

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

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SOP Reference:	SOP/RG33
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Authorised By: Dr Daniel Michelson Designation: Sponsorship Sub-Committee Chair		29.3.21

Version	Effective Date	Reason for Change
1.0		

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- 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 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

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