SOP & Document list

STUDY START UP	
SOP number	**Title**
SOP14	Writing a protocol to Good Clinical Practice for Clinical Trials of Investigational Medicinal Products
SOP18	Trial Set Up in Clinical Trials of Investigational Medicinal Products
SOP19	Preparing and maintaining case report forms (CRF) for use in Clinical Research
SOP23	Completion of Delegation Log
SOP28	Sponsorship of Clinical Trials
SOP29	Application for Sponsorship of Health and Social Care Research Studies (excluding Drug (e.g., CTIMP) and Device Studies)
SOP45	Establishing and Maintaining a Trial Master File, Investigator Site File and Pharmacy Site File for use in Clinical Research
SOP47	The use of Version Control of Study Documents used in Health and Social Care Research Studies
SOP54	Training Records
SOP61	Registering and Reporting Research in a Publicly Accessible Database
SOP64	Risk Assessment of Clinical Research on Behalf of the Sponsor
SOP66	Planning Patient and Public Involvement (PPI) in Clinical Research

STUDY IN PROGRESS	
SOP number	**Title**
SOP07	Receiving Informed Consent from Potential Participants in Clinical Research
SOP12	Establishing Identity of Participants in Clinical Research
SOP15	Preparing and Submitting Reports for Clinical Research
SOP40	Randomisation, Blinding and Code Breaking in Clinical Research
SOP59	Reporting Breaches in Clinical Research
SOP63	Amendments to Healthcare Research Projects
SOP65	Preparing and Submitting DSURs for CTIMPS

SOP & Document list

STUDY CLOSE OUT	
SOP number	**Title**
SOP13	Archiving Clinical Studies
SOP16	Closure of Health and Social Care Research Studies
SOP32	Locking Clinical Study Databases
SOP61	Registering and Reporting Research in a Publicly Accessible Database

DATA MANAGEMENT AND STATISTICS	
SOP number	**Title**
SOP05	Statistical Analysis Plans for Clinical Research
SOP48	Data Management in Clinical Research Studies using Excel
SOP53	Data Management in Clinical Research
SOP55	Creating Reports for the Independent Data Monitoring Committee
SOP56	The Preparation and Peer Review of Sample Size Calculation for Clinical Research
SOP57	Implementation of Statistical Analysis in Clinical Research

LABORATORIES	
SOP number	**Title**
SOP34	Implementation and Maintenance of a Quality Assurance System in Clinical Research Laboratories
SOP35	Management of a Chain of Custody for Samples in Clinical Research
SOP36	Preparation of an Analytical Plan for Laboratories Associated with Clinical Research

PHARMACOVIGILANCE AND INVESTIGATIONAL MEDICINAL PRODUCTS	
SOP number	**Title**
SOP11	Identifying, Recording and Reporting Adverse Events for Clinical Trials of Investigational Medicinal Products (CTIMPs)
SOP15	Preparing and Submitting Reports for Clinical Research
SOP37	Accountability, Returns and Destruction of Investigational Medicinal Products in CTIMPs
SOP38	Manufacturing, Assembly, Packaging and Labelling of Investigational Medicinal Products in Clinical Trial Investigational Medical Products

SOP39	Supply, Transport and Storage of Investigational Medicinal Products in Clinical Trial Investigational Medical Products
SOP43	Handling Product Recalls of Clinical Trial Investigational Medicinal Products or Other Trial Related Drugs
SOP65	Preparing and Submitting DSURs for CTIMPS

QUALITY ASSURANCE AND MONITORING	
SOP number	**Title**
SOP01	Preparation, Approval and Review of Standard Operating Procedures for TASC
SOP03	Monitoring Clinical Trials of Investigational Medicinal Products (CTIMPs)
SOP17	Preparing and Participating in a Regulatory Inspection
SOP20	Performing Quality Assurance Audits
SOP44	Preparation and Review of Policies for TAyside medical Science Centre (TASC)

Associated Documents

Associated Documents	**SOP**	**SOP Title**	**Section**
Doc Ref 001 TASC SOP Template	SOP01	The Preparation, Approval and Review, of Standard Operating Procedures for TASC	QA and Monitoring
Doc Ref 006 Breach Log	SOP59	Reporting Breaches in Clinical Research	Study in Progress
Doc Ref 016 Drug Product Recall Notice	SOP43	Handling Product Recalls of CTIMPs or Other Trial Related Drugs	Pharmacovigilance and Investigational Medicinal Products
Doc Ref 018 TMF Index	SOP18 SOP45	SOP018 Trial set up in CTIMPs. SOP45 Establishing and Maintaining a Trial Master File, Investigator Site File and Pharmacy Site File for use in Clinical Research.	Study Start up
Doc Ref 019 ISF Index	TASC SOP18 TASC SOP45	SOP018 Trial set up in CTIMPs.	Study Start up

		SOP45 Establishing and Maintaining a Trial Master File, Investigator Site File and Pharmacy Site File for use in Clinical Research.	
Doc Ref 039 Monitoring Plan	SOP03	Monitoring CTIMPs	QA and Monitoring
Doc Ref 057 Delegation Log	SOP18, SOP19 & SOP23	SOP018 Trial set up in CTIMPs. SOP19 Preparing and Maintaining Case Report Forms (CRF) for use in Clinical Research. SOP23 Completion of Delegation Log	Study Start up
Doc Ref 058a Pregnancy Notification Form	SOP11	Identifying, Recording and Reporting Adverse Events for Clinical Research	Pharmacovigilance and Investigational Medicinal Products
Doc Ref 058b Pregnancy Follow-up	SOP11	Identifying, Recording and Reporting Adverse Events for Clinical Research	Pharmacovigilance and Investigational Medicinal Products
Doc Ref 064 Potential Breach Reporting Form	SOP59	Reporting Breaches in Clinical Research	Study in Progress
Doc Ref 071 Participant Randomisation Log	SOP18	Trial set up in CTIMPs	Study Start up
Doc Ref 072 SAE Form	SOP11	Identifying, Recording and Reporting Adverse Events for Clinical Research	Pharmacovigilance and Investigational Medicinal Products
Doc Ref 076 Screening Log	SOP18	Trial set up in CTIMPs	Study Start up
Doc Ref 077 Training Log	SOP54	Training Records	Study Start up
Doc Ref 086 AE Log	SOP11	Identifying, Recording and Reporting Adverse Events for Clinical Research	Pharmacovigilance and Investigational Medicinal Products

SOP & Document list

Doc Ref 087 Amendment Log	SOP47 & SOP63	SOP47 The use of Version Control of Study Documents used in Health and Social Care Research studies. SOP63 Amendments to Healthcare Research Projects.	SOP47 Study Start up SOP63 Study in Progress
Doc Ref 089 TASC Policy Template	SOP44	Preparation, Approval and Review of Policies for TASC	QA and Monitoring
Doc Ref 091 Monitoring versus Auditing	SOP20	Performing Quality Assurance Audits	QA and Monitoring
Doc Ref 094 Recording Form for Product Recalls or Alerts	SOP43	Handling Product Recalls of CTIMPs or Other Trial Related Drugs	Pharmacovigilance and Investigational Medicinal Products
Doc Ref 095 IMP Mock Recall report	SOP43	Handling Product Recalls of CTIMPs or Other Trial Related Drugs	Pharmacovigilance and Investigational Medicinal Products
Doc Ref 097 Excel for CTIMP	SOP48	Data Management in Clinical Research Studies Using Excel	Data Management
Doc Ref 099 DSUR	SOP65	Preparing and Submitting DSURs for CTIMPS	Study in Progress & Pharmacovigilance and Investigational Medicinal Products
Doc Ref 105 Study Lock Checklist	SOP32	Locking Clinical Study Databases	Study Close Out
Doc Ref 114 Sample Size Calculation	SOP56	The Preparation and Peer Review of Sample Size Calculation for Clinical Research	Data Management
Doc Ref 115 Signature Sheet Template	SOP57	Implementation of Statistical Analysis in Clinical Research	Data Management
Doc Ref 118 PSF Index	SOP45	Establishing and Maintaining a Trial Master File, Investigator Site File and Pharmacy Site File for use in Clinical Research.	Study Start up

SOP & Document list

Doc Ref 120 Recall from Archive Request Form	SOP13	Archiving Clinical Studies	Study Close Out
Doc Ref 122 Clinical Research Study Archiving Record Form	SOP13	Archiving Clinical Studies	Study Close Out
Doc Ref 123 TASC Sample Batch Certificate of Destruction	SOP35	Management of a Chain of Custody for Samples in Clinical Research	Laboratories
Doc Ref 126 Delegation Log – wet signature not possible	SOP23	Completion of Delegation Log	Study Start up
Doc Ref 128 TASC PPI Plan Template	SOP66	Planning Patient and Public Involvement (PPI) In Clinical Research	Study Start up
Doc Ref 129 Reference Safety Information	SOP11	Identifying, Recording and Reporting Adverse Events for Clinical Research	Pharmacovigilance and Investigational Medicinal Products