Macquarie University Clinical Trials Unit

Clinical Trial Start-up of sponsored trials

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Clinical Trial Start Up at MQ

We are delighted you have chosen the Macquarie University Clinical Trial Unit (MQ CTU) to work with on your clinical trial, and we look forward to collaborating with you. This guide is intended to facilitate the start-up process. If you have any questions regarding start-up, please do not hesitate to reach out to our start-up manager, Gabriel Quinlan (gabriel.quinlan@mq.edu.au).

Before commencing work on the HREC submission we complete an initial review of the study budget, as the data we have demonstrates that budget and contract negotiation process takes longer than the HREC submission process.

BUDGET, CONTRACTS AND FINANCE

NEGOTIATING A BUDGET WITH THE CTU

A draft budget with a breakdown of protocol procedures and reflecting the standard costs should be supplied to the MQ CTU start up team (contracts.ctu@mq.edu.au) prior to or with the HREC submission package.

We will calculate the cost of conducting your trial at Macquarie University as follows:

- We have fixed costs to cover start up, management and administration of a clinical trial (see Appendix 2).
- Protocol procedures are costed at Australian Medical Association (AMA) rates at the time of study start up. The AMA fees list is indexed annually, usually on November 1st.
- Clinician time is charged in line with the AMA consultation rates and according to the type of visit and/or fees charged by the investigator. For the initial screening visit, $745 will be charged, and $375 for subsequent visits.
- Study coordinator time is charged at $120 per hour. Study coordinator time includes preparation for the visit including making appointments, reviewing procedure results, arranging IP dispensing, conducting a face-to-face visit, documenting the visit and any participant interaction in between, entering data into eCRF, working with the CRA during monitoring visits, and query resolution. As a rule, a screening visit takes 8 hours.
- AE/SAE Treatment cannot be predicted for cost calculation. If a participant is treated for a trial-related AE/SAE at Macquarie University Hospital, rather than expecting the participant to cover those costs, the CTU will pay the hospital bills and claim the costs back from the sponsor. To document this practice the following wording will be included in schedule 7 of the CTRA:

Where Treatment at MQ Health is Required for Research Injury

In this clause "Research Injury" means an Adverse Event related to investigational product or study procedure which the Investigator considers requires immediate medical treatment. The Institution may arrange for the immediate medical treatment and in doing so may incur costs on behalf of the Study Participant. The [Local] Sponsor will pay the costs promptly on receipt of a valid tax invoice from the Institution together with any supporting documentation or information reasonably requested by the [Local] Sponsor. The Institution will inform the [Local] Sponsor as soon as practicable of a Research Injury.

- Participant travel reimbursement:
  - We provide trial participants with a voucher to cover the costs of their petrol, tolls and parking for attending each trial visit (including Screen Failure visits and Unscheduled Visits and visits for scans). Where Sponsors engage third party vendors to manage these payments, the CTU can utilise these services with the implementation of the reimbursement schedule outlined below.
  - The value of the voucher is adjusted depending on the distance travelled for a return trip. The distance is based on the shortest time calculated using google maps and is reimbursed as per the below:
    - Less than 100km: $70
    - 101 to 250km: $100
    - 251 to 500km: $200
    - Greater than 500km: $400
  - For regional participants, approval will be sought from the sponsor to cover a participant's expenses for meals and accommodation as applicable.

- Macquarie University charges 25% overhead on all clinical trials income, therefore an institutional overhead of 25% shall be applied to all costs.

- If a trial extends beyond 5 years, all fees will be increased by 10% for any procedures conducted from the 5th anniversary of the trial initiation visit.

CLINICAL TRIAL RESEARCH AGREEMENT

The MQ CTU uses the MA CTRA or MTAA CIRA template for sponsored trials.
Once the budget is agreed upon, the sponsor customises the CTRA template. Page 1 of the template is customised as follows:

Name of Institution:	Macquarie University
Address:	Balaclava Road, North Ryde, NSW, 2109, Australia
ABN:	90 952 801 237
Contact for Notices:	Clinical Trial Unit Head
Email for Notices:	clinicaltrials@mq.edu.au
Fax for Notices:	+61 2 9850 5747
Phone Number:	+61 2 9812 3500/ +61 2 9812 2968 (D)

Payee details should be inserted into Schedule 2 as follows:

Name of Institution:	Macquarie University
Name of Bank	National Australia Bank (NAB)
Bank Address:	Macquarie Shopping Centre, Herring Road, North Ryde, NSW 2113
Account Name:	Macquarie University
BSB Number:	082 344
Account Number:	530802756
Swift Code:	NAT AAU 3303M
Payment Notices to:	CTU Finance team, ctu_finance@mq.edu.au

The CTRA/CIRA template will be reviewed by the assigned Start Up and Regulatory team member.

- If there are additions to the CTRA/CIRA Schedule 7, MQ legal team review is also required and will typically take 4 to 8 weeks. SEBS approval for the schedule 7 changes requested,

should be provided prior to MQ legal review, however, will not by-pass the review process. This schedule 7 review can be undertaken in parallel to budget negotiations.

- The CTU does not accept withholding payments.
- Nor do we accept Recipient Created Tax Invoices. We will track our participant visits and provide an invoice once the visit is complete and entered into the eCRF.
- If trial procedures are separate to participant visits and listed as invoiceable items in the CTRA, the sponsor should provide a quarterly listing of all invoiceable items completed.
- MQ University has payment terms of **30 days**.
- We expect payment upon completion of visit and data being entered into the CRF/EDC. We cannot support waiting for data to be monitored before payment.
- Insurance certificate/ statement of insurance for $20 million AUD

Once the final CTRA is reviewed and approved, electronic signatures with an auditable platform such as AdobeSign or DocuSign is preferred. Alternatively, 2 copies of the CTRA signed by the sponsor are sent to the CTU to arrange wet ink signatures.

INDEMNITY

Indemnities for clinical trials conducted by the CTU are required for the following organisations:

- Macquarie University
- Macquarie University Hospital
- MUH Pharmacy

MACQUARIE UNIVERSITY INDEMNITY DETAILS

Macquarie University (ABN: 90 952 801 237) Balaclava Road, North Ryde, NSW, 2109, Australia (Indemnified party)

Indemnified party signatory: Professor Isak Pretorius / Deputy Vice Chancellor, Research

MACQUARIE UNIVERSITY HOSPITAL INDEMNITY DETAILS

Macquarie University Hospital (ABN 46 141 203 125) 3 Technology Place, Macquarie University, NSW 2019

Signatory: Walter Kmet / Chief Executive Officer

MUH PHARMACY INDEMNITY DETAILS

MUPharm Pty Limited trading as Macquarie University Hospital Pharmacy (ABN: 25 132 806 289) Ground Floor, 3 Technology Place, Macquarie University, NSW 2019, ABN 46 141 203 125

Signatory: Jane Stidworthy / Director of Pharmacy

CLINICAL TRIAL NOTIFICATION (CTN)

CTN DETAILS

Site Details	
Site Name	Macquarie University
Site Physical Location	Balaclava Road, North Ryde NSW 2109
Expected Trial Site Start Date	
Principal Investigator Details	
Name	
Contact Phone Number	0298122956 (General Number)
Contact Email	
Human Research Ethics Committee (HREC) Details*	
HREC Name	Macquarie University HREC Medical Sciences
HREC Code	EC00448
HREC Contact Officer	Tammy Harwood
Position	HREC Team Leader & Secretary Medical Sciences *(Note only, full version 'Human Research Ethics Team Leader & Secretary to HREC Medical Sciences' does not fit eCTN)*
Contact Phone	0298504459
Contact Email	ethics.secretariat@mq.edu.au
Approving Authority Details	
Name of Approving Authority	Macquarie University
Approving Authority Contact Officer	Isak Pretorius
Position	Deputy Vice Chancellor of Research
Contact Number**	+61-2-9850-8645
Contact Email**	holly.edwards@mq.edu.au

*HREC details applicable for Macquarie University submissions only. HREC approval letter for Bellberry applications will list the committee to be added to the CTN.

**Please note the contact number and email are for Holly Edwards the executive assistant to the Deputy VC of Research.

Hospital Details	
Name:	Macquarie University Hospital
Physical Location:	3 Technology Place Macquarie University,
State/Territory:	NSW, 2109
Approving Authority	
Name of Approving Authority:	Macquarie University Hospital
Approving Authority Contact Officer:	Walter Kmet
Position:	Chief Executive Officer
Contact Number:	02 9850 2841
Contact Email:	muh.ceo@mqhealth.org.au

Pharmacy Details	
Name:	MUPharm Pty Limited trading as Macquarie University Hospital Pharmacy
Physical Location:	Ground Floor, 3 Technology Place Macquarie University,
State/Territory:	NSW, 2109
Approving Authority	
Name of Approving Authority:	Macquarie University Hospital Pharmacy
Approving Authority Contact Officer:	Jane Stidworthy
Position:	Director of Pharmacy
Contact Number:	02 9812 3911
Contact Email:	Jane.Stidworthy@muh.org.au

Our start up and regulatory team (contracts.ctu@mq.edu.au) can negotiate a budget with sponsors in parallel to HREC review of a trial.

The MUH Pharmacy is independent of Macquarie University. Budgets and separate contracts must

be negotiated directly with the Pharmacy. Pharmacy fees cannot be included in the CTU CTRA. Details for pharmacy agreements are outlined in Appendix 3.

THE MACQUARIE UNIVERSITY ETHICS PROCESS

All trials conducted through the MQ CTU require ethical approval. All phase II to IV studies must have Ethics approval from the Macquarie University Human Research Ethics Committee (HREC). For phase II to IV studies, MQ CTU does not offer to be the 'lead site' as MQ HREC is outside of mutual acceptance schemes. All phase I studies are submitted to Bellberry for review and approval and MQ CTU may be able to offer 'lead site' for other sites covered under the Bellberry application. The details of the ethics submission pathways available to MQ CTU are outlined in the Appendix 1 decision tree.

HREC SUBMISSIONS

The MQ CTU start up and regulatory team (ethics.ctu@mq.edu.au) will make the submission to the MQ HREC through their Infonetica (FORA) submission system for phase II to IV studies and through Bellberry eProtocol for phase I studies.

DOCUMENTS REQUIRED FOR HREC SUBMISSION

To facilitate the HREC submission a complete package of the following documents needs to be supplied:

- The final clinical trial protocol
- Study medication Investigator Brochure, product information or instructions for use
- A site-specific participant information and consent form. Our preference is that Sponsor consider using the CT:IQ template (https://www.informedpicf.com.au/download). Alternatively a participant information and consent form consistent with the NHMRC
- Where the CT:IQ template is not use, a participant study summary will be included as part of the site-specific consent form
- Any additional information that will be provided to trial participants (customised with site specific details if applicable)
- A list of documents being submitted. Please include document version numbers.
- Draft TGA CTN/CTX form
- Any Advertising Materials that will be used (if applicable)
- For applications involving radiation in excess of Clinical Care, a Radiation Safety report (assessed by MQ Radiation officer)

For MQ Uni HREC submissions only

- NHMRC HREA form (https://hrea.gov.au/)
- HREC invoice form (Emailed to you to complete – information must align with the CTRA)
- Data Management Plan
- For Phase II to IV studies, where another HREC approval letter for the trial is available, this should be provided to your Start Up contact.

HREC SUBMISSION TIMELINES

The MQ HREC terms of reference, costs and meeting dates are provided on their website (https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics).

Bellberry HREC submission requirements are provided on their website (https://bellberry.com.au/).

Submission packages including all the documents listed above must be received by the CTU start up team no less than 3 weeks prior to the HREC submission deadline.

MQ RESEARCH GOVERNANCE

MQ Research Governance is overseen by the Macquarie University Faculty of Medicine, Health and Human Sciences Clinical Research Executive. Governance procedures for sponsored trials conducted by the CTU include an expedited review. The procedure and cost for Governance review is outlined on the MQ website: https://www.mq.edu.au/about/about-the-university/our-faculties/medicine-and-health-sciences/our-research/fmhs-research-resources/clinical-research-governance.

The CTU will make an initial application to the Governance team for endorsement simultaneously to the HREC submission. The CTU will then apply for final Governance Authorisation after receiving HREC approval, fully executed CTRA, fully executed Pharmacy agreement, fully executed standard indemnity and current insurance certificate. Governance review for final Authorisation takes approximately 15 business days of the CTU application. Governance Authorisation will occur shortly thereafter depending on the number of queries raised.

Site Initiation visits (SIV) may be scheduled 15 business days after the Governance submission for final Authorisation has been made. If Sponsor processes do not allow for SIVs to be conducted without all approval in place, the SIV should not be scheduled until Governance Authorisation has been received. Governance Authorisation cannot be expedited.

FACILITIES

INVESTIGATIONAL PRODUCT MANAGEMENT

We contract all our investigational product management to Macquarie University Hospital Pharmacy. Please include the pharmacy team when you set up site selection or site initiation visits:

Macquarie University Hospital Pharmacy

3 Technology Place, Macquarie University NSW 2109
Tel: +61 2 9812 3914
Email: trialsonc.pharmacy@mqhealth.org.au

If the IP is for IV infusion or SC injection and is cytotoxic, it needs to be compounded at Baxter or Slade. When Baxter or Slade is involved, Pharmacy will inform the sponsor and e-mail the Baxter or Slade Startup pack to the Sponsor. The pack has all the information on making the SIV appointment and monitoring visits.

IMAGING

Imaging including management of uploading scans and reports to sponsor databases is managed by the Macquarie Medical Imaging (MMI).

Ground Floor, 3 Technology Place, Macquarie University, NSW 2109
Tel: +61 2 9430 1100
Email: mmi.research@mqhealth.org.au

If there are protocol specific requirements regarding imaging, the MMI team needs to be included in initiation visits and training. Contact Margery Pardey using the email above.

CTU DOCUMENTATION

ELECTRONIC INVESTIGATOR SITE FILES (ISF)

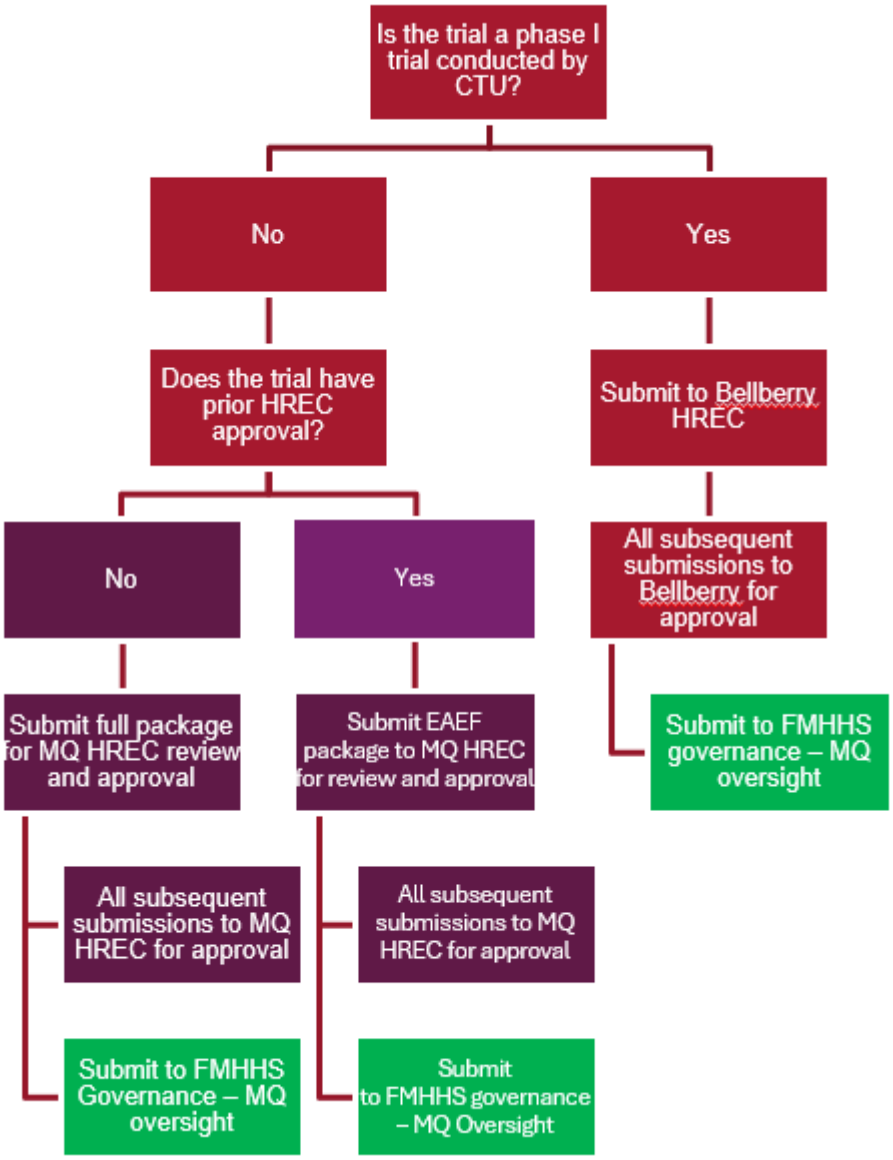
The Clinical Trial Management System we use is REALTIME (https://www.realtime-ctms.com/). All new trials at MQ CTU will have an electronic ISF. RealTime-eDOCS™ is a fully validated, 21 CFR Part 11 compliant, electronic document management system. The monitor portal allows monitors access to their assigned study records. All filed documents may be reviewed, tracked and

downloaded as needed by the monitor. This portal is unique to each user and only reveals records specific to the user's study assignment and records can't be altered through this portal. A manual with additional information can be provided upon request. By having access during the study start-up phase, sponsor start up teams will be able to download start up documents directly for their TMF.

CLINICAL TRIAL ARCHIVING

The electronic ISF in Real Time allows indefinite document storage. The participant paper files are archived off site at Iron Mountain. The CTU maintains an archived study file to keep track of what trials have been archived and the Iron Mountain tracking number etc for straight forward retrieval if required

Appendix 1 – HREC Decision Tree



Appendix 2 – CTU fixed costs

MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees			Site Comments
SR. NO.	**ITEM DESCRIPTION**	**Total Incl 25% OH (AUD $) Excl GST**	
A	Institutional overhead (IO)	Applied to all costs	Macquarie University applies an Institutional overhead to all research projects at the University. The minimum Overhead and Infrastructure Costs that must be recovered on all funded research projects is **25%**.
Start up and Administrations fees			
1a	Site Start Up Fee (payable for cancelled studies on which work has commenced or from Site Initiation Visit)	$10,500	Includes HREC processes, admin costs, teleconference/ training time, and all study-related start-up activities including electronic Investigator Site File covering the RealTime CTMS vendor costs used for storing ISFs. Applicable to all clinical trial phases.
1b	Site Start Up Fee - Lead Site	$250/site	Includes collection of documentation required, from other participating sites, for HREC submission and distribution of HREC approval documentation, and will be charged at the time of additional site submissions
2a	Quarterly Site ongoing administration and PI fee (from Site Initiation Visit)	$2600	This fee accounts for all activities and admin work undertaken by site to deliver as per study protocol and the PI oversight beyond patient/clinic time.
2b	Quarterly Lead site fee	$250/site	This fee accounts for communication and distribution of HREC documentation post HREC approval, including but not limited to collection of information for annual and final reporting, distribution of amendment approvals, safety updates etc.
3	Site Close down fee (payable after completion of Sponsor close out visit)	$1950	Including but not limited to completion of data clearing, data lock, inventory reconciling, returning of trial provided materials/ commodities, preparing study material for archiving, monitoring close out activities, data lock for eCRF, HREC final reporting.
4	Archiving fee	$1456	One-off fee payable after approval of Final Report. Standard archiving period is **15 years**. Cost will increase if longer archival period is required. Includes pharmacy files. N/A if sponsor is Archiving.
5	Annual maintenance fee for Sponsor TMF platform use (from Site Initiation Visit)	$500	Covers the creation of site profile and ongoing management of study TMF. **Annual Fee, charged from SIV.** This fee only applies for Sponsors using a Sponsor specific TMF platform.
6	Radiology Set Up fee (from Site Initiation Visit)	$1300	One-off fee. Review of Protocol & set up of trial specific requirements (Central upload). Collation of essential documentation establishment of files. Education/training of staff. **This fee is applicable to all studies with an imaging component.**

MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees			Site Comments
SR. NO.	**ITEM DESCRIPTION**	**Total Incl 25% OH (AUD $) Excl GST**	
7	Ophthalmology Set up Fee (from Site Initiation Visit)	$1300	One-off fee. Review of Protocol and Collation of essential documentation establishment of files. Education/training of staff. Receipt and storage of initial study materials. **This fee is applicable to all studies with an ophthalmology component**.
8	Respiratory Lab Set Up Fee (from Site Initiation Visit)	$1300	One-off fee. Review of Protocol and Collation of essential documentation establishment of files. Education/training of staff. Receipt and storage of initial study materials. **This fee is applicable to all studies with a respiratory component**.
9	Laboratory Set up Fee (from Site Initiation Visit)	$1300	One-off fee. Review of Protocol & Collation of essential documentation establishment of files. Education/training of staff. Receipt and storage of initial study materials. **This fee is applicable to all studies that require local pathology testing.**
9a	Quarterly Laboratory Storage Fee (from first patient screened)	$390	Fee is only applicable for studies where batch processing is required. This fee accounts for the storage of samples for shipment to the central laboratory and maintenance of logs.
Per occurrence fees			
10	Amendment Preparation Fee	$1,500	Major amendments fee to be paid to CTU. This fee accounts for processing and handling of amendments submitted to HREC and/or MQ CRG. Amendments will be determined to be major at the discretion of the CTU. All amendments that include changes to the PICF or require multiple documents to be submitted will be classified as major. This cost is independent of the HREC and MQ CRG fees.
11	Amendment Preparation Fee	$300	Minor amendments fee to be paid to CTU. This fee accounts for processing and handling of amendments submitted to HREC and/or MQ CRG. Amendments will be determined to be minor at the discretion of the CTU. This cost is independent of the HREC and MQ CRG Fees.
12	SAE Reporting	$425	Per SAE. This includes follow-up reports
13	Re-consent fee	$175	Per patient reconsented if reconsenting is required to be done.
14	Completion of pathology reference ranges by Site	$505	This fee is incurred if the Sponsor requires Macquarie University CTU staff (i.e. Trial Coordinator) to enter pathology reference ranges into the eCRF. This applies to Douglass Hanly Moir Pathology only. Other pathology centres will incur additional fees. This fee covers 4.5 hours staff time (includes time spent entering data and responding to queries generated by DM/CRA etc).

MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees			Site Comments
SR. NO.	ITEM DESCRIPTION	Total Incl 25% OH (AUD $) Excl GST	
15	Archiving retrieval fee (where applicable)	$195	Fee charged by the storage company to retrieve stored documents. Charged per occasion.
16	Audit/Quality Compliance Check fee	$600/day	Accounts for time invested by site before, during, and after an audit/quality compliance check visit.
17	Radiation Assessment Fee	$520	In the event radiation assessment is required for patient safety. Ethics committee requirement in NSW.
18	NSWHP set up fee	$1250	Only applicable when archival tissue is required for the trial and is obtained from NSW Health Pathology
19	Oncology Day Care – chair costs	$975	Cost per occurrence (1 chair/1 day) of intravenous infusion(s) of study IP (to be included in the per participant budget).
Pass through costs			
20	MQ Health Governance authorisation Assessment Fee	As invoiced by CRG	A fee structure applies for the review of documents from the submission of the application through to final authorisation for the clinical trial at Macquarie University. Please note any post-authorisation amendments and reporting will incur an additional fee per submission. RGO Review Fees will be paid directly to the RGO by Local Sponsor on a pass-through basis upon receipt of invoice and supporting documentation. Fees are listed on the following website: https://www.mq.edu.au/about/about-the-university/our-faculties/medicine-and-health-sciences/our-research/fmhs-research-resources/clinical-research-governance/governance-for-fully-sponsored-clinical-trials
21	MQ HREC Fees	As invoiced by HREC	Fees are applied by the Macquarie University HREC. Invoices are directly payable to Macquarie University HREC and may be generated prior to receiving HREC approval. Terms of the HREC are available on the MQ HREC website – https://www.mq.edu.au/research/our-research/research-ethics-and-integrity/human-ethics/applications-and-approvals
22	Interpreter Services (where applicable)	Per Invoice	In instances where Medicare rebate for interpreter services is unavailable, Sponsor shall reimburse the Institution for interpreter services provided to the Participants from screening and during the study. Payment shall be made upon receipt of supporting documentation (including participant number, date, visit type (screening, informed consent etc), language and duration of visit). Actual costs will be approximately $150 per hour but are subject to variation (due to factors such as complexity, language, duration of visit, availability of interpreters, and service used).

Appendix 3 – MUH Pharmacy Payment details and Clinical Trial costs

Macquarie University hospital Pharmacy can bill the pharmaceutical company directly for the fees and charges associated with establishing and managing clinical trials.

Trial will be invoiced by Mupharm Pty Limited, trading as MUHospital Pharmacy.

Name of Institution:	MUPharm Pty Ltd trading as Macquarie University Hospital Pharmacy
ABN:	25 132 806 289
Address:	Ground Floor, Macquarie University Hospital, 3 Technology Place, Macquarie University, NSW 2109
Name of Bank	Commonwealth Bank of Australia
Bank Address:	11 Harbour St, Sydney NSW 2000
Account Name:	MUPharm Pty Ltd
BSB Number:	062-320
Account Number:	11584462
Swift Code:	CTBAAU2S
Payment Notices to:	accounts@mupharm.com.au

Additional fees may apply to clinical trials that require complex compounding or extra administration. This pricing will be advised at the trial setup as it will depend on the complexity of compounding/administration.

Remittance to accounts@mupharm.com.au

Invoicing for trials is automated from the pharmacy accounts system. ***No third-party account systems****, such as Greenphire,* ***can be utilised for billing****. Invoices will be generated monthly or quarterly and emailed to the appropriate email address for payment.*

The pharmacy fees are adopted from "Determination of standard costs associated with conducting clinical trials in Australia: Standard List of Clinical Trial Items", which was released by independent Hospital Pricing Authority in June 2015 under subsection 131(1) of the National Health Reform Act 2011 (Commonwealth). The development of the standard costs was funded by Department of Health and revised by the National Health and Medical Research Council (NHMRC). The costs were based on principles of cost-recovery of services provided by clinical trials pharmacy staff. The costs in June 2015 determination relate to the 2014-15 financial year. The annual EBA and CPI adjustments and benchmarking have been applied since.

If a clinical trial continues beyond the period of 2 years, fees may need to be re-negotiated.

Quote will remain valid for a period of 60 days.

Clinical trials Schedule of Fees 2026 – Sponsored

The fees below do not include GST

Item	Inclusions (and not limited to)	Payable	Cost
Administrative Fees			
Set-up Fee	This fee is independent of participant accrual and includes all administrative procedures associated with setting up the study. This may be charged even if the study is ceased before SIV, to cover for services utilised, including but not limited to: • Protocol familiarisation, including attendance at relevant meetings, e.g. SIV, pre-site visits. • Liaising with Sponsors and study coordinators and monitors, including budget negotiations. • Establishing pharmacy start-up procedures. • Initial stock management, handling and storage set up. • Education of staff. • Completion of study monitoring and documentations, accountabilities, etc. • Completion of SIV training. • Does not include 1st year administration fee.	Once per study, payable following Site Activation.	**$2,800.00**
Annual Administration Fee	This fee is fixed for the first year and will be prorated for any partial years thereafter. Includes all procedures associated with the ongoing administration for the study, but not limited to: • Management and handling of shipments, receiving/recording stock and expiry management. • Ongoing liaison with Investigators, study coordinators and monitors. • Managing standard documentation, review of amendments where no change in the Pharmacy process is required. • Handling of participant returned investigational product. • Monitoring visits - booking visit and making available materials for visit and query resolution.	Annually, payable from site activation or first shipment arrival (whichever occurs first) and then each activation anniversary until Pharmacy COV.	**$2,800.00**

	• Updating Standard Operating Procedures. • Email correspondence. • Managing financial aspects of the study.		
Amendment Fee	Applicable to a Protocol amendment that includes a major amendment to the drug protocol and a change in Pharmacy process and revision of Pharmacy fees is required, e.g. for additional drug/s, cohorts, etc.	Per Protocol amendment.	**$1,500.00**
Close Out Fee	Covers the pharmacy close-out activities and finalisation of study requirements upon study completion by Sponsor including, but not limited to: • Finalising all relevant documentation and processes. • Completion of drug accountability logs / IWRS drug accountability final reconciliation. • Archiving of records. • Final monitoring meetings.	Once per study, following the Pharmacy COV and completion of all required follow up actions.	**$600.00**
Annual Storage Fees *For bulky goods that occupy more than the standard allocated space, the storage fee may need to be revised to commercial rates.*			
Room Temperature (ambient) Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$990.00**
Refrigerator Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,100.00**
-20°C Freezer Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,200.00**
-65-80°C Freezer Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,400.00**
Cytotoxic, Schedule 8 or	• This fee is fixed for the first year and will be prorated for any partial years thereafter.	Annually, payable from date first IP	**$1,100.00**

Schedule 9 Storage	• Includes temperature monitoring and temperature log device calibration.	shipment received.	
Storage of Returned Stock Fee	When participant returns or outer cartons are kept for periods beyond 3 months awaiting a monitor's visit or for a shorter period where the study packaging takes up a large amount of space and the returns process requires Pharmacy involvement.	Annually, only if required.	**$400.00**
Dispensing Fees *Will appear on the invoice as the drug name.*			
IP Dispensing Fee (Simple)	• Includes drug accountability. • Cancelled doses are subject to a dispensing fee if a dose has been dispensed/prepared.	Per participant, per dispensing visit, per item, per strength.	**$110.00** for the first kit **$40.00** per each subsequent item dispensed on the same visit
IP Dispensing Fee (Complex)	• Additional tasks are required such as using both trial logs and narcotic registers • A trial where pharmacy conducts additional IWRS transaction such as logging data for the randomisation, kit verification or other steps during or after the dispensing process • Study specific requirements e.g. double handling/signing of all logs and prescriptions	Per participant, per dispensing visit, per item, per strength.	**$220.00** for the first kit **$40.00** per each subsequent item dispensed on the same visit
Aseptic Preparation Fee (Simple)	• Includes drug accountability. • Cancelled doses are subject to a dispensing fee if a dose has been dispensed/prepared.	Per Preparation	Min. **$280.00** for the first 3 vials **$65.00** for each additional vial if >3
Aseptic Preparation Fee (Complex)	• Multiple manipulations/additional product handling • Compounding time ≥ 20 minutes • IMP with short shelf life (≤12 hours) • Special requirements • Actual compounding fee will depend on the level of complexity	Per Preparation	Min. **$350.00** for the first 3 vials **$65.00** for each additional vial if >3
Additional Fees			
Pharmacy Call Back	Charged when a pharmacist is required to complete IP dispensing outside of standard hours. Applies to activity before 8:00am and	Per occurrence.	**$800.00** (for IP dispensation) **$2,000.00**

(Afterhours) Fees	after 4:30pm Monday - Friday, weekends and public holidays.		(for aseptic preparation)
Onsite Destruction / Reconciliation Fee	For used/unused IP or any retained packaging destroyed on-site and completion of associated documentation.	Per occurrence.	**$160.00**
Destruction of Shipping Containers Fee	Time taken for on-site destruction of any shipping containers left behind by the delivering courier (if required).	Per occurrence.	**$35.00**
Pharmacist Training Fee	For undertaking IMP-specific mandatory online training modules	Per occurrence.	**$160.00**
Remote Monitoring Fee	To cover the time that the Pharmacist is engaged to the remote call and pre- and post-monitoring tasks including scanning the paperwork and sending electronic documents to the CRA.	Per hour (minimum 1 hour), per occurrence.	**$200.00**
Relabelling Fee	When the Pharmacists need to relabel all relevant IMPs with new Sponsor-provided labels (e.g. with updated retest date or other changes) and complete documentation.	Per hour (minimum 1 hour), per occurrence,	**$160.00**
Drug Transfers Fee	Includes but not limited to: • Transfer of study drug/shipment to external compounding facility via external courier vendor. • Transfer of study drug to another site (at discretion of PI and/or Sponsor). • Direct to patient transfers.	Per occurrence, only as required, with Sponsor request and/or approval.	**$110.00 handling fee plus transport costs**
Miscellaneous Pharmacy Services	For undertaking any additional activities not described in the Pharmacy manual, requested by the Sponsor.	Per hour, per occurrence at Sponsor request.	**$160.00**
Drug Costs	For any supportive medications to prevent and/or treat study-drug related AEs. If eligible for PBS subsidy, the Sponsor will be required to pay the co-payment (this will increase as dictated by the PBS each calendar year).	Payable only if required.	**20% handling fee plus drug costs**
Late invoice payment fee	Applies to an undisputed invoice that remains unpaid for more than 3 months from the date of issue.	Every 3 months the invoice remains overdue.	**$100.00**

	This fee will be applied every 3 months that each invoice remains overdue.		
Pharmacy fees will increase annually by 3.5% rounded to whole dollar (5 or 10) and applied from the initiation date.			

Clinical trials Schedule of Fees 2026 – Sponsored Complex* Trials

The fees below do not include GST

Item	Inclusions (and not limited to)	Payable	Cost
Administrative Fees			
Set-up Fee	This fee is independent of participant accrual and includes all administrative procedures associated with setting up the study. This may be charged even if the study is ceased before SIV, to cover for services utilised, including but not limited to: • Protocol familiarisation, including attendance at relevant meetings, e.g. SIV, pre-site visits. • Liaising with Sponsors and study coordinators and monitors, including budget negotiations. • Establishing pharmacy start-up procedures. • Initial stock management, handling and storage set up. • Education of staff. • Completion of study monitoring and documentations, accountabilities, etc. • Completion of SIV training. • Does not include 1st year administration fee.	Once per study, payable following Site Activation.	**$3,300.00**
Annual Administration Fee	This fee is fixed for the first year and will be prorated for any partial years thereafter. Includes all procedures associated with the ongoing administration for the study, but not limited to: • Management and handling of shipments, receiving/recording stock and expiry management. • Ongoing liaison with Investigators, study coordinators and monitors. • Managing standard documentation, review of amendments where no change in the Pharmacy process is required. • Handling of participant returned investigational product. • Monitoring visits - booking visit and making available materials for visit and query resolution.	Annually, payable from site activation or first shipment arrival (whichever occurs first) and then each activation anniversary until Pharmacy COV.	**$2,800.00**

	• Updating Standard Operating Procedures. • Email correspondence. • Managing financial aspects of the study.		
Amendment Fee	Applicable to a Protocol amendment that includes a major amendment to the drug protocol and a change in Pharmacy process and revision of Pharmacy fees is required, e.g. for additional drug/s, cohorts, etc.	Per Protocol amendment.	**$1,500.00**
Close Out Fee	Covers the pharmacy close-out activities and finalisation of study requirements upon study completion by Sponsor including, but not limited to: • Finalising all relevant documentation and processes. • Completion of drug accountability logs / IWRS drug accountability final reconciliation. • Archiving of records. • Final monitoring meetings.	Once per study, following the Pharmacy COV and completion of all required follow up actions.	**$600.00**
Annual Storage Fees *For bulky goods that occupy more than the standard allocated space, the storage fee may need to be revised to commercial rates.*			
Room Temperature (ambient) Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1000.00**
Refrigerator Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,200.00**
-20°C Freezer Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,200.00**
-65-80°C Freezer Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$2,000.00**

Cytotoxic, Schedule 8 or Schedule 9 Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,200.00**
Storage of Returned Stock Fee	When participant returns or outer cartons are kept for periods beyond 3 months awaiting a monitor's visit or for a shorter period where the study packaging takes up a large amount of space and the returns process requires Pharmacy involvement.	Annually, only if required.	**$400.00**
Dispensing Fees *Will appear on the invoice as the drug name.*			
IP Dispensing Fee (Simple)	• Includes drug accountability. • Cancelled doses are subject to a dispensing fee if a dose has been dispensed/prepared.	Per participant, per dispensing visit, per item, per strength.	Min. **$110.00** for the first kit **$40.00** per each subsequent item dispensed on the same visit
IP Dispensing Fee	• Additional tasks are required such as using both trial logs and narcotic registers • A trial where pharmacy conducts additional IWRS transaction such as logging data for the randomisation, kit verification or other steps during or after the dispensing process • Study specific requirements e.g. double handling/signing of all logs and prescriptions	Per participant, per dispensing visit, per item, per strength.	Min. **$220.00** for the first kit **$40.00** per each subsequent item dispensed on the same visit
Aseptic Preparation Fee (Simple)	• Includes drug accountability. • Cancelled doses are subject to a dispensing fee if a dose has been dispensed/prepared.	Per Preparation	Min. **$350.00** for the first 3 vials **$80.00** for each additional vial if >3
Aseptic Preparation Fee (Complex)	• Multiple manipulations/additional product handling • Compounding time ≥ 20 minutes • IMP with short shelf life (≤12 hours) • Special requirements • Actual compounding fee will depend on the level of complexity	Per Preparation	Min. **$440.00** for the first 3 vials **$80.00** for each additional vial if >3
Additional Fees			

Pharmacy Call Back (Afterhours) Fees	Charged when a pharmacist is required to complete IP dispensing outside of standard hours. Applies to activity before 8:00am and after 4:30pm Monday - Friday, weekends and public holidays.	Per occurrence.	**$800.00** (for IP dispensation) **$2,000.00** (for aseptic preparation)
Onsite Destruction / Reconciliation Fee	For used/unused IP or any retained packaging destroyed on-site and completion of associated documentation.	Per occurrence.	**$160.00**
Destruction of Shipping Containers Fee	Time taken for on-site destruction of any shipping containers left behind by the delivering courier (if required).	Per occurrence.	**$35.00**
Pharmacist Training Fee	For undertaking IMP-specific mandatory online training modules	Per occurrence.	**$160.00**
Remote Monitoring Fee	To cover the time that the Pharmacist is engaged to the remote call and pre- and post-monitoring tasks including scanning the paperwork and sending electronic documents to the CRA.	Per hour (minimum 1 hour), per occurrence.	**$200.00**
Relabelling Fee	When the Pharmacists need to relabel all relevant IMPs with new Sponsor-provided labels (e.g. with updated retest date or other changes) and complete documentation.	Per hour (minimum 1 hour), per occurrence,	**$160.00**
Drug Transfers Fee	Includes but not limited to: • Transfer of study drug/shipment to external compounding facility via external courier vendor. • Transfer of study drug to another site (at discretion of PI and/or Sponsor). • Direct to patient transfers.	Per occurrence, only as required, with Sponsor request and/or approval.	**$110.00 handling fee plus transport costs**
Miscellaneous Pharmacy Services	For undertaking any additional activities not described in the Pharmacy manual, requested by the Sponsor.	Per hour, per occurrence at Sponsor request.	**$160.00**
Drug Costs	For any supportive medications to prevent and/or treat study-drug related AEs. If eligible for PBS subsidy, the Sponsor will be required to pay the co-payment (this will increase as dictated by the PBS each calendar year).	Payable only if required.	**20% handling fee plus drug costs**

Late invoice payment fee	Applies to an undisputed invoice that remains unpaid for more than 3 months from the date of issue. This fee will be applied every 3 months that each invoice remains overdue.	Every 3 months the invoice remains overdue.	**$100.00**
Pharmacy fees will increase annually by 3.5% rounded to whole dollar (5 or 10) and applied from the initiation date.			

***Complex trial:** Any early-phase trial with multiple dose cohorts or involving genetically modified organisms (GMOs), that require multiple manipulations to prepare the investigational product or additional product handling. This also includes any manufacturing process that requires a substantial amount of staff time.*

Clinical trials Schedule of Fees with Slade Health 2026 – Sponsored

The fees below do not include GST

Item	Inclusions (and not limited to)	Payable	Cost
Administrative Fees			
Set-up Fee	This fee is independent of participant accrual and includes all administrative procedures associated with setting up the study. This may be charged even if the study is ceased before SIV, to cover for services utilised, including but not limited to: • Protocol familiarisation, including attendance at relevant meetings, e.g. SIV, pre-site visits. • Liaising with Sponsors and study coordinators and monitors, including budget negotiations. • Establishing pharmacy start-up procedures. • Initial stock management, handling and storage set up. • Education of staff. • Completion of study monitoring and documentations, accountabilities, etc. • Completion of SIV training. • Does not include 1st year administration fee.	Once per study, payable following Site Activation.	**MUH Pharmacy $2,800.00** **Slade Health $3,500.00**
Annual Administration Fee	This fee is fixed for the first year and will be prorated for any partial years thereafter. Includes all procedures associated with the ongoing administration for the study, but not limited to: • Management and handling of shipments, receiving/recording stock and expiry management. • Ongoing liaison with Investigators, study coordinators and monitors. • Managing standard documentation, review of amendments where no change in the Pharmacy process is required. • Handling of participant returned investigational product. • Monitoring visits - booking visit and making available materials for visit and query resolution.	Annually, payable from site activation or first shipment arrival (whichever occurs first) and then each activation anniversary until Pharmacy COV.	**MUH Pharmacy $2,800.00** **Slade Health $2,000.00**

	• Updating Standard Operating Procedures. • Email correspondence. • Managing financial aspects of the study.		
Amendment Fee	Applicable to a Protocol amendment that includes a major amendment to the drug protocol and a change in Pharmacy process and revision of Pharmacy fees is required, e.g. for additional drug/s, cohorts, etc.	Per Protocol amendment.	**MUH Pharmacy $1,500.00**
Close Out Fee	Covers the pharmacy close-out activities and finalisation of study requirements upon study completion by Sponsor including, but not limited to: • Finalising all relevant documentation and processes. • Completion of drug accountability logs / IWRS drug accountability final reconciliation. • Archiving of records. • Final monitoring meetings.	Once per study, following the Pharmacy COV and completion of all required follow up actions.	**MUH Pharmacy $600.00** **Slade Health $600.00**
Annual Storage Fees *For bulky goods that occupy more than the standard allocated space, the storage fee may need to be revised to commercial rates. If IMP is stored at Slade Health, the annual storage fee will depend on the storage condition and the number of IMPs.*			
Room Temperature (ambient) Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$990.00**
Refrigerator Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,100.00**
-20°C Freezer Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,200.00**
-65-80°C Freezer Storage	• This fee is fixed for the first year and will be prorated for any partial years thereafter. • Includes temperature monitoring and temperature log device calibration.	Annually, payable from date first IP shipment received.	**$1,400.00**
Cytotoxic, Schedule 8 or	• This fee is fixed for the first year and will be prorated for any partial years thereafter.	Annually, payable from date first IP	**$1,100.00**

Schedule 9 Storage	• Includes temperature monitoring and temperature log device calibration.	shipment received.	
Storage of Returned Stock Fee	When participant returns or outer cartons are kept for periods beyond 3 months awaiting a monitor's visit or for a shorter period where the study packaging takes up a large amount of space and the returns process requires Pharmacy involvement.	Annually, only if required.	**$400.00**
Dispensing Fees *Will appear on the invoice as the drug name.* *Slade Health Compounding fee also includes MUH Pharmacy dispensing/handling fee.*			
IP Dispensing Fee (Simple)	• Includes drug accountability. • Cancelled doses are subject to a dispensing fee if a dose has been dispensed/prepared.	Per participant, per dispensing visit, per item, per strength.	**$110.00** for the first kit **$40.00** per each subsequent item dispensed on the same visit
IP Dispensing Fee (Complex)	• Additional tasks are required such as using both trial logs and narcotic registers • A trial where pharmacy conducts additional IWRS transaction such as logging data for the randomisation, kit verification or other steps during or after the dispensing process • Study specific requirements e.g. double handling/signing of all logs and prescriptions	Per participant, per dispensing visit, per item, per strength.	**$220.00** for the first kit **$40.00** per each subsequent item dispensed on the same visit
Aseptic Preparation Fee (Simple)	• Includes drug accountability. • Cancelled doses are subject to a dispensing fee if a dose has been dispensed/prepared.	Per Preparation	Min. **$280.00** for the first 3 vials **$65.00** for each additional vial if >3
Aseptic Preparation Fee (Complex)	• Multiple manipulations/additional product handling • Compounding time ≥ 20 minutes • IMP with short shelf life (≤12 hours) • Special requirements • Actual compounding fee will depend on the level of complexity	Per Preparation	Min. **$350.00** for the first 3 vials **$65.00** for each additional vial if >3
Slade Health Compounding Fee	• Aseptic preparation of IMP in GMP-compliant, TGA-licensed compounding facility using Class 2/3 safety cabinets • Processing compounding orders from hospital pharmacy	Per Preparation	**$TBC** as per complexity tier

	• Ensuring correct batch/vial numbers are used per site IRT instructions • Clinical trial labelling on finished product • Provision of clinical trial batch production report for every prepared dose • Return of empty cartons to hospital pharmacy • Transport of compounded dose to hospital pharmacy in a validated SH shipper within the scheduled delivery times		
Additional Fees			
Pharmacy Call Back (Afterhours) Fees	Charged when a pharmacist is required to complete IP dispensing outside of standard hours. Applies to activity before 8:00am and after 4:30pm Monday - Friday, weekends and public holidays.	Per occurrence.	**$800.00** (for IP dispensation) **$2,000.00** (for aseptic preparation)
Onsite Destruction / Reconciliation Fee	For used/unused IP or any retained packaging destroyed on-site and completion of associated documentation.	Per occurrence.	**$160.00**
Destruction of Shipping Containers Fee	Time taken for on-site destruction of any shipping containers left behind by the delivering courier (if required).	Per occurrence.	**$35.00**
Pharmacist Training Fee	For undertaking IMP-specific mandatory online training modules	Per occurrence.	**$160.00**
Remote Monitoring Fee	To cover the time that the Pharmacist is engaged to the remote call and pre- and post-monitoring tasks including scanning the paperwork and sending electronic documents to the CRA.	Per hour, per occurrence.	**$200.00**
Relabelling Fee	When the Pharmacists need to relabel all relevant IMPs with new Sponsor-provided labels (e.g. with updated retest date or other changes) and complete documentation.	Per hour (minimum of 1 hour), per occurrence.	**MUH Pharmacy** **$160.00** per hour
		Per occurrence. Minimum charge of $140.00	**Slade Health** **$140.00** for first 10 kits **$10** per each additional kit (>10 kits)

Drug Transfer Fee (from MUH)	Includes but not limited to: • Transfer of study drug/shipment to external compounding facility via external courier vendor. • Transfer of study drug to another site (at discretion of PI and/or Sponsor). • Direct to patient transfers.	Per occurrence, only as required, with Sponsor request and approval.	**$110.00 handling fee plus transport costs**
Adhoc Delivery of Prepared IP from Slade Health to MUH	• Outside the scheduled standard delivery times. • The actual cost may vary depending on the urgency and time of the day.	Per occurrence.	Min. **$190.00**
Miscellaneous Pharmacy Services	For undertaking any additional activities not described in the Pharmacy manual, requested by the Sponsor.	Per hour, per occurrence at Sponsor request.	**$160.00**
Drug Costs	For any supportive medications to prevent and/or treat study-drug related AEs. If eligible for PBS subsidy, the Sponsor will be required to pay the co-payment (this will increase as dictated by the PBS each calendar year).	Payable only if required.	**20% handling fee plus drug costs**
Late invoice payment fee	Applies to an undisputed invoice that remains unpaid for more than 3 months from the date of issue. This fee will be applied every 3 months that each invoice remains overdue.	Every 3 months the invoice remains overdue.	**$100.00**
Pharmacy fees will increase annually by 3.5% rounded to whole dollar (5 or 10) and applied from the initiation date.			

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