Government of **Western Australia**
Child and Adolescent Health Service

A guide to costs and payments for sponsored clinical trials

CAHS Research Department




Neonatology | Community Health | Mental Health | Perth Children's Hospital

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Overview

This document is designed to assist Sponsors in developing and negotiating clinical trial budgets. It has three sections: overview, site facilities and support, and standard charges from the CAHS research departments and external vendors. This document is not an exhaustive list of potential fees but a guide to key activities associated with clinical trials. Each activity represents a service that may incur a cost. In developing final fees and budgets for clinical trials, Sponsors must consider the actual cost of these services and how these costs will be reimbursed. Some activities may be regarded as standard care and should be identified separately. Not all activities listed are necessarily relevant to a specific clinical trial or circumstance.

Payee information

For finance details please contact CAHS.financialaccounting@health.wa.gov.au

Contents

Clinical trial budget preparation for CAHS

Withholding of payments

- CAHS does not accept any withholding of per-study participant payments.

Institutional overhead

- All budgets must contain a minimum 25% overhead on study participant costs to support research infrastructure within CAHS.

Review of budgets

- Please submit your Agreements with budgets attached/inserted for review to the CAHS CAHS Research Ethics and Governance (REG) office: CAHS.RGO@health.wa.gov.au
- Advice regarding the completion of these forms can be found by contacting CAHS.RGO@health.wa.gov.au

Contract research organisation / Local sponsor payment

- In consideration of the Institution conducting the study, the Local Sponsor will pay the Institution as nominated in **Schedule 2** in the manner and based on the amounts and at the times set out in **Schedule 2.** The amounts set out in **Schedule 2** do not include GST. At the time of payment, the Local Sponsor must pay the Institution any amount of GST in addition to the amounts set out in **Schedule 2** and by GST Law.
- The Local Sponsor will make payments upon either receipt of a valid tax invoice or a "Recipient Created Tax Invoice" issued by the Local Sponsor.

CAHS Human Research Ethics Committee (HREC) and Research Governance Office (RGO) review fees

- To be completed and signed by the Sponsor/Local Sponsor for every study.
- Available for download from Child and Adolescent Health Service | CAHS - Application fees to Research Governance Office (RGO) and use the CAHS payment form.
- If payment does not accompany the initial submission or amendment, the Ethics / Governance review process cannot start.
- For any queries relating to payment, please contact CAHS.RGO@health.wa.gov.au or CAHS.ethics@health.wa.gov.au

Pharmacy fees

- Pharmacy fees are invoiced separately by CAHS Pharmacy and must not be included in the per study participant fees.

Breakdown of Study Site Support

Site start-up

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.)
- Feasibility determination 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 review HREC and RGO

Reviewing HREC

- Activities associated with preparing and submitting 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

- Site specific assessment (SSA) Application activities include:
    - Activities associated with the preparation and submission of the SSA and Budget forms, including:
        - Completion of the forms
        - Obtaining authorising signatures
        - Liaising with inter-institutional departments
        - 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 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

- Amendment preparation and submission
  - Activities associated with the preparation of protocol amendments to the reviewing HREC and RGO, including amendments to the PICFs, investigator brochures, and any other study information that has been updated or amended.
  - Activities associated with response to reviewing HREC and RGO queries and requests for additional information and forwarding copies of relevant authorisations (once obtained) and associated documentation to the study's Sponsor/Local Sponsor

Site implementation

Study initiation

- Start-up meetings (including transference of study documentation, information sessions for principal or coinvestigators, clinical trial managers/coordinators, representatives of the participating departments, and any personnel training 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 receipt from the Sponsor/Local Sponsor of any equipment (including ICT infrastructure), including the equipment's required set-up/customisation/commissioning to ensure its suitability for use in the study and ongoing maintenance.

Study participant accrual

Pre-screening activities directly linked with study cohort identification and may include:

  - Database and medical records review
  - Development of recruitment plans, suggested strategies, timelines, and costs.
  - Develop and execute 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 study participants
- Organisation of screening visits (including any required assessment and 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 the 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 and 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 CAHS 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 using 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 is required to ensure the 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 collecting, processing, and transporting (e.g., quarantine permits, etc.) 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 representative) at the study site for a series of meetings with personnel 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 are 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 all trial material ready for archiving/storage.
    - Includes the secure storage of the material for up to the agreed number of years.
    - Should the Sponsor/Local Sponsor require documents to be kept beyond this period, additional payment will be made according to the market rate at that time.
- **Investigational product return/destruction**
    - Activities associated with the return of the Investigational Products to the Sponsor/Local Sponsor and 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 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 associated with the transfer of biospecimens obtained throughout the study to a tissue bank (if provided for by the study protocol) and 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 the 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 nonclinical) that must be conducted by an investigator 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 nonclinical) that need to be conducted by a research nurse, which is 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 nonclinical) that need to be carried out by a clinical research coordinator, which is 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 nonclinical) that need to be conducted by an interpreter, which is 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 the 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 theatre to receive clinical services (including investigation) that are specific to the study (i.e., the services do not represent the 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 include 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 the ongoing operation of the study at the study site that occur post-initiation of the study include:
        - Annual administration fee advised to cover administration costs.
        - Liaising with investigators and Sponsor/Local Sponsor (including monitors)
        - Preparation of materials for, involvement in, and monitoring visits
        - CRF completion and entry,
        - Endpoint recording
        - Accrual reporting
        - Safety and adverse event reporting
        - Management of study documentation
        - Retrieval of medical and 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. Any provision for study participant payment would be described in the agreement and 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 the 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 need to stay close to the study site for an extended period.
- Screen failures
- Unscheduled study participant visits

Clinical Trial Budget

Table inserts for schedule 2: Payments

Below are tables that should be used in Schedule 2: Payments of the Agreement.
The invoiceable items below may/may not apply to each study; however, they are there as a starting point to ensure all fees are covered.

Payments and Invoicing

Please contact CAHS.financialaccounting@health.wa.gov.au for banking details.

Invoiceable Items

Site Fees	Fee (AUD)	Occurrence
HREC and RGO review fees		
New ethics applications	$3850.00	Including submissions under NMA where CAHS is the lead site
HREC review on behalf of each additional site	$660.00	
Review of an amendment	$660.00	Excludes extensions up to 3 years
Further review of an amendment	$320.00	Requirement for resubmission of an amendment
New governance applications **(SSA and Budget forms)**	$3850.00	
Review of an amendment	$660.00	Excludes extensions up to 3 years
Review of Governance only amendment	$660.00	
Further review of an amendment	$320.00	Requirement for resubmission of an amendment
Site Fees		
Site set-up fee		Non-negotiable, non-refundable, due at the effective date of the Agreement
Site monthly fee		Per month from the execution of the Agreement to the removal of items for archiving
Remote monitoring		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		Non-negotiable, non-refundable fee due at the end of study
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 hour (if required)
Senior Clinical Research Coordinator/ Sub Investigator(s)		Per hour (if required)
Study participant fees		
Study participant travel – Applicable if not included per study participant visit cost.		Per visit
Study participant food voucher		Per fasting visit
Note: The above charges are blank as they vary depending on the study department, the nature of the study, and the patient visit schedule.		

Research Departments in CAHS – Costs

Anaesthesia and pain management

Item	Fee (AUD)	Occurrence
Anaesthetist	$251.56	Per hour
Anaesthesia for endoscopy or biopsy	$548.00	
Anaesthetic technician	$61.27	Per hour
Medical Records	$15.00	Per item

Audiology

Item	Fee (AUD)	Occurrence
Audiology appointment	$381.00	Standard fee

Cardiology

Item	Fee (AUD)	Occurrence
Echocardiogram	$300.00	reported
ECG	$50.00	reported

Clinic D

Item	Fee (AUD)	Occurrence
Annual administration	$2500.00	
Room booking	$40.00	Per hour
Room booking	$120.00	Half day (4 hours)
Room booking	$220.00	Full day (8 hours)
Re-consent fee	$210.00	
Research nurse time		Calculated based on the visit schedule

Endocrinology and diabetes

Item	Fee (AUD)	Occurrence
Study start-up	$6000-9000	Start-up meetings/SIV/study training
Study closeout	$1300-2000	Closeout visit
Laboratory set-up	$450.00	Lab tests and procedures
Study coordinator fees	$1500.00	Annually
Screen failure	$1912.00	Per subject (based on study)
Monitoring fee	$500.00	Per visit
Administration fee	$2000.00	On SIV and annually thereafter

Gastroenterology

Item	Fee (AUD)	Occurrence
Colonoscopy with specimen collection	$2387.00	Includes biopsy handling, supplies, coordinator, and Physician fee
Level IV – Surgical pathology	$373.00	Gross and microscopic examination
Sigmoidoscopy	$843.00	Single or multiple per instance

General surgery

Item	Fee (AUD)	Occurrence
Muscle biopsy under GA	4944.00	Per participant

Health information and administrative services

Item	Fee (AUD)	Occurrence
Record archiving	$2500.00	
Medical record review	$15.00	Per time

Immunology and allergy

Item	Fee (AUD)	Occurrence
Study closeout	$3960.00	
Department Set up fee	$10488.00	
Annual administration fee	$11516.00	Administration, monitoring & reporting
Study-specific training	$3960.00	

Medical imaging

Item	Fee (AUD)	Occurrence
General Fees		
Establishment for single modality	$850.00	Only applicable to X-ray, US, CT, and Fluoroscopy.
Establishment fee	$1500.00	For single modality of MRI, DSA, or PET. Multi-modality studies
Medical physics risk assessment.	$600.00	
Amendment to Medical Imaging services	$1000.00	(Additional imaging modality not initially agreed to)
Amendment to Medical Physicist report	$600.00	(Additional imaging added to protocol)
Training session for a radiologist	$360.00	(Fee per hour – 1 hour minimum)
Training session for a MIT	$100.00	(Fee per hour – 1 hour minimum)
Clinical audit/Data transfer fee per examination	$15.00	(For electronic transfer of retrospective studies)
Specific Radiologist reporting template	$200.00	
General Xray		
Abdomen Xray	$106.80	
Bone age Xray	$89.80	
Chest Xray	$105.70	
Chest and abdomen Xray	$212.50	
OPG	$106.40	
Scoliosis Xray	$246.60	
Unilateral tibia and fibular Xray	$97.40	
Unilateral knee Xray	$97.40	
Skeletal survey	$200.50	
Wrist Xray	$89.10	
Computed Tomography		
CT Brain	$437.50	
CT Brain with contrast	$560.70	
CT chest	$661.60	
CT chest with contrast	$897.00	
High-resolution CT chest	$1323.20	Inspiration and expiration
CT chest, abdomen, and pelvis with contrast	$1255.90	

CT abdomen and pelvis with contrast	$1076.60	
CT extremity	$493.40	
Dental/TMJ cone beam CT	$253.80	
CT Phantom scan	$1612.80	
Magnetic Resonance Imaging		
MRI brain	$882.90	
MRI brain with contrast	$981.00	
MRI of the brain and neck	$1079.20	
MRI spine	$784.80	1 or 2 contiguous regions
MRI spine	$981.00	3 contiguous regions or 2 non-contiguous regions
MRI abdomen and pelvis	$1373.40	
MRI abdomen and pelvis with contrast	$1471.50	
MRI liver	$853.00	
MRI liver with contrast	$1261.70	Not primovist
MRI extremity	$833.90	
MRI extremity with contrast	$932.00	
MRI of cardiovascular system	$1872.70	
MRI foetal	$2627.70	
MRI phantom scan	$1612.80	
Ultrasound		
US abdomen	$249.40	
US abdominal doppler	$380.20	
US head	$244.80	
Unilateral US Doppler arm veins	$380.20	
Unilateral US Doppler arm arteries	$380.20	
Unilateral US Doppler leg veins	$380.20	
Unilateral US Doppler leg arteries	$380.20	

Neurology and neurosurgery

Item	Fee (AUD)	Occurrence
Study closeout	$1625.00	
Site authorisation	$3500.00	
Annual administration fee	$3250.00	
Monitoring visit	$500.00	Per visit
Monitoring visit	$1000.00	Per audit
Annual reporting	$1690.00	
Trial-specific equipment set-up	$90.00	Maintaining per item
Records archiving	$1950.00	
SAE & incident report	$500.00	Per report

Pharmacy

Please click here for more details about Pharmacy charges.

Other external vendors – costs

Lions Eye

Item	Fee (AUD)	Occurrence
Set-up fee	$350.00	
Ophthalmologic examination	$440.00	
Annual fee	$350.00	

PathWest

Item	Fee (AUD)	Occurrence
Clinical trial set-up and quote	$450.00	Set-up and quotation fees
Amendment processing	$130.00	
Protocol amendment fee	$100.00	
Biospecimen collection and processing	$60.00	Central lab (performed by CRC)
Specimen reception processing and shipping	$40.00	Per item
Lab tests		Study-specific

Ronald McDonald Housing

Item	Fee (AUD)	Occurrence
Accommodation	$110.00	Per night. If a child is inpatient and escort only
Accommodation	$125.00	Per night. Escort and patient

Contact

This document will be revised regularly as the fee structures change over time.

For updated fees of the CAHS supporting departments and external vendors, contact CAHS.Clinicaltrials@health.wa.gov.au

For finance queries contact CAHS.ResearchBusinessSupport@health.wa.gov.au

For pharmacy queries contact PCH.pharmacyclinicaltrials@health.wa.gov.au