

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

**This is a controlled document**  
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|                        |          |
|------------------------|----------|
| <b>SOP Reference:</b>  | SOP/RG33 |
| <b>Version Number:</b> | 1.0      |

|                                                                                                  |                  |                                     |
|--------------------------------------------------------------------------------------------------|------------------|-------------------------------------|
| <b>Antony Walsh</b><br><b>Designation:</b> Research Governance Officer                           | <b>Signature</b> | <b>Date</b><br><br>26 March<br>2021 |
| <b>Authorised By:</b> Dr Daniel Michelson<br><b>Designation:</b> Sponsorship Sub-Committee Chair |                  | 29.3.21                             |

| <b>Version</b> | <b>Effective Date</b> | <b>Reason for Change</b> |
|----------------|-----------------------|--------------------------|
| 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](http://www.document-options.co.uk)

**Tel. 01293 300352**