University of Sussex CTIMP Management Framework

Policy Reference	University of Sussex CTIMP Framework				
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Approver	Prof Kevin Davies (Chair of Sponsorship Sub-Committee)	Signature		Date	28 July 2020
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			Approval, HRA Approval and relevant site management approval.	
D1	Trial Master File (TMF)	SI 2004/1031 Part 4 31 A	CIs, supported by the CTU, are delegated responsibility for creating, maintaining and archiving a Trial Master File (TMF).	The TMF is managed in accordance with the Trial Master Files and Investigator Site Files SOP (

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				All trials must convene a Data Monitoring Committee (DMC) and Trial Steering Committee (TSC). The DMC / TSC must agree the trial protocol and statistical analysis plan.
K1	Pharmacovigilance and Safety Reporting	SI 2004/1031 3A, Part 5 32, 33, 24 and 35	SAEs Suspected Unexpected Serious Adverse Reactions (SUSARs) Identification and reporting of SAEs and SUSARs is delegated to the CI and CTU.	The CI/CTU is required to notify the Sponsorship Sub-Committee (researchsponsorship@sussex.ac.uk) of any event meeting the definition of an SAE in accordance with University of Sussex Adverse Events in CTIMPs (Sponsor SOP SOPRG21). To be included in the study progress report which is submitted to the SSC periodically. The CI/CTU is required to notify the Sponsorship Sub-Committee (researchsponsorship@sussex.ac.uk) of any event meeting the definition of an SUSAR in accordance with (Sponsor SOP SOPRG24 - Adverse Events in CTIMPs) with immediate notification to the Chair of the SSC and escalated accordingly.
K1.1			Development Safety Update Report (DSUR) Completion of the DSUR is delegated to the CI and CTU for annual submission to the MHRA An annual report of all the SAEs that occurred.	The DSUR/Reference Safety Information (RSI) must be copied to the Sponsorship Sub-Committee upon submission to the Regulatory Authorities in accordance with the CTU's SOP for DSUR handling (CTU SOP 29 - Reference Safety Information Definition and Updates). This allows the Sponsor to assess any changes to the Risk: Benefit ration of the trial. Any areas of concern may be referred to the CI first for action, and if areas of concern continue to be identified by the Sponsor, these will be discussed at the Sponsorship Sub-Committee.
L1	End of trial	SI 2004/1031 27, Part 4 31A	Responsibility for submission of the End of Trial Notification (or Notification of	The notification of Close-Out of a CTIMP Research Study (SOPRG09a) (or Notification of Early Termination) must be

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			Early Termination) is delegated to the CI and CTU.	copied to the Sponsor upon submission to the Regulatory Authorities. (CTU SOP 5: Trial Close Out Procedures).
L1.1			Publication of results and end of trial report The CI must ensure that clinical trial results are published in a timely manner, in a peer-reviewed and open access journal, and in accordance with funder requirements.	The end of study report must be copied to the Sponsor (researchsponsorship@sussex.ac.uk). (CTU SOP Trial Reporting Project Publication and Dissemination SOP (PRG/35).
L1.2			End of study reporting on EudraCT The CI and CTU are delegated responsibility for reporting results on the EudraCT Results Database in accordance with regulatory requirements.	The Research Governance Officer has authority for the trial EudraCT accounts on behalf of the University. The Research Governance Officer gives access

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				The Sponsor reserves the right to monitor or audit documentation relating to trials that it sponsors.
N1	Training	SI 2004/1031 Schedule 1 Part 2(2)	Individuals involved in the sponsorship of and management of clinical trials are expected to be adequately trained and / or experienced to perform their tasks	
N1.1			Sponsor	Individual staff members are responsible for identifying training requirements within the team as applicable to their role. All new members of staff are required to read all SOPs relevant to their job role and maintain their own training file.
N1.2			CIs, CTUs and Researchers CTUs and CIs are responsible for identifying and addressing individuals' training needs within their trial teams as applicable to the trial. Training in new / complex Sussex Sponsor procedures may be undertaken as required.	Minimally, CIs and CTU research staff must be trained in the requirements of GCP, and this should usually be evidenced through a current (within the last 2 years) certificate. Where identified as required, the Research Governance Office will deliver training on Sussex's sponsorship processes on an ad hoc basis.

Section E References

Clinical Trials Regulations 2004 (SI 2004/1031)

http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

Section F List of SOPs cited in this Framework

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			Code of Practice for Research
			Procedure for the Investigation of Allegations of Misconduct in Research
H1 - Amendments	SI 2004/1031 Part 3 22, 24, 25, 26	SOPRG16	

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F1- IMP Management	SI 2004/1031 Part 4 28, Part 6 36, 37, 43, Schedules 6, 7, 8 and part 7 46	CTUSOP013 CTUSOP014	IMP Supply and Management IMP Labelling
I1 – Data Management	SI 2004/1031 3A, part 5 32, 33, 24 and 35	CTUSOP027 CTUSOP028	Data Management DataRequests and Transfer
J1- Statistics		CTUSOP030	Statistical Oversight
L1 – End of Trial	SI 2004/1031 27 Part 4 31A	CTUSOP015 CTUSOP017	Trial Closure Archiving

Section F Version Control details

Version	Date	Reason for change

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