

NTW Research Sponsorship Quality Management System
Standard Operating Procedures Library
April 2019

Quality Assurance Series

SOP	Title	Associated Documents
NTW-SOP-001-V1	Development and Maintenance of Research SOP's	<ul style="list-style-type: none"> • NTW-WD-001-V1 Research SOP Template
NTW-SOP-002-V1	Audit	<ul style="list-style-type: none"> • NTW-WD-002-V1 Confidential Audit Report • NTW-WD-003-V1 ISF Audit Self-assessment checklist • NTW-WD-004-V1 TMF Audit Self-assessment checklist
NTW-SOP-003-V1	Corrective and Preventative Action	<ul style="list-style-type: none"> • NTW-WD-005-V1 NTW Research CAPA Form
NTW-SOP-004-V1	Document Version Control	
NTW-SOP-005-V1	Training of Research Staff	<ul style="list-style-type: none"> • NTW-WD-017-V1 Delegation Log
NTW-SOP-006-V1	Archiving	<ul style="list-style-type: none"> • NTW-WD-006-V1 Archiving Box Label • NTW-WD-007-V1 Archiving Chain of Custody • NTW-WD-008-V1 Archiving Checklist TMF • NTW-WD-009-V1 Archiving Checklist ISF

Project Development Series

SOP	Title	Associated Documents
NTW-SOP-007-V1	Sponsorship	<ul style="list-style-type: none"> • NTW-WD-010-V1 Risk Assessment Form • NTW-WD-011-V1 Chief Investigator Conditions of Sponsorship • NTW-WD-012-V1 Delegation of Duties
NTW-SOP-008-V1	Use of Vendors	<ul style="list-style-type: none"> • NTW-WD-013-V1 Vendor Assessment Form • NTW-WD-014-V1 Vendor Selection Form • NTW-WD-015-V1 Vendor Information Form



NTW-SOP-009-V1	Management of Contracts and Agreements	
NTW-SOP-010-V1	Risk Assessment	<ul style="list-style-type: none"> • NTW-WD-010-V1 Risk Assessment Form

Project Activity Series

SOP	Title	Associated Documents
NTW-SOP-011-V1	Annual Update of Investigator Brochure	
NTW-SOP-012-V1	Site Selection and Site Initiation	<ul style="list-style-type: none"> • NTW-WD-017-V1 Delegation Log
NTW-SOP-013-V1	Regulatory Green Light Process	<ul style="list-style-type: none"> • NTW-WD-018-V1 Regulatory Green Light Checklist
NTW-SOP-014-V1	Essential Documents TMF/ISF	<ul style="list-style-type: none"> • NTW-WD-019-V1 ISF index • NTW-WD-020-V1 TMF index
NTW-SOP-015-V1	Informed Consent	<ul style="list-style-type: none"> • NTW-WD-021-V1 Screening and Recruitment Log Template
NTW-SOP-016-V1	Randomisation and Unblinding	
NTW-SOP-017-V1	Monitoring	<ul style="list-style-type: none"> • NTW-WD-010 Risk Assessment Form
NTW-SOP-018-V1	Monitoring Plan	<ul style="list-style-type: none"> • NTW-WD-010-V1 Risk Assessment Form
NTW-SOP-019-V1	Safety Reporting AE & SAE	<ul style="list-style-type: none"> • NTW-WD-022-V1 SAE Form • NTW-WD-023-V1 SUSAR Checklist • NTW-WD-024-V1 SUSAR Report Form
NTW-SOP-020-V1	Safety Reporting SUSARS	<ul style="list-style-type: none"> • NTW-WD-025-V1 SUSAR checklist
NTW-SOP-021-V1	Serious Breaches of Protocol or GCP	<ul style="list-style-type: none"> • NTW-WD-026-V1 Serious Breach Form
NTW-SOP-022-V1	Protocol Deviations, Violations and Urgent Safety Measures	<ul style="list-style-type: none"> • NTW-WD-027-V1 Protocol Deviation Tracking Log • NTW-WD-028-V1 Notification of Protocol Violation form
NTW-SOP-023-V1	End of Study Procedures	

Data Management Series

SOP	Title	Associated Documents
NTW-SOP-024-V1	Data Management	
NTW-SOP-025-V1	Case Report Forms	