

## Epworth Research Training Curriculum Clinical Trials (non-CTN)

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			X
	SOP-FI-02	Participant Payments			X
Trial Management	SOP-TM-01	Feasibility and Trial Start-Up	X		X
	SOP-TM-02	Investigator Site File and Essential Documents	X		X
	SOP-TM-03	Informed Consent	X	X	X
	SOP-TM-04	IMP accountability, dispensing, storage and destruction	J-I-T		J-I-T
	SOP-TM-05	Handling and Shipping of Biological Samples	J-I-T		J-I-T
	SOP-TM-06	Management and Reporting of Safety Events			
	SOP-TM-07	Source Document Management	X	X	X
	SOP-TM-08	Data Entry and Query Resolution	X	X	X
	SOP-TM-09	Monitoring Management – routine visit	J-I-T		J-I-T
	SOP-TM-10	Maintenance of Equipment	J-I-T		J-I-T
	SOP-TM-11	Monitoring of temperature controlled storage areas	J-I-T		J-I-T
	SOP-TM-12	Trial Close-out	X		X
	SOP-TM-13	Trial Archiving	X		X
	SOP-TM-14	Delegation of Duties	X	X	X
	SOP-TM-15	Working with Cancer Trials Australia	X		X
Quality	SOP-QA-01	Documentation of Qualifications and Training Records	X	X	X
	SOP-QA-02	Management of Serious Breaches and CAPA Process	X	X	X
	SOP-QA-03	Hosting an audit/regulatory inspection	J-I-T	J-I-T	J-I-T
	SOP-QA-04	Vendor assurance and oversight	J-I-T	J-I-T	J-I-T
	SOP-QA-05	Clinical Trial Internal Quality Assurance	J-I-T	J-I-T	J-I-T
Research Governanc	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		<a href="#">Epworth Research Policy</a>	X	X	X
Epworth		<a href="#">Epworth Research Handbook</a>	X	X	X
Epworth		<a href="#">Research QMS Protocol</a>	X	X	X
National		<a href="#">National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)</a>	X	X	X
National		<a href="#">Australian Code for the Responsible Conduct of Research (2018) (the 2018 Code)</a>	X	X	X
National		<a href="#">Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)</a>	recommended	recommended	recommended
National		<a href="#">Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (2018)</a>	X	X	X
National		<a href="#">Safety monitoring and reporting in clinical trials involving therapeutic goods guidance document (2016)</a>	recommended	recommended	recommended
National		<a href="#">TGA Clinical Trials Handbook</a>	recommended	recommended	recommended

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