University of Hertfordshire

DATA BACKUP, RECOVERY AND CONTINGENCY

Clinical Trials Support Network (CTSN)

Standard Operating Procedure for the backup, recovery, and contingency for clinical trial data

SOP Number: gSOP-45-01	**Effective Date**: 28th July 2022
Version Number: 1.0	**Review Date:** 3 years (or as required)

1. BACKGROUND

This is a University of Hertfordshire (UH) standard operating procedure (SOP).

This document sets out the procedures to be followed by all UH staff who are involved with data management processes to ensure that all clinical trial data shall be stored securely in accordance with the approved clinical trial protocol, the principles of Good Clinical Practice (GCP) and with the UH policy on data management. All SOPs are required to assist researchers in conducting research in accordance with the principles of ICH Guidelines for Good Clinical Practice (ICH GCP E6 (R2), 2016), Clinical Trials Regulation EU No 536/2014 and the UK Policy Framework for Health and Social Care Research.

2. PURPOSE

This SOP applies to the storage of electronic data used for UH sponsored/co-sponsored and/or adopted by the CTSN clinical trials and is in place to minimise risk of data loss due to human or system error.

Where there are potential conflicts between different collaborating organisations' SOPs project level working instructions should be developed to determine precedence.

3. APPLICABLE TO

Data managers, statisticians, research assistants, and anyone wishing to provide assurance that a system is operating to its specification and requirements and that it is fit for its intended purpose.

4. RESPONSIBILITIES

The Chief Investigator (CI) has overall responsibility for developing and ensuring plans for data backup.

5. PROCEDURE

5.1 Electronic Data Backup

All electronic data saved on the X drive, R drive or Document Management System (DMS) is backed up at the end of every working day each week. The data is stored on UH servers for the period of a year.

The document management system has an inbuilt recycle bin which means you can recover an item if it's deleted by accident without going through the backup recovery process. The recycle bin keeps items for a period of 90 days before permanent deletion.

Files sent using exchange file will remain on the server for a month before permanent deletion.

Data which is held via the online platform REDCap is backed up daily on to the University's Commvault system.

All clinical trial related email correspondence should be saved on Teams to ensure accessibility to the team and adequate backup. Confidential trial emails should be stored in access restricted folders on Teams.

5.2 Backup/Recovery Checks

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 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 'Data sharing SOP' gSOP-27. These will be subject to organisational backups.

5.3 Data Restore

In the event that data needs to be restored from the UH server, staff should make a request for this restore via the UH IT Helpdesk. helpdesk@herts.ac.uk

Data which needs to be transferred between staff can be achieved using the file exchange programme. Files are stored for 30 days, after which time they are deleted. The files are backed up on the UH server. Any files not recovered within the 30-day period will be removed and are unable to be restored.

5.4 Audit Trail

Any changes to clinical trial data should be logged, to include information regarding:

- All data changes made and the reason for the change (e.g., data entry error)
- Who made the changes
- When the changes were made

6. RELATED DOCUMENTS

- gSOP-40 Data Management Overview
- gSOP-27 Data sharing SOP

7. APPENDICES

- Appendix 1 – Definitions

8. VERSION HISTORY/REVISIONS

Version Number	Effective Date	Reason for Change

9. AUTHORSHIP & APPROVAL

Author

Signature  **Date 20th July 2022**

Megan Smith

Pro-Vice Chancellor (Research & Enterprise) Approval

Signature  **Date 16 June 2022**

Professor J M Senior

10. AGREEMENT (MOVE ON TO SEPARATE SHEET BEFORE PRINTING)

Please detach and retain within <u>your training files</u>

I have read and understood the contents and requirements of this SOP (ref gSOP-045-01) and accept to follow University policies implementing it.

Recipient

Signature: ……Date: …….

Name & Position: ……

Please retain copy of the signed form for your reference in your training file

Appendix 1 – Definitions

Validation
The assurance that a system meets the needs of the customer and other identified stakeholders

Verification
The evaluation of whether a system complies with the requirements and specification of the system

Software Requirements
The business needs for the system are defined in terms of the user, system and interface needs of the system.

Functional Specification
A functional specification documents the operations and activities that a system must be able to perform.

Installation Qualification
Installation Qualification verifies the proper installation and configuration of a system

Operational Qualification
Operational Qualification verifies the proper functioning of a system

Performance Qualification
Performance Qualification validates that a system performs according to the user requirements of the system and is therefore fit for purpose