# Macquarie University Clinical Trial Unit

## CLINICAL TRIAL START UP OF SPONSORED TRIALS

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Clinical Trials is what we do so that our patients have access to state of the art treatments. 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 and expedite 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).

## OUR TEAM AND FACILITIES

### THE MQ CTU TEAM

Our portfolio includes phase I to phase IV trials and a wide range of therapeutic areas particularly oncology, cardiovascular, respiratory, ophthalmology, endocrine, gastrointestinal, neurology, surgical drug & medical devices and radiological interventions. The PIs that work with the CTU are chosen because they see patients with the condition outlined in the inclusion criteria of the protocol and because they have clinical trial experience. The CTU supports the conduct of the trial with clinical trial coordinators, clinical trials assistants, a quality team, clinical trial trainees and start up and finance associates. A CTU organogram is provided in Appendix 1.

### MQ CTU FACILITIES

The trials at Macquarie University CTU draw on the world class facilities at the Macquarie University Hospital and the clinical expertise within the Faculty of Medicine, Health and Human Sciences. Our CTU offices are located on Level 3 at 75 Talavera Road, Macquarie University next door to the Macquarie University Hospital (3 Technology Place Macquarie University). We use clinic space for seeing trial patients at 2 or 3 Technology Place, Macquarie University. Bloods are processed and stored in a clinical trial dedicated section of specialised PC-2 labs at 2 Technology Place. The infusion suite, imaging and pharmacy services are provided onsite in the hospital.

Our PIs use electronic medical records, and we have an electronic investigator site file (ISF) system that facilitates remote monitoring. We also have a dedicated monitoring space to accommodate on site monitoring and can accommodate a maximum of 6 monitors a day. For ease of monitoring, we provide monitor screens that the Sponsor monitors can utilise, allowing them to view electronic medical records and the eCRF at the same time.

## INVESTIGATIONAL PRODUCT MANAGEMENT

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

Pharmacy Macquarie University Hospital

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. When Baxter is involved, Pharmacy will inform the sponsor and e-mail the Baxter 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.

# CONFIDENTIALITY AGREEMENTS (CDAS)

To expedite review of protocols for feasibilities our PIs will sign Investigator CDAs. To further facilitate the trial feasibility process, especially if we are likely to have multiple protocols to review, the Macquarie University Research Office can sign an umbrella institutional CDA. If the CDA is a pre-approved MQ template the turnaround time can be as little as a day or two. If the CDA requires legal review it can take 4 to 6 weeks.

# THE MQ CTU FEASIBILITY PROCESS

## WHAT HAPPENS WHEN YOU SEND US A PROTOCOL TO REVIEW?

Protocols received by the CTU are allocated by the relevant Program Lead or CTU Manager to potential PIs to review and consider. The PI reviews the protocol with the Program Lead/CTU managers to estimate the number of participants that would be feasible; the resources we would need and the expected start up times are considered in light of our current trials. Oncology trials are further reviewed at a fortnightly oncology clinical trial meeting.

We welcome feedback. Whether we are selected or not, please let us know if the study will be proceeding at Macquarie University. We try to limit competing studies and are balancing studies to ensure treatment options for a range of patient groups.

## SITE SELECTION VISITS

We conduct site selection visits in person, by Zoom/MS Teams and by phone. The PI and one of the Program Leads/CTU Managers usually attend those meetings. The Clinical Trial Pharmacist is usually able to accommodate a separate meeting on the same day. A virtual tour of our facilities is preferred to in person tours where possible (https://www.youtube.com/watch?v=8OFakdfyjyA).

# 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. For phase I studies, in the case of multicentre studies, MQ CTU can accept ethical approval from another participating centre, provided MQ University is listed as site on the ethics approval letter. For single centre phase I studies, MQ CTU submit applications to Bellberry. Depending on resource availability at the time of submitting, 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 our outlined in the Appendix 2 decision tree.

## MQ 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.

## DOCUMENTS REQUIRED FOR THE MQ 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 patient information and consent form consistent with the NHMRC template (https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources)
- Participant study summary (1 page) which 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)
- NHMRC HREA form (https://hrea.gov.au/)
- A list of documents being submitted. Please include document version numbers.
- MQ Ethics Checklist (to be completed by the MQ start up and regulatory associate)
- Draft TGA CTN/CTX form
- HREC invoice form (Emailed to you to complete – information must align with the CTRA)
- Expected date of first participant included
- 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)
- 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.

## NOT FOR HREC SUBMISSION, REQUIRED FOR BUDGET / CTRA

- Contract:
    - Pharmaceutical clinical trials: A Medicines Australia (MA) Clinical Trial Research Agreement including a draft trial budget https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/
    - Medical Device Clinical Trials: Medical Technology Association of Australia (MTAA) Clinical Investigation Research Agreement including a draft budget https://www.mtaa.org.au/clinical-investigation-research-agreements
- Indemnity Form – Standard (HREC indemnity only form is not required as MQ HREC is covered under the standard indemnity)

  - Pharmaceutical clinical trials: MA Standard Indemnity Form https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/
  - Medical Device Clinical Trials: MTAA Standard Indemnity Form https://www.mtaa.org.au/clinical-investigation-research-agreements
- Insurance certificate/ statement of insurance for $20 million AUD

## 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). The Clinical Trial Unit endeavours to support the submission of up to 5 new trials to each HREC meeting. Notify our start up team as far in advance as possible which meeting you would like to aim for.

**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 (require protocol synopsis minimum) simultaneously to the HREC submission. The CTU will then apply for final Governance Authorisation after receiving HREC approval, fully executed CTRA (including Pharmacy agreement if separate to the MU CTRA), fully executed standard indemnity and current insurance certificate. Final Governance Authorisation to commence the trial occurs within 5-10 days of the CTU application.

Site Initiation visits (SIV) may be conducted once these approvals are in place.

# INDEMNITY, CTN, BUDGET, CONTRACTS AND FINANCE

## INDEMNITY DETAILS

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

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

## 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 | Jennifer Rowland |
| 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 | 0298504194 |
| 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* | rebecca.ohanessian@mq.edu.au |

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

| **Pharmacy Details** | |
|---|---|
| Name: | MUPharm Pty Limited trading as Macquarie University Hospital Pharmacy |
| Physical Location: | Ground Floor, 3 Technology Place<br>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.

## NEGOTIATING A BUDGET WITH THE CTU

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 3).
- Protocol procedures are costed at Australian Medical Association (AMA) rates.
- 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, $680 will be charged, and $340 for subsequent visits.
- Study coordinator time is charged at $90 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 patient 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 patient is treated for a trial related AE/SAE at Macquarie University Hospital, rather than expecting the patient 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 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 Sponsor. The Institution will inform the Sponsor as soon as practicable of a Research Injury.*

- Patient travel reimbursement:
    - We provide trial participants with a $70 gift card to cover the costs of their petrol and parking in attending each trial visit.
    - Travel Expenses for Study Participants travelling beyond 50 km will be reimbursed at the current ATO rate per kilometre if travelling by own car, or taxi fees. Such reimbursement shall be based on actual receipts, odometer readings or information provided by the Study Participant. Such reimbursement will require prior approval from the Sponsor.
    - For regional participants, approval will be sought from the sponsor to cover a participant's expenses for travel, meals, and accommodation at the onsite Mercure Hotel.
- 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.

The MUH Pharmacy (independent of Macquarie University) has fixed costs as well (Appendix 4). Budgets and contracts should be negotiated directly with the Pharmacy. If the pharmacy costs are paid to the CTU to pass onto the pharmacy, they will incur the Macquarie University 25% overhead fees. This overhead can be saved by paying the pharmacy directly. A separate CTRA can be set up between the pharmacy and the sponsor OR pharmacy can be added as a second payee on the Macquarie University CTRA.

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) with the HREC submission package.

## 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: | Head of Clinical Operations |
| 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 |

If Pharmacy costs are being paid to the pharmacy directly (this is what we recommend), the following payee details should also be included in the CTRA:

| | |
|---|---|
| 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 | BankWest |
| Bank Address: | 403 George Street, Sydney, NSW 2000 |
| Account Name: | MUPharm Pty Ltd |
| BSB Number: | 302 598 |
| Account Number: | 0007512 |
| Swift Code: | BKWAAU6P |
| Payment Notices to: | accounts@mupharm.com.au |

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

- If there are additions to the CTRA Schedule 7, an 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 patient 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.

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.

# CTU DOCUMENTATION

The MQ CTU has an electronic medical records system for most therapeutic areas as well as an electronic Clinical Trial Management System (CTMS) with electronic site document storage capacity supporting the documentation of most of our clinical trials.

## ELECTRONIC MEDICAL RECORDS (EMR)

The eMR system many of our PIs use is Odyssey (https://odysseyemr.com.au/). Odyssey is customised for clinical trials including supporting adverse event logs and concomitant medication logs with electronic investigator sign off. We can provide direct (onsite or remote) access to Odyssey eMR to relevant third parties (eg Sponsor). Prior to granting access, third parties will be required to sign a Deed of Confidentiality and Request for eMR Access Form which details the conditions under which access is provided. Creation of the eMR account will take up to 2 weeks. Access will be provided up to 24 hours prior to and following the duration of confirmed monitoring visit/audit.

In cases where direct access is not permitted, certified printed copies will be available. Our coordinators will provide support for periodic reviews of the eMR to ensure paper records are accurate. Please note that the CTU does not have the resources available in general to support redacting source data to support remote source data verification unless in circumstances where on-site monitoring is not allowed per institution policy (e.g. COVID-19 restrictions).

## 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, 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.

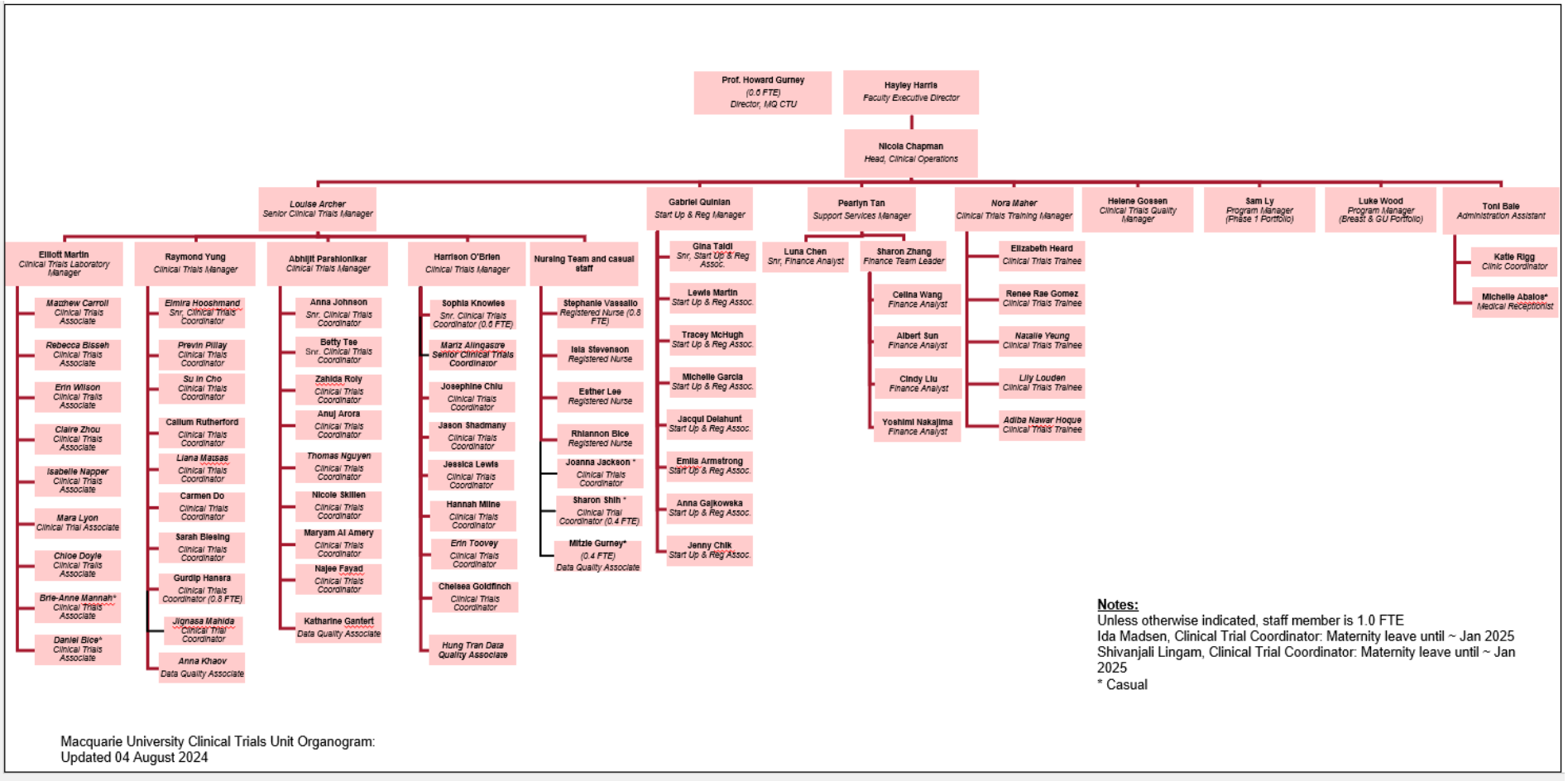
## CLINICAL TRIAL ARCHIVING

The electronic ISF in Real Time allows indefinite document storage. The patient 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.

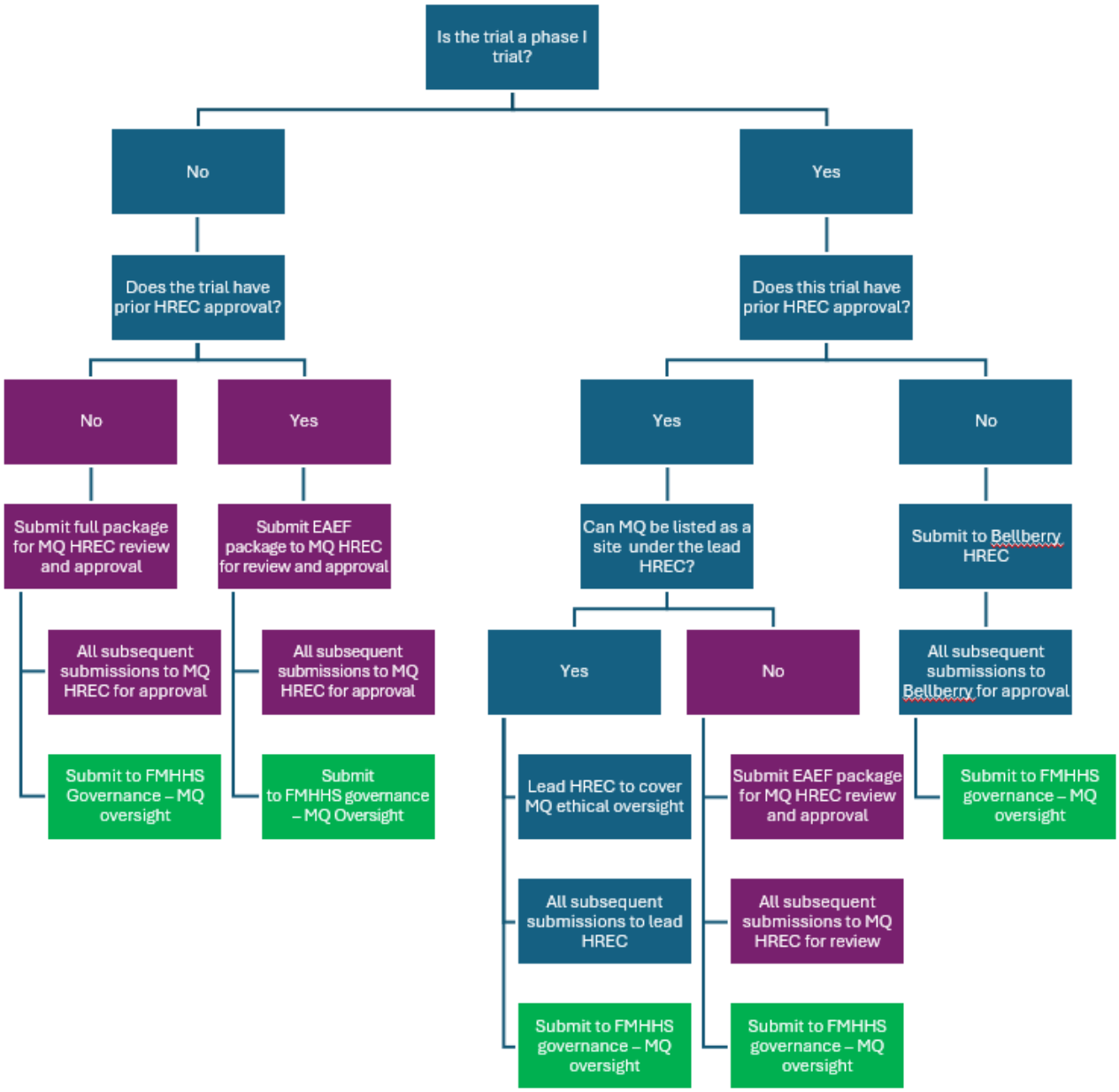
# Clinical Trial start up at MQ



## Appendix 1 – CTU organogram



## Appendix 2 – HREC Decision Tree



## Appendix 3 – 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) | $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. It includes but is not limited to HREC reporting, monitoring visit, query resolution, data locks, stationary costs, RealTime CTMS vendor costs, recovery of material/ docs from other institutes, ordering study supply, mailouts/ couriers, filing, stationary, device ongoing accountability, device storage, device courier, staff training for protocol amendments, PI correspondence with sponsors, additional review of AEs/SAEs, data review, discussion of patients and sign-off and review of protocol amendments, annual reports, SUSARs and other HREC submitted documents etc. |
| 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 | $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. |

| MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees | | | Site Comments |
|---|---|---|---|
| **SR. NO.** | **ITEM DESCRIPTION** | **Total Incl 25% OH (AUD $) Excl GST** | |
| 6 | Radiology Set Up fee | $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.** |
| 7 | Ophthalmology Set up Fee | $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 | $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 | $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 | HREC Amendment Preparation Fee | $650 | Major amendments fee to be paid to CTU. This fee accounts for processing and handling of amendments submitted to MQ HREC. 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 MQ HREC fee. |
| 11 | HREC Amendment Preparation Fee | $260 | Minor amendments fee to be paid to CTU. This fee accounts for processing and handling of amendments submitted to MQ HREC. Amendments will be determined to be minor at the discretion of the CTU. This cost is independent of the MQ HREC Fee. |
| 12 | SAE Reporting | $375 | Per SAE. This includes follow-up reports |
| 13 | Re-consent fee | $175 | Per patient reconsented if reconsenting is required to be done. |

| MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees | | | Site Comments |
|---|---|---|---|
| SR. NO. | ITEM DESCRIPTION | Total Incl 25% OH (AUD $) Excl GST | |
| 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). |
| 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 (initial operational area) | $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 | Fee is directly payable to Governance. Please refer to the MQ policy online regarding the fee (within step 2: Initial MQ Health governance endorsement) 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 4 - MUH Pharmacy Clinical Trial costs

### MUH Pharmacy Clinical trials Schedule of Fees – Oral and Injection (excluding Phase I trials) 2024

***The fees below do not include GST and are subject to an additional MQ University 25% OH if paid to the CTU. This additional OH can be avoided by negotiating a direct agreement with the MUH Pharmacy or including MUH Pharmacy in the CTU contract as 2nd payee***

***Fees will increase annually by 3.5% rounded to whole dollar (5 or 10) and applied from the initiation date.***

| | |
|---|---|
| **Establishment (Initial) –** Does not include 1st year administration fee<br>This is independent of participant accrual and includes all administrative procedures associated with setting up the trial. This may be charged even if trial is ceased before SIV, to cover for services utilised.<br>• Protocol familiarization, including attendance at relevant meetings eg SIV, pre-site visits<br>• Liaising with sponsors and trial coordinators & monitors<br>• Education of staff<br>• Initial stock management and handling<br>• Completion of trial monitoring and documentations, accountabilities etc. | $2300 (one off) |
| **Establishment Fee (Amendments)**<br>Applicable to protocol amendments that include an amendment to the drug protocol. (For additional drug/s, cohorts, etc) | $1500 /occasion |
| **Annual Administration –** Charged from trial start up SIV or first shipment arrival (whichever occurs first). This fee is fixed for the first year and will be prorated for any partial years thereafter.<br>This includes all procedures associated with the ongoing administration of the trials.<br>• Management and handling of shipments and receiving/recording stock.<br>• Ongoing liaison with investigators, trial coordinators and monitors.<br>• Managing documentation, review amendments where no change in the pharmacy process is required.<br>• Handling of patient returned investigational product.<br>• Monitoring visits: Booking visit and making available materials for visit and query resolution.<br>• Updating Standard Operating Procedures<br>• Email correspondence.<br>• Managing financial aspects of trial. | $2300 /year |
| **Completion –** Payable following the close our visit.<br>• Completion of drug accountability logs / IWRS drug accountability final reconciliation<br>• Archiving of records<br>• Final monitoring meetings | $600 |
| **Dispensing** | |
| IMP dispensing (simple) | $100 /first kit/item/ /patient/visit/strength |
| IMP dispensing (complex)<br>A dispensing episode which requires additional time when compared to a simple dispensing. This may include but is not limited to: | $130 /first kit/item/ /patient/visit/strength |

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| • Additional tasks are required such as using both trial logs and narcotic registers<br>• 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<br>• Study specific requirements e.g. double handling/signing of all logs and prescriptions | |
| Additional recordable drug | $30 /subsequent kit on the same visit |
| Aseptic reconstitution (simple) | $260 /preparation (up to 3 vials) |
| Aseptic reconstitution (complex)<br>• Multiple manipulations/additional product handling<br>• Compounding time ≥ 20 minutes<br>• IMP with short shelf life (≤12 hours)<br>• Special requirements | $330 /preparation (up to 3 vials) |
| Additional Aseptic reconstitution | $65 /each additional vial ( >3vials/ preparation, additional charge) |
| **Call back** (M-F before 8am&after 4:30pm, Weekends, Public Holidays) | $600 for IP dispensing<br><br>$1500 for aseptic preparation |
| **Storage*** *Payable at 12-month intervals from arrival of Investigational Product at the Institution. This fee is fixed for the first year and will be prorated for any partial years thereafter.*<br>**For bulky trials taking up a large amount of space, this may need to be negotiated at commercial rates. Note: Current commercial rates are $200 per month for 0.21m² + retrieval fees.* | |
| Room temperature | $975 /year |
| Refrigerator/freezer (-20 degree Celsius) storage | $1100 /year |
| Freezer (-80 degree Celsius) storage | $1400 /year |
| Cytotoxic storage (room or fridge) | $1100 /year |
| **Destruction/Reconciliation**<br>For used/unused IMPs or any retained packaging destroyed on-site. | $160 /occasion |
| **Administrative fee incurred for the return of IMP**<br>When pharmacists need to organise the courier and process paperwork on behalf of the CRA | $160 /occasion |
| **Destruction of Shipping containers**<br>For on-site destruction of shipping containers left behind | $35 /occasion |
| **Storage of returned Stock** (kept for periods beyond 3 months)<br>When patient returns are kept for periods beyond 3 months awaiting a monitor's visit or for a shorter period where the trial packaging takes up a large amount of space and the returns process requires pharmacy involvement. | $350 /year |
| **Pharmacist training**<br>For undertaking IMP-specific training due to protocol/pharmacy manual amendment | $160 / occasion |
| **Remote Monitoring** | $200 /hour |

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| To cover the time that pharmacist is engaged to the remote call and pre and post monitoring tasks including scanning the paperwork and sending electronic documents to CRA | |
| **Relabelling**<br>When pharmacists need to re-label the IMPs with new sponsor-provided labels (e.g. with updated retest date or other changes) | $160 / hour (minimum $160) |
| **Miscellaneous Pharmacy Services**<br>For undertaking any additional activities not described in pharmacy manual requested by the sponsor | $160 / hour |
| **Drug costs**<br>20% handling fee for any drugs required to be bought by the pharmacy for the study.<br>Patients should not be out of pocket for their participation in clinical trials. Where a trial involves using drugs reimbursed under the PBS the sponsor will be required to pay the co-payment which is current for that year, and this will increase as dictated by the PBS each calendar year. | |
| **Drug transfers**<br>Includes but not limited to:<br>• Transfer of study drug/shipment to external compounding facility via external courier vendor<br>• Transfer of study drug to another site (at discretion of PI and/or sponsor)<br>• Direct to patient transfers | $100 handling fee /event plus transport costs*<br><br>**Commercial rates apply* |

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

*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.*

*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.*

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

## MUH Pharmacy Clinical trials Schedule of Fees – Phase 1 Trials

***The fees below do not include GST***

***Fees will increase annually by 3.5% rounded to whole dollar (5 or 10) and applied from the initiation date.***

| | |
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| **Establishment (Initial) –** Does not include 1st year administration fee<br>This is independent of participant accrual and includes all administrative procedures associated with setting up the trial.<br>• Protocol familiarization, including attendance at relevant meetings eg SIV, pre-site visits<br>• Liaising with sponsors and trial coordinators & monitors<br>• Education of staff<br>• Initial stock management and handling<br>• Completion of trial monitoring and documentations, accountabilities etc. | $3000 (one off) |
| **Establishment Fee (Amendments)**<br>Applicable to protocol amendments that include an amendment to the drug protocol. (For additional drug/s, cohorts, etc) | $1500 /occasion |
| **Annual Administration –** Charged from trial start up SIV or first shipment arrival (whichever occurs first). This fee is fixed for the first year and will be prorated for any partial years thereafter.<br>This includes all procedures associated with the ongoing administration of the trials.<br>• Management and handling of shipments and receiving/recording stock.<br>• Ongoing liaison with investigators, trial coordinators and monitors.<br>• Managing documentation, review amendments where no change in the pharmacy process is required.<br>• Handling of patient returned investigational product.<br>• Monitoring visits: Booking visit and making available materials for visit and query resolution.<br>• Updating Standard Operating Procedures<br>• Email correspondence.<br>• Managing financial aspects of trial. | $2800 /year |
| **Completion –** Payable following the close our visit.<br>• Completion of drug accountability logs / IWRS drug accountability final reconciliation<br>• Archiving of records<br>• Final monitoring meetings | $800 |
| **Dispensing** | |
| IMP dispensing (simple) | $150 /first kit/item/ /patient/visit/strength |
| IMP dispensing (complex)<br>A dispensing episode which requires additional time when compared to a simple dispensing. This may include but is not limited to:<br>• Additional tasks are required such as using both trial logs and narcotic registers<br>• 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<br>• Study specific requirements e.g. double handling/signing of all logs and prescriptions | $200 /first kit/item/ /patient/visit/strength |

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| Additional recordable drug | $50 /subsequent kit on the same visit/item |
| Aseptic reconstitution (simple) | $350 /preparation (up to 3 vials) |
| Aseptic reconstitution (complex)<br>• Multiple manipulations/additional product handling<br>• Compounding time ≥ 20 minutes<br>• IMP with short shelf life (≤12 hours) | $400 /preparation (up to 3 vials) |
| Additional Aseptic reconstitution | $80 /each additional vial ( >3vials/ preparation, additional charge) |
| **Call back** (M-F before 8am&after 4:30pm, Weekends, Public Holidays) | $1000 for IP dispensing<br><br>$2000 for aseptic preparation |
| **Storage*** *Payable at 12-month intervals from arrival of Investigational Product at the Institution. This fee is fixed for the first year and will be prorated for any partial years thereafter.*<br>**For bulky trials taking up a large amount of space, this may need to be negotiated at commercial rates.*<br>*Note: Current commercial rates are $200 per month for 0.21m² + retrieval fees.* | |
| Room temperature | $1000 /year |
| Refrigerator/freezer (-20 degree Celsius) storage | $1200/year |
| Freezer (-80 degree Celsius) storage | $2000 /year |
| Cytotoxic storage (room or fridge) | $1200/year |
| **Destruction/Reconciliation**<br>For used/unused IMPs or retained packaging destroyed on-site | $160 /occasion |
| **Administrative fee incurred for the return of IMP**<br>When pharmacists need to organise the courier and process paperwork on behalf of the CRA | $160 /occasion |
| **Destruction of Shipping containers**<br>For on-site destruction of shipping containers left behind | $35 /occasion |
| **Storage of returned Stock** (kept for periods beyond 3 months)<br>When patient returns are kept for periods beyond 3 months awaiting a monitor's visit or for a shorter period where the trial packaging takes up a large amount of space and the returns process requires pharmacy involvement. | $350 /year |
| **Pharmacist training**<br>For undertaking IMP-specific training due to protocol/pharmacy manual amendment | $160 / occasion |
| **Remote Monitoring**<br>To cover the time that pharmacist is engaged to the remote call and pre and post monitoring tasks including scanning the paperwork and sending electronic documents to CRA | $200 /hour |
| **Relabelling** | $160 / hour (minimum $160) |

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|---|---|
| When pharmacists need to re-label the IMPs with new sponsor-provided labels (e.g. with updated retest date or other changes) | |
| **Miscellaneous Pharmacy Services**<br>For undertaking any additional activities not described in pharmacy manual requested by the sponsor | $160 / hour |
| **Drug costs**<br>20% handling fee for any drugs required to be bought by the pharmacy for the study.<br>Patients should not be out of pocket for their participation in clinical trials. Where a trial involves using drugs reimbursed under the PBS the sponsor will be required to pay the co-payment which is current for that year, and this will increase as dictated by the PBS each calendar year. | |
| **Drug transfers**<br>Includes but not limited to:<br>• Transfer of study drug/shipment to external compounding facility via external courier vendor<br>• Transfer of study drug to another site (at discretion of PI and/or sponsor)<br>• Direct to patient transfers | $100 handling fee /event plus transport costs*<br><br>**Commercial rates apply* |

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

MACQUARIE University

*Macquarie University is a vibrant hub of intellectual thinkers, all working towards a brighter future for our communities and our planet.*

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