Standard Operating Procedure (SOP) for:			
Non-compliances			
SOP Number:	**31**	Version Number:	**3.0**
Effective Date:	**25th June 2018**	Review Date:	**25th June 2020**

Signatures:			
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Reviewer:	**Mays Jawad, R&D Governance Operations Manager**		
Signature:		**Date:**	

Authorisation:	
Name/Position:	**Coleen Colechin, Interim Director of Research Services and Business Development**
Signature:	
Date:	

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Reviewer:	**Mays Jawad, R&D Governance Operations Manager**

Authorisation:	
Name/Position:	**Coleen Colechin, Interim Director of Research Services and Business Development**

Purpose:

The purpose of this standard operating procedure (SOP) is to describe the management of incidences of non-compliance in medical research across Barts Health NHS Trust (BH) and Queen Mary University of London (QMUL). This SOP describes recording, corrective actions, and escalating incidences of non-compliance.

For the management of serious breaches refer to *JRMO SOP 37 Reporting serious breaches of GCP or trial protocol*.

Scope:

All staff involved in medical research taking place at BH and QMUL.

Abbreviations:

BH	Barts Health NHS Trust
CAPA	Corrective and Preventative Action
CI	Chief Investigator
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
PI	Principal Investigator
QA	Quality Assurance
QMS	Quality Management System
QMUL	Queen Mary University of London
R&D	Research and Development
SOP	Standard Operating Procedure

Definitions:
• Non-compliance (in relation to clinical trials): A breach or deviation from clinical trial protocols, written procedures, GCP and/or applicable regulatory requirement(s). • Non-serious breaches: deviations from clinical trial protocols, written procedures and GCP that do not result in harm to trial participants' or significantly affect the reliability of trial data. Examples can include but are not limited to: o A missed visit window o Boxes on the consent form ticked rather than initialled o Incorrect sample handling/processing • Sponsor oversight group: A JRMO group of senior managers that meet to address significant issues in the conduct of trials sponsored and hosted by BH/QMUL.
Relevant SOPs:
• SOP 37 Reporting serious breaches of GCP or trial protocol

SOP Text:		
	Responsibility	**Activity**
1.	All (JRMO staff, CI, PI, research team, sponsor, third parties)	**Non-compliance identified and reported** Non-compliance can be identified in a number of ways including complaints, monitoring, internal and external audits. Upon becoming aware of a non-compliance report it to the JRMO GCP & Governance Manager via email to JRMO-ResearchGovernance@qmul.ac.uk. The notification email should include: • Project ID if applicable (ReDA No, Title, PI), • Sponsor, • Date non-compliance identified, • Date non-compliance occurred, • Description of non-compliance/event, • Details of proposed corrective and preventative actions (CAPA), Details of lead point of contact for follow-up.
2.	GCP & Governance Manager	**Review non-compliance and escalate if required.** Confirm receipt of the non-compliance notification, via email, to the sender of the event. Review and assess the non-compliance and request any follow-up details. Review the event to determine whether it is a serious or non-serious breach (for a serious breach refer to *JRMO SOP 37*). Agree who is the owner of the event to ensure CAPA and follow-up as needed (for example a non-compliance related to amendments submission may be owned by a Research Management & Governance Officer or Governance Team Leader).

		Following review and assessment, if the GCP & Governance Manager has any immediate concerns, the event will be escalated to the R&D Governance Operations Manager.
3.	QA Manager	**Add event to JRMO non-compliance log.** The JRMO non-compliance log is a record of all non-compliances reported in medical research across BH/QMUL. The log is stored electronically as part of the JRMO quality management system (QMS). It is managed and maintained by the QA Manager and will be used by JRMO staff to identify patterns/trends in non-compliance. The QA Manager will add each reported non-compliance to the JRMO non-compliance log. Non-compliances will be classified as "critical", "major" and "minor": • **Critical:** non-compliances that adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data; o where evidence exists that the safety, well-being or confidentiality of study subjects has been jeopardised, and/or; o where evidence exists that reported data are unreliable, and/or; o where inappropriate, insufficient or untimely corrective action taken place regarding major non-compliances; o where there is significant failure to comply with relevant legislative requirements. • **Major:** non-compliances that might adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data; o where evidence exists that the safety, well-being or confidentiality of study subjects may have been jeopardised, and/or; o where evidence exists that reported data may be unreliable, and/or; o where inappropriate, insufficient or untimely corrective action taken place regarding minor non-compliances; o where there is unjustified failure to comply with relevant legislative requirements. **Minor:** non-compliances that would not be expected to adversely affect the rights, safety or well-being of the subjects and/or the quality and integrity of data.
4.	QA Manager / GCP & Governance Manager	**Ensure that each non-compliance is actioned and subsequently closed.** The QA Manager will work with the GCP & Governance Managers (and where applicable the event owner) to ensure all non-compliances are actioned and closed; and that all relevant documentation is filed in the JRMO sponsor oversight file. Ongoing events will be reviewed as part of the JRMO QMS meeting.
5.	R&D Governance Operations Manager	**Assess escalated non-compliance.** When non-compliances are escalated, assess which parties should be notified (e.g. sponsor, medical director) as needed, and any sanctions necessary (e.g. removing NHS permission, full investigation, temporary halt to a project).

		If review and assessment of non-compliances identifies serious and/or persistent non-compliance on the part of an investigator/institution the R&D Governance Operations Manager will escalate the event(s) to the sponsor oversight group.
6.	Sponsor oversight group	**<u>Review and discuss non-compliance trends.</u>** Members of the sponsor oversight group will receive the JRMO non-compliance log to review as part of the sponsor oversight group meeting, which occurs approximately every 3 months. At each meeting the R&D Governance Operations Manager and/or GCP & Governance 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.

Change control

This section outlines changes from version **2.0** to version **3.0**

Section changed	Summary and description of changes
Definitions	Addition of non-compliance, non-serious breach, sponsor oversight group
All	Removed references to research related complaints
All	General administrative changes

List of appendices

There are no appendices for this SOP.

List of associated documents

There are no associated documents for this SOP.