non-CTIMPs: Non - Clinical Trial of Investigational Medicinal Products (non-drug trials).

Relevant JRMO SOPs:	
SOP 11a	Sponsorship of CTIMPs – guide for researchers
SOP 28	Monitoring
SOP 34b	JRMO Staff training and induction
SOP 41	JRMO Oversight of CTG and Study specific SOPS
SOP 45	Essential Documents
SOP 46	Site selection, site initiation and site activation

SOP text

	Responsibility	Activity
1.	All Staff	**Trials Sponsored by QMUL or BH** **CTIMPs** – the CI and lead team must attend the JRMO Good Clinical Practice (GCP) training course before the JRMO will issue the Final Declaration of Sponsorship. See SOP 11A (Sponsorship of CTIMPs – guide for researchers) • The full-day GCP course is suitable for all new researchers conducting trials of medicinal products (drug trials). If a researcher has not previously attended a GCP course and are currently or likely to be working on one or more Clinical Trials of Investigational Medicinal Products (CTIMPS/drug trials) then they are required to take the GCP (Full Course). • GCP Refresher course is suitable for those who are working on Clinical Trial of Medicinal Products (CTIMPs/drug trials) who have previously attended GCP training but need to refresh and update their knowledge. This course is mandatory for all researchers working on CTIMPs every two years. • CI training – all CI's must attend annual CI workshops provided by the JRMO. Workshop dates will be sent to CI by the JRMO GCP managers. • New CI's – it may be a sponsorship requirement for new CI's to participate in a mentorship agreement with an experienced CTIMP CI. See SOP 11A – Sponsorship of CTIMP for further information. **Non-CTIMPs** – the CI and lead team should attend the JRMO's Research Governance Framework (RGF for non-CTIMP studies) course prior to being delegated responsibilities on any research project. • The RGF Course is suitable for researchers who have not previously attended a GCP session and who are not expecting to work on any trials involving Investigational Medicinal Products (non-CTIMP/non-drug trials). For example qualitative research i.e. questionnaires and interviews, or on studies limited to working on human tissue, or medical device studies, or surgical studies. Please note, this course does not meet the minimum training requirements for CTIMP (drug trials) studies. Therefore, if a researcher is subsequently required to work on CTIMP studies, they will need to attend the appropriate GCP course. • The JRMO requires staff members to attend JRMO training unless the GCP Manager (CTIMPs & non-CTIMPs) or Research Governance Team leader (non-CTIMPs) waivers attendance based upon evidence of acceptable external training or an agreed external supplier, such as NIHR. **Trials Hosted at QMUL or BH (externally sponsored studies)** All staff who work on 'hosted' studies i.e. sponsored by organisations other than QMUL or BH, should receive GCP (if a CTIMP) and/or an equivalent Research Governance Framework training (if a non-CTIMP), prior to commencing work on any project at the BH or QMUL 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 BH/QMUL Investigator Site File (see SOP 45 – Essential documents for guidance). Staff are requested to keep themselves up to date with regulatory changes and attend a GCP refresher every 2 years (mandatory for staff working on CTIMPs and advisory for staff working on non CTIMPs).
2.	All Researchers (Site , Co-ordination and central facility staff)	**Individual researchers working on a research project should ensure an up to date CV is present in the trial file** (TMF or ISF as applicable). It is advised that researchers use the HRA short CV template to ensure relevant information is captured. CVs should be updated at least on a 2 yearly basis or when a new role or training is undertaken.
3.	Chief Investigators	**The CI of BH or QMUL sponsored trial is overall responsible for coordinating and 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 trial master file prior to commencing work on the project. CVs should be updated on a 2 yearly basis, when undertaking a new role, when training is undertaken or for sites external to BH and QMUL as per local site Institutional procedures. • 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 activation). Evidence of training needs to be filed as per SOP 45 (Essential Documents). It is advised that all research personnel maintain a training record (template contents page can be found in appendix A). When researchers leave, they should take the original copies of training with them but a copy should be retained by the team leader.
4.	Principal Investigator	**The BH or QMUL PI is to ensure that all site personnel have had appropriate* training prior to commencing work on the project**. Evidence needs to be filed as per SOP 45 (Trial master file). This should be reviewed as part of routine monitoring (see SOP 28 – Monitoring)
5.	All researchers	**All researchers should ensure that they are appropriately* trained prior to commencing work on any research project, trial or study.** Training should be proportionate to the researcher's role within the study team. *Appropriate training should include • 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 CRF completion). This can be delivered as part of a site initiation visit but should also be carried out for all new staff. • GCP/ RGF 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 GCP refresher course.
6.	All Researchers	**Researchers should work in compliance with BH and QMUL research polices and the JRMO standard operating procedures**.

		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). Staff should maintain a reading log (see Associated Document 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 Quality Assurance Manager.
7.	CI/Lead team	CI/lead team must review JRMO SOPs and BH/QMUL requirements to ensure compliance. This can be delegated to a Clinical Trials Unit if applicable. 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).
8.	All Staff	**Booking a JRMO training course** Dates of courses and booking details are available on the JRMO website under *Training*. http://www.bartshealth.nhs.uk/research/governance/training/ Course are booked online only via the QMUL training website which can be accessed by QMUL, BH and external staff. JRMO courses are available for all staff who work for Queen Marys University of London and Barts Health NHS Trust, and North Thames CRN who will not be charged for. Delegates should register before the course and will be issued a certificate upon completion of the course. https://www.esdcourses.org.uk/userlistcourse.php Courses are free to all BH and QMUL staff, JRMO retains the right to request a budget code as a small charge will be applied if staff do not attend. External staff or training queries should be emailed to the JRMO Clinical Trial Facilitator on Reseach.training@bartshealth.nhs.uk Information on costs for external staff are available on the JRMO website or via the research.training@bartshealth.nhs.uk Please note certificates are provided on the day at the course to all delegates who have pre-booked attendees. 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/scan and save a copy of their training certificate. Should a certificate be lost by a course delegate, the JRMO will send an email confirming their attendance was recorded on the course sign-in sheet.

Change Control

This section outlines changes from version 5.0 to version 6.0 of this SOP.

Summary and description of change
1. Clarification of training requirements for the CI/Lead team on BH and QMUL Sponsored Projects. 2. Clarification of the need for CI/lead team to review SOPs and BH/QMUL requirements.

List of appendices

Appendix	Appendix name
Appendix A	Contents of Personal Training File

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.

List of Associated Documents *(these are standalone documents)*

Number	Name
1	SOP Training Log