Reference	Version	Title	Associated Document(s)	Associated SOPs
BU RDS SOP 001	1	Archiving Clinical Research Records	Records Management Code of Practice for Health and Social Care 2016	BU RDS SOP 006 – File Management for Clinical Research BU RDS SOP 019 - Data Management for Clinical Research
BU RDS SOP 002	3	Amendments	UK Policy Framework for Health and Social Care Research	BU RDS SOP 006 – File Management for Clinical Research
BU RDS SOP 003	1	Clinical Quality Assurance	None	BU RDS SOP 008 – Monitoring of Research Projects BU RDS SOP 012 - Sponsorship
BU RDS SOP 004	1	Review of Study Protocol and Associated Documents	None	BU RDS SOP 002 - Amendments
BU RDS SOP 005	1	Deviations, Violations and Serious Breaches	None	BU RDS SOP 011 – Safety Reporting
BU RDS SOP 006	1	File Management for Clinical Research	RDS Suggested TMF (ISF and Sponsor File) template	BU RDS SOP 001 – Archiving Clinical Research
BU RDS SOP 007	1	Informed Consent	None	None
BU RDS SOP 008	1	Monitoring of Clinical Research Projects	Sponsor file monitoring form Monitor Form - participating sites	BU RDS SOP 006 - File Management for Clinical Research BU RDS SOP 011 – Safety Reporting
BU RDS SOP 009	1	NHS Site Set-up and Amendment Procedures	HRA terminology Attributing the costs of health and social care Research and Development (AcoRD)	BU RDS SOP 002 - Amendments
BU RDS SOP 10	1	Recruitment (NHS Patients)	None	BU RDS SOP 007 – Informed Consent
BU RDS SOP 11	1	Safety Reporting	Non-CTIMP safety report to REC form	None
BU RDS SOP 12	4	Sponsorship	Chief Investigator Declaration	BU RDS SOP 009 – NHS Site Set-up and Amendment Procedures
BU RDS SOP 13	1	Staffing and Delegation	HR Good Practice Resource Pack	BU RDS SOP 002 - Amendments

BU RDS SOP 14	1	Study Progress Reporting	None	None
BU RDS SOP 15	1	Study Closure	None	BU RDS SOP 002 - Amendments BU RDS SOP 011 – Safety Reporting
BU RDS SOP 16	1	MHRA Inspection	How to prepare for an inspection for Good Clinical Practice by the Medicines and Healthcare products Regulatory Agency (MHRA): a guide for organisations that sponsor or host non commercial clinical trials of medicinal products.	None
BU RDS SOP 17	1	Sponsorship Role	Good Clinical Practice Guide Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products.	BU RDS SOP 001 - Archiving Clinical Research Records BU RDS SOP 016 – MHRA Inspection
Information Document (formerly BU RDS SOP 18)	1	Types of Clinical Studies (inc. NIHR Portfolio)	None	BU RDS SOP 017 - Sponsorship Role
BU RDS SOP 19	1	Data Management for Clinical Research	None	BU RDS SOP 001 – Archiving Clinical Research Records BU RDS SOP 022 – Case Report Form Design
BU RDS SOP 20	1	Preparation and Management of SOPs	Template SOP	None
BU RDS SOP 21	1	Study Dissemination	None	None
BU RDS SOP 22	1	Case Report Form Design	None	BU RDS SOP 019 – Data Management for Clinical Research
BU RDS SOP 23	1	Randomisation and Blinding	None	None
BU RDS SOP 24	1	Human Tissue for Research Purposes	None	None
BU RDS SOP 25	1	Investigator Brochure, Summary of Product Characteristics and Investigational Medicinal Product Dossier	None	BU RDS SOP 002 – Amendments BU RDS SOP 011 – Safety Reporting BU RDS SOP 014 – Study Progress Reporting

Missing SOPs