STANDARD OPERATING PROCEDURE (SOP)

TITLE: WORKING WITH CANCER TRIALS AUSTRALIA

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Date:	Nov 29, 2019

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TITLE: WORKING WITH CANCER TRIALS AUSTRALIA

1. PURPOSE:

The purpose of this SOP is to describe the roles and responsibilities where Cancer Trials Australia (CTA) is involved in supporting trial related activities.

CTA is contracted to assist with ethics and governance submissions for all industry Sponsored, Collaborative and Investigator Initiated Clinical Trials conducted at Epworth. CTA will co-ordinate the ethics and governance related activities as well as undertake the negotiation of budgets and contracts and financial management on behalf of the site.

2. SCOPE:

All research activities including clinical trials conducted at Epworth where CTA is contracted to provide the service listed above.

3. APPLICABILITY:

This applies to all Epworth employees, non-employed staff and Visiting Medical Officers (VMOs) and to all relevant external persons or parties engaged in the research activity at Epworth.

4. GLOSSARY OF TERMS:

Please refer to Epworth SOP Glossary of Terms (see Related Documents).

5. PROCEDURE:

The Principal Investigator (PI) is responsible for the research project conducted at Epworth and must be familiar with all regulatory and institutional requirements as per the Research Policy[1] and Research Handbook[2]. Where CTA is involved the PI delegates the trial duties outlined in APPENDIX A and APPENDIX B to CTA. The PI remains responsible for any delegated activity.

The pathway for working with CTA at Epworth is outlined in APPENDIX C: Epworth CTA process map.

APPENDIX D provides a list all CTA contacts involved in coordinating the activities outlined below.

5.1 Feasibility/Pre-Site Selection

- The PI will undertake feasibility and pre-site selection activities as per SOP-TM-01: Feasibilities and Trial start-up.
- CTA is not involved at this stage.

5.2 Site Selection

- Once the site has been approved to participate in the trial (site selection), the study team Is responsible for requesting supporting documentation from the Sponsor and ensuring continued support from the relevant departments/divisions and third party providers is in place prior to proceeding to study start up activities (as per SOP-TM-01).

- The PI/study team should also notify CTA of the proposed study via the Study Start-Up Manager (SSUM) at this stage.
- The PI/study team will advise the Research Operations Manager (ROM), CTA SSUM and Ethics Submission Specialist (ESS) that the trial is operationally feasible to conduct at Epworth and will request CTA to commence start-up activities.
- The ESS will provide the current version of the CTA New Trial Assessment Form (NTAF) for the study team to complete.

5.3 Study Start-up Assistance

- The CTA study start-up process will commence upon provision of the NTAF and written confirmation from the study team that the appropriate departmental and external service provider support is in place.
- The CTA ESS will coordinate preparation of all study documentation required for ethics and governance submission (as outlined in APPENDIX A), and will provide updates on the progress as appropriate to the ROM, Study team, Sponsor and Research Development and Governance Unit (RDGU).
- The ESS will provide all ethics and governance submission documentation to the ROM and study team for review and sign-off prior to submission.
- Upon ethics /governance approval the ESS will provide a copy of all submission documents approved by the reviewing HREC and institution.
- The CTA Budgets and Contracts Specialist (BCS) will liaise directly with the supporting departments and external service providers for quotations (as outlined in APPENDIX B).
- The ROM and the study team will be required to review the itemised budget provided by CTA and provide approval to proceed with negotiations, and assistance with queries as required.
- The BCS will negotiate the budget and Clinical Trial Research Agreement directly with the sponsor until finalised.
- The BCS and CTA Clinical Trials Contracts Manager (CTCM) will review the Clinical Trial Research Agreement (CTRA) and send to the ROM and the study team for review.
- The ROM and the study team will be required to review the CTRA provided by CTA and provide approval to proceed with negotiations and assistance with queries as required.
- The BCS will negotiate the CTRA with the sponsor until finalised.

5.4 Post Approval Assistance

- Upon notification from the Sponsor/study team of a study amendment ESS will coordinate preparation of study amendments.
- The BCS will follow-up where any amendments to the budget or contract as required.

- The study team must ensure the Clinical trial Management System (Velos) used by CTA is updated with the relevant patient visits.
- The study team will be required to undertake training prior to using Velos for the first time (see APPENDIX D for CTA contacts).
- Process for generating invoices will be as per Clinical Trial Research Agreement.

6. REFERENCES:

1. Epworth Research Policy
2. Epworth Research Handbook

7. RELATED DOCUMENTS:

7.1 Related Forms and Templates

- New Trial Assessment Form – Cancer Trials Australia

7.2 Related SOPs

- SOP-Glossary-of-Terms
- SOP-TM-01 Feasibilities and Trial Start-up
- SOP-RG-01 Research Governance

8. VERSION CONTROL

Document History	
Version	**Summary of Changes**
1.0	N/A - First issue

APPENDIX A: CTA Site Roles and Responsibilities – Ethics and Governance

KEY: RACI - Responsible/ Accountable /Informed/ Consulted

Step	Task	Site			SPONSOR	CTA	
		Clinical Team	Research Operations Manager	Site's Service Provider		Budget & Contracts	Ethics/ Governance
FEASABILITY	Request finalised copies of operations documents: protocol, lab manual, imaging manual, pharmacy manual, IB, CRF entry guidelines/required data points	R/A	I		R/A		
	Review all supporting documentation to assess feasibility of running the trial at site. Assess available and required resources	R/A	I	C			
	Approach core third parties (Pharmacy, Pathology, Radiology, Day Oncology) with relevant documentation	R/A	I	C			
	Confirm core third parties can support the trial	R/A	I	C			
	Assess operational feasibility: Trial is not feasible to run at Epworth	R/A	I	I	I		
	Assess operational feasibility: Trial is feasible to run at Epworth	R/A	I	I	I		
SITE SELECTION	Communicate Site Selection and activate CTA	R/A	I	I	I	I	I
	Obtaining evidence of relevant departmental/divisional support	R/A	I				I
	Identify service providers required for the study	R/A	R/A			I	I
	Request New Trial Assessment Form (NTAF) completion by Study Team	R/A					I
	Complete NTAF and return to CTA Ethics	R/A					I
	Request study documents required for submission and overall trial set-up from Sponsor and requests separate Slade Pharmacy Indemnity (if applicable)				C	I	R/A
	Provide study documents required for submission and overall trial set-up				R/A	I	C
START-UP	Coordination of Protocol/IB Signature pages	R/A					
	Coordination of Financial Disclosures/1572s	R/A			R/A		
	Confirmation of submission pathway	I	I		R/A		R/A
	Preparation of ethics and /or governance submission package	I	I		C		R/A
	Review of CTN, Site Indemnity	I	I		R/A		R/A
	Provide submission updates to site	I	I			I	R/A
	Provision of approved submission/approval docs to site (via email)		I				R/A
	Request study budget from Sponsor and all relevant study manuals		I		C	R/A	

Step	Task	Site			SPONSOR	CTA	
		Clinical Team	Research Operations Manager	Site's Service Provider		Budget & Contracts	Ethics/ Governance
	Request and follow-up on all relevant quotes from departments and third-party service providers		**I**	**R**	**C**	**R**	**I**
	Co-ordinate execution of third-party service provider agreements Signatories: **Slade Pharmacy Quotes** – Operations Manager and Slade **Melbourne Pathology Quotes** – Operations Manager, Clinical Team and Epworth finance		**R/A**	**R**		**I**	**R**
	Prepare itemised budget for site review					**R/A**	
	Review itemised budget provided by CTA and provide approval to proceed with negotiations	**R/A**	**R/A**			**I**	
	Negotiate and finalise budget with Sponsor	**I**	**I**		**R/A**	**R/A**	
	Review draft CTRA					**R**	
	Review and provide approval to proceed with CTRA	**C**	**R/A**			**C**	
	Negotiate and finalise CTRA with Sponsor	**I**	**I**		**R/A**	**R/A**	
	Co-ordinate Governance submission and CTRA execution	**I**	**I**		**I**	**R**	**R/A**
	Scheduling of estimated SIV	**R**	**I**		**R**	**I**	**I/C**
POST-APPROVAL	Annual reports/Correspondence/Noting Items	**R/A**	**I**				
	Review any new study requirements requiring new services	**R/A**	**I**				
	Request itemised quote for new services	**C**	**C**			**R/A**	
	Update budget based on protocol amendment changes/changes requested by Sponsor or Site		**I**			**R/A**	**I**
	Preparation of amendment for ethics / governance submission/approval	**I**	**I**		**I**		**R/A**
	Safety Reporting	**R/A**			**R/A**		
	Request and follow-up on all relevant quotes from departments and third-party service providers			**R**	**C**	**R/A**	**I**
	Co-ordinate execution of third-party service provider agreements			**R**		**C**	**R/A**
	ONLY IF CHANGES ARE SUBSTANTIAL - Review updated budget and provide approval to proceed	**C**	**R/A**				
	Negotiate and finalise updated budget with Sponsor				**R**	**R**	
	Review draft CTRA addendum					**R**	
	Review and provide approval to proceed with CTRA addendum	**R**	**R**			**I**	
	Co-ordinate Governance submission and CTRA addendum execution	**I**	**I**		**I**	**R**	**R/A**

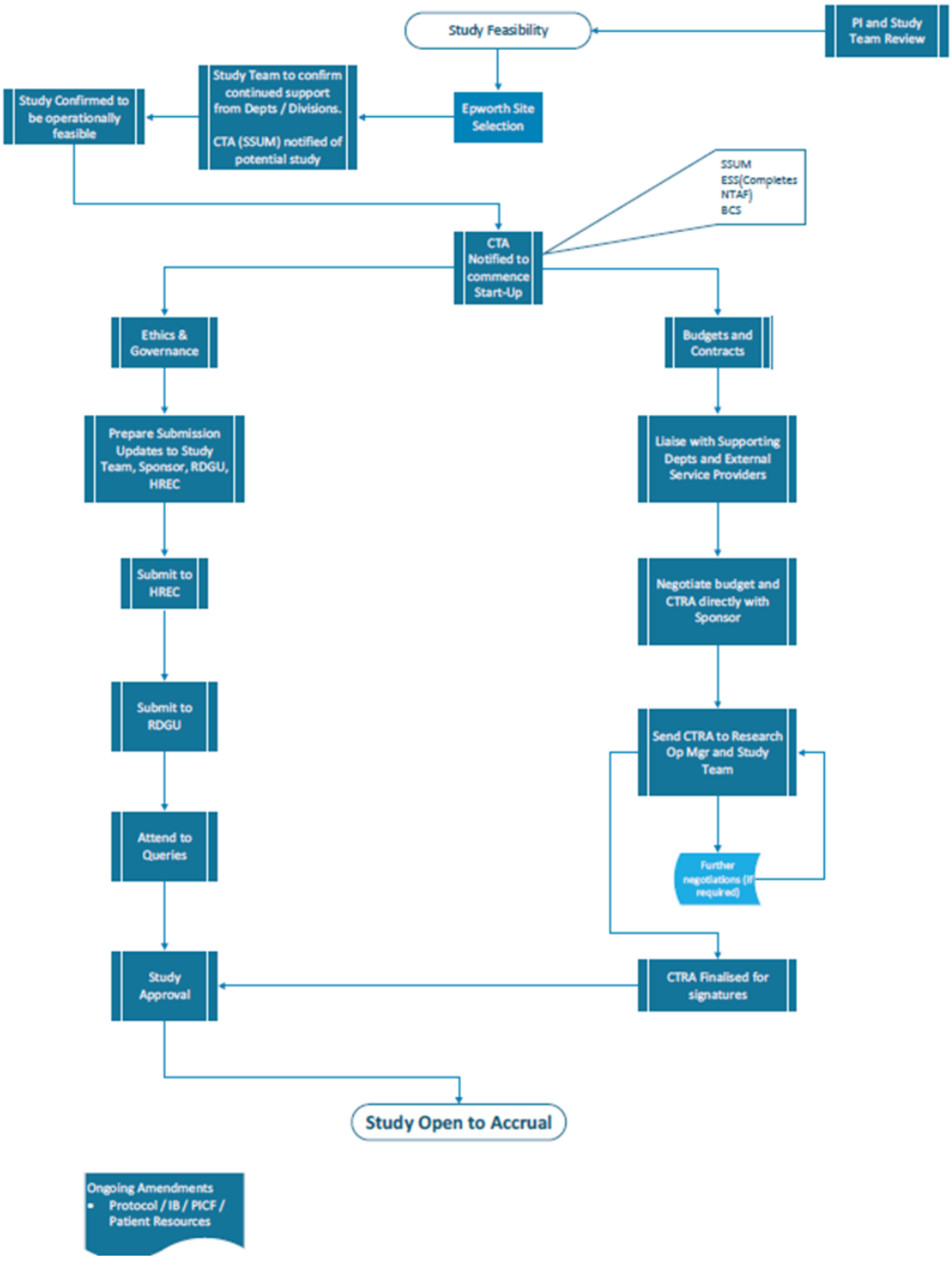
APPENDIX B: CTA Site Roles and Responsibilities - Finance

RACI - Responsible/ Accountable /Informed/ Consulted

Step	Task	Site			SPONSOR	CTA
		Clinical Team	Research Operations Manager	Site Finance		Finance
START-UP	Advise date of Site Initiation Visit (SIV)	R/A				I
	Enter the SIV date into Velos					R
	Review all clauses in Schedule 2 and note triggers for Velos items. Set up billing triggers for any manual items.			I		R/A
	Send a copy of the contract to Site Finance			I		R
	Once the SIV date is entered, invoice the Establishment fees in that same month			I		R/A
	Invoice the Annual Fees in the month due or follow up with Sponsor (if RCTI) and / or Greenphire if applicable			I		R/A
	Site to Invoice CTA for HREC fees in the current month of submission					R/A
	CTA to Invoice sponsor for HREC fees in the month the invoice is received			I		R/A
POST-APPROVAL	Record new trial patients with correct Patient ID and Patient Status in Velos within 7 days	R/A				I
	Attach the appropriate calendar and record the exact date of the visit or procedures in Velos within one week of end of the month.	R/A				I
	Ensure monitoring and data entry into ECRF within 90 days of occurrence	R/A				
	Invoice sponsor for Major or Minor Ethics Amendment Fees			I		R/A
	Collate and invoice Screen Failures using the Patient Status, taking into account the Schedule 2 payment clause, 3 times per year			I		R/A
	Contact sponsor and obtain list of monitored patient visits for invoicing on a quarterly basis, escalate to Epworth if not provided within 60 days					R/A
	Reconcile monitored patient visits invoiced to the Sponsor against the Velos data entry, 3 times per year. Follow up with the sponsor and invoice any visits outstanding.					R/A
	Collate, reconcile and invoice all Additional Assessments and Unscheduled Items in conjunction with the sponsor and ECRF 3 times per year					R/A
	Provide all Pharmacy invoices to CTA on a monthly basis.			R/A		I
	Review all Pharmacy invoices to identify study specific items that can be invoiced (eg. Pharmacy call back, relabelling, drugs) within any given bimonthly transfer period	R/A				R/A

Step	Task	Site			SPONSOR	CTA
		Clinical Team	Research Operations Manager	Site Finance		Finance
	Provide all patient travel receipts to CTA, at a minimum, on a quarterly basis, including details of the patient ID, name of visit, date of visit and provide sponsor approval (if applicable)	**R/A**				**I**
	Review all patient travel receipts and invoice where applicable as per Schedule 2 within any given bimonthly transfer period.	**R/A**				**R/A**
	Collate and transfer cash to Epworth on a bimonthly basis based on invoices raised in the same bimonthly period, including a detailed list of all transactions.			**I**		**R/A**
	On a bi monthly basis, provide a reminder to track any manual items (items not tracked in Velos for billing)			**I**		**R/A**
	Provide a debtor collection service for all invoices raised		**I**	**I**		**R/A**
	Review each contract amendment and ensure invoicing triggers have been set up for each new item			**I**		**R/A**
STUDY CLOSE-OUT	Enter close out date into Velos in the same month of the close out visit	**R/A**	**I**			**I**
	When the date of the close out visit is provided, CTA will invoice the sponsor for any close out fees within one month			**I**		**R/A**
	Provide number of archiving boxes in the same month of the close out visit, if required per Schedule 2, CTA will send a reminder		**R/A**			**I**
	Undertake a full reconciliation of all transactions at close out, by ensuring all items in Velos have been reviewed and/ or paid, in consultation with the sponsor, within 3 months of being advised of the close out visit date		**I**	**I**		**R/A**
	CTA will archive the financial records of the trial after close out		**I**	**I**		**R/A**

APPENDIX C: Epworth CTA Process Map



APPENDIX D: Cancer Trials Australia Contacts

Name	Position	Notes	Contact
Nicola Howell	Clinical Trials Start-Up Manager	Notify of new studies, initial submission and approval. Regularly report progress of initial submissions (send tracker weekly). Escalate any issues in a timely manner.	Nicola.howell@ctaust.org 0413 467 044
Alexandar Christov	Ethics Submissions Specialist	Coordinates ethics and governance submission process	Alexandar.christov@ctaust.org 03 9936 8067
Clara Mena	Budgets & Contracts Specialist	Coordinates commercial budgets and contracts.	Clara.mena@ctaust.org 03 8559 7252
Marie Luci	Clinical Trial Contracts Manager	Coordinates non-commercial budgets and contracts.	Marie.luci@ctaust.org 03 8559 7250 0402 422 423
Karen Ting	Data Integrity Analyst	Contact for Velos support	Karen.ting@ctaust.org 03 8559 7497
Andrew Chong	Information Analyst	Contact for Velos training and support	Andrew.chong@ctaust.org 0409 431 291
Michelle Button	Finance Manager		Michelle.button@ctaust.org 03 8559 7247
Coleen Mok	Senior Management Consultant		Coleen.mok@ctaust.org 03 8559 7245