Joint Research Management Office Standard Operating Procedure for:			
Data Protection for research studies			
SOP Number:	**16a**	Version Number:	**8.0**
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Authorship:		**Signature and Date:**
Author:	Michael Garvey-Eckett, Data & AI Research Governance Lead	Michael Garvey-Eckett Digitally signed by Michael Garvey-Eckett Date: 2025.02.13 09:34:46 Z

This SOP has been reviewed by Paul Smallcombe, Records & Information Compliance Manager and Sarah Palmer-Edwards, Head of Information Governance.

Authorisation:		**Signature & Date:**
Name/Position:	Mays Jawad, Research and Governance Operations Manager	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2025.02.14 08:17:37 Z

Purpose and Scope:

The purpose of this standard operating procedure (SOP) is to provide guidance to ensure that clinical research studies comply with the U.K. General Data Protection Regulation (GDPR), the Data Protection Act 2018 (DPA), Caldicott guidelines 1997, and the NHS Confidentiality Code of Practice alongside organisations policies (see *Associated Document 1 Data Protection Guidance*).

This SOP also provides guidance for investigators concerning maintaining patient and staff confidentiality whilst conducting the research study.

This SOP applies to all clinical research studies submitted to the Joint Research Management Office (JRMO) for approval.

Abbreviations:

Barts Health	Barts Health NHS Trust
CAG	Confidentiality Advisory Group
CI	Chief Investigator
DPA	Data Protection Act
DPIA	Data Protection Impact Assessment
GDPR	General Data Protection Regulation
ICO	Information Commissioner's Office
IG	Information Governance
IRAS	Integrated Research Application System
JRMO	Joint Research Management Office
Queen Mary	Queen Mary University of London
RMGO	Research Management & Governance Officer
SOP	Standard Operating Procedure

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SOP Text:		
	Responsibility	**Activity**
During planning and set up		
1.	Chief Investigator (CI) or delegated other	**Data protection and security safeguards must be considered in the earliest stages of study design and settings must default to the most conservative version with respect to the data subject, only granting additional authorisations as required.** Initially, potential risks and vulnerabilities must be identified, then wherever possible, considerations should be given to mitigations and safeguards. Consideration must additionally be given to any data processors who may also have access to the data during the course of the study and the role they will have in the execution of the study. These considerations must be documented in the protocol. Please see *Associate Document 1 Guidance* for full details of considerations. All research seeking sponsorship by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) must submit a Data Protection Impact Assessments (DPIA) pre-screening form *(Associated Document 2)* to the relevant organisation's team (see *SOP 11a Barts Health NHS Trust/Queen Mary University of London sponsorship of MHRA-regulated studies: Process for researchers* for further details) prior to sponsorship being granted.
2.	CI or delegated other	**Consider and identify issues** or processes where advice is needed on any Information Governance (IG), Data Protection and Security, or Confidentiality issues which arise during the ethical submission of a research study; or to receive advice on studies requiring Confidentiality Advisory Group (CAG) approval. Please see *Associated Documents 3 and 4* for details of how to apply to CAG for Barts Health and Queen Mary.
3.	RMGO/IG	**The Research Management and Governance Officer (RMGO) should check that the information within the Integrated Research Approval System (IRAS) form, information sheets and consent forms are consistent with the DPA, GDPR and local policy requirements.** Items for scrutiny: • Recruitment and consent process. • Storage and use of data during and after the end of the study. • Transfer of data outside of the UK. • Data sharing (UK and beyond). • Data Storage (information asset). • Data Flow mapping. • DPIA requirements. • Data Protection and Confidentiality measures. • Encryption of portable device. Advise investigators on changes to be made to the documentation or procedures in order to comply with the Barts Health and Queen Mary policies with regard to data protection, confidentiality and Caldicott requirements.

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		Suggest that current templates on the IRAS, JRMO and Information Commissioner's Office (ICO) websites are used where appropriate. If required, further information/guidance should be sought from IG.
4.	RMGO /IG	**Complete Data protection review** The RMGO must complete the relevant sponsor review outlined below: • *SOP 11b Governance team sponsorship review for MHRA regulated studies* • *SOP 12b JRMO Governance Team Sponsorship Review for interventional studies* • *SOP 13b JRMO Governance Team Sponsorship Review for research studies* When satisfied that the study meets DPA/GDPR requirements and Barts Health/Queen Mary IG criteria, proceed with remaining steps of sponsor review. If required, further information/guidance should be sought from IG. Any unmitigated data protection risks identified through the process which may cause undue harm to the data subject must be notified to the ICO by IG.
5.	RMGO	**Save a copy of any related documents and clarifying data protection questions into EDGE study files and file the original with the study file.**
During Study		
6.	Research team and/or JRMO Governance Team	**Update any risk related documents as necessary through the lifecycle of the study.** Assess the need for update when any significant changes are made to the study - for example substantial amendments or change in vendors. The DPIA screening questionnaire or actual completed DPIA needs to re-reviewed if updates/changes are introduced.
7.	Research team	Ensure access to source data is provided for Monitors, auditors, and inspectors according to *SOP 16b External access to Patients Electronic Health Record.*
8.	Research team	**Follow *SOP 31 Non-compliance* to report data protection or confidentiality issues.** In addition, follow your organisation and site policy.
9.	Research Governance team	**Ensure all data protection and confidentiality issues are flagged to the relevant organisation IG team.** In general: **For Barts Health** IG team 020 3594 6028 bartshealth.infogov@nhs.net **For Queen Mary:** Paul Smallcombe, Records & Information Compliance Manager 020 7882 7596

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		data-protection@qmul.ac.uk **For external organisations**- contacted the sponsor representative or R&D department
At Study Closure		
10.	Research team and JRMO staff	**Ensure organisation retention policies are adhered to for all forms of data.**

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Change control

This section outlines changes from version **7.0** to version **8.0**

Section changed	Summary and description of changes
Throughout	General administrative changes

List of appendices

There are no appendices for this SOP.

List of associated documents

Document ref.	Document name
Associated Document 1	Guidance Document
Associated Document 2	Data Protection Impact Assessment screening checklist
Associated Document 2	Barts Health CAG (Section 251) application form guidance
Associated Document 3	Queen Mary CAG (Section 251) application form guidance

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