UNIVERSITY OF LINCOLN

CLINICAL GOVERNANCE - STANDARD OPERATING PROCEDURE

ARCHIVING (CLINICAL DATA)

CG-QMS SOP CG15

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Approved by: Signature:	UREC See original

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OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED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 process for archiving clinical research data in accordance with the University's Code of Practice for Research, associated regulatory framework / legislative and for clinical trials the Good Clinical Practice (GCP) requirements.

2. SCOPE

This SOP applies to archiving of all clinical research data. This may be data that is completely anonymous, or fully identifiable. All data must be stored for at least 5 years after the completion of a study, as defined by the Regulations or as defined in the sponsor's protocol.

3. BACKGROUND

3.1 The University of Lincoln Code of Practice for Research states that the archiving of research data shall be for a *minimum* of five years after the date of any publication which is based upon them.

3.2 Data for Clinical Trials of Investigational Medicinal Products (CTIMPs) will require adherence to specific regulations.

3.3 This SOP complies with the requirements of the Medicines for Human Use (Clinical Trials) Regulations, 2004 and its subsequent amendments, the UK Policy Framework for Health and Social Care Research 2017 (3rd edition, v3.3 07/11/2017) and its subsequent amendments, and Good Clinical Practice as outlined by the EU Clinical Trials Regulation 2001/20/EC.

3.4 Where the research has included the collection and use of human tissue and comes under the definition of a scheduled purpose according to the Human Tissue Act, 2004, then archiving of relevant data shall be in accordance with the guidance notes issued by the Human Tissue Authority and the University of Lincoln's Human Tissue Quality Management System (HT-QMS).

3.5 A controlled document is a reference document which, through the course of its lifecycle, may be reviewed, modified and distributed several times. Examples of a controlled document include: Clinical Governance Quality Manual, Clinical Governance Standard Operating Procedures and associated Record forms/Work Instructions; Clinical Trial/Study documents including but not limited to protocol, information sheets, consent forms and any other study related document which requires ethical review.

3.6 Trial/study data are all documents (paper and electronic) and patient records generated in relation to the setting up, conduct, analysis and closure of clinical trial/study and include source data that are generated solely during the trial/study. Patient medical notes other than trial notes are not considered as trial data.

3.7 Trial/study datasets and associated meta data should be stored on an appropriate storage medium.

3.8 The Chief Investigator has overall responsibility for the archiving of trial/study data. This may be delegated (as appropriate) on the Delegation Log.

3.9 Completed documents, clinical data/dataset should not be archived until after the first publication and/or in accordance with any funder terms and conditions.

3.10 Where University of Lincoln Clinical Trials Unit (LinCTU) is preparing documentation, collecting/collating clinical data/datasets - archiving should be in accordance with Sponsor requirements.

3.11 The University has a contract with an external company for the storage and archiving of electronic data, known as ePrints (ePrints.lincoln.ac.uk).

4. CROSS REFERENCES

4.1 Code of Practice for Research https://lncn.ac/copr
4.2 CG-QMS RF CG08-RF01 Study Delegation Log
4.3 CG-QMS SOP CGD2 Data Management
4.4 HT-QMS

5. PROCEDURE

Following first publication, the Data Custodian (may be known as Chief Investigator (CI), Principal (PI) Investigators, or delegated nominee) shall:

5.1 Prepare all appropriate signed consent and industrial consents for storage of data

5.2 Prepare all trial/study records, data and metadata for archiving

5.3 To pursue the Open data strategy, anonymise all data where:

- Anonymisation is feasible

  Where anonymisation is not feasible, or where special category data is processed the University's Information Compliance Office should be consulted accordingly.

- Data will be published
- Data custodian has approved anonymisation process

5.4 With electronic data, where Open data publication is not feasible, data should be stored in a restricted access 'OneDrive' folder. Access will be restricted to the data custodian and any relevant trial/study personnel and the Research Governance Manager.

5.5 Paper records may be scanned and uploaded in accordance with SOP CGD2 Data Management these should by someone with appropriate authority (e.g. trial manager) as identified on the RF CG08-RF01 Study Delegation Log.

5.6 When uploading paper records there must be an appropriate mechanism in place to check the following:

- Accuracy of the metadata attributed to the document
- Quality of the image, for readability and other possible reasons
- Whether it was the correct document (as expected)
- That the document had the correct number of pages
- The eTMF audit trail associated with the document (with a link to any changes)
- Chain of custody documentation and timeliness of uploading into the eTMF
- Approval process (where applicable)

5.7 After anonymisation and approval the data should be uploaded to ePrints (ePrints.lincoln.ac.uk) service. The upload should contain the data, metadata, and sufficient instructions for use by an independent researcher.

6. FLOW CHART

None required.