

Epworth HealthCare Research Training Curriculum (non-Clinical Trials)

Category	SOP Number	SOP Name	Principal Investigator	Sub-Investigator	Clinical Research Coordinator / Research Nurse / Trial Manager
Administrative	SOP-AD-01	SOP Creation, Implementation and Revision	X	X	X
	SOP-AD-02	Staff Induction			
Finance	SOP-FI-01	Invoicing and payment terms			
	SOP-FI-02	Participant Payments			
Trial Management	SOP-TM-01	Feasibility and Trial Start-Up			
	SOP-TM-02	Investigator Site File and Essential Documents			
	SOP-TM-03	Informed Consent	recommended	recommended	recommended
	SOP-TM-04	IMP accountability, dispensing, storage and destruction			
	SOP-TM-05	Handling and Shipping of Biological Samples	recommended		recommended
	SOP-TM-06	Management and Reporting of Safety Events			
	SOP-TM-07	Source Document Management			
	SOP-TM-08	Data Entry and Query Resolution			
	SOP-TM-09	Monitoring Management – routine visit			
	SOP-TM-10	Maintenance of Equipment	recommended		recommended
	SOP-TM-11	Monitoring of temperature controlled storage areas	recommended		recommended
	SOP-TM-12	Trial Close-out			
	SOP-TM-13	Trial Archiving	recommended		recommended
	SOP-TM-14	Delegation of Duties	recommended	recommended	recommended
	SOP-TM-15	Working with Cancer Trials Australia			
Quality	SOP-QA-01	Documentation of Qualifications and Training Records			
	SOP-QA-02	Management of Serious Breaches and CAPA Process			
	SOP-QA-03	Hosting an audit/regulatory inspection			
	SOP-QA-04	Vendor assurance and oversight			
	SOP-QA-05	Clinical Trial Internal Quality Assurance			
Research Governance	SOP-RG-01	Research Governance	X		X
	SOP-RG-02	Insurance and Indemnity	X		X
	SOP-RG-03	Developing Contracts and Budgets	X		X
	SOP-RG-04	Researcher Credentialing	X	X	X
	SOP-RG-05	Conducting Research with Ionising Radiation	J-I-T	J-I-T	J-I-T
	SOP-RG-06	Research Misconduct	X	X	X
	SOP-RG-07	Research Related Complaints	J-I-T	J-I-T	J-I-T
	SOP-RG-08	Non-HREC Review Process for Research Involving no more than low-risk	J-I-T	J-I-T	J-I-T
Glossary	SOP-Glossary	Glossary of Terms	J-I-T	J-I-T	J-I-T
Epworth		Epworth Research Policy	X	X	X
Epworth		Epworth Research Handbook	X	X	X
Epworth		Research QMS Protocol	X	X	X
National		National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)	X	X	X
National		Australian Code for the Responsible Conduct of Research (2018) (the 2018 Code)	X	X	X
National		Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)			
National		Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018)			
National		Safety monitoring and reporting in clinical trials involving therapeutic goods guidance document (2016)			
National		TGA Clinical Trials Handbook			

Key	
Required	X
Just-In-Time	J-I-T