**Computerised system survey**

**Guidance and sample questions for assessment of risk**

1. Introduction: Purpose of this document, scope, author, additional information

*To identify, risk assess, and document which computer systems need to have systems validation. (*[*See SOP 38b Electronic data management systems for MHRA-regulated studies*](http://www.jrmo.org.uk/performing-research/standard-operating-procedures-sops/sop-38b/)*)*

*List: sites, support departments, teams, subcontractors, and service providers who have computer systems that may impact on trial data integrity or patient safety*

1. Details of the computer system(s)
   * What software/app/computer system(s) are being used? Consider imaging departments, pharmacy, support department, health records.
   * Are the computer systems critical for the assurance of patient safety, data integrity or the trial end points?
   * Is it used to transfer data between sites? What process is in place to assure participants’ data protection (e.g., anonymisation of data)?
   * If an external party (e.g., a subcontractor or lab) is being used, how have they assured GCP compliance of the computer system as part of the subcontract?
   * Who purchased the computer system/equipment/software/app, and for what purpose?
   * Is it an NHS computer system used in clinical practice? (If so, it is deemed low risk, but oversight is still required).
   * If not purchased for this study, is it fit for purpose? Does it need to be tested against a specification?
   * What version?
   * How is the computer system hosted? I.e., is the system on a secure network?
   * Who is the custodian of the computer system?
   * When was the computer system implemented?
   * Are there any relevant policies, manuals, or SOPs for the computer system?
   * If the system is maintained by Barts Health or Queen Mary IT, who is responsible for the system? Include what network it is on where servers, refer to Barts Health/Queen Mary ICT SOPs)
   * What will the data generated by the system be used for?
2. Security of system
   * Who has access to the computer system?
   * Detail the process of how access is granted (i.e., username and passwords).
   * Who allocates roles?
   * What are the permissions associated with each role?
3. Training evidence for computer system users
   * How are personnel trained in the computer system?
   * How is this training documented and where are user training records kept?

1. Access to the computer system by regulators
   * Will Clinical Trial Monitors/Auditors/Inspectors have access to the computer system? If no, what should be done to enable this? (Consider patient healthcare records that need to be monitored as source data).
   * Will Clinical Trial Monitors/Auditors/Inspectors only have access study specific patient records?
   * Is there a clear process for gaining and using the computer systems for Clinical Trial Monitors/Auditors/Inspectors i.e., a manual to use once on site?
   * Who arranges access to the computer systems? (Name and contact details)
2. Backup systems for clinical records system (CRS), disaster recovery, Barts Health/Queen Mary IT SOPs/policies
   * Provide details of the back-up systems, including frequency (SOP, manual, policy)
   * Provide details of the disaster recovery process (SOP, manual, policy)
3. Computer system audit trails
   * Description included?
   * Who is in control
   * Who can see it?
   * How can it be accessed?
   * How often are audit trails reviewed, and by whom?
   * What is the escalation procedure if anomalies are observed?
4. Computer system approval process
   * What is the approval / authorisation process i.e., what do authorisation signatures confirm has been done?
5. Computer system validation
   * Has the computer system been validated and tested?
   * The CI will need to be supplied with documentation of the validation and testing.
   * Who validated the software? Software provider details.
   * Was the software validated by the research site/service provider/department?
6. Change control systems
   * What systems are in place for governing any change to the computer system? (SOP, manual, policy)
   * Who is responsible for change control authorisation/QC?
7. Archiving
   * How long is clinical trial data kept for archiving?
   * Where is the data archived?
   * What is the process for archiving the data?
   * Who is the archivist (name and role) responsible for archival of the computer system?