RESEARCH & ENTERPRISE SERVICES RESEARCH ETHICS, INTEGRITY & GOVERNANCE

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	Signature	Date
Designation: Research Governance Officer		
		26 March 2021
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 spon 2(o)003 (n) (2(8s)1.7 (th)16. Tc 0 T.6 (o)a)2.7 (t)9/al	DItIID (
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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 Adver 0.48 ref528.2.6 (m)e3.7 3ET@66.48 61959 r

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