

Clinical Trial Budget / Schedule 2 Preparation, Invoicing and Payments Guidelines

Please note:

- All Clinical Trial Agreements must contain clause(s) regarding invoicing and payment arrangements under the Agreement (preferably in the payments section of the Agreement)
- All payment of invoices must be made by EFT or BPay Payment.
- A remittance advice **must** be sent to the Principal Investigator or Clinical Trials Coordinator **and also** copied to the CALHN Research Office – Finance:
Health.CALHNResearchFinance@sa.gov.au
- **Every invoice and remittance advice relating to a study should include the CALHN Research Office MyIP Reference number and ORACLE code within the invoice description as it is a mandated Treasury requirement.**

Invoicing

All requests to raise an invoice are to be sent to CALHN Research Office – Finance utilising the Oracle Assist Accounts Receivable forma & ADI Templates “Tax Invoice Request” form located at: <http://in.health.sa.gov.au/OracleAssist/OracleTemplatesandForms.aspx>

- Please send completed form to: CALHN Research Office – Finance:
Health.CALHNResearchFinance@sa.gov.au

CALHN Bank Details

Account Name	CALHN Oracle Operating
ABN	96 269 526 412
Bank Name	Commonwealth Bank
Bank Address	96 King William Street, Adelaide, SA 5000
BSB Number	065 266
Account Number	1002 0240
Swift code	CTBAAU2S

Schedule 2 – Payments

Please find below an example for layout of Schedule 2. This is not an exhaustive list of items, please refer to the “Clinical Trial Budget Guidelines and Assistance” document found at: <http://www.rah.sa.gov.au> under the “Research” tab for further assistance, or contact CALHN Research Office - Finance: Health.CALHNResearchFinance@sa.gov.au

Note: Reference to terms must be what is defined in the body of the agreement.

Example: Patients or Subjects must be referred to as “Study Participants”.

Do not provide payment details that have already been included in clause 6 Payments of the Agreement

In accordance with **clause 6.1**, all amounts provided in this **Schedule 2** are in Australian Dollars (AUD) and exclude any GST payable. All payments will be made by the Sponsor in Australian Dollars, including any GST payable, upon receipt from Institution of a valid tax invoice.

Sponsor will pay the Institution via Electronic Funds Transfer (EFT) or BPay as per Institution banking details outlined on the valid tax invoice.

The Institution will send tax invoices to the attention of:

Name of [Sponsor Employee/Department to receive tax invoice]
Address & Phone number

For non-refundable fees- insert the following:

Fees for Site Set-up, Research Governance, HREC submission, review and approval and Pharmacy Set up are fixed, non-cancellable, non-refundable costs payable on receipt of valid tax invoice.

If the Sponsor decides to use a CRO AND the CRO will make payments - insert the following:
The Sponsor has subcontracted with NAME OF CRO (ABN XX XXX XXX XXX), of FULL ADDRESS OF CRO, to provide certain administrative services with respect to this Agreement, including payment to the Institution. Sponsor has authorised CRO to make payments to Institution on its behalf. All invoices for services under this Agreement will be made out to the Sponsor and sent to CRO for payment. For the avoidance of any doubt, the Sponsor remains responsible for all payments under this Agreement.

Item	Total in Australian dollars excluding GST
Site setup fee This fee covers time associated with all aspects of study set up including, but not limited to: review and familiarisation of protocol by study staff; preparation of start-up documents required for study; attendance at site pre-study/initiation visit; development of any study specific site specific checklists; liaison with other departments such as pathology, pharmacy, radiology etc.	\$xxxx to be paid on execution of this agreement
Site Annual Administration Fee @ \$xxxx per month (starting from study initiation to study closure)	\$xxxx /year
Major Protocol/Patient Information Sheet and Consent Form Amendments	\$xxxx per amendment that does require re-consent of study participants
Minor Protocol/Patient Information Sheet and Consent Form Amendments	\$xxxx per amendment that does not require re-consent of study participants
Serious Adverse Event (SAE)/Suspected Unexpected Serious Adverse Reaction (SUSAR) reporting fee	\$xxxx per SAE/SUSAR incident
Investigator Meeting Attendance	\$xxxx
Site Staff Training Initial Refresher/Remedial	\$xxxx \$xxxx
Audit Fee	\$xxxx
Site Closure Fee	\$xxxx

Item	Total in Australian dollars excluding GST
HREC Fees Multi-site Sponsored Trials <ul style="list-style-type: none"> • Review of a marketed or unapproved drug/device • Sub-study add-on review (submitted for review after REC approval is granted to the overarching [full] application) • Collaborative Research Group (CRG) application Single-site Sponsored Trials <ul style="list-style-type: none"> • Using a marketed drug/device • Using an unapproved drug/device • Using an unapproved drug/device in a very early phase study Non-sponsored Trials <ul style="list-style-type: none"> • Investigator Initiated 	\$xxxx \$xxxx \$xxxx
Amendment Evaluation Fees – Sponsored Studies <ul style="list-style-type: none"> • Minor/Administrative amendments (those that do not impact or alter the risk level of the project, and which can be reviewed and assessed easily e.g. updated contact details on a participant information sheet) • Other Amendments (e.g. Protocol amendments, Investigator Brochure revisions, and other amendments which are more complex in nature or which may alter the risk level of the project) • HREC Fees are review annually and are subject to change Please refer to http://www.rah.sa.gov.au/rec/index.php 	\$xxxx \$xxxx \$xxxx

Item	Total in Australian dollars excluding GST
Governance Fees	
Commercially Sponsored Trials	\$xxxx
<ul style="list-style-type: none"> Full Site Specific Assessment (SSA) review 	
Collaborative Group (CRG) Trials (with no commercial funding)	\$xxxx
<ul style="list-style-type: none"> Full Site Specific Assessment (SSA) review 	
Non-Sponsored Trials	\$xxxx
<ul style="list-style-type: none"> Investigator Initiated 	
Amendments	\$xxxx

Item	Total in Australian dollars excluding GST
Pharmacy Costs	
<ul style="list-style-type: none"> Pharmacy set-up fee 	\$xxxx
Please contact Peter Slobodian to obtain a quote for all pharmacy costs Peter.Slobodian@sa.gov.au	
<ul style="list-style-type: none"> Pharmacy dispensing fee per dispensing per study participant 	\$xxxx
<ul style="list-style-type: none"> Pharmacy annual maintenance fee (from start of year 2 of the study) 	\$xxxx

Item	Total in Australian dollars excluding GST
Radiology Costs	
<ul style="list-style-type: none"> For all RAH quotes please contact Michael Consalvo 	
Michael.Consalvo@sa.gov.au	\$xxxx
<ul style="list-style-type: none"> For all TQEH quotes please contact Steven Meinel 	
Steven.Meinel@sa.gov.au	

Item	Total in Australian dollars excluding GST
Nuclear Medicine Costs	
<ul style="list-style-type: none"> For all nuclear medicine cost enquiries and quotes please contact Rachael Dobson 	\$xxxx
Rachael.Dobson@sa.gov.au	

Item	Total in Australian dollars excluding GST
Non-standard of Care Pathology	
<ul style="list-style-type: none"> For cost enquiries, form 687 and quotes please contact Dimitrios Zissis 	\$xxxx
Dimitrios.Zissis@sa.gov.au	

Item	Total in Australian dollars excluding GST
Study Participant Related Payments	
(For Medicines Australia Agreements please ensure that the patient/client is referred to as "Study Participant" throughout Schedule 2 as this is the definition used within the body of the MAMTAA Agreements – refer to http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/ or http://www.mtaa.org.au/policy-initiatives/clinical-investigations)	\$xxxx
Note: The table below is a guide only. Please refer to the Protocol and Time and Events Schedule for further information regarding study procedures. Please ensure every activity is documented and sufficient time allocated to each activity.	
Per-Patient Costs	
Please see the document on the following page for an example of Per Study Participant Costs layout.	\$xxxx