SOP TRAINING RECORD LOG - Research and Development Senior Managers

SOP No:	SOP Title	Version No:	Review Date	Training Undertaken	Signature and Date
001	Production, Approval and Review	8.0	May 2019	Read only	
002	Training Records for Research Active Staff	7.0	July 2020	Read only	
003	Informed Consent for Research Studies	7.0	August 2020	Read only	
005	Ethics Approval of Research Studies	3.0	May 2019	Read only	
009	Project Management of Research Studies	5.0	June 2020	Read only	
011	Archiving of Research Studies	7.0	April 2020	Read only	
012	Adverse Event Reporting	4.0	April 2019	Read only	
013	Trial Master File and Site File Creation and Maintenance	5.0	Nvoember 2018	Read only	
014	Gaining Regulatory Approval from the MHRA	3.0	March 2019	Read only	
015	Site Recruitment and Initiation for Papworth Sponsored Studies	4.0	August 2019	Read only	
016	Monitoring Research Studies	6.0	March 2019	Read only	
017	Statistical Input into Clinical Trials	2.0	July 2018	Read only	
018	Randomisation of Research Studies	3.0	December 2018	Read only	
019	Research Protocol Design	3.0	July 2019	Read only	
020	Patient Information Sheets and Consent Forms: Development, Implementation	3.0	December 2018	Read only	
021	Trial Closure & End of Trial Reporting	3.0	June 2019	Read only	
023	Financial Procedures for Research Studies	3.0	June 2019	Read only	
024	Contract Negotiation and Review	3.0	June 2019	Read only	
025	Assessment and Registration of Trust Risk Rating for Research Studies	5.0	April 2018	Read only	
029	Management of Research and Development Freezers	1.0	November 2016	Read only **staff listed on the out of hours emergency contact list must familiarise themselves with the Freezer Room located within Pathology*	
030	Roles and Responsibilities/Delegation Log	4.0	September 2019	Read only	
031	Patient Recruitment	3.0	October 2019	Read only	
034	Research Studies: Trust Confirmation of Capacity and Capability to Conduct Research Studies	8.0	March 2020	Read only	

By signing this sheet the employee agrees to undertake the procedure with the scope of their role

035	Research Database Application (ReDA)	5.0	April 2018	Read only	
037	Amendments to Research Studies	7.0	July 2019	Read only	
038	Change of Investigator	4.0	October 2019	Read only	
040	Management of External Research Staff - Research Passport Scheme	4.0	March 2020	Read only	
041	File Notes	3.0	February 2018	Read only	
044	Emergency Trolley in CTBI	3.0	May 2019	Read only	
048	Papworth Sponsorship of Research Studies	4.0	July 2020	Read only	
049	GCP Training for Research Staff	2.0	September 2018	Attendance at GCP event	
050	Handling of Protocol Non-Compliance	3.0	June 2019	Read only	
051	Serious Breach of Protocol or GCP in CTIMPs and Non-CE Marked Devices	3.0	April 2019	Read only	
052	Dealing with Misconduct and Fraud: Good Research Practice	2.0	March 2018	Read only	
055	Roles and Responsibilities for the Conduct of Research Studies and Clinical Trials including CTIMPs	2.0	April 2019	Read only	
060	Version Control of Study Documents	2.0	July 2019	Read only	
062	Preparation of RegulatoryProgress Reports including Periodic Safety Reporting and Annual Reports	3.0	August 2019	Read only	
063	Research and Development: Internal Good Clinical Practice (GCP) Audit	3.0	May 2020	RO class room based training, as required	
064	Email Correspondence: Study Related	2.0	April 2020	Read only	
065	Risk-adapted Approach to the Management of Clinical Trials of Investigational Medicinal Products	3.0	July 2019	Class room based for Investigators and Ros, as required for setting up new CTIMP studies	
066	Subcontracting of Research Activities	3.0	April 2019	Read only	
067	Tissue Bank (Deposits and Withdrawals)	3.0	July 2019	Read only	
069	Code Breaking/Unblinding of Clinical Trials, training and procedure testing	2.0	January 2020	Read only	
070	Expedited Trust Approval of Urgent Public Health Research Studies	1.0	August 2017	Read only	
071	Urgent Safety Measures	2.0	September 2019	Read only	
072	Supply of Clinical Trials Investigational Material Dispensing Returns and Accountability	1.0	March 2018	Read Only	

073	Sourcing of Clinical Trial Investigational Medicinal Products for Papworth Sponsored Studies: Manufacturing, Assembly and Labelling	1.0	March 2018	Read only	
074	Handling of drug alerts and recalls of IMPs or other trials related drugs	1.0	March 2018	Read only	
075	Quarantine of CTIMPs	1.0	March 2018	Read only	
076	Transport Storage and Environmental Monitoring of IMP's	1.0	March 2018	Read Only	
077	Data Management Overview	1.0	May 2020	Read only	
079	Reference Safey Information	2.0	February 2020	Read only	
080	Study Data - Collection and Entry	1.0	July 2020	Read only	