Central Adelaide Local Health Network
Research Services

Guidelines for Budgets, Payments & Invoicing

Clinical Trial Budgets (Schedule 2: Payments)Preparation

Overview

This document has been developed in line with Clinical Trails Action Group (CTAG) and National Health and Medical Research Council (NHMRC) aims and guidelines and is designed to assist researchers in developing and negotiating clinical trial budgets.

This document is not an exhaustive list of potential fees, but a guide to key activities that are associated with clinical trials. Each activity represents a service that may incur a cost. In developing final fees and budgets for clinical trials, researchers must consider the actual cost of these services and how these costs will be reimbursed. Some activities may be considered standard care and should be identified separately. Not all activities listed are necessarily relevant to a specific clinical trial or circumstance.

Acronyms & Definitions

ABN	Australian Business Number
Agreement	Is the Clinical Trial Research Agreement which includes all the Schedules
CALHN	Central Adelaide Local Health Network Incorporated
CRG	Collaborative Research Group
CT	Computed Tomography
CTMS	Clinical Trial Management System
CTN	Clinical Trial Notification
GP	General Practitioner
Investigational Product	Is the medicine or device being trialled or tested in the Study, as set out in Schedule 1 of the Agreement, and includes where relevant any placebo.
Investigator's Brochure	Is a compilation of the clinical and non-clinical data on the Investigation Product(s) which are relevant to the Study of the Investigational Product in humans
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System randomisation systems
Local Sponsor	Means the Contract Research Organisation or clinical research organisation that is described on the first page of the Agreement.
MRI	Magnetic Resonance Imaging
Organisation	Means the Organisation as described in Schedule 1 of the Agreement. Also known as the Global Sponsor.
PET	Positron Emission Tomography
PICF	Participant Information Consent Form
Principal Investigator (PI)	Means the person responsible for the conduct of the Study at the Study Site
Protocol	Means the document identified in Schedule 6 which describes the objective(s), design, methodology, statistical considerations and organisation of the Study, and subject to clause 2.3, as amended from time to time, as agreed by the parties, and most recently approved by the Reviewing HREC
Reviewing HREC	Means the Human Research Ethics Committee reviewing the Study on behalf of the Institution as described in Schedule 1 of the Agreement.
RGO	Research Governance Office
Sponsor	Means the corporate entity so described on the first page of the Agreement.
SSA	Site Specific Assessment
Study	Means the investigation to be conducted in accordance with the Protocol
Study Materials	Means all the materials and information created for the Study or required to be submitted to the [Local] Sponsor including all data, results, Biological Samples, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how and the like, whether patentable or not, relating to the Study, which are discovered or developed as a result of the Study, but excluding the Institution's ordinary patient records.
Study Participant	Means a person recruited to participate in the Study.

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Invoicing

All Clinical Trial Research Agreements (Agreement) must contain clause(s) regarding invoicing and payment arrangements. In Medicines Australia and Medical Technology Association of Australia templates, this information must be entered into Schedule 2: Payments.

For information regarding the invoicing procedure, please contact CALHN Research Finance at: Health.CALHNResearchFinance@sa.gov.au

- All invoices must be issued for payment by the contracting party, regardless of who is making the payment on behalf of the Local Sponsor/Sponsor/CRG. This is a Treasury requirement.
- Payment of invoices must be made by Electronic Funds Transfer (EFT) or BPay Payment.
- Remittance advice must be sent to HealthReceiptingOperations@sa.gov.au with cc to the Study Coordinator.
- Every invoice and remittance advice relating to a study must include the CALHN Research Services Reference Number (MyIP Reference) within the invoice description as it is a mandated Treasury requirement.

CALHN Banking Details

Bank Name	**Commonwealth Bank of Australia**
Bank Account Name	CALHN Oracle Operating
BSB	015-101
Account Number	838568388
Branch Details	18/83 Pirie Street, Adelaide, South Australia 5000
Swift Code	ANZBAU3MXXX
ABN	96 269 526 412
Remittance Advice	Remittance advice to the Institution must reference **MYIPXXXXX** and the tax invoice number and be sent to HealthReceiptingOperations@sa.gov.au. With cc to: Study Participant Payments: <Enter your email/appropriate persons email address> Pharmacy Payments: Select applicable email if Pharmacy is involved - RAH - Peter.Slobodian@sa.gov.au - TQEH – TQEHclintrials@sa.gov.au Reviewing HREC & RGO Payments: Health.CALHNClinicalTrials@sa.gov.au

CALHN Ethics and Governance Invoicing Fee Form

- To be completed and signed by Sponsor/Local Sponsor for every Study.
- Available for download here from the Downloads section, titled "Invoicing and Fee Form Governance and Ethics CALHN".

Clinical Trial Budget Preparation *for* Medicines Australia / Medical Technology Association of Australia Templates

Withholding of Payments

- CALHN does not accept any withholding of per Study Participant payments. Any reference to withholding payments such as "ten percent (10%) of each payment will be withheld until the final payment" must be deleted in Schedule 2: Payments.
- CALHN can accept withholding of the final payment until Local Sponsor/Sponsor is satisfied that CALHN has met all obligations under the Agreement.

Institutional Overhead

- All budgets must contain a minimum 25% overhead on Study Participant costs to support research infrastructure within CALHN.

Review of Budgets

- Please submit your Agreements with budgets attached/inserted for review to CALHN Clinical Trials: Health.CALHNClinicalTrials@sa.gov.au
- For further assistance with working out salary rates, on-costs etc. please contact CALHN Research Finance: Health.CALHNResearchFinance@sa.gov.au

Contract Research Organisation / Local Sponsor – Payment Wording

- Where contracting with a Local Sponsor, the Local Sponsor is responsible for all payments as per clause 6.1 of the Agreement. Local Sponsor is responsible for payment regardless of whether or not the Organisation provides the funding to the Local Sponsor. Therefore, CALHN does not accept wording such as, "Payments due under this agreement are pass-through payments from Local Sponsor that will be sent after such payments are received by a third-party vendor/Organisation".
- The Organisation (Global Sponsor) cannot make direct payments to CALHN.

Subcontracting of Payments by Local Sponsor/Sponsor

- If the Local Sponsor/Sponsor will use a Contract Research Organisation (CRO) or other third party to make payments on behalf of the Local Sponsor/Sponsor the following wording or similar should be inserted into Schedule 2: Payments:

  "The [Local Sponsor/Sponsor] has subcontracted with [Name of CRO/Third Party (ABN XX XXX XXX XXX)], of [full address], to provide certain administrative/payment services with respect to this Agreement, including payment to the Institution".

  "The Local Sponsor/Sponsor has authorised [CRO/third party] to make payments to Institution on its behalf. All invoices for services under the Agreement will be made out to the Local Sponsor/Sponsor and sent to [CRO/third party] for payment. For the avoidance of any doubt, the Local Sponsor/Sponsor remains responsible for all payments under this Agreement."

Reviewing HREC and Research Governance Office (RGO) Review Fees

- CALHN Research Services charge as per the SA Health Research Ethics and Governance Fee Schedule. These fees are subject to change.
- The following wording should be inserted into every Agreement (with the exception of CRG and Investigator Initiated agreements where it has been established funding is not available):

  "[Reviewing HREC and/or RGO] review fees will be charged as per the SA Health Research Ethics and Governance Fee Schedule (which is subject to change) and will be paid directly to the Institution on receipt of a valid tax invoice made out to the [Sponsor/Local Sponsor]."

CALHN Research Services IT/Software Fee

- CALHN Research Services provide a Clinical Trial Management System (CTMS) to all CALHN Clinical Trial Units. CALHN Research Services is entirely self-funded, therefore in order to cover the annual cost of the license a fee was implemented in 2019. The fee is only applied to new studies, and is not applied retrospectively.

- The fee is $2250 per study, however is subject to change upon annual review. The following wording should be inserted into every Agreement (with the exception of CRG and Investigator Initiated agreements where it has been established funding is not available):

  "A once off fee of AUD $2250.00 to cover licensing fees for the clinical trial management system will be paid directly to the Institution on receipt of a valid tax invoice made out to the [Local Sponsor/Sponsor]."

SA Pharmacy Fees

- SA Pharmacy fees are invoiced separately by SA Pharmacy and must not be included in the per Study Participant fees (unless negotiated with SA Pharmacy with evidence provided - provide relevant correspondence).
- Ensure the fees match the quote and the wording in the table as attached in the Table Inserts Section below on page 13.

Breakdown of Study Site Fees

Site Fees

Feasibility Assessment

- Exchange of reciprocal confidentiality agreements and preliminary review of the Study Protocol.
- Protocol review by heads of host and supporting units (e.g. pharmacy, radiology etc.)
- Feasibilitydetermination of trial alignment with site mission, research priorities and risk management profile
- Feasibility determination of Study Participant recruitment ability
- Feasibility determination of Personnel skills and knowledge, and resource availability
- Feasibility determination of proposed budget and contract

Preparation and Submission of Applications to Reviewing HREC and RGO

- **Reviewing HREC**
  - Activities associated with the preparation and submission of the Reviewing Human Research Ethics Committee (HREC) application form
  - Activities associated with the review of the ethics application by the Reviewing HREC (including any requests for additional information and subsequent consideration of that information)
  - Administrative costs associated with activities conducted only at the lead Study Site
- **RGO**
  - SSA Application activities include:
    - Activities associated with the preparation and submission of the SSA form including:
      - Completion of the form
      - Obtaining authorising signatures
      - Liaising with inter-institutional departments
      - Adapting Reviewing HREC approved master Participant Information and Consent Form (PICF)(s) with site specific letterhead and contact details
      - Liaison with the sponsor for relevant documentation
    - Activities associated with the processing of regulatory documents (e.g. Clinical Trial Notification (CTN) Form
    - Activities associated with the processing of insurance and indemnity documents
    - Activities associated with the processing of safety and/or biosafety reports
    - Activities associated with the processing of Clinical Trial Research Agreements
    - Activities associated with the provision of additional information for SSA review

- **Post Approval Monitoring Fees**
  - Amendment preparation and submission
    - Activities associated with the preparation of Protocol amendments to the Reviewing HREC and/or RGO including amendment to the PICFs, investigator brochures and any other Study information which has been updated or amended.
    - Activities associated with response to Reviewing HREC and/or RGO queries and/or requests for additional information and forwarding copies of relevant authorisations (once obtained) and associated documentation to the Study's Sponsor/Local Sponsor

Site Implementation Fees

Study Initiation

- Start-up meetings (including transference of Study documentation, information sessions for principal or co-investigators and/or clinical trial manager/coordinators and representatives of the participating departments, and any training of Personnel directly involved in the Study). This may include payment of travel and accommodation for participating Personnel, where appropriate.
- Activities associated with each department's preparation for Study operation (including preparation of Study request forms, coordination with investigators, identification of locations for storage of samples, development of supporting documentation and instructions, and any necessary preparation of medical records)
- Activities associated with the hire, purchase and/or receipt from the Sponsor/Local Sponsor of any equipment (including ICT infrastructure) and includes the required set- up/customisation/commissioning of the Equipment to ensure its suitability for use in the Study and ongoing maintenance.

Study Participant Accrual

- Pre-screening activities directly inked with Study cohort identification and mayinclude:
  - Database and medical records review
  - Development of recruitment plans, suggested strategies, timelines and costs

- Development and execution of a consultation plan to support Study recruitment and provide opportunities to increase awareness about and participate in clinical research
- Interviewing potential Study Participants to discuss issues of suitability (either by telephone or face to face)
- Documenting pre-screening activities (irrespective of eligibility)

- Recruitment activity associated with involving potential and recruited Study Participants between the completion of pre-screening and the final determination of the assessment for suitability, may include:
  - Provision of education and information to possible Study Participants
  - Organisation of screening visits (including any required assessment and/or tests)
  - Documentation of recruitment activity (irrespective of the number of potentially eligible Study Participants that fail the screening assessment)

Clinical Services

- Screening and health assessment including:
  - Physical examination
  - Obtaining a medical history
  - Measuring vital signs
  - Diagnostic tests
  - Imaging examinations
  - Confirmation of diagnosis (which may include genomic eligibility confirmation)
  - Provision of information about the Study to Study Participants and Personnel
  - Explanation of the requirements of involvement
  - Ensuring understanding and, where appropriate, obtaining consent to participate in the Study
- Laboratory tests and procedures including:
  - Pathology
  - Histopathology
  - Haematology
  - Chemical
  - Microbiology
  - Immunology
  - Tissue pathology
  - Cytology
  - Genetics
- Imaging examination and procedures including:
  - Plain radiography
  - Computed tomography (CT)
  - Magnetic resonance imaging (MRI)
  - Ultrasound
  - Nuclear medicine
  - Position emission tomography (PET)
- Radiation therapy planning and treatment including:
  - External beam radiation therapy
  - Brachytherapy
- Other clinical tests or procedures including:
  - Surgical an non-surgical procedures (e/g/ diagnostic and treatment related procedures)
- Specialist medical consultations:
  - Provided by medical specialists, General Practitioners (GPs), dentists and any other registered medical practitioner
- Nursing services:
  - Provided by enrolled, registered and specialist nurses, midwives and nurse practitioners
- Allied health services
  - Provided by credentialed (for CALHN sites) allied health professionals (e.g. pharmacists, physiotherapists, dietitians, occupational therapists)

Pharmacy/Investigational Product Related

- Study Personnel training (Investigational specific) including:
  - Activities associated with the training of pharmacy Personnel (including site specific dispensing guidelines)
  - Activities associated with training in the use of Interactive Voice Response System (IVRS)/Interactive Web Response System (IWRS) randomisation systems

- Activities associated with training of other Personnel including doctors, nurses etc. on the Investigational Product-specific aspects of the Study Protocol

- Stock management
  - Activities associated with the receiving of pharmacy stock
  - Inventory checking
  - Downloading of temperature logs
  - Transferring logs and Investigational Product receipts to the Sponsor/Local Sponsor
  - Stock management during the implementation phase including:
    - Expiry management
    - Labelling
    - Storage of used/unused products
    - Monitoring required to ensure viability of the product
    - Data entry associated with expired or unused medicines
    - Returning used or unused medicines to the Sponsor/Local Sponsor
- Investigational Product preparation and dispensing including:
  - Activities associated with the manufacturing of the Investigational Product (if applicable)
  - Activities associated with the preparation of the Investigational Product (e.g. aseptic, cytotoxic or placebo preparation)
  - Development and maintenance of special dosage forms (including the activities associated with the randomisation process if applicable)
  - Activities associated with the conduct of dispensing (including the provision of counselling to Study Participants)
  - Review of Study Participants' adherence to the Study Protocol
  - Costs related to on-call/call back and recording details in the Study Participant's medical record

Biospecimen Related

- Biospecimen collection and processing (central labs) including:
  - Activities associated with the collection, processing and transport (e.g. quarantine permits, etc.) of Study biospecimens
  - Processing of biospecimens including those activities involved in preparing the biospecimen for analysis following collection

Study Site Closeout

Site Closeout Visit

- Activities that occur at the end of a Study as part of the attendance by the Sponsor/Local Sponsor (and/or representative) at the Study Site for a series of meeting with Personnel that were involved in the Study.
- Includes
  - Verifying that the Study procedures have been completed
  - Verifying that all relevant data have been collected and transferred to the Sponsor/Local Sponsor
  - Preparing and implementing plans to un-blind/unmask and debrief Study Personnel
  - Arranging for the Study intervention to be returned to the responsible party or prepared for destruction
  - Activities undertaken to confirm that the Study Site's Study obligations have been met and post Study obligations are understood
  - Covers the provision of assurances that the relevant data have been collected and transferred

Record Archiving

- Archiving of Study Materials
  - Activities associated with archiving the Study records for the required period
  - Includes the boxing up of all trial material ready for archiving/storage
  - Includes the secure storage of the material for up to the agreed number of years
  - Current fees for 15 year storage is $500 per archive box, should the Sponsor/Local Sponsor require documents be kept beyond this period, additional payment will be made according to market rate at that time.
  - If the Sponsor/Local Sponsor is paying for archiving directly with the archiving facility, the clause should read: "[Sponsor/Local Sponsor] will pay for archiving of Study documents for the 15 year period, directly with the agreed archiving facility."
- Investigational Product return/destruction
  - Activities associated with the return of the Investigational Products to the Sponsor/Local Sponsor and/or the destruction of the Investigational Products according to the Institution's policy, Sponsor/Local Sponsor requirements (if applicable), safe operating practice and the requirements of

the Study.

- Biospecimen transfer/destruction
    - Activities associated with archiving the trial records for the required period Activities associated with the transfer of biospecimens obtained throughout the Study to a tissue bank (if provided for by the Study Protocol) and/or the destruction of bio specimens according to the Institution's policy, Sponsor/Local Sponsor requirements (if applicable), safe operating practices and the requirements of the Study.
    - Activities associated with the transfer of biospecimens obtained throughout the Study to a tissue bank (if provided for by the Study Protocol) and/or the destruction of biospecimens according to the Institution's policy, Sponsor/Local Sponsor requirements (if applicable), safe operating practices and the requirements of the Study.
    - Activities involved in arranging transfer of the biospecimen(s) to central laboratories (for biospecimens tested on-site, biospecimen collection and processing is covered by the appropriate test in the clinical services category.
- Biospecimen storage
    - Activities associated with the local storage (if required) of biospecimens collected as part of the Study.

Clinical Resources

- Principal Investigator time
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for any activities (clinical or non-clinical) that need to be carried out by an investigator, that are specific to the Study, and not covered by an item listed elsewhere
- Research nurse time
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for any activities (clinical or non-clinical) that need to be carried out by a research nurse, that are specific to the Study, and not covered by an item listed elsewhere
- Clinical research coordinator (non-research nurse) time
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for any activities (clinical or non-clinical) that need to be carried out by a clinical research coordinator, that are specific to the Study, and not covered by an item listed elsewhere
- Interpreter services
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for any activities (clinical or non-clinical) that need to be carried out by an interpreter, that are specific to the Study.
- Ward bed days
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for a Study Participant admitted to a ward to receive clinical services (including monitoring) that are specific to the Study (i.e. the services do not represent standard of care).
- Clinic/theatre time
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for a Study Participant spending time in clinic and/or theatre to receive clinical services (including investigation) that are specific to the Study (i.e. the services do not represent standard of care)
- Outpatient time
    - Unit labour cost (fully absorbed hourly rate, i.e. inclusive of overheads) for a Study Participant receiving clinical services in an outpatient department.

Study Operation

- Lead Study Site coordination:
    - Activities conducted only at the lead Study Site associated with the ongoing coordination and management of all the nominated sites participating in the Study (i.e. excluded those activities conducted at the lead Study Site that are site's participation in the Study but includes activities associated with coordinating information flow to and from the Reviewing HREC, Sponsor/Local Sponsor and other sites)
- Administration, monitoring and reporting
    - Activities associated with ongoing operation of the Study at the Study Site that occur post initiation of the Study, includes:
        - Annual administration fee advised to cover administration costs
        - Liaison with investigators and/or Sponsor/Local Sponsor (including monitors)
        - Preparation of materials for, in involvement in, monitoring visits
        - CRF completion and entry,
        - Endpoint recording

- Accrual reporting
- Safety and adverse event reporting
- Review of SAE reports
- Management of Study documentation
- Retrieval of medical and/or clinical records
- Invoicing
- Annual reporting (including annual Reviewing HREC report and final report)
- Audit preparation and hosting

Study Participant related

- Study Participant time
  - The unit cost for the time involved in participating in the Study (This item is only intended to be used for Phase 1 health volunteer Study, where payment for Study Participant time is the norm. Any provision for Study Participant payment would be described in the Agreement and in the PICF and will have been considered by the Reviewing HREC).
- Study Participant costs
  - The unit cost that may be necessarily incurred by a Study Participant due to participating in the Study (may include transport to and from Study location, car parking, meal allowances (where extended time attendance is required), and overnight accommodation costs where Study Participants need to travel significant distances to and from the Study location and/or need to stay in close proximity to the Study Site for an extended period (Any provision for imbursement of Study Participant costs would be described in the Agreement and in the PICF and will have been considered by the Reviewing HREC).
- Screen Failures
- Unscheduled Study Participant Visits

Table Inserts for Schedule 2: Payments

Below are tables that should be utilised in Schedule 2: Payments of the Agreement. The below invoiceable items may/may not be applicable for each Study, however are there as a starting point to ensure all fees are covered.

Payments & Invoicing:

Payment to the [Institution/Payee] will be sent to the following details by Electronic Funds Transfer:

Bank Name	**Commonwealth Bank of Australia**
Bank Account Name	CALHN Oracle Operating
BSB	065-266
Account Number	10020240
Branch Details	96 King William Street, Adelaide, South Australia 5000
Swift Code	CTBAAU2S
ABN	96 269 526 412
Remittance Advice	Remittance advice to the Institution must reference **MYIPXXXXX** and the tax invoice number and be sent to HealthReceiptingOperations@sa.gov.au. With cc to: Study Participant Payments: <Enter your email/appropriate persons email address> Pharmacy Payments: Select applicable email if Pharmacy is involved - RAH - Peter.Slobodian@sa.gov.au - TQEH – TQEHclintrials@sa.gov.au Reviewing HREC & RGO Payments: Health.CALHNClinicalTrials@sa.gov.au

Invoiceable Items:

Site Fees	**Fee (AUD)**	**Rate**
Reviewing HREC and Research Governance Office (RGO) Fees		
Reviewing HREC and RGO Review Fees	As invoiced	[Reviewing HREC and/or RGO] review fees will be charged as per the SA Health Research Ethics and Governance Fee Schedule (which is subject to change) and will be paid directly to the Institution on receipt of a valid tax invoice made out to the [Sponsor/Local Sponsor].
Institution IT/Software Fee Covers licensing fees for the CTMS.	$2250.00	A once off fee will be paid directly to the Institution on receipt of a valid tax invoice made out to the [Sponsor/Local Sponsor]
Notifications and Amendments		
Agreement Amendment [Sponsor/Local Sponsor] initiated		Per amendment
Major Protocol/Participant Information Sheet and Consent Form (PICF) Amendments (requires re-consent of Study Participants)		Per occasion
Minor Protocol/PICF Amendments (does not require re-consent of Study Participants)		Per occasion
Notifications Including but not limited to: Amendments, Protocol clarification letters, Investigator Brochures, Insurance documentation, six-monthly SUSAR line listing, etc. Reporting documentation to RGO/Reviewing HREC.		Per occasion
Serious Adverse Event (SAE) Reporting Fee		Per SAE reported for Institution's Study Participants (includes all follow up reports)

SAE Management (If Lead Site)		Per SAE reported for non-Institution Study Participants, per report
Recruitment Fee Evidence of time spent, documentation of source review and/or telephone contact and the outcome will be required by [Sponsor/Local Sponsor] prior to payment		Per Study Participant reviewed
Reviewing HREC - Lead Site Fees (if applicable)		
Reviewing HREC Application Lead Site Completion of HREA, Principal Investigator signature obtained, adaptation of [Sponsor/Local Sponsor] provided approved PICF collation and submission of HREA/and Victorian module to Reviewing HREC, response to queries raised by Reviewing HREC until resolution and approval obtained, forward relevant authorisations and documents to [Sponsor/Local Sponsor]		Once off fee
Each additional participating Site included prior to initial approval (inclusion fee)		Per Site
Each additional participating Site included after to initial approval (addition fee)		Per Site
Lead Site Reviewing HREC Fee		Per Site per annum under submission
Site Fees		
Site Set Up Fee Completion of Site Specific Assessment (SSA) form, Principal Investigator and departmental head signatures obtained. Obtai inter-departmental quotes for Study Specific work from schedule of assessments, obtain signatures on SSA form, adaptation of approved SIS with Site specific letterhead, contact details, site specific policies, collation and submission of SSA and attachments to RGO, response to queries raised by RGO until resolution and approval obtained, forward relevant authorisations and documents to [Sponsor/Local Sponsor].		Non-negotiable, non-refundable due at the effective date of the Agreement
Site Monthly Fee Includes but not limited to: review of Protocol, Investigator Brochure, Study Materials and administrative amendment(s), circulation of Reviewing HREC amendment etc. approval to Study Personnel and appropriate training, manage Site essential documents, provide ongoing storage space for Study files, and supplies, continuing administration for the Study tasks outside of direct Study Participant management including maintenance of temperature logs, shipping documentation, preparation for monitor visits etc., photocopying and stationery supplies		Per month from execution of Agreement to removal of items for archiving
Remote Monitoring Includes: teleconferences, webinars, additional requests for information requiring more than 10 minutes of Study Personnel time		Per hour per Study Personnel required (non Principal Investigator)
Study Audit Preparation		Per audit
Audit ongoing daily fee		Per day, for a maximum of four days
Archiving		
Site Close Out Includes but not limited to: final Study		Non-negotiable, non-refundable fee due at end of Study

completion costs including resolution of database queries, manage Site essential documents folder, review of supplies from [Sponsor/Local Sponsor/Vendor] for completeness, accuracy and readability, provision of Study Personnel skills, Reviewing HREC and RGO notification of cessation of Study procedures, dissemination of acknowledgements to [Sponsor/Local Sponsor], review filing and discarding of duplicates, updating monitor central files, circulation of final Study report to Reviewing HREC and RGO, Study code break administration to Study Participants		
Study Personnel Training		
Clinical Research Coordinator		Per hour (if required)
Principal Investigator/sub-investigator		Per hour (if required)
Attendance at Investigator Meeting		
Principal Investigator		Per half day
Senior Clinical Research Coordinator/Sub-Investigator(s)		Per half day
Study Participant Fees		
Study Participant Travel – Applicable if not included in per Study Participant visit cost		Per visit
Study Participant Food Voucher		Per fasting visit

Radiology Fees	Fee	Rate
Radiology Set Up		
Administration		
MRI etc.		

Pharmacy Fees	Fees	Amount (AUD)	Occurrence
Pharmacy Administration Costs	Establishment Fee		Payable at Study commencement
	Annual Fee		Payable at Study commencement
	Protocol/Pharmacy Manual Amendment Fee		Up to 2 hours
			Per hour thereafter
	Completion Fee		Once off payment due at the end of the Study
Pharmacy Storage Fees	Room Temperature		Per year, payable at receipt of Investigational Product and thereafter annually
	Refrigerated		Per year, payable at receipt of Investigational Product and thereafter annually
	Freezer		Per year, payable at receipt of Investigational Product and thereafter annually
Pharmacy Dispensing Fees	**Simple Dispensing**		
	1st Item		Per Study Participant per visit
	Add Additional Items		Per additional item per Study Participant per visit
	Complex Dispensing		
	1st Item		Per Study Participant per visit
	Add Additional Items		Per additional item per Study Participant per visit
	Complex Dispensing with Sterile or Non-sterile Manufacturing		
	1st Item		Per item to reconstitute up to 5 vials
			Plus for each additional vial
	Add Additional Items		Per additional item
Additional Pharmacy Charges	IVRS/IWRS Dispensing Fee		Per Study Participant per visit (Only charged if Institution's Pharmacy is required to perform this activity)
	IWRS Investigational Product Reconciliation Fee		Per Study Participant per return (Only charged if Institution's Pharmacy is required to perform this activity)
	On-Call Fee		Per call plus per dispensing fee. On-call fee charged for doses dispensed outside of normal business hours (e.g. 0845hrs to 1700hrs Monday to Friday)
	Investigational Product Transfer Costs		Per event plus transport costs
	CRA Pharmacy Service		Per hour and part thereof, for any significant post monitoring visit requests that would take more than 10 minutes to complete
	Remote Monitoring Fee		Per hour
	Returns Storage Fee		Per month, following Investigational Product reconciliation by the CRA, i.e. check returns must be immediately destroyed on the Study Site or returned within 10 business days to [Sponsor/Local Sponsor]
	Re-labelling Fee		Per hour