UNIVERSITY OF LINCOLN

STANDARD OPERATING PROCEDURE

Data Storage, Security and Backup
SOP: CG 008

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Version History	**Reason for change**

NOTE: All SOPs are subject to regular review.

Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

1. PURPOSE

To outline the security and back-up requirements of clinical research to mitigate against potential loss or corruption of electronic data.

2. SCOPE

This SOP applies to all University of Lincoln (UoL) sponsored clinical research or where Lincoln Clinical Trials Unit (LinCTU) are providing ICT and/or database system support.

3. BACKGROUND

3.1 Clinical research data shall be stored on the University's OneDrive except where an Electronic Data Capture (EDC) System is used.

3.2 The UoL, as sponsor, and LinCTU has responsibility for providing Good Clinical Practice compliant records management systems. This SOP should be considered along with the requirements for data protection legislation and ethics and UoL ICT policies and guidance.

3.3 All data stored on UoL servers is backed up daily. All data stored on the UoL OneDrive account are stored in the cloud and have the added protection of Microsoft Office 365 Advanced Threat Protection (ATP).

3.4 Any new EDC systems used by any Trial team / LinCTU (cloud based or based on University Servers) must meet the data protection and security requirements of the UoL ICT Department. Approval for the purchase and use of such systems must be sought from the ICT Department prior to using them in accordance with UoL policy and SOP CGI1 ICT Purchasing.

3.5 Clinical Trials of Investigational Medicinal Products (CTIMPs) are subject to statutory inspection by the Medicines and Healthcare products Regulatory Agency (MHRA) and the principles set out in the Electronic Health Records MHRA Position Statement.

4. CROSS REFERENCES

4.1 Electronic Health Records MHRA Position Statement

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/470228/Electronic_Health_Records_MHRA_Position_Statement.pdf

4.2 CG-QMS RF CGD3-RF01 Data and Document Storage Record

4.3 CG-QMS SOP CG01 Training

4.4 CG-QMS SOP CG10 Adverse Events and Safety Reporting

4.5 CG-QMS SOP CG11 Serious Breach

4.6 CG-QMS SOP CG13 Monitoring and Audit

4.7 CG-QMS SOP CG15 Archiving (Clinical data)

4.8 CG-QMS SOP CGD2 Data Management

4.9 CG-QMS SOP CGD4 Database design

4.10 CG-QMS SOP CGI1 ICT Purchasing

4.11 Clinical Trials Regulation 536/2014

4.12 Ten Steps to better Data Security: https://staffnews.lincoln.ac.uk/2018/04/05/ten-steps-to-better-data-security/

4.13 https://ict.lincoln.ac.uk/tag/office-365/

5. PROCEDURE

5.1 There should be a clear record within each trial/study master file (TMF) of all data systems and/or associated electronic storage or hard copy storage space and any back-up processes used to collect

data and maintain records for the study (see suggested template for documenting this at the end of this document).

WHAT TO DOCUMENT

5.2 There should be a formal catalogue of the following items which is maintained by the trial manager/data manager in collaboration with the CI (including, but not limited to):

- recruitment and screening logs
- signed consent
- electronic versions of the trial master file and associated study protocols and documents
- any letters or correspondence to/from study participants
- any scans, images, transcripts, data downloaded from devices (e.g. heart monitors, wrist bands, glucose monitors), or other such media relating to the data captured in the study/trial.
- any commercially sourced electronic data capture system (for example CASTOR EDC), or other database/spreadsheet used to capture information in eCRFs or source documents.
- any spread sheets of pseudo-anonymised data that has been downloaded from the data capture systems and is ready for analysis by the trial statistician

5.3 Use suggested RF CGD3-RF01 Data and Document Storage Record for documenting data and document storage (this can be used for any item whether paper-based, physical or electronic) and may be adapted to fit the needs of the study/trial.

RECOMMENDATIONS FOR SECURE STORAGE

5.4 For all items mentioned in 5.1-5.2, where trials, are sponsored by Lincoln and/or managed by LincTU, the CI and/or trial data manager or delegated nominee should use Office 365 and associated OneDrive and Microsoft software (available at UoL) to create trial / study specific Microsoft Teams for storage. The advantage of using Office 365 for storage is that files can be accessible from any location (provided there is internet access) and they area secure. Guidance and support for using Office 365 at UoL can be found at: https://ict.lincoln.ac.uk/tag/office-365/

Trial staff associated with the trial/study can be provided with access to the Microsoft Team file space on a need-to-know basis and a record of this shall be maintained. Only those that are listed on RF CG08-RF01 Study Delegation Log should be given access commensurate to their role and read, write, edit rights can be assigned as needed.

Where individual documents placed within the Microsoft Team space need further protection (for example enrolment and screening logs which contain personal identifiers) then additional password protection shall be employed and/or encryption or assignation of more restricted user rights for those specific documents/files.

5.5 Details of the Electronic Data Capture (EDC) system used shall be recorded in the TMF/ISF and this should include details of:

- physical security*
- restricted access -who has access to the system
- record of roles and access rights
- data protection -any considerations that were made in respect of personal identifiers and the associated encryption and access rights
- back-up of systems*

*where an EDC system is commercially sourced and cloud based and has been approved by University of Lincoln ICT Department, it is acceptable to refer to information supplied by the EDC system provider for these items.

5.6 For any spreadsheets of pseudo-anonymised data that has been downloaded from the data capture system(s)/other source data/databases and is ready for analysis by the trial statistician, the trial data

manager should use OneDrive and create a separate trial/study specific Microsoft Team for storage of data which is ready for analysis/interim analysis. Access should be restricted to the trial data manager and trial statistician until the results of the trial have been formally published.

5.7 The UoL (as sponsor) and/or LinCTU shall have oversight systems in place to ensure compliance with these processes and to enable potential serious breaches of GCP to be detected and reported e.g. if source data are lost or destroyed.

Where LinCTU is coordinating or managing a trial, the LinCTU trial or data manager will ensure the set-up of the Microsoft Teams file space for each study/trial and any associated electronic Data Capture System for the trial. This will be done during the trial set-up stage prior to the recruitment of the first participant in accordance with SOP CG01 Training.

Where LinCTU is providing support for on-going data management, then they will monitor the quality of data entered into the system, raise data queries and report any data-related problems to the CI in accordance with SOP CG13 Monitoring and Audit. If problems are considered as serious breaches of protocol or data protection is compromised, then LinCTU will seek guidance from the sponsor (UoL Research Governance Team) and/or University of Lincoln Information Compliance Team in accordance with SOP CG12 Serious Breach and the University's Data Protection Policy.

Where UoL is acting as sponsor and LinCTU are not involved, the UoL research governance team will ensure that CIs are aware of this SOP and advise (prior to the start of the study) that Office 365 Microsoft Teams should be used routinely for storage and that appropriate choices and security considerations should have been made and documented with respect to any database for the study. Training will be in accordance with SOP CG01 Training.

CIs should seek direct guidance from the sponsor (UoL Research Governance Team) and/or University of Lincoln Information Compliance Team if they experience adverse events and / or serious breaches of protocol or suspect that data protection has been compromised in accordance with SOP CG10 Adverse Events and Safety Reporting and / or SOP CG11 Serious Breach as well as the University's Data Protection Policy.

Where UoL is sponsor, the UoL Research Governance Team will also have the right to undertake ad-hoc checks and/or audits of all clinical trials or clinical research studies and check that this SOP is being followed in accordance with SOP CG13 Monitoring and Audit.

5.8 Use suggested Record Form CGD3-RF01 Data and Document Storage Record to document data and document storage (this can be used for any item whether paper-based, physical or electronic) and can be adapted to fit the needs of the study/trial.

6. FLOW CHART

None required.