UNIVERSITY OF SUSSEX

Standard Operating Procedures for Archiving Paper Trial Documents (for Sussex Sponsored trials)

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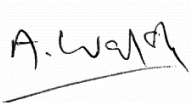
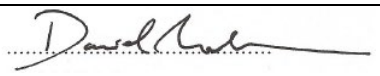
Author: Antony Walsh **Designation:** Research Governance Officer	**Signature** 	**Date** 26 March 2021
Authorised By: Dr Daniel Michelson **Designation:** Sponsorship Sub-Committee Chair		29.3.21

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1.0		

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[1] http://www.sussex.ac.uk/staff/research/governance

Acknowledgement , University of Keele

1. Purpose & Scope

1.1 The EU Good Clinical Practice (GCP) Directive 2001/20/EC was introduced to establish standardisation of research activity in Clinical Trials throughout the European Union (EU). It was transposed into UK law as the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) which came into force on 1st May 2004. The Medicines for Human Use (Clinical Trials) Regulations together with subsequent amendments will be referred to as the Regulations in the rest of this document[2].

1.2 This Standard Operating Procedure (SOP) sets out the procedure for archiving study documents in a Clinical Trial of an Investigational or Medicinal Study (CTIMP) study being sponsored by the University of Sussex (US).

1.3 The scope of the document is for all schools at the University of Sussex, all members of staff with substantive employment and students registered at the University (including Brighton and Sussex Medical School).

2. Introduction

2.1 Essential documents must be kept so that trial data remains accessible after the study has been completed. The documentation may be needed for a number of reasons including:

- Future studies suggesting a further period of follow-up
- Allegations of fraud or any other breach of research integrity
- Patients or participants needing to be contacted due to concerns over side-effects
- Compliance with audit or inspection requirements

2.2 Commission Directive 2005/28/EC dated 8th April 2005, Chapter 4, Article 19 states that:

"The sponsor shall appoint individuals within its organisation who are responsible for its archives. Access to archives shall be restricted to the named individuals for the archives"[2].

3. Responsibilities

Trial Manager

3.1 The Trial Manager is responsible for the coordination and compliance of all archiving performed. This includes the following functions:

- Sending documents for archiving
- Retrieving documents from archiving

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005L0028&from=EN

- Authorising destruction of archived documents

Chief Investigator (CI)

3.2 It is the responsibility of the CI to ensure that all the essential documents are correct and complete before sending them to the archivist for transfer off-site.

This responsibility may be delegated to another member of the research team but must be recorded on the Sponsor's delegation of responsibilities log.

Sponsor

3.3 It is the Sponsor's responsibility to ensure the essential documents are archived. For multi-centred studies, Investigator Site File archiving is delegated to the Principal Investigator at each site.

3.4 It is the Sponsor's responsibility to inform the Principal Investigator (PI) at each site when documents can be destroyed or are ready for archiving at the end of the study.

4. Procedure

4.1 The essential documents for the sponsor are maintained within the Trial Master File (TMF).

4.2 The Sponsor is responsible for ensuring that there is an appropriate archiving procedure for essential documents held at each site.

4.3 The managing CTU's SOP on Trial Master Files and Investigator Site Files provides details of the of the essential documents for a CTIMP.

4.5 A full review of the TMF should be carried out and documented prior to approval to archive being given. Unless the study documentation stipulates that the ISF needs to be retained at site until the final published report is available, the ISF can be archived prior to this.

4.6 For multi-centred studies where US is the sponsor, the clinical trial agreement with each site will document that it is each participating research site's responsibility to maintain and archive study documentation for their site. The TMF will contain details of the participating sites local archiving arrangements. This will include location of archive and Named Archivist contact details.

4.7 A close out monitoring visit may be performed by the Trial Manager prior to archiving and a close out monitoring report produced. The Sponsor will inform PIs at participating sites when the essential documentation is ready to archive.

4.8 TMFs and ISFs for US sponsored trials should normally be archived for at least five years unless otherwise specified by the funder of the research trial or if the data is to be used for a Marketing Authorisation. In studies where the data is used to support a marketing authorisation, documents should be retained for at least 15 years after completion of the study. Trial participants' medical records must be retained for at least ten years.

4.9 The Sponsor will inform the PIs of sites when the archived documents can be destroyed.

5. Training

5.1 This is a 'read and understand' SOP. Please note that REIGO department discourages the retention of hard copies of SOPs and can only guarantee that the most up-to-date version is on the University website.

6. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational or Medicinal Product
CTU	Clinical Trials Unit
EU	European Union
GCP	Good Clinical Practice
HRA	Health Research Authority
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ISF	Investigative Site File
MHRA	Medicine and Healthcare Products Regulatory Agency
PI	Principal Investigator
REIGO	Research Ethics and Integrity Office
SOP	Standard Operating Procedure
TMF	Trial Master File
US	University of Sussex

7. Cross Referenced SOPs

SOPRG01	Sponsorship Approval CTIMPs
SOPRG03	Notification of Serious Breach of Good Clinical Practice or the Protocol
SOPRG04	Risk Assessment of CTIMPs
SOPRD05	Monitoring CTIMP Research Studies
SOPRG21	Adverse Events in CTIMPs
SOPRG9A	Procedures for Close out of a CTIMP
SOPRG16	Amendments, Urgent Safety Measures and Temporary Halt to a Trial

8. References

Clinical Trials Regulations 2004 (SI 2004/1031)
http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

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

Clinical Trials Regulations 2006 (SI 2006/1928)
http://www.legislation.gov.uk/uksi/2006/1928/pdfs/uksi_20061928_en.pdf

UK Policy Framework for Health and Social Care Research

https://www.hra.nhs.uk/planning-and-improving-research/policies-standardslegislation/ukpolicy-framework-health-social-care-research/

International Conference on Harmonisation Good Clinical Practice Guidelines E6

Good Clinical Practice, International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use
http://ichgcp.net/

MHRA Good Clinical Practice Guide, The Stationery Office: London, (2012)

Appendix 1

Pre-archiving checklist

The purpose of this document is to ensure that all archiving is completed to an approved standard, that all archived materials are stored appropriately and for the correct period of time.

Please note that archived documents must NEVER be sent to the Sponsor and must be facilitated by an intermediary e.g. Sponsor Monitors.

Please complete the form clearly and if not using typescript, please **PRINT** the words to enable legibility.

Full Study Title	
Study Reference Number	
Chief Investigator	
Point of Contact (contact details)	

	Yes/No/Comments
Has the Sponsor confirmed close out?	
Do you have copies of the close out documentation to evidence Sponsor close out?	
Have all patient completed all treatments & visits?	
Has all data been collected?	
Where appropriate, has all drug accountability been performed?	
Have all outstanding issues been resolved?	
Are all data queries resolved?	
Is the site file complete?	
Has the Sponsor stipulated length of archive?	
Have all documents relating to the study been collected from all other departments e.g. Laboratory, Pharmacy etc?	
Have all records on thermal paper been transferred to normal paper e.g. ECGs, faxes etc?	
Have all plastic / metal clips, rubber bands and plastic wallets been removed?	
Have files been removed from Lever arch files or Manilla wallets?	
Has a cover sheet been created for each section?	
Has an index been created for each box and a complete archive index retained?	
Have dates of destruction been recorded?	

Chief Investigator:……Date: ……

Sponsor: ……Date: ……..

Appendix 2

University of Sussex Document Archiving Contractor

Document Options
Burridge House, Priestley Way, Crawley, West Sussex, RH10 9NT
www.document-options.co.uk

Tel. 01293 300352