Joint Research Management Office Standard Operating Procedure for:			
Use of computerised equipment, software, and systems in clinical research			
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Purpose:

The purpose of this standard operating procedure (SOP) is to outline the overarching requirements for use of computer equipment and systems within Barts Health NHS Trust (Barts Health) and Queen Mary University of London (Queen Mary) research studies.

This SOP provides guidance to ensure that all computerised systems used in research at Barts Health/Queen Mary (not just the study databases) have been identified by the Chief Investigator (CI) or Principal Investigator (PI) as part of sponsorship or site activation.

There is separate and specific guidance on research database systems (systems used to collect the data needed to answer the study research question) validation including case report form (CRF) guidance and user acceptance testing and quality control-sign-off processes (Please see *SOP 38b Electronic data management systems for MHRA-regulated studies*, *SOP 38c Computer System Validation for Interventional and Research studies* and *SOP 38d Data Management*).

There is a clear MHRA requirement for organisations and sponsors to be aware of all computerised systems used to store or process data that may be used for research. For further information please see: https://mhrainspectorate.blog.gov.uk/2017/04/20/computer-system-validation-gcp/ and https://https://mhrainspectorate.blog.gov.uk/2017/04/20/computer-system-validation-gcp/forums.mhra.gov.uk/showthread.php?1885-Electronic-Health-Records-MHRA-Position-Statement .

Scope:

This SOP applies to all computer systems used in research at Barts Health/Queen Mary and particularly to systems that holds source data, impact on the quality of the study data or subject safety.

This SOP is relevant to all staff involved in research which is sponsored or hosted by Barts Health or Queen Mary; this includes support departments at Barts Health, and external sites.

Abbreviations:

ATIMP	Advanced Therapy Investigational Medicinal Products
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CRF	Case Report Form
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
IG	Information Governance
IMP	Investigational Medicinal Product
ISF	Investigator Site Files
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedure
TMF	Trial Master File

Definitions:

- Clinical Investigation: A clinical trial of a non-CE marked medical device, or a medical device used outside of the scope of its CE marking, where there is scope to commercialise the device
- Computer system validation: Is the process of establishing documented evidence that a computerised system will consistently perform as intended in its operational environment.
- Data Governance: All of the arrangements to ensure that data, irrespective of the format in which it is generated, is recorded, processed, retained, and used to ensure a complete, consistent, and accurate record through the data lifecycle. This includes the processes and systems (including computer systems validation), ownership, monitoring and audit, environment, and training.
- Data Integrity: The extent to which the data is maintained, complete, consistent, and accurate throughout the data lifecycle.
- Data Lifecycle: All phases in the life of the data (including raw data) from initial generation and recording through processing (including transformation or migration), use, retention, archiving / retrieval, and destruction.
- Medicines and Healthcare products Regulatory Agency (MHRA) Regulated studies: Clinical trials of investigational medicinal products (CTIMPs), clinical trials of advanced therapy investigational medicinal products (ATIMPs) and clinical investigations.
- Source data: Any information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the study.

Relevant SOPs:	
• SOP 11a	Barts Health/Queen Mary sponsorship of MHRA-regulated trials (Process for researchers)
• SOP 11b	Barts Health/Queen Mary sponsorship of MHRA-regulated trials (Process for JRMO)
• SOP 38b	Electronic data management systems for MHRA-regulated studies
• SOP 38c	Computer System Validation for Interventional and Research studies
• SOP 38d	Data Management
• SOP 40	Vendor assessment
• SOP 46	Site selection, site initiation and site activation

SOP Text:		
Study set up- Queen Mary/ Barts Health Sponsored studies		
	Responsibility	**Activity**
1.	CI	**Consider the costs of computer systems when preparing grant or funding applications** There will be costs associated with buying a licence for a new computer system, for installing and configuring the system to meet the requirements of the study, and for hosting the system on a server. Be aware that free online tools may not be suitable for all research studies, or that premium versions may need to be purchased. There will also be a need for staff to maintain the system and work with IT to install. For MHRA-regulated studies, all computer systems should be discussed with the Good Clinical Practice (GCP) & Governance Manager at the costing stage. The CI may not need to include any computer system costs in the grant/funding application if the study will only be using existing computer systems for which the sponsor or site already has a licence.
2.	CI	**At the protocol design stage, the CI should ensure that all computerised systems that will be used for the study are identified, risk assessed, and validated where appropriate.** The CI and team should identify all computerised systems that they plan to or envisage will be using in their study, either within the protocol or in a data management SOP/plan. Consideration should be given to both CI coordination and site level systems. These may include but are not limited to: • Pharmacovigilance systems • Electronic CRF systems • Databases (including electronic edit checks, statistical analysis) • Electronic data transfer (e.g., laboratory data or imaging data to a central database) • Randomisation systems • Unblinding systems • Investigational Medicinal Product (IMP) Management systems • Specialist imaging software (e.g., cameras, scanners of all types) • Data input devices i.e., apps, electronic prescribing systems that may be stand alone. • Laboratory computer systems.

		All vendors or service providers should detail computer systems to be used in agreement and contracts. For MHRA regulated studies these computer systems must be declared to the GCP & Governance Manager as part of the 'Sponsorship with conditions' process (see *SOP 11a Barts Health/Queen Mary sponsorship of MHRA-regulated trials: Process for researchers*). CIs should note that software and web applications used to may be considered a clinical device and should seek advice regarding their use in studies with the GCP & Governance Manager and the Barts Health clinical physics department (see Joint Research Management Office (JRMO) website for contact details).
3.	CI	**Consider and document the risk of each computer system.** • The CI should ensure that appropriate controls are in place to support and safeguard their data at all stages in the data lifecycle. This includes when delegating or subcontracting aspects of their study management to other parties e.g., departments, labs, central facilities, and sites. • The CI should ensure that departments and organisations have systems in place that are designed to provide an acceptable state of control of the data, based upon the data integrity risk of the computer system. • The CI should consider that the governance and control of the computer system is commensurate with the significance of the computer system to the data integrity. • Where a computer system is critical to the data integrity or patient safety, ensure that the resource and governance of the computer system is robust before the computer system is used. The risk assessment of the computer system should be documented (see *Associated Document 1 Computerised system survey*)
4.	CI	**Ensure that the computer systems used are validated.** To ensure research data integrity, computer systems need to be validated and processes put in place to ensure quality of the data. The computer systems need to be reviewed to ensure that they are trustworthy and reliable. All computerised systems should be assessed and deemed fit for purpose. This should be achieved by validation and testing (for principles that can be applied to all systems please refer to *SOP 38b Electronic data management systems for MHRA-regulated studies* for a step-by-step guide to system validation). All aspects of this process should be documented and must include: • Specifications • Testing against specifications (traceability – are the data accurate, reliable, have integrity, available, and authentic) • Approval and release of the computer system • Change control **Minimum requirements for outsourced computer systems** Vendor assessment should be performed for all computerised system providers to the sponsor and key stakeholders. For vendor assessment definitions and procedures see *SOP 40 Vendor assessments*.

		For commercial software or software provided by a vendor CIs should note that a computer system's vendor is likely to have performed functional verification of activities. It is the CI's responsibility to ensure that the purchased system has demonstrated its fitness for its intended use. This should include installation checks, performance, configuration, SOPs, and staff training.
5.	CI	**Assess computer systems at each research site, sub-contractor, and service provider.** As part of site selection and feasibility the CI and team must clearly identify and document each research site's computerised systems which will be utilised during the study (for further guidance see *SOP 46 Site selection, site initiation and site activation*). The CI should ask the PI to provide details of local computer systems. Examples of which local computerised systems need to be identified can be found in Section 2. Particular attention should be paid to electronic health record/patient record systems and pharmacy electronic prescribing systems. *Associated document 2 JRMO Electronic-Health Records Validation Audit Checklist* can be used to collect this information. The CI must ensure that the PI or subcontractor has provided evidence that their local computer systems have been validated and that they are fit for purpose. Once the details of the local computer systems have been collected, the CI should assess whether the systems can be used within the study. The decision whether or not the local site computer system can be used, or whether it will be used as source data should be documented as part of site activation or before sending regulated study work to a sub-contractor e.g., laboratory or central imaging centre. Systems used for standard clinical care within NHS sites are often overlooked and deemed as low risk and automatically assumed trustworthy. However, information should still be collected and assessed. Any system used for sponsored studies maybe subject to audit by the JRMO so ensure you comply with this SOP and have the appropriate checklist/survey completed prior to commencing your study.
6.	CI	**Computer systems used to transfer data should be tested and validated, for example computer systems that transfer scans between sites.** Any system being used to transfer data or images must be tested prior to its use e.g., transfer of de-identified images for central review. This testing must be part of site initiation (see *SOP 46 Site selection, initiation, and activation*). Any identifiable data must be encrypted before transfer.
During the study		
7.	JRMO Auditor	**Audit the computerised systems of selected research studies.** The JRMO will select on-going studies to be audited. During audit visits, the auditor will confirm that computerised systems comply with regulations and with SOPs. This may include: • Examining documentation in the Trial Master File (TMF) to confirm that systems have been risk assessed and validated • Physically inspecting hardware • Inspecting software using a read-only account.

		For more information on the audit process see *SOP 22 JRMO Audits*.
At the end of the study		
8.	CI	**Ensure that all computerised systems are appropriately decommissioned, and all data and documentation is archived.** The CI must ensure that all clinical trial data stored on computerised systems is appropriately managed throughout the life cycle of the study. Data and metadata from a system should be archived and stored as per current sponsor requirements. The CI must also confirm that all appropriate documentation relating to computerised systems is present in the TMF and Investigator Site Files (ISF) prior to archiving. For more information see *SOP 20 Archiving*.
Study set up- Local Site Source data systems		
9.	PI	**Identify all computerised systems that will be used to collect, store, access, or process source data, within the area.** Once identified it is good practice to ensure the sponsor of the study is aware of these and agreed their use. Most sponsors will request information to assess the systems. Contact the System owner to request their completed and signed *JRMO Electronic-Health Records Validation Audit Checklist (AD2).*
10.	System owners	**Complete *Associated Document 2 JRMO Electronic-Health Records Validation Audit Checklist*** Work with JRMO GCP team to signoff of checklist. If the system is a Barts Health system, the system owner should contact the Information Governance (IG) department to ensure Barts health assess register is up to date for the system.
11.	Research Governance Operations Manager	**Together with the GCP team, work with system owners and PIs to identify all relevant systems are appropriately documented.** This is an ongoing work in progress for additional information and details of the JRMO E-HR Plan contact research.governace@qmul.ac.uk

Change control

This section outlines changes from version **3.0** to version **4.0**

Section changed	Summary and description of changes
All	Administrative changes throughout

List of associated documents

Associated Documents 1	Computer systems survey, including support departments i.e., imaging departments/labs/pharmacy/subcontractors
Associated document 2	JRMO Electronic-Health Records Validation Audit Checklist

List of appendices

There are no appendices for this SOP.