Joint Research Management Office Standard Operating Procedure for:			
Non-Compliance and Serious Breach Reporting			
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Purpose:

The purpose of this standard operating procedure (SOP) is to describe the management of incidences of non-compliances, potential serious and serious breaches in medical research across Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary). This SOP describes recording, corrective and preventative actions (CAPA), root cause analysis (RCA) establishment and escalating these incidences.

Scope:

This SOP is applicable to all staff (including Joint Research Management Office (JRMO) staff) and students involved in medical research taking place at Barts Health and Queen Mary. This SOP applies to all clinical research sponsored or hosted by Barts Health or Queen Mary.

It is the responsibility of all staff involved in a study to identify incidences of non-compliance and report potential serious breaches occurring during the day to day running of a clinical trial to the sponsor. The sponsor is responsible for assessing potential serious breaches to decide whether the event is considered to be a serious breach and for notifying the regulatory authority of these.

Abbreviations:

Barts Health	Barts Health NHS Trust
CAPA	Corrective Action Preventative Action
CI	Chief Investigator
GCP	Good Clinical Practice
HRA	Health research Authority
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance

QMS	Quality Management System
Queen Mary	Queen Mary University of London
RCA	Root Cause Analysis
REC	Research Ethics Committee
SOG	Sponsor Oversight Group
SOP	Standard Operating Procedure

Definitions:

For definitions, please see *Associated Document 1 Non-compliance guidance*.

SOP Text:

	Responsibility	Activity
1.	All (JRMO staff, Chief Investigator (CI), Principal Investigator (PI), research team, sponsor, third parties)	**Identify the occurrence of a non-compliance** All non-compliances/breaches must be reported and recorded for the duration of the study. Upon becoming aware of a non-compliance, report it directly to the JRMO Good Clinical Practice (GCP) and Governance Manager or Quality Assurance (QA) Manager or via email to *research.safety@qmul.ac.uk*. The email should clearly indicate a non-compliance is being reported. See *Associated Document 1 Non-compliance document guidance document* for further details. The JRMO may request completion of a non-compliance notification form to capture further information where necessary (*Associated document 2 Non-Compliance notification form*)
		Potential Serious Breach
2.	CI/PI/Study team	**Notify the sponsor immediately of any potential serious breaches.** If the study is sponsored by Barts Health or Queen Mary, the JRMO GCP team must be notified of any potential serious breaches, by emailing *research.safety@qmul.ac.uk* ensuring the GCP & Governance Managers and QA Manager are copied into the email. As much information as possible should be provided. The initial notification, if made by telephone/MS Teams, should be followed by written notification of the potential serious breach. The CI/PI (or delegate) should send the notification to the sponsor representative within 24hrs of becoming aware of the potential serious breach. If the incident involves a Barts Health patient or staff member, consider if it meets the requirements of the Barts Health Incident Reporting policy, as necessary.

		If the incident is related to confidentiality or data protection, please see *SOP 16a Data Protection* for research studies for further contact and reporting details.
Barts Health and Queen Mary sponsored studies		
3.	JRMO GCP & Governance Manager and/or QA Manager	**Review the event.** When notified of a potential serious breach, the information should be reviewed in a timely manner to ensure that the event can be reported within the appropriate timelines. Any additional information required should be requested from the study team. The QA manager will log the breach on the non-compliance log, update with all significant information and retain all pertinent correspondence. For further details see *Associated document 1 Non-Compliance guidance document.*
4.	JRMO GCP & Governance Manager and/or QA Manager	**Assess the event and decide if it is a serious breach.** Once the necessary information has been received, the GCP & Governance Manager/QA Manager must assess the event and decide whether it is a serious breach (please refer to the Medicines and Healthcare products Regulatory Agency (*MHRA*) and Health Research Authority (*HRA*) website for further guidance on the notification of serious breaches of GCP or the trial protocol). For UK studies, notify the MHRA if a serious breach at a non-UK site significantly impacts participant integrity both there and in the UK. If a serious breach occurs in a sponsored study, complete the report and send it to: 1. MHRA for regulated studies, using the form specified on their website. 2. Relevant ethics committee for interventional or research studies, following their SOPs. Usually, the CI/PI and research team agree on serious breach assessments. If disagreements persist, escalate to the Research Governance Operations Manager and Sponsor Oversight Group (SOG) for a decision, documenting the reasons. .
5.	JRMO GCP & Governance Manager and/or QA Manager	**For Sponsored MHRA-regulated studies notify the MHRA about the serious breach within 7 days.** Details about how to submit to the MHRA can be found on the *MHRA website*. Ensure the notification sent to the MHRA includes the agreed corrective and preventative actions. Also ensure that a copy of the notification is sent to the study team and filed in the JRMO sponsor oversight files. The MHRA will confirm receipt of the serious breach.

6.	CI (Or delegate)	**Notify the Research Ethics Committee (REC) about the serious breach using the agreed documents** For MHRA regulated studies: Notify the REC within 7 days, as per HRA website. Please copy the GCP manager in when making this submission. For Interventional/Research studies Notify the REC within 15 days. A cover letter should also be submitted to the REC and the generic safety mailbox *(research.safety@qmul.ac.uk*) copied in.
7.	JRMO GCP & Governance Manager and/or QA Manager or CI (Or delegate)	**Provide relevant information and follow up to the MHRA and/or REC.** The GCP & Governance Manager, QA Manager and CI (or delegate) should work together to provide relevant additional information to the MHRA and/or REC and follow up any further actions the MHRA and/or REC request. The GCP & Governance Manager, QA Manager and CI (or delegate) must ensure all required actions are completed and that the breach is then closed. The MHRA will formally email to state no further information is required. The REC will acknowledge in writing and further information or clarification may be requested until the event is closed.
Serious breaches for Barts Health and Queen Mary Hosted studies		
8.	PI (or delegate)	**Inform the JRMO of potential serious breach and forward all relevant paperwork.**
9.	JRMO GCP & Governance Manager and / or QA Manager	**Review potential serious breach** Review serious breach and record with study documentation. As it is the sponsor's responsibility to assess the breach and ensure resolution, the GCP & Governance Manager and QA Manager will assist only where requested or where necessary.
Non-Compliance reporting for all study types (Non-Serious breach)		
10.	QA Manager or agreed delegate/ GCP and Governance manager	**Initial review of the non-compliance and escalate if required.** Confirm receipt of the non-compliance notification via email. Review and assess the non-compliance and request any follow-up details, if needed. Review event and if major or critical or a potential serious breach discuss with the GCP and Governance Manager. Assign an owner from the Governance Section to ensure CAPA completion. If the QA Manager has any immediate concerns escalate to the Senior GCP and Compliance manager or delegate. Following review and assessment, if the Senior GCP and Compliance Manager has any immediate concerns, escalate to the Research Governance Operations Manager.

11.	QA Manager or agreed delegate	**Add event to JRMO non-compliance log.** The QA manager will log the incident on the non-compliance log, categorise as appropriate, update with all significant information and retain all pertinent correspondence. Further details see *associated document 1 guidance document*.
12.	Quality Management System (QMS) group	**QMS meeting to review Non-Compliances** All non-compliances are reported, discussed and any required actions taken within the QMS meeting. Decisions regarding escalation of open non-compliances will be made and documented through this meeting. Bespoke non-compliance meetings may be arranged outside the QMS meeting should there be need for a more details review of the non-compliance.
13.	QA Manager and/or GCP and Governance Manager	**Waivers to JRMO SOPs and processes** The JRMO does not routinely expect study teams to deviate from JRMO SOPs and processes. If a deviation is agreed by the sponsor, the QA manager logs it as a waiver, which remains open until fully implemented and approved. Clear timelines will be assigned to the actions of the waiver and escalation through the Quality Management System will occur if not met. Eligibility criteria changes are always amendments, not waivers.
14.	QA Manager / GCP and Governance Managers	**Ensure that each non-compliance is sufficiently reviewed and actioned.** The QA Manager will work with the GCP and Governance Managers (and where applicable the event owner) to ensure all non-compliances are actioned, with sufficient CAPA plan in place; and that all relevant documentation is filed in the JRMO sponsor oversight file. Where there are unnecessary delays in CAPA completion, escalation may be required as per points 15 to 18.
Further escalation, review follow up of all events		
15.	QA Manager/Non-Compliance Owner/Study Group	**RCA and Risk Impact Assessment** RCA and impact assessment process will be implemented where events are reported as a serious breach, non-compliances are classified as critical, where multiple majors occur in one study or where a non-compliance remains unresolved or a direct CAPA plan is difficult to establish. The *RCA proforma (Template 1)* is used to document this procedure and can be adapted to suit the needs of the investigation

		Further details on RCA can be found in *Associated Document 1 JRMO Non-Compliance guidance document.*
16.	QA Manager or agreed delegate	**Escalating non-compliances.** As appropriate and depending on severity of the incident and lack of researcher engagement, an escalation to the QMS group will occur. If unresolved or the identification of a serious or persistent non-compliance by the QMS and the Research Governance Operations manager, escalation to SOG may be required.
17.	SOG	**SOG review** Every 3 months, SOG members review papers detailing all open and closed critical non-compliances during that period. At each meeting, QA Manager will present updates on escalated non-compliances. The group will review and discuss non-compliance trends, any serious or persistent non-compliance and agree actions to be taken to secure compliance and prevent reoccurrences.
Event Closure		
18.	QA Manager or agreed delegate	**Review of closed non-compliances** A non-compliance can be considered closed at the QMS level when there is evidence that all CAPA has been sufficiently completed. The QA Manager will provide papers of the Major and Other Non-Compliances for review and agreement at the QMS meeting. All closed critical findings will be reviewed for agreement at the SOG.

Change control

This section outlines changes from version **6.0** to version **7.0**

Section changed	Summary and description of changes
Section 12	Removal of reference to a bespoke non-compliance meeting
Section 13	Clarification on waiver issuing to study processes
Section 14	Stronger guidance on non-compliance CAPA
Section 18	Removal of non-compliance closure certificates
Associated document 1	Implementation of impact assessment as part of CAPA review
Template 1	Change of document from an associated document to a template

List of appendices

There are no appendices associated with this SOP.

List of associated documents

Document number	Document name
Associated Document 1	Non-Compliance guidance document
Associated Document 2	Non-Compliance notification template
Associated Document 3	Roof Cause Analysis Proforma

Templates

Template number	Document name
Template 1	Root Cause Analysis and Risk Impact Assessment Template