Standard Operating Procedure

VALIDATION AND BACKUP OF COMPUTER SYSTEMS USED IN RESEARCH

SETTING Trust-wide

AUDIENCE Chief Investigators and associated Research Staff setting up and managing research studies sponsored by UHBW

ISSUE Data must be collected, stored, and analysed using systems which are compliant with the applicable regulations, laws, and Good Clinical Practice (GCP).

QUERIES Contact R&D department via research@uhbw.nhs.uk

Document History

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Effective Date	28/APR/2026	**Review Date**	28/APR/2028

Review date	Version number	Version date	Effective date	Author/ Reviewer	Authorised by
-	1.0	27/OCT/2015	03/NOV/2015	Diana Benton	Diana Benton
NOV/2016	1.1	23/JUN/2017	03/JUL/2017	Genna Nicodemi, Jess Bisset & Debbie McPhee	Diana Benton
07/DEC/2017	1.2	19/FEB/2018	21/FEB/2018	Trusha Rajgor	Jess Bisset
27/AUG/2020	1.3	07/SEP/2020	07/SEP/2020	Katharine Wale & Debbie McPhee	Jess Bisset
12/AUG/2022	2.0	16/SEP/2022	21/NOV/2022	Sarah Bishop & Debbie McPhee	Diana Benton on behalf of Trust Research Group
FEB/2023	2.1	16/FEB/2023	01/APR/2023	Lucy Riddolls	Jake Harley
OCT/2024	2.2	25/OCT/2024	25/OCT/2024	Debbie McPhee	Jess Bisset
Jan/2026	2.3	07/JAN/2026	28/APR/2026	Sarah Bishop	Jess Bisset

Version Number	Reason for change
Original V1.0	n/a –original
1.1	Annual review – addition of CTIMP verification appendix and minor updates and clarifications
1.2	Annual review and applied new SOP template
1.3	Biennial review with minor updates (including change of Trust name to UHBW)
2.0	Major update as part of biennial review to expand scope to include non CTIMPs
2.1	Departmental name change from Research & Innovation to Research & Development. Updated throughout SOP as a minor amendment.
2.2	Biennial review which included a minor update to bring SOP in line with Trust SOP template.
2.3	Minor update to include reference to updated Medicines for Human Use (Clinical Trial) (Amendment) Regulations 2025

1. Introduction

Clinical Trials of Investigational Medicinal Products (CTIMPs) are subject to the Medicines for Human Use (Clinical Trials) Regulations 2004 as amended by the Medicines for Human Use (Clinical Triasl) (Amendment) Regulations 2025 and any other amendments.

Part 4 (Regulation 28) of SI 2025/538 states that the functions of the sponsor include functions in relation to the development and maintenance of trial specific computerised systems. Further information can be found in *SOP_016 Research Contracts and Vendor Selection.*

Data therefore must be collected, stored, and analysed using systems which support compliance with the law and all research studies must comply with Good Clinical Practice (GCP).

2. Purpose

The purpose of this SOP is to describe how to test and document that a computer system and its use within a research study is fit for purpose and supports sponsor compliance with applicable legislation and Good Clinical Practice (GCP). Please note this SOP exists to ensure UHBW sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs) are compliant however the principles of validation also apply to non CTIMPs and therefore should be considered and applied to those studies in a risk proportionate way.

3. Scope

In Scope: Computer systems, both hardware and software, that are used in CTIMPs sponsored by UHBW
Out of Scope: Computer systems used in studies hosted and not sponsored by UHBW

4. Responsibilities

All research staff setting up and managing UHBW sponsored research are responsible for ensuring that the computer systems in use are fit for purpose through adequate and continuous validation. They must also ensure any validation carried out is appropriately documented.

The R&D department (as sponsor representative) is responsible for ensuring research staff are aware of their responsibilities and for maintaining sponsor oversight of validation. The R&D department must also validate any applicable systems in use within R&D (e.g., EDGE). For systems developed in R&D it is the responsibility of the Information Officer to carry out appropriate validation.

5. Abbreviations and Definitions

Abbreviations	
GCP	Good Clinical Practice
CTIMP	Clinical Trial of Investigational Medicinal Product
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
DMP	Data Management Plan

6. Procedure

6.1 Validation

- All computer systems, used to manage and record study data for UHBW sponsored research must be validated. This applies to systems procured from an external supplier or developed within the trust.
- Validation for all types of systems should include robust controls throughout the system's use, demonstrable evidence that a computer system in use is fit for purpose and any supporting documentation as applicable (e.g., a Data Management Plan (DMP)). Please refer to *SOP_012 Study Data* and *TMPL_041 Data Management Plan* for further information on a DMP.
- For activities within the scope of this SOP that are carried out by a third party (e.g. a clinical trials unit), evidence of validation of relevant systems must be provided prior to their use.
- For a CTIMP, the CI will document the computer systems that (s)he intends to use to collect and manage data in the DMP (or agreed alternative). The DMP and subsequent amendments must be agreed with the trial sponsor prior to implementation in accordance with *SOP_012 Study Data*.
- For non CTIMPs, proportionality must be applied when deciding how best to document computer system validation. For example, for studies with large datasets run outside of registered trials unit it may be appropriate to use a DMP. For studies with small datasets (feasibility/rare diseases/pilots etc) which intend to use previously validated computer systems a simple data flow diagram to capture data processing mechanisms and any quality control checks may be sufficient.

6.1.1 Risk-Assessed Validation

- The level of validation required must be determined by making a risk-based assessment of the nature of the system. This assessment will include:
    - Identification of all risks posed to the system validity
    - Measures taken to mitigate those risks
    - What evidence is required to demonstrate risk mitigation

This assessment should be carried out by the CI (or delegated other), agreed with the sponsor during study set up and documented in the DMP.

6.1.2 Examples of systems and levels of validation required

- **Off the shelf:** e.g. Microsoft Excel for simple data management and analysis (not recommended for CTIMP trials): Field 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 use the correct formulae.
- **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.

6.2 Change control

- Any change to the system must be controlled and documented.
- The following information should be included:
  - Person requesting changes
  - Reason for changes
  - Risk assessment
  - Assessment of the changes
  - What actions are required
  - Approval of the changes
  - Testing
  - Validation report
  - Release documentation.

6.3 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 DMP.
- Local copies of different versions of data sets/databases should be retained if there is no audit software in place, in accordance with *SOP_012 Study Data*. These should be subject to organisational backups.

6.4 Other Considerations

- System security (who has access and how this access is controlled)
- Interaction of different systems (for example direct electronic information/results from separate computer systems or merging of information between systems)
- Audit trails (the ability to verify who entered or changed data in the system, when this was done and what was changed)
- Continued accessibility (for the duration of the trial and the archiving period)

7. Dissemination and training in the SOP

This SOP will be disseminated to applicable research staff (including R&D) and will be available on the R&D website.

Plan Elements	**Plan Details**
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A – replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination will be: 1. To Chief Investigators of UHBW Sponsored CTIMPs

	2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust Document Management System 2. Updated on the R&D website 3.
Is Training required:	All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training UHBW*

RELATED DOCUMENTS AND PAGES	SOP_003 Developing and Designing your Study SOP_007 Research Training SOP_008 Investigator Oversight of Research SOP_010 Monitoring and Oversight of Research Activity SOP_012 Study Data SOP_014 Essential Research Records SOP_016 Research Contracts and Vendor Selection TMPL_041 Data Management Plan WI_004 R&D Work Instruction for verification of UHBW Sponsored CTIMP data on EDGE
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development Department via research@uhbw.nhw.uk
AUDIT REQUIREMENTS	R&D departmental Quality Management System audits are undertaken annually.