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 validation (systems used to collect the data needed to answer the study research question) including case report form 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 Medicines and Healthcare products Regulatory Agency (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/

Abbreviations:	
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
GCP	Good Clinical Practice
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

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. 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 have 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. All vendors or service providers should detail which computer systems are 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).
3.	CI	**Consider and document the risk of each computer system.** • The CI must 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 others. • The CI must 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 must 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). **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 must include installation checks, performance, configuration, SOPs, and staff training as a minimum.
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). Particular attention should be paid to electronic health record/patient record systems and pharmacy electronic prescribing systems. Computerised System review checklist (Associated Document 2) 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 must also be confirmed as fit for purpose.
6.	CI	**Computer systems used to transfer data should be tested and validated,** This testing must be part of site initiation (see SOP 46 Site selection, initiation, and activation). Any identifiable data must be encrypted before transfer.

At the end of the study		
7.	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 Trial Master File and Investigator Site Files prior to archiving. For more information see SOP 20 Archiving.
Study set up- Local Site Source data systems		
8.	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 Joint Research Management Office (JRMO) Computerised System review checklist (Associated Document 2).
9.	System owners	**Complete Associated Document 2 Computerised System review checklist** Work with JRMO GCP team to sign-off of the checklist. If the system is a Barts Health system, the system owner should contact the Information Governance department to ensure Barts health assess register is up to date for the system.
10	Research Governance Operations Manager	**Together with the GCP team, work with system owners and PIs to identify all relevant systems are appropriately documented.**

Change control

This section outlines changes from version **4.0** to version **5.0**

Section changed	Summary and description of changes
All	Administrative changes throughout
Associated Document 1	Additional guidance on data transfer and re-validation of computer systems

List of associated documents

Associated Document 1	Computer systems survey
Associated Document 2	Computerised System review checklist

List of appendices

There are no appendices for this SOP.