

Joint Research Management Office Standard Operating Procedure for:

Data Protection for research studies

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Authorship & Review:

Author:	Marie-Claire Good, Senior GCP and Governance Manager		
Signature:	<i>The signed original is held within the JRMO office</i>	Date:	
Reviewer:	Paul Smallcombe, Records & Information Compliance Manager		
Signature:	<i>The signed original is held within the JRMO office</i>	Date:	
Reviewer:	Sarah Palmer-Edwards, Head of Information Governance		
Signature:	<i>The signed original is held within the JRMO office</i>	Date:	
Reviewer:	Mays Jawad, Research Governance Operations Manager		
Signature:	<i>The signed original is held within the JRMO office</i>	Date:	

Authorisation:

Name/Position:	Coleen Colechin, Senior Operations Manager (Pre-Award)		
Signature:	<i>The signed original is held within the JRMO office</i>	Date:	

Purpose:

The purpose of this standard operating procedure (SOP) is to provide guidance to ensure that clinical research studies comply with the 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 Appendix 1).

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

Scope:

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

Definitions:

Clinical Research: For the purposes of this SOP this term is used to mean any research surrounding health and social care, including but not limited to:

- Regulated Studies: Any study that needs to be submitted to the MHRA.
- Interventional Studies: Research involving a change in treatment, care or other services made for the purpose of the research.

- Research Studies: Any study related to human research where no change to participant care or treatment occurs.

Data Controller: Determines the purposes for which and the means by which personal data is processed.

Data Processor: Processes personal data only on behalf of the controller. The data processor is usually a third party external to the organisation.

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
PI	Principle Investigator
Queen Mary	Queen Mary University of London
RM & GO	Research Management & Governance Officer
SOP	Standard Operating Procedure

Relevant SOPs:

SOP 16b External access to Patients Electronic Health Record
SOP 31 Non-Compliance

SOP Text:

	Responsibility	Activity
During planning and set up		
1.	Chief Investigator (CI)/Principal Investigator (PI) and research teams	<p>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.</p> <p>Initially, potential risks and vulnerabilities must be identified, then wherever possible, considerations should be given to mitigations and safeguards.</p> <p>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.</p> <p>These considerations must be documented in the protocol.</p> <p>Please see <i>Associated Document 1</i> Guidance for full details of considerations.</p> <p>All research seeking sponsorship by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary) must submit a Data</p>

		Protection Impact Assessments (DPA pre-screening form (Associated Document 2 to the relevant organisations team (see <i>SOP 11a Barts Health NHS Trust/Queen Mary University of London sponsorship of MHRA-regulated studies: Process for researchers</i> for further details) prior to sponsorship being granted.
2.	PI and research teams	<p>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.</p> <p>Please see <i>Associated documents 3 and 4</i> for details of how to apply to CAG for Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary).</p>
3.	JRMO RM&GO /IG	<p>The Research Management and Governance Officer (RM & GO) 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.</p> <p>Items for scrutiny:</p> <ul style="list-style-type: none"> • Recruitment and consent process. • Storage and use of data during and after the end of the study. • Transport of data outside of the EU. • Data sharing (UK and beyond). • Data Storage (information asset). • Data Flow mapping. • DPIA • Data Protection and Confidentiality measures. • Encryption of portable device <p>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.</p> <p>Suggest that current templates on the IRAS, JRMO and Information Commissioner's Office (ICO) websites are used where appropriate.</p> <p>If required, further information/guidance should be sought from IG.</p>
4.	JRMO RM&GO /IG	<p>Any unmitigated data protection risks identified through the process which may cause undue harm to the data subject must be notified to the ICO.</p> <p>The RM&GO must complete the relevant sponsor review checklist listed below:</p> <ul style="list-style-type: none"> • SOP 11b Associated Document 5 Governance team sponsorship review for MHRA regulated studies • SOP 12b Associated Document 1 JRMO Governance Team Sponsorship Review for interventional studies • SOP 13b Associated Document 1 JRMO Governance Team Sponsorship Review for research studies <p>When satisfied that the study meets DPA/GDPR requirements and Barts Health/Queen Mary IG criteria, sign off the checklist.</p> <p>If required, further information/guidance should be sought from IG.</p>

5.	JRMO RM&GO	Save a copy of the checklist and any related documents into EDGE study files and file the original with the study file.
During Study		
6.	Research team and/or JRMO GCP and 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.
7.	Research team	Ensure access to source data is provided for Monitors, auditors, and inspectors according to <i>SOP 16b External access to Patients Electronic Health Record</i> .
8.	Research team	Follow SOP 31 Non-compliance to report data protection or confidentiality issues. In addition, follow your organisation and site policy.
9.	JRMO GCP and 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 data-protection@gmul.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.

Change control

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

Section changed	Summary and description of changes
All	Replace DPA 1998 with DPA and the new GDPR
Throughout	Clarify the requirement for conducting data protection impact assessments as part of the approvals process. Outline the approach to data protection by design and default Added escalation process to the ICO for unmitigated data protection risks that may cause undue harm to data subjects.

List of appendices

Document ref.	Document name
Appendix 1	Organisational Policies

List of associated documents

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

Appendix 1

Organisational Policies

Queen Mary

<http://www.arcs.qmul.ac.uk/governance/information-governance/data-protection/>

<http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Data-Protection-Policy-v03.0.pdf>

Barts Health

<https://weshare.bartshealth.nhs.uk/information-governance>

<https://weshare.bartshealth.nhs.uk/download.cfm?ver=19593>