



Macquarie University Clinical Trial Unit

CLINICAL TRIAL START UP OF SPONSORED TRIALS





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Clinical Trial start up at MQ

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, Cathie Chester (catherine.chester@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 in the 2 Technology Place, Macquarie University. Bloods are processed and stored in a clinical trial dedicated section of specialised PC-2 labs in the same building. The infusion suite, imaging and pharmacy services are provided onsite in the hospital.

Most of 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.

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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

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 particular protocol 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)

In order to expedite review of protocols for feasibility our Principal Investigators will sign Investigator CDAs. In order 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 has to go to legal review it can take 4 to 8 weeks.

THE MQ CTU FEASIBILITY PROCESS

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WHAT HAPPENS WHEN YOU SEND US A PROTOCOL TO REVIEW?

Protocols received by the CTU are allocated by the start up team to potential Principal Investigators to review and consider. The PI reviews the protocol with the 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 fortnightly oncology clinical trial meetings.

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 many 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 Clinical Trial Managers usually attend those meetings. The Clinical Trial Pharmacist is usually able to accommodate a separate meeting on the same day and we are happy to provide a tour of our facilities.

THE MACQUARIE UNIVERSITY ETHICS PROCESS

All trials conducted through the MQ Clinical Trial Unit must have Ethics approval from the Macquarie University Human Research Ethics Committee. MQ is outside of the mutual acceptance schemes.

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 submission system.

DOCUMENTS REQUIRED FOR THE MQ HREC SUBMISSION

In order 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

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(<https://www.nhmrc.gov.au/research-policy/ethics/ethical-issues-and-resources>)

- Any additional information that will be provided to trial participants (customised with site specific details if applicable)
- NHMRC HREA form (<https://hrea.gov.au/>)
- Participant study summary
- A list of documents being submitted. Please include document version numbers.
- Another HREC approval letter for the trial if the trial is **phase I**. If MQ is the only site we will submit the study to Bellberry prior to MQ HREC. Ongoing HREC oversight will be transferred from Bellberry to MQ after the preliminary review. *Please note this is required for phase I trials only!*
- MQ Ethics Checklist (to be completed by the MQ start up and regulatory associate)
- 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 form is not required)
 - Pharmaceutical clinical trials: A MA Standard Indemnity Form
<https://www.medicinesaustralia.com.au/policy/clinical-trials/indemnity-compensation-guidelines/>
 - Medical Device Clinical Trials: A MTAA Standard Indemnity Form
<https://www.mtaa.org.au/clinical-investigation-research-agreements>
- TGA CTN/CTX form
- HREC invoice form (https://www.mq.edu.au/data/assets/pdf_file/0003/580422/HRECFee-schedule.pdf)
- Expected date of first participant included
- Insurance certificate/ statement of insurance for \$20 million AUD
- Any Advertising Materials that will be used (if applicable)
- For applications involving radiation in excess of Clinical Care, a Radiation Safety report
- Data Management Plan

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

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the CTU start up team no less than 2 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://staff.mq.edu.au/research/resources-and-support/fmhs-research-resources/clinical-research-governance>

The CTU will make an initial application to the Governance team (Step 1) simultaneously to the HREC submission. Final Governance Authorisation to commence the trial (Step 4) occurs within 5-10 days of receiving a signed CTRA and HREC approval.

Site Initiation visits (SIV) can be conducted once the CTRA has been executed and Governance approval is in place.

BUDGET, CONTRACTS AND FINANCE

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 2).
- 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, up to \$635 will be charged, and up to \$350 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

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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.

- We provide most trial participants with a \$50 gift card to cover the costs of their petrol and parking in attending each trial visit. However, if participants live further than 50km away, we reimburse mileage at the current ATO rate. For the current financial year this is set at 78 cents per kilometre.
- 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.
- We cannot support the use of the Greenphire system
- Macquarie University charges 25% overheads 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 3). 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 costs. 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 break down 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

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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

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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 Manager.

- 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 FINANCE AND BILLING

The CTU does not accept recipient created invoices. Invoices will be generated quarterly and will

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reflect trial visits and procedures completed. We are also unable to accommodate withholding of part payments until the end of the study.

Our payment terms include that payment is due within 30 days of receipt of invoices.

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. At this stage the eMR does not allow FDA compliant access for monitoring so certified paper copies of eMR records will be provided for monitoring. Our coordinators will support periodic review of the eMR to confirm paper records are complete.

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 etc.

CLINICAL TRIAL ARCHIVING

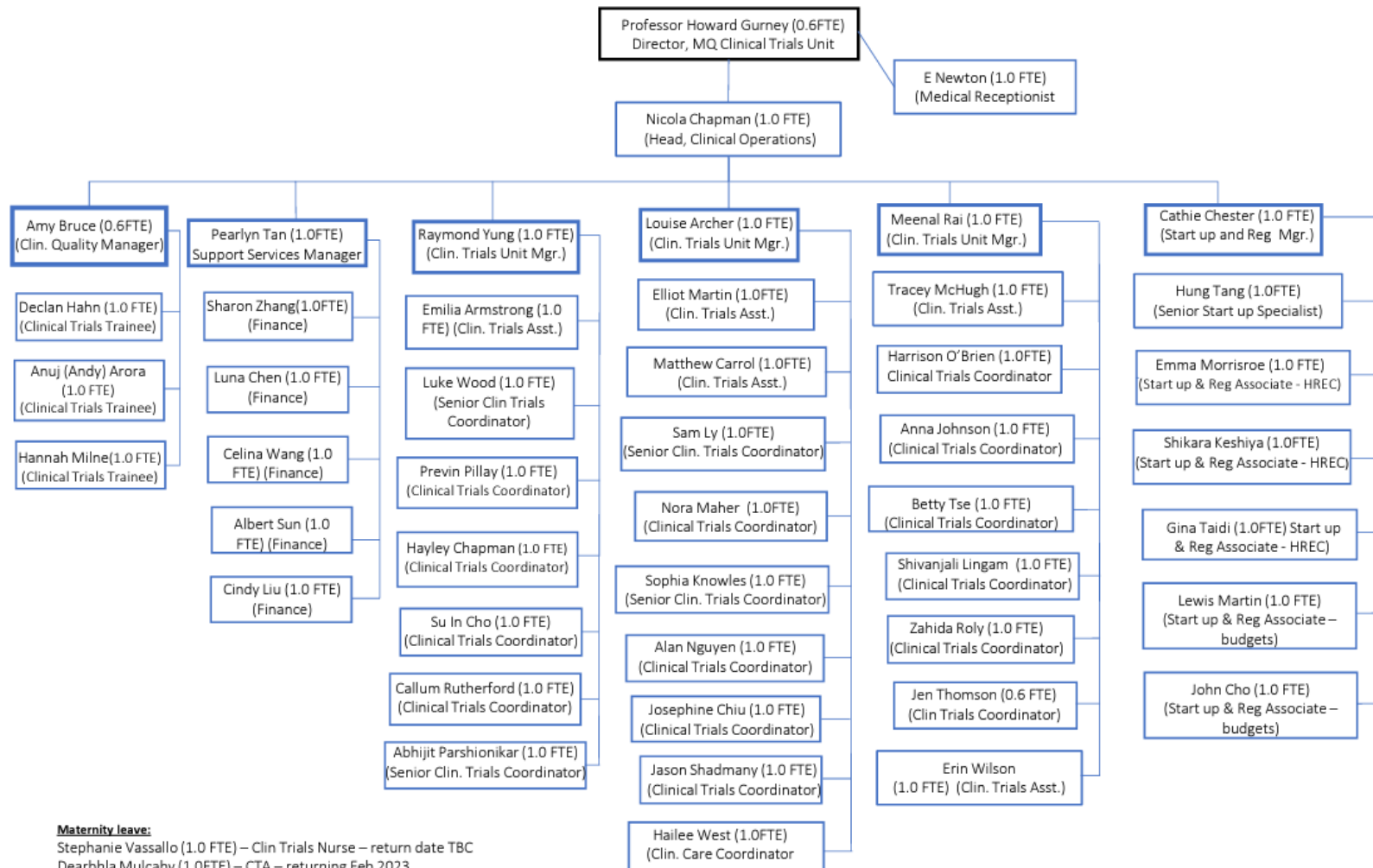
The electronic ISF in Real Time allows indefinite document storage. The patient paper files are

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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.

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Appendix 1 – CTU organogram



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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	
1a	Site Start Up Fee	\$7800.00	Includes HREC processes, admin costs, teleconference/training time, and all study related start up activities.
1b	Site Start Up Fee – FOR PHASE 1 TRIALS	\$8840.00	Includes HREC processes, admin costs, teleconference/training time, and all study related start up activities. This increased fee is only applicable for Phase 1 trials whereby MQ University CTU is required to submit to Bellberry HREC in addition to MQ University HREC. Only one start up fee will be charged.
2	Radiology Set Up fee	\$1300.00	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.
3	Laboratory Set up Fee	\$1300.00	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 with a pathology component.
3a	Quarterly Laboratory Storage Fee (from first patient screened)	\$390.00	Fee is only applicable for studies where batch processing and shipment of central samples is required. This fee accounts for the storage of samples and maintenance of logs.
4	Ophthalmology Set up Fee	\$1300.00	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.
5	Site Close down fee	\$1950.00	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.
6a	Quarterly Site ongoing administration fee (from Site Initiation Visit)	\$1040.00	This fee accounts for all activities and admin work undertaken by site to deliver as per study protocol. It includes but is not limited to HREC reporting; monitoring visit, query resolution, data locks, stationary costs, recovery of material/ docs from other institutes, ordering study supply, mailouts/ couriers, filing, stationary, device ongoing accountability, device storage, device courier, etc.
6b	Quarterly Site ongoing administration fee (from Site Initiation Visit) – FOR ALL PHASE 1 TRIALS	\$2340.00	This fee accounts for all activities and admin work undertaken by site to deliver as per study protocol. It includes but is not limited to HREC reporting; monitoring visit, query resolution, data locks, stationary costs, recovery of material/ docs from other institutes, ordering study supply, mailouts/ couriers, filing, stationary, device ongoing accountability, device storage, device courier, etc.

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MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees			Site Comments
SR. NO.	ITEM DESCRIPTION	Total Incl 25% OH (AUD \$) Excl GST	
			Additional cost associated with Principal Investigator or Sub-Investigator attending Safety Review Committee (SRC) meetings up to every 2 weeks (between 30min – 2hours per meeting). Including associate paperwork (i.e. pre-meeting patient reports by PI/Sub-I, post SRC dosing discussion review and approval reports).
7	HREC Amendment Fee (per occurrence)	\$650.00	Major amendments fee to be paid to CTU. This fee is to account 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.
8	HREC Amendment Fee (per occurrence)	\$260.00	Minor amendments fee to be paid to CTU. This fee is to account 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.
9	Tele-conference and protocol training fee	\$438/hour (investigator) \$113/hour (trial coordinator)	This fee is charged when site staff are required by Sponsor to attend a tele-conference/telephone call for medical follow up regarding medical events. This fee is also applicable for study training required by Sponsor for protocol amendments.
10	Remote Monitoring Fee	\$208/hour	Remote monitoring visits are not encouraged at MQ Uni CTU, however this fee should be applied in extraordinary circumstances when on-site monitoring visits are not allowed per institution policy (e.g. during COVID-19 lockdown). This hourly rate is charged for the time spent by the CTC to prepare for remote monitoring visits (redact source document, provision of redacted source to the Sponsor). The time will be tracked by the CTC, no more than 2 hours shall be spent preparing for each remote monitoring visit.
11	Archiving fee	\$1456.00	One off fee payable after Approval of Final Report. Standard archiving period is 15 years. Cost will increase if longer archival period is required. N/A if sponsor is Archiving.
12	Archiving retrieval fee (where applicable)	\$195.00	This fee is charged by the storage company to retrieve stored documents. It is charged per occasion.
13	Audit fee (if and when applicable)	\$1300.00	Accounts for time invested during, before and after audit by site. This is a conditional cost. Charged per audit, max of 3 days.
14	Radiation Assessment Fee	\$520.00	In the event radiation assessment is required for patient safety. Ethics committee requirement in NSW.

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MACQUARIE UNIVERSITY CLINICAL TRIALS - Standard Site Fees			Site Comments
SR. NO.	ITEM DESCRIPTION	Total Incl 25% OH (AUD \$) Excl GST	
15	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 - https://staff.mq.edu.au/research/resources-and-support/fmhs-research-resources/clinical-research-governance/governance-for-fully-sponsored-clinical-trials
16	MQ HREC Fees	As invoiced by HREC	All HREC Fees are payable directly to HREC & are available on the MQ HREC website - https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/human-ethics/resources
17	Electronic Investigator Study Files	\$1950.00 (set up) \$100/quarter (maintenance fee)	MQ CTU uses RealTime CTMS system for storing the ISF. These fees cover the costs charged by the vendor. The set-up fee is a one-time initial set up fee which includes the first 2 years of quarterly maintenance fee. If the study is ongoing for more than 2 years, \$100/quarter shall be charged to account for the maintenance fee.
18	Oncology Day Care – chair costs	\$975.00	Cost per occurrence (1 chair/1 day); intravenous infusion(s) of study IP
19	Administration of Sub Cutaneous intra muscular IP in clinic	\$506.25	Includes x2 Nurses to check & administer drug (SC/IM, no more than 15mins administration time). Plus 1 hour observation by CTC. Additional observation period will be charged accordingly at \$113 per hour if required.
20	Completion of pathology reference ranges by Site	\$440.00	If Sponsor requires Macquarie University CTU staff (i.e. Trial Coordinator) to enter pathology reference ranges into the eCRF, a fee is required for the time spent. This applies to Douglass Hanly Moir Pathology only and additional pathology centres would incur additional costs. Current budget is 4.5 hours (includes time spent entering data and responding to queries generated by DM/CRA etc). Fee is payable for each pathology practice, per year.
21	SIP platform use	\$187.50	Creation of site profile and ongoing management of study staff profiles. Annual Fee, charged from SIV.
22	Respiratory Lab Set Up Fee	\$1300.00	One off fee whereby respiratory lab staff are required to complete study specific training, and set up of the study in the respiratory lab.
23	Institutional overhead (IO)	Applied to all costs	Macquarie University apply 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%. To waive or reduce this overhead, the Sponsor will need to make a written request explaining the rationale behind their request and submit to the Deputy Vice Chancellor – Research. Please note that this will incur extra time for contract approval.

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Appendix 3 - MUH Pharmacy Clinical Trial costs



Clinical trials Schedule of Fees – Oral and Injection 2023

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

Fees will increase annually by 2.5% rounded to whole dollar (5 or 10) and applied from the initiation date.

<p>Establishment (Initial) – Does not include 1st year administration fee This is independent of participant accrual and includes all administrative procedures associated with setting up the trial.</p> <ul style="list-style-type: none"> • Protocol familiarization, including attendance at relevant meetings eg SIV, pre-site visits • Liaising with sponsors and trial coordinators & monitors • Education of staff • Initial stock management and handling • Completion of trial monitoring and documentations, accountabilities etc. 	\$2200 (one off)
<p>Establishment Fee (Amendments) Applicable to protocol amendments that include an amendment to the drug protocol. (For additional drug/s, cohorts, etc)</p>	\$1500 /occasion
<p>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. This includes all procedures associated with the ongoing administration of the trials.</p> <ul style="list-style-type: none"> • Continued stock management and handling • Continued management of trial documentations • Monitor visits 	\$2200 /year
Dispensing	
Oral dispensing	\$100 /item/patient/visit/strength
Additional recordable drug	\$30 /subsequent item on the same visit
Aseptic reconstitution (For Phase 1 study, please note there might be higher preparation fee if complex/multiple dose escalation parts are involved.)	\$240 /preparation (simple, up to 3 vials)
Additional Aseptic reconstitution	\$65 /vial (>3vials/ preparation additional charge)
Call back (M-F before 8am&after 4:30pm, Weekends)	\$600 for orals \$1500 for aseptic preparation
<p>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. *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.</p>	
Room temperature	\$850 /year

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Refrigerator/freezer storage	\$950 /year
Cytotoxic storage (room or fridge)	\$950 /year
Destruction/Reconciliation	\$160 /occasion
Destruction of Shipping containers	\$30 /occasion
Administrative fee incurred for the return of IP	\$160 /occasion
Storage of returned Stock (kept for periods beyond 3 months) 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
Remote Monitoring	\$200 /hr
Relabelling	\$160 / hour (minimum \$160)
Drug costs 20% handling fee for any drugs required to be bought by the pharmacy for the study. 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 to another institution or study participant	\$100 /event plus transport costs
Completion	\$550

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.

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



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

A PLACE OF INSPIRATION

Macquarie is uniquely located in the heart of Australia's largest high-tech precinct, a thriving locale which is predicted to double in size in the next 20 years to become the fourth largest CBD in Australia.

Our campus spans 126 hectares, with open green space that gives our community the freedom to think and grow. We are home to fantastic facilities with excellent transport links to the city and suburbs, supported by an on-campus train station.

RENOWNED FOR EXCELLENCE

We are ranked among the top two per cent of universities in the world, and with a 5-star QS rating, we are renowned for producing graduates that are among the most sought after professionals in the world.

A PROUD TRADITION OF DISCOVERY

Our enviable research efforts are brought to life by renowned researchers whose audacious solutions to issues of global significance are benefiting the world we live in.

BUILDING SUCCESSFUL GRADUATES

Our pioneering approach to teaching and learning is built around a connected learning community: our students are considered partners and co-creators in their learning experience.

FIND OUT MORE

Macquarie University NSW 2109 Australia
T: +61 (2) 9850 7111
mq.edu.au

ABN 90 952 801 237
CRICOS Provider 00002J