

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

This is a controlled document
Any printed versions of this document will be classed as uncontrolled

SOP Reference:	SOP/RG33
Version Number:	1.0

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

Version	Effective Date	Reason for Change
1.0		

Disclaimer

- When using this document ensure that the version you are using is the most up to date either by checking on the Research Governance webpages¹ for any new versions or by contacting the author to confirm the current version
- Staff and students may print off this document for training and reference purposes but are responsible for regularly checking for the current version. Any print-off of this document will be classed as uncontrolled
- Out of date documents must not be relied upon

139.96.48 679.96.71.bty112 70 Td(-)eEMC /Link #MCID 104 8BDC 0.0cg.0.494 Td()TJEMC /L/ArSpan#MCID 104 9BDC BT/T9 (39.96.48 67289.6871.bty112)TJET/A0.i1

RESEARCH & ENTERPRISE SERVICES

- 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 sponsor should ensure that the sponsor's copy of the ISF is retained at the sponsor's site until the final published report is available, the ISF can be archived prior to this.

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 Event Reporting (CTIMPs)

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