Joint Research Management Office Standard Operating Procedure for:			
Monitoring			
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Purpose:

The purpose of this standard operating procedure (SOP) is to outline the monitoring process for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) sponsored studies.

This SOP does not cover audits, which are designed to assess and assure the reliability and integrity of a studies Quality Control systems. For auditing procedures, refer to *SOP 22 – JRMO Audits*.

Scope:

This SOP is applicable to Joint Research Management Office (JRMO) staff and external monitors performing monitoring activities on the JRMO's behalf. The JRMO will maintain oversight for monitoring conducted by:

- Clinical Trial Groups within Barts Health/Queen Mary
- Clinical Trial Groups/organisations external to Barts Health/Queen Mary, e.g., externally based Clinical Trials Units (CTUs)

For clinical trials that are not Clinical Trial of an Investigational Medicinal Products, Advanced Therapy Investigational Medicinal Products or clinical investigations, the processes described in this SOP should be considered best practice. In these cases, the Good Clinical Practice (GCP) Team will provide advice only to study teams regarding suggested levels of monitoring.

Monitoring of hosted studies, i.e., those which are sponsored by external organisations, remains the responsibility of the external sponsor.

Abbreviations:	
Barts Health	Barts Health NHS Trust
CTU	Clinical Trials Unit
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MVR	Monitoring Visit Report
PI	Principal Investigator
Queen Mary	Queen Mary University of London
ReDA	Research Database Application
SDV	Source Data Verification
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure
TMF	Trial Master File

SOP Text:		
	Responsibility	**Activity**
1.	GCP Managers	**Selection and training of monitors.** All monitors, both JRMO and external, delegated to monitor Barts Health/Queen Mary sponsored studies, must be appropriately trained to monitor the study adequately. Training records reflecting study specific training, relevant qualifications and certificates must be kept and maintained by the monitors as per *SOP 34a Researcher Training* and *SOP 34b JRMO Staff training and induction*. Non-JRMO monitors (including CTU monitors) must provide evidence of appropriate training and competence. From herein, the term 'monitor' will be used to indicate all JRMO delegated monitors, both JRMO and external. The term 'supervisor' indicates the monitor's line manager and/or monitoring report authoriser. When there is a monitoring supervisor this will be indicated in the monitoring plan *(Associated document 1: Monitoring plan template*).
2.	CTUs / Clinical Trials Groups, performing monitoring on the sponsors behalf	**External monitors use of JRMO approved monitoring tools and templates** Delegated monitors must use the JRMO associated documents (*Associated Documents 2a to 2g*) and implement the JRMO categorisation and findings classification. Monitoring associated documents can be adapted to include study specific requirements with prior approval by the GCP and Governance Managers. The CI is responsible for ensuring that the GCP team is provided with regular updates (standard reporting period is quarterly) on the monitoring findings, (timelines for informing the JRMO will be defined in the monitoring plan and monitoring summaries). The report must take the form of the JRMO summary report (see *associated document 3*).
3.	GCP Managers	**Extent of Monitoring and Monitoring Plan.** See *Associated Document 5 Monitoring guidance* for a considerations list relating to the frequency and type of monitoring. It is the GCP and Governance Manager's responsibility to determine the appropriate level and nature of the monitoring required for the study . This will be based on the risks assessed in line with JRMO's *SOP 23 - Risk assessment*. All studies under the scope of this SOP, must include a degree of on-site monitoring. See *Associated Document 5* for guidance on remote monitoring. The monitoring design must be detailed in the final monitoring plan (see *Associated Document 1*) and signed by the CI and the GCP and Governance Manager. A copy of the plan must be kept in the Trial Master File. The JRMO does not allow self-monitoring of a site, i.e., site staff monitoring their own site or monitoring of a Barts Health site by the CI or CI staff if the CI Staff are part of or work closely with the Barts Health site team. Central monitoring, where data checks are performed by the co-ordinating team (CI team), may be used in conjunction with on-site monitoring as part of risk adaptive monitoring plan.
Monitoring		

4.	Monitor	**Monitors' responsibilities are detailed in *Associated Document 5 Monitoring Guidance.***
5.	Monitor	**Schedule a monitoring visit.** The monitor must schedule the monitoring visit in accordance with the monitoring plan; (this should be at least two weeks in advance, wherever possible). Monitors will provide site staff with a list of the documentation they will require and members of staff that they would like to see during their visit. Monitors must schedule a short meeting with the Principal Investigator (PI) during their visit (as a minimum this must occur at every other visit). Where required as per the monitoring plan, the pharmacy must be visited at every onsite visit and should include reviews of the pharmacy logs. Supporting departments will also be subject to monitoring as outlined in the monitoring plan.
6.	Monitor	**Preparing for a visit.** The monitor must review the relevant study documentation prior to the visit. A list of relevant documentation can be found in *Associated Document 5 Monitoring guidance.*
7.	Monitor	**Conduct the monitoring visit.** All monitoring visits must be logged on the site-monitoring log (See *Associated document 4 Site visit log*).
8.	Monitor	**Verify the studies data collection.** The proportion of source data verification (SDV) performed must be in accordance with the studies monitoring plan.
9.	Monitor	**Monitoring of central facilities and laboratories.** NHS Trust laboratories: In instances where the JRMO risk assessment has identified that the study laboratory work falls under the Trust's United Kingdom Accreditation Service ISO accreditation; the laboratory will not be routinely monitored unless it is acting as a central laboratory. Central laboratories: Must be monitored as per the studies monitoring plan, using *associated document 2e JRMO Laboratory set-up monitoring form and 2g Laboratory ongoing monitoring form*. Other central facilities (e.g., imaging facilities) must be monitored according to the studies monitoring plan. A study and facility specific form will be created by modifying existing JRMO templates depending on the role of the facilities and will be agreed by the GCP and Governance Manager prior to use.
10.	Monitors	**Monitoring the main study specific database.** Studies monitored by a JRMO monitor: All study databases should be reviewed at least once a year. Databases will be assessed on correct agreed formatting use and time efficiency of data entry. Studies NOT monitored by a JRMO based monitor: All quarterly monitoring summaries to the JRMO must include confirmation that: • The database is in the correct agreed format. • Case Report Forms have been received and reviewed as planned. • Data has been entered in a timely manner from all sites.

11.	Monitor	**Classify the monitoring report findings.** All Monitoring Visit Report (MVR) findings will be classed as either critical, major or other and also sub categorised based on the deviation area. Where findings are classed as critical, the CI, GCP and Governance Manager and Research Governance Operations Manager must be notified immediately. See *Associated Document 5* for escalation procedures and timelines. For further details on classifications and categories see *SOP 31 Associated Document 1 Non-Compliance Guidance*.
12.	Monitor	**Writing and finalising the MVR.** • Critical or major findings that were not resolved during the visit must be dealt with/escalated immediately to the PI, CI, GCP and Governance Manager before finalising the MVR. See *Associated Document 5* for escalation procedures and timelines • Draft the MVR and submit to the GCP and Governance Manager, ideally within 10-working days of the visit • Reports should accurately describe which documents and source data were reviewed during the visit and what was discussed with the study team. • The MVR should be issued to the site within 20-working days of the visit. ○ The PI must be sent copies of all site, site lab, site pharmacy, and site support departments MVR. • Actions should be followed up to resolution. If study teams fail to respond or complete actions within given timeframes, this must be escalated accordingly (See *Associated Document 5* for guidance on escalations.) • If the site cannot meet the monitoring visit reporting timelines this must be agreed and documented by the monitor. • The finalised MVR, along with answers from the team, once resolved must be filed in the relevant section of the TMF and for JRMO monitors the sponsor oversight file. • Copies of all MVRs will be sent to the CI. • Document any other pertinent communication with the study site. • Document any deviations. External monitors will also provide the Sponsor Oversight Group (SOG) with Summary monitoring reports (see *associated document 4 Summary monitoring report*) that summarise the study's on-going performance and monitoring compliance. The standard time interval for summary monitoring reports will be a minimum of twice annually. Summary monitoring reports will be logged with the JRMO as *Associated Document 5 Monitoring Guidance*.
13.	All staff	**Triggered monitoring, audits and suspending recruitment** Any concerns that are raised about a study by a monitor or by a monitoring report may trigger a JRMO audit visit, and/or the JRMO may revise the study's monitoring plans/schedules. On rare occasions where there are serious concerns that have arisen from monitoring, the JRMO may request the suspension of recruitment at a site and will work with the CI to assess whether there is a requirement to temporarily suspend the study for safety or other urgent reasons. Any monitoring concerns

		may be escalated to the SOG which in turn escalated to the Joint Clinical Research Board in accordance with the JRMO escalation process. Please see the Medicines and Healthcare Regulatory Agency website for guidance on suspending and halting study and *SOP 18a - Study closure: guidance for research staff of sponsored studies*; or *SOP 19 - Study closure: guidance for JRMO staff*.
JRMO oversight activities		
18.	JRMO Monitor	**Update the sponsor's database and track the monitoring.** Following permission to activate sites, the monitor will update the study's monitoring schedule and, where applicable, the JRMO research database application (ReDA) and/or EDGE with site approvals and first monitoring visit due date.
19.	JRMO monitor	**Maintain and update JRMO GCP Monitoring schedule tracker and JRMO GCP Monitoring finding tracker.** The tracker is located and accessed via the JRMO SharePoint site. With restricted access. The tracker is available for regulatory inspection as a verified copy on request.
20.	GCP and Governance Manager	**Ensure appropriate Monitoring meeting are held to maintain oversight of Tracker and findings Trackers.** Ensure meetings and actions are documented and actioned. (See *section 8 Associated Document 5 Monitoring Guidance*)
21.	Senior GCP and Governance manager	**When issues are escalated take actions to facilitate resolution** Ensure CI is aware of escalated issues. If unable to close issue satisfactorily or there is disagreement escalate to the Research Governance Operations Manager.
22.	Research Governance Operations Manager	**When issues are escalated take actions to facilitate resolution or escalate to SOG if unable to close issue satisfactorily.** Ensure Senior GCP Manager and If different allocated GCP manager is aware
23.	SOG	**When issues are escalated take actions to resolve to the SOG satisfaction.**
24.	JRMO Monitor	**Logging of summary reports within JRMO as *per Associated Document 5 Monitoring Guidance*** This is the responsibility of the JRMO Monitor and GCP team. The EDGE workflow "JRMO Summary Monitoring Report" must be completed for each report reviewed

Change control

This section outlines changes from version 9 to 10

Section changed	Summary and description of changes
Throughout	Addition of a guidance document to include the more details descriptions of monitoring activities
Appendix A and B	Transfer of information to a guidance document
Section 2	Section added on the use of JRMO approved monitoring tools and templates by external monitors
Section 14 to 17	More detailed guidance on remote monitoring
Sections 18 to 24	More detailed guidance on the escalation procedures for incomplete findings.

List of appendices

There are no appendices for this SOP.

List of associated documents

Document ref.	Document name
1	Monitoring plan template
2a	ISF monitoring form
2b	TMF monitoring form
2c	Single site monitoring form
2d	Pharmacy monitoring form
2e	Laboratory set-up monitoring form
2f	SDV monitoring form
2g	Laboratory ongoing monitoring form
3	Summary monitoring report
4	Site visit log summary monitoring report
5	Monitoring Guidance