

APPENDIX 3

CTIMP Studies - Generic SOP read list for all studies

Details and access to the most current version of SOPs can be attained via the Sponsor website.

Link: <http://www.leicestersresearch.nhs.uk/standard-operating-procedures/sop-downloads-sponsor/>

Document	Document Title	Specific to	
S-1004	Development safety update report for CTIMPs sponsored by UHL	CI/PI	
S-1006	Informed consent for research sponsored by UHL	CI/PI	Research team
S-1007	Site management (monitoring) for UHL NHS Trust when acting as Sponsor	CI/PI	Research team
S-1008	Training for staff engaged in research sponsored by UHL	CI/PI	Research team
S-1009	Processing and reporting of SAEs, SARs & SUSARs for all research sponsored by UHL	CI/PI	Research team
S-1010	Chief Investigator responsibilities for research sponsored by UHL	CI/PI	
S-1011	Site initiation for research sponsored by UHL	CI/PI	Research team
S-1013	Identifying and reporting serious breaches of GCP and/or the protocol for clinical trials sponsored by UHL	CI/PI	Research team
S-1014	Green light process for research sponsored by UHL	CI/PI	
S-1015	Management of essential documents and trial filing for research sponsored by UHL	CI/PI	Research team
S-1016	Procedure in non-compliance in research sponsored by UHL	CI/PI	
S-1017	Green light process for amendments to research sponsored by UHL	CI/PI	Research team
S-1018	Approval of amendments or additions to documents for studies sponsored by UHL	CI/PI	Research team
S-1019	Procedure for the management of fraud and misconduct in research sponsored by UHL	CI/PI	
S-1022	Process for submission of annual progress reports for research sponsored by UHL	CI/PI	
S-1023	Process for the IB/SPC preparation, review, approval and amendment for research sponsored by UHL	CI/PI	
S-1024	Process for study close down for research sponsored by UHL	CI/PI	Research team
S-1026	Urgent safety measures SOP for research sponsored by UHL	CI/PI	
S-1027	Creating a statistical analysis plan for research sponsored by UHL	CI/PI	
S-1028	Amendments to contracts for research sponsored by UHL	CI/PI	
S-1029	Archiving of essential documents for research sponsored by UHL	CI/PI	Research team
S-1030	End of study and study reporting for research sponsored by UHL	CI/PI	Research team

S-1031	Data management process for research sponsored by UHL	CI/PI	Research team
S-1035	Case report form production for research sponsored by UHL	CI/PI	Research team
S-1036	Quality assurance for research sponsored by UHL	CI/PI	Research team

CTIMP Studies: Additional list where applicable

Document	Document Title	Specific to	
S-1012	Management and production of corrective and preventative action plan (CAPA) for studies sponsored by UHL	CI/PI	
S-1025	SOP for convening a data safety monitoring committee for research sponsored by UHL	CI/PI	
S-1033	Randomisation and blinding for research studies sponsored by UHL	CI/PI	Research team
S-1037	Healthy Volunteers for research sponsored by UHL	CI/PI	Research team