RD&I	NHS University Hospitals Plymouth NHS Trust **STANDARD OPERATING PROCEDURE**

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/researchers

Computerised Systems for Supporting Clinical Trials

SOP No: P14

Version No: 2.1

Effective Date: Jan 2019

Supersedes: Version 2.0, Sep 2017

Page: **1** of **7**

Last Review Date: Jan 2019 Next review date: Jan 2022

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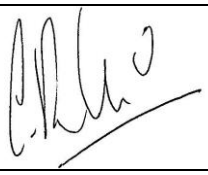
Signature:	
Date:	21st Jan 2019

1 Purpose and Scope

Any research data that is stored on the University Hospitals Plymouth NHS Trust (UHPNT) networked computers, laptops or tablets must be stored whenever possible in an anonymised form with no personally identifiable information. All laptop computers and devices (e.g. pen drives) will be password encrypted. Users have a duty of care to protect the confidentiality of any information which they might access through the UHPNT network in the course of legitimate employment activities or through academic studies.

In scope: this Standard Operating Procedure (SOP) will focus on computerised systems that UHPNT may utilise as Sponsor of a clinical trial and as such, will not be an exhaustive list of all computerised systems used in clinical trials. Information and Communication Technology (ICT) at UHPNT maintain a database of all registered information systems connected to the Trust network).

Definitions

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
eCRF	Electronic Case report Form
GCP	Good Clinical Practice
HCA	Health Care Assistants
HRA	Health Research Authority
ICT	Information Communication Technology
MHRA	Medicines and Healthcare products Regulatory Agency
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigators
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOP	Standard Operating Procedure

2 Who should read this document?

Staff involved in setting up of research e.g. Chief Investigators (CI), Principal Investigators (PI), Trial Co-ordinators / managers, RD&I Managers.

3 Procedure to Follow

3.1. Evaluation and Purchasing

It is the responsibility of the Sponsor and Chief Investigator (CI) of the clinical trial to ensure that any computerised system used during the study complies with Trust policies as well as relevant legislation.

3.2 Validation

All systems, whether procured from an external supplier, or developed within the Trust, must be validated. Validation must demonstrate that a computer system in use is fit for purpose.

For research the Sponsor and the CI must ensure when using electronic trial data and/or remote electronic trial systems that the system conforms to established requirements:

- All clinical information shall be recorded, handled and stored in a way that it can be accurately reported, interpreted and verified, while the confidentiality of records of the trial subjects remain protected – Schedule 1, Part 2 (9) Statutory Instrument 2004/1031 (as amended).
- 'All Computer systems used in clinical trials, in particular those that impact on the quality of the trial data (and participants safety), should be validated' – GCP Guide, MHRA, 2012 (Grey Guide).
- 'When using electronic data handling and/or remote electronic trial data systems, the sponsor should ensure and document that the electronic data processing system(s) conforms to the sponsors established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation)' – ICH E6 (R1) Guideline for Good Clinical Practice

3.2.1. Scope and extent of validation

Examples of systems and levels of validation required.

Off the shelf: Microsoft Excel for data management and simple analysis:

Cell formatting and formulae should be checked to ensure the required specification is met, and the checks made should be documented. For example, confirm that columns intended to receive a date are appropriately formatted; confirm the required number of decimal places is captured, confirm that values calculated from a number of cells are correct.

Trial specific: Adaptation of a commercially available off the shelf package (e.g. randomisation systems, eCRFs): Document the agreed and approved specification, how

the system will be tested (both by the users and the developers), that any issues with the system identified through testing have been resolved and the specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.

Bespoke system: Purpose built system solely for the trial: Document the process by which the decision to use a bespoke system was made and the risk assessment conducted as part of that decision making process, the agreed and approved specification (functional and user requirements), validation plan, code-testing documentation, that any issues with the system identified through testing have been resolved and the specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.

3.3. Change control

Any change to the system must be controlled and documented. The following information should be included: reason for changes and person requesting changes, risk assessment, assessment of the changes and what actions are required, approval of the changes, testing, validation report and release documentation. These are complementary to the processes described in section 3.2.1.

3.4. System Backup

Arrangements should be in place to ensure that data can be retrieved if there is a computer system failure. Computer systems should be located within an infrastructure which provides for routine backups and disaster recovery in order to protect against accidental loss. Confirmation of this should be documented within the data management plan, or on a global level if more appropriate. Local copies of different versions of data sets/databases should be retained if there is not audit software in place, in accordance with the 'Study Data' SOP. These will be subject to organisational backups.

3.5. Implementation

Any study that wishes to use new computerised systems (as opposed to systems already approved) must seek the approval from the Trust to ensure that Trust policies as well as relevant legislation is complied with. Any new computerised systems and software must be compliant with ICT UHPNT local policies.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

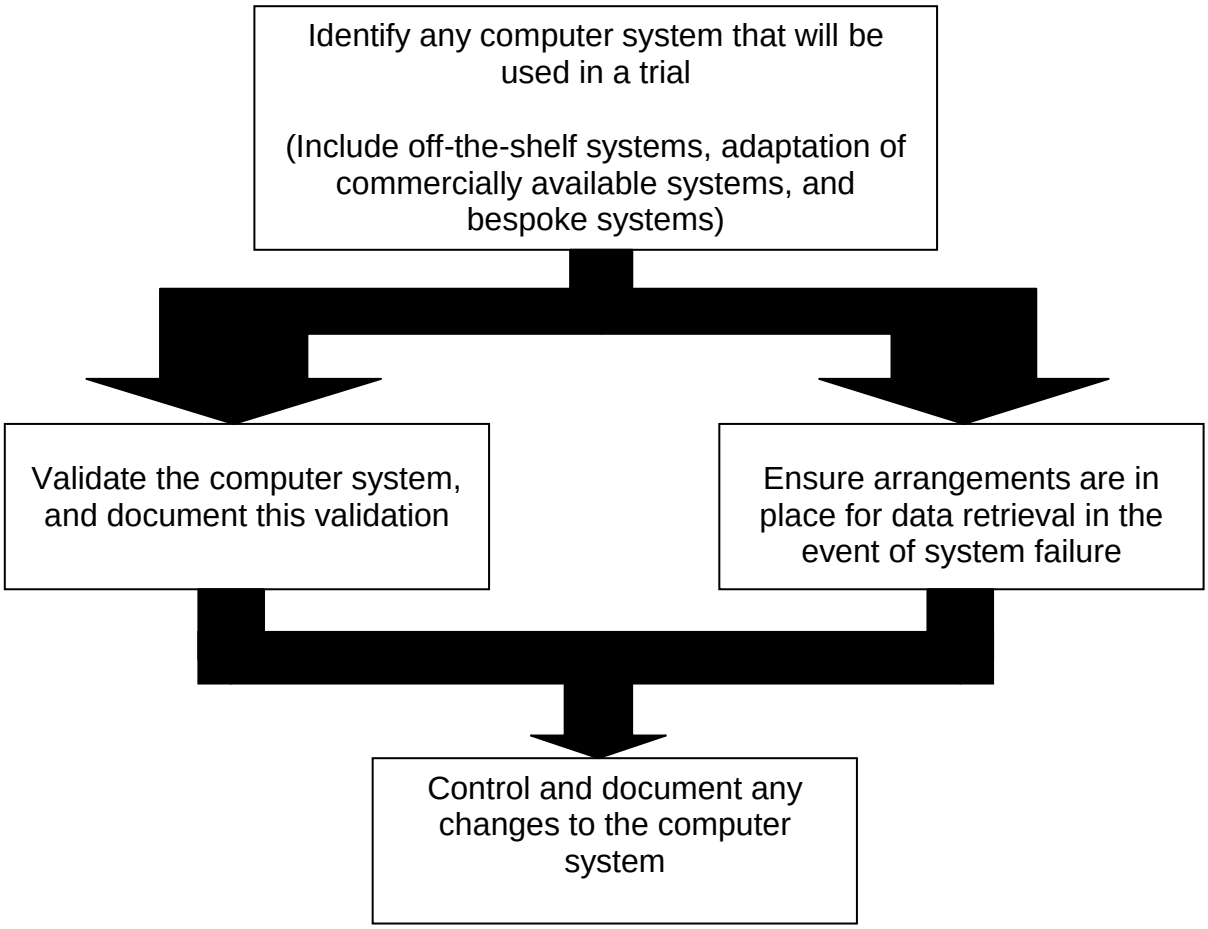
5 Reference material

Medicines for Human Use (Clinical Trials) Regulations 2004
www.legislation.gov.uk/uksi/2004/1031/contents/made

Good clinical practice guide (The Grey Guide) 2012 by Medicines and Healthcare products Regulatory Agency.

ICH Harmonised tripartite guideline. Guideline for Good Clinical Practice E6(R1)
http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf

Appendix: Flow Chart of considerations when using computer sytems for research — Appendix 1



6 Amendment History

Version Number:	2.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name; Reduce signature requirement to single senior RD&I Manager.

Version Number:	2.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. SOP reviewed and updated.

Version Number:	1.1 (minor amendment)
Date of Amendment:	Mar 2012
Details of Amendment:	Cover page - Change of SOP location address.