Standard Operating Procedures (SOP) for:			
Reporting Incidents Related to Research			
SOP Number:	***027***	Version Number:	***4.0***
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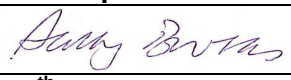
Signature	
Date	**13th August 2015**

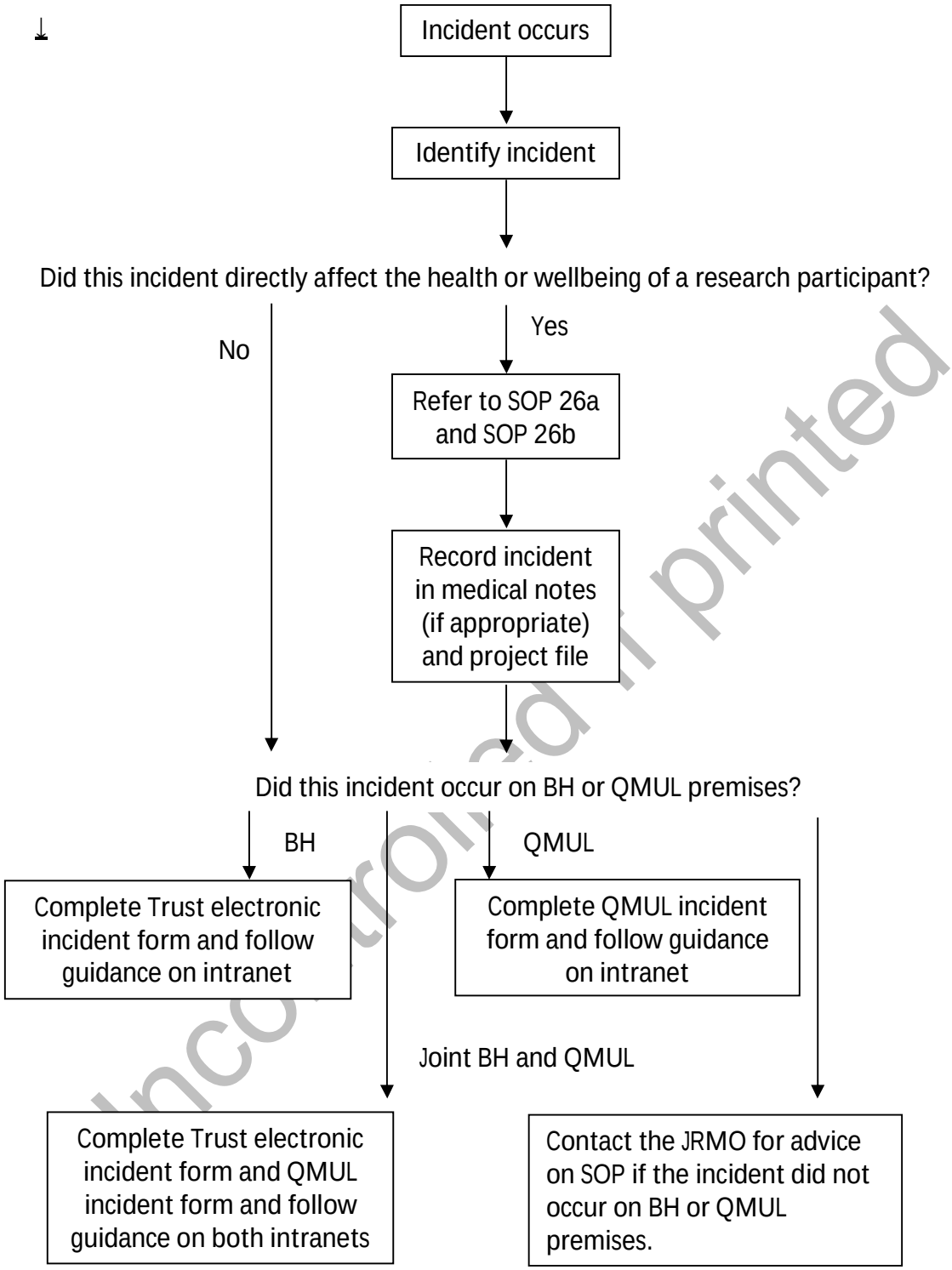
Purpose and Objective:
This SOP provides instruction to researchers regarding the reporting process when incidents occur that are related to research projects.
Scope:
This SOP applies to all staff involved in research using human participants at Barts Health NHS Trust and Queen Mary University of London.

Abbreviations:	
BH	Barts Health NHS Trust
CRC	Clinical Research Centre
JRMO	Joint Research Management Office
QMUL	Queen Mary University of London
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction
Definitions *(if needed)*	
Incident: An event occurring on QMUL or Barts Health NHS Trust premises, or in the course of work undertaken by QMUL or Barts Health staff that could have directly or indirectly led to harm or loss to participants of research, staff, visitors, contractors, QMUL or Barts Health NHS Trust. Serious incident: An incident that that did result in harm or loss.	
Relevant SOP s	
JRMO SOP 26a Pharmacovigilance and Safety Reporting for Sponsored CTIMPs/ ATMPs; JRMO SOP 26b Pharmacovigilance and Safety Reporting for Sponsored non-CTIMPs.	

SOP Text		
	Responsibility	Activity
1.	Research Team/ Principal Investigator	**Ensure that incidents are identified and the appropriate processes are followed.** The process below must be followed whenever an incident that needs to be reported occurs during a research project. Examples of incidents occurring within research that would require reporting are: drug errors, near misses, needle-stick injuries, verbal abuse from a research participant or family member towards a research team member, disclosure of data or personal information etc. If an incident directly affects the health or well-being of a research participant, follow the processes in SOPs 26a (Pharmacovigilance and Safety Reporting for Sponsored CTIMPs/ATMPs) and 26b (Pharmacovigilance and Safety Reporting for Sponsored non-CTIMPs) as well to ensure that the event is reported appropriately. Examples of incidents that must be reported following the processes in SOPs 26a and 26b include a drug error on a trial of a medicinal product that results in a Serious Adverse Event (SAE). There are additional reporting processes in these circumstances. If there is any doubt as to whether an incident should be reported, contact the JRMO for advice. Please Note: All Suspected Unexpected Serious Adverse Reactions (SUSARs) occurring to Trust patients should be reported on the Trust incident system in addition to the other reporting requirements for SUSARs (outlined in SOPs 26 a and b).
2.	Research Team/ Principal Investigator	**Ensure incidents are appropriately recorded and reported.** Record all incidents (whether or not they involve research participants) on the relevant incident form(s). For incidents occurring on Barts Health NHS Trust premises, complete the appropriate Trust electronic incident form which is located on the Trust intranet, and follow the guidance provided there. For incidents occurring on QMUL premises, complete the QMUL incident form which is located on the QMUL intranet, and follow the guidance provided there. Some premises (e.g. the Wingate Institute, the Clinical Research Centre, the William Harvey Heart Centre) share joint custodianship. In such instances report incidents in line with both the Trust and QMUL guidance.

		Assessment of incidents must be conducted in line with institutional policies and procedures. <u>Please note:</u> For incidents involving participants, additional documentation of the incident is required; incidents that directly affect the health or well-being of research participant/s must be recorded in the participants' medical notes, (where applicable) and also in the investigator site file.

Flow Chart



Change Control

This section outlines changes from version 3.0 to version 4.0 of this SOP.

Section	Description of change
Abbreviations, Definitions, Relevant SOPs	Sections added.
1	Heading added. Reference to SOPs 26a and 26b added. Phrasing amended for clarity.
2	Heading added. Clarified that incidents may not involve research participants. Added paragraph regarding premises which share joint custodianship.
3	Heading added. Changed “project file” to “investigator site file”
Flow chart	Added.

List of appendices

No appendices for this SOP.

List of Associated Documents

No associated documents for this SOP.