Joint Research Management Office Standard Operating Procedure for:			
Site Level Safety Reporting for Clinical Investigations of Medical Devices			
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Purpose:

This Standard Operating Procedure (SOP) describes the actions that Principal Investigators (PIs) at sites must complete, and that Chief Investigators (CIs), device manufacturers and study coordinators must be aware of in order to comply with the regulatory requirements for safety reporting in Clinical Investigations of medical devices.

This SOP discusses the safety reporting requirements as described in *ISO 14155:2020 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice* and the *Medical Device Regulations 2017*.

Scope:

This SOP applies to Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) sponsored Clinical Investigations of Medical Devices. This SOP describes the responsibilities of research teams and manufacturers. For the Joint Research Management Office's (JRMO) and CI's responsibilities, please see *SOP 26c Pharmacovigilance (Process for the Sponsor and CI).*

For other medical device studies, please refer to *SOP 26b Site level Pharmacovigilance for Interventional and Research studies.*

For medical device studies sponsored by organisations other than Barts Health or Queen Mary, please refer to the sponsor's safety reporting SOPs. Please only report safety events for Barts Health and Queen Mary sponsored studies to the JRMO.

Further guidance can be found in *Associated Document 1 Guidance on safety reporting for Clinical Investigation Plans*

Abbreviations:	
ADE	Adverse Device Effect
AE	Adverse Event
ASADE	Anticipated Serious Adverse Device Effect
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CIP	Clinical Investigation Plan
CRF	Case Report Form
GCP	Good Clinical Practice
IB	Investigators Brochure
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
Queen Mary	Queen Mary, University of London
REC	Research Ethics Committee
SAE	Serious Adverse Event
SADE	Serious Adverse Device Effect
SOP	Standard Operating Procedure
USADE	Unanticipated Serious Adverse Device Effect

Definitions:
See SOP 26a AD1 Pharmacovigilance Definitions

Relevant SOPs:	
• SOP 26a	Site level Pharmacovigilance for MHRA regulated studies
• SOP 26b	Site level Pharmacovigilance for Interventional and Research studies
• SOP 26c	Pharmacovigilance (Process for the Sponsor and CI)
• SOP 17a	Amendments for sponsored studies (including halting studies) - Process for JRMO
• SOP 17b	Amendments for hosted studies
• SOP 17c	Amendments for sponsored studies (including halting studies) - Process for researchers

SOP Text:		
	Responsibility	**Activity**
Recording and reporting of events for Barts Health & Queen Mary sponsored studies.		
1.	PI or delegate	**Record all identified Adverse Events (AE) in the participant's medical records and transcribe into the case report forms.** Each AE must be identified and reported separately. Where multiple symptoms are caused by an underlying condition, only the underlying condition should be reported as an adverse event.

		As AEs are medical events, they must be recorded in the participant's medical records as the source document. Records of AEs and device deficiencies should be transcribed into the case report form (CRF). All adverse events should be followed up to resolution. If the Clinical Investigation Plan (CIP) specifies any adverse events that must be reported immediately they should be managed according to step 5 of this procedure.
2.	PI or medical delegate	**Assess each adverse event to confirm whether it is a Serious Adverse Event (SAE).** Record the seriousness assessment in the participant's medical records and transcribe into the CRFs. **All SAEs must be reported within 24 hours of becoming aware of the event – see step 5.**
3.	PI or medical delegate.	**Assess each adverse event to determine whether it is an Adverse Device Effect (ADE).** Assess whether there is a reasonable possibility that the AE could have been caused by the investigational medical device. This assessment should be based on the assessors medical and scientific knowledge and so must only been completed by the PI or by an experienced delegate medic at the site. Also assess whether the AE could be related to a comparator or to the investigation procedure. Document the assessment in the participant's medical records and transcribe to the CRF.
4.	PI or medical delegate.	**Assess each Serious Adverse Device Effect (SADE) to confirm whether it is anticipated.** Compare each SADE to the list of anticipated SADEs, which is normally located within the device's Investigators Brochure (IB). The CIP should confirm the location of the Anticipated Serious Adverse Device Effect (ASADE) list. All SADEs which are not listed are USADEs. Document the assessment in the participant's medical records and transcribe to the CRF.
5.	PI	**Report all SAEs (including SADEs, ASADEs and USADEs) to the sponsor and device manufacturer within 24 hours of becoming aware of the event.** Report all SAEs to the sponsor by emailing a completed Clinical Investigation Safety Reporting Form (Associated Document 2) to research.safety@qmul.ac.uk. Ensure that you receive an acknowledgement to confirm that the report has been received. Also email the forms to the study mailbox if applicable. The Clinical Investigation Safety Reporting Form should be signed by the PI or medical delegate to evidence their assessment of the event. Report all SAEs to the device manufacturer according to their procedures. Record all device vents in the study device events log (Associated document 3). All SAEs must be followed-up until resolution. When follow-up information about the SAE becomes available, the PI or delegate should reassess the event and

		submit an updated Clinical Investigation Safety Reporting Form to research.safety@qmul.ac.uk and the study mailbox if applicable.
6.	PI	**Respond to SAE queries** The sponsor will confirm acknowledgement of all reported SAEs. These confirmations should be filed in the site file. Site teams should respond to queries about SAEs within one week. Queries about USADEs and queries which could change whether an SAE is related or anticipated should be answered immediately.
		Recording and Reporting of Device Deficiencies
7.	PI or delegate.	**Record all identified device deficiencies in the participant's medical records and transcribe into the case report forms.** Record all device deficiencies in the study device deficiency log (Associated document 4). Actual AEs which have been caused by device deficiencies should be processed according to steps 1-6 of this procedure and may need to be reported as SADEs or USADEs. If the CIP specifies any device deficiencies that must be reported in an expedited manner, they should be managed according to step 9 of this procedure.
8.	PI or medical delegate.	**Assess whether each device deficiency could have caused a SADE.** Assess whether the device deficiency could have caused a SADE: • If suitable action had not been taken; or • If intervention had not been made; or • If circumstances had been less fortunate. Document this assessment on the device deficiency log (*Associated Document 4*).
9.	PI or medical delegate.	**Report device deficiencies that could have caused a SADE to the sponsor and device manufacturer within 24 hours.** Report the device deficiency to the sponsor by emailing a completed Clinical Investigation Safety Reporting Form to research.safety@qmul.ac.uk and to the study mailbox if applicable. Ensure that you receive an acknowledgement to confirm that the report has been received. The device deficiency must be assessed by the PI or by a suitable medical delegate, and evidenced through their signature of the appropriate form. Report device deficiencies to the device manufacturer according to their procedures. If follow-up information about the device deficiency becomes available, the PI or delegate should reassess the event and submit an updated Clinical Investigation Safety Reporting Form to research.safety@qmul.ac.uk (and the study mailbox if applicable) and report to the manufacturer according to their procedures.
10.	PI	**Respond to Device Deficiency Queries** Queries about Device Deficiencies that could have caused SADEs should be answered immediately.
		Pregnancy Reporting
11.	PI	**Report pregnancies to the sponsor according to study procedures.**

		If a participant becomes pregnant while taking part in the Clinical Investigation, follow the procedures described in the CIP and other essential documents. Where site teams are required to report pregnancies to the sponsor, this must be done within 24 hours of becoming aware of the event. The JRMO pregnancy report form (*JRMO SOP 26a associated document 2*) or a study specific adaptation must be used. The completed form should be sent to research.safety@qmul.ac.uk and the study mailbox if applicable.

List of associated documents

Document ref.	Document name
Associated Document 1	Guidance on safety reporting for Clinical Investigation Plans
Associated Document 2	Clinical Investigation Safety Reporting Form
Associated Document 3	Device Event form
Associated Document 4	Device Deficiency log