HUMAN RESEARCH (CLINICAL): UTILISATION OF HOSPITAL RESOURCES - CHW

POLICY©

DOCUMENT SUMMARY/KEY POINTS

- This policy governs the use of The Children's Hospital at Westmead's (CHW) clinical resources for human clinical research activities. These include access to Pharmacy, Pathology, Nuclear Medicine, Medical Imaging, Allied Health, Nursing, Blood and Marrow Transplant and Turner Unit facilities and services.
- It is mandatory that all investigators abide by these policies.
- Briefly, the use of all CHW clinical resources for conducting human clinical research is on a "user-pay" basis unless otherwise negotiated by the Principal Investigator and the appropriate Manager of the facility/service.
- The use of all CHW clinical resources for human clinical research activities will be at the discretion of the relevant service/facility Manager and will depend on the criteria outlined in this document.
- This document is relevant for :
  - Sponsored Clinical Trials
  - Investigator driven trials
  - Investigator driven collection of clinical data or specimens

CHANGE SUMMARY

Update to the following sections:

- Background – Abbreviations, Turner Unit, Pharmacy, Diagnostic Services, Nuclear Medicine.
- Prerequisites for Access to CHW Clinical Services & Facilities for Clinical Research and Clinical Trials
- Bookings – Turner Unit, Nuclear Medicine, Diagnostic Services, Nursing
- Additional Roles and Responsibilities – Turner Unit, Nuclear Medicine
- Schedule of Fees – Pharmacy, Turner Unit, Diagnostic Services
- Administration of Fees, Contacts, Summary, References

READ ACKNOWLEDGEMENT

- Clinical investigators and other health workers involved in human clinical research activities are to read and acknowledge they understand the contents of this document.
- Key staff in Pharmacy, Pathology, Nuclear Medicine, Medical Imaging, Allied Health, Nursing, Blood and Marrow Transplant and Turner Unit where requests for use of their services will be made, are to read the document.

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Abbreviations

CRN = Clinical Research Nurse

CTC = Clinical Trial Coordinator

GCP = Good Clinical Practice

ICH = International Conference on Harmonisation

NUM = Nurse Unit Manager

PI = Principal Investigator

SSA = Site Specific Application

Background

The Children's Hospital at Westmead (CHW) strongly supports clinical research and clinical trials. Access to CHW resources for the conduct of clinical trials and clinical research has been forthcoming and generous to date. The Clinical Research Centre, was established to ensure the number of research projects conducted at CHW increases. There will be a concomitant increase in demand for some CHW services and facilities. To optimally manage changes in demand and prevent an exhaustion of resource capacity, policies and procedures are required that direct a more consistent and transparent process for accessing, booking and remunerating those CHW departments impacted by clinical research. This policy and related links have been created for this purpose of better resource management and to assist clinical investigators in planning their study.

Turner Unit

Turner Unit is a unique combination of a Medical Day Stay, Care by Parent and Endocrine Testing. Together it provides specialist care to chronic and acutely unwell children 0-18 yrs. This includes Haematology, Immunology, Dermatology, Endocrinology, Gastroenterology, Bone Service and Cardiology. The Medical Day Stay Unit primarily treats children who require regular treatment, pre and post general anaesthetic or oral sedation care. The Care by Parent Unit provides accommodation to families whose children require hospital services without the need for 24 hour nursing care. The Endocrinology Testing Unit operates as an out-patient and day stay unit where children attend for short periods and undergo specialist testing and treatment. Given the breadth of experience and excellent reputation of the nursing staff in Turner Unit, the facility is a popular choice for clinical investigators wishing to conduct clinical trials that involve outpatient or short-stay interventions, especially endocrine studies.

Pharmacy

The Pharmacy Department has a dedicated Clinical Trials Pharmacist and operates a Clinical Trials Service. The primary aim of the Pharmacy Clinical Trials Service is to optimise patient's outcomes by working to achieve the best possible quality use of investigational medicines that is safe, ethical and complies with the relevant Acts, Standards and Professional Codes of Practice. The Service is working alongside with the hospital clinical

trials multidisciplinary teams and has its unique contributions towards the participants care, and the institutional management of Investigational drugs, research and development of new drugs.

Diagnostic Services

Diagnostic Services provides a comprehensive and integrated specimen collection and testing service to The Children's Hospital at Westmead. The Department has been a long-term supporter of clinical research and clinical trials and has used its experience and knowledge to support the dissemination of new knowledge within the academic community. A list of available tests and services is available by contacting the Pathology Services Manager.

Nuclear Medicine

The Department of Nuclear Medicine provides a comprehensive, specialised, paediatric service for both inpatients and outpatients. The service includes:

- performing research into the application of Nuclear Medicine in paediatrics at a clinical and basic research level,
- using radiopharmaceuticals, both in vivo and in vitro, for diagnostic, therapeutic and investigative purposes,
- incorporating Nuclear Medicine images with other modalities such as CT and MRI to improve diagnostic sensitivity, and
- the measurement and interpretation of bone mineral density and body composition.

Medical Imaging

The Department of Medical Imaging provides the following paediatric digital imaging and interventional services: General Radiography, Fluoroscopy, Ultrasound, Computed Tomography, Magnetic Resonance Imaging and Interventional Radiology. These services are available for research projects pending adequate resources being available.

Please note: Projects involving ionising radiation must have the dose calculations and associated risk information reviewed by a qualified Medical Physicist, this can be organised via the Radiation Safety Officer. The RSO will review all protocols submitted to the Human Research Ethics Committee that involve ionising radiation. It is highly recommended that all clinical investigators seek assistance from the RSO before submitting their Ethics Application.

Blood and Marrow Transplant

The Oncology Unit provides Bone Marrow Transplant (BMT) services for:

- Consultation
- Collection, cryo-preservation, manipulation, storage and infusion of Hematopoietic Progenitor Cells
- Pre-, peri- and post - transplant care of patients undergoing Blood and Marrow Transplant.

It is possible for Hematopoietic progenitor cells to be collected for research purposes but the logistics of this would make it imperative that the BMT service was consulted at an early stage in planning any study that required such cells.

Allied Health

The Division of Allied Health at The Children's Hospital at Westmead (CHW) constantly seek to develop a research culture and to improve clinical practice through strengthening its evidence base. The Division views cooperative research with other departments and units as a strategic advantage in developing research skills and programs.

Access Prerequisites for CHW Clinical Services & Facilities*

*(*for Clinical Research and Clinical Trials)*

In order to be eligible for accessing the clinical services and facilities of CHW for clinical research, including clinical trials, the following criteria must have been met:

1. The study must receive approval from a Human Research Ethics Committee (HREC) or its sub-committee. Quality Improvement Activities should be submitted to the Clinical Governance Unit for approval through CHARLI.
2. The study must receive Site Specific Authorisation from the Research Governance Manager and the Site Specific Application must have been signed off by all of the relevant Heads of Department (or delegates) or Divisions of the supporting Departments/ Wards/Units/Divisions.
3. Researchers must acknowledge that all CHW clinical resources must prioritise primary patient care. Please note that ethics approval does not automatically mean that CHW clinical services are bound to participate in the research project. This decision is at the discretion of each department and will depend on available resources.
4. **The Principal Investigator or delegate (e.g. Project Manager, CRA or CTC) must have attended a Planning Meeting with the appropriate Department or Division Manager** (see: Contacts). **This meeting should take place BEFORE submitting grant applications, ethics applications or site specific applications to ensure that sufficient capacity exists to support the study and also to agree on any appropriate remuneration and specific study requirements. Individual departments reserve the right to refuse any research project if it has not been previously discussed with the department, even if it already has site specific authorisation**.
5. 5. All requirements for the study must be presented to the appropriate manager during the Planning Meeting.

   The investigator must provide a copy of the protocol with study aims to each supporting group. This is essential since some Departments will need to confirm that the proposed methodology is appropriate and safe. *For example, Nuclear Medicine must confirm that the scan methodology and radiation doses are safe and will deliver the desired results BEFORE they can agree to support the project*. It is preferable to supply a copy of the protocol two weeks before the Planning Meeting so that these issues of safety and efficacy can be addressed at the Planning Meeting.

   At the planning meeting it should be determined the respective roles and responsibilities of all participants as part of the study protocol. The parties should reach agreements

about work-loads, duties, authorship or acknowledgement in presentations and publications at this stage. Agreements should be documented and ideally signed by all parties.

6. Issues taken into consideration before giving approval are:
   - The tasks involved
   - Desired appointment days, times and over-time requirements
   - The possible impact of the study on current workload and staffing requirements
   - Costs and available remuneration
   - Backup and storage of data or samples
7. Adequate funding for the trial must exist to cover service costs (as a guide some supporting services have provided guidance on what fees should be used to build budgets for review. Contact the Clinical Research Centre Manager at CHW for access to these. The funding must cover all staffing, consumables and other trial-related costs.
8. Provision of all equipment or consumables that are specific to the study and not usually available in the supporting Department should be provided by the Principal Investigator.
9. All study participants/recruits that fulfil the standard admission criteria of The Children's Hospital at Westmead must be admitted to the Hospital as either inpatients or outpatients and be allocated an MRN number.
10. The utilisation of CHW Nursing Staff, Medical Technologists, Allied Health Practitioners and Research Assistants should be the first choice for all research studies. In rare circumstances, personnel that are not employees of CHW may be assisting with clinical trials and be interacting with CHW patients. In these instances, these external personnel must become honorary (clinical) or contingent (non-clinical) CHW employees, which would involve mandatory safety checks that include criminal record, NSW Health Services and working with children checks. Additionally, relevant insurance and vaccination details must be confirmed. They must also attend a CHW orientation day and a ward/department orientation where they should provide comprehensive education to the relevant CHW staff about the trial/study and their planned activities.
11. The Nurse Unit Manager or Allied Health Department or Manager of a supporting group must be satisfied that any external clinical research nurses, trial coordinators or allied health practitioners active within CHW have the appropriate training and experience to independently perform the interventions specified in the study.

Bookings

Turner Unit

- To make bookings please call 51121 and discuss with NUM, TL or Ward Clerk.
- Bookings are to be made 4 weeks in advance of the admission date or commencement of the study/trial. These dates should be discussed at the original planning meeting.

- A Recommendation for Admission must be completed for all patients to be admitted to Turner Unit.
- Problems/clashes will be reviewed on a case by case basis.
- Clinic bookings will be given priority over research requests.

Nuclear Medicine

- Nuclear Medicine hours of business are 0900 to 1700, Monday to Friday. Any after hours requirements need to be discussed at the Planning Meeting.
- Medical Records Numbers will need to be allocated, and electronic orders created before contacting the department to arrange appointment times.
- To request an appointment, call 9845 2890 during business hours, or email Bone Density Bookings (dexam@chw.edu.au).

Medical Imaging

- General Radiography is available 0900 to 1700 Monday to Friday. After hours services are available by arrangement as agreed in the Planning Meeting.
- The Medical Imaging services will provide a schedule suitable for both parties after the evaluation of the resource required. In general, investigators should make their arrangement as soon as possible as demand on this clinical service is very high.
- As a minimum, four weeks will be required for general radiography or fluoroscopy, and 3 months for other modalities such as CT, MRI and US.

Pharmacy

- Contact the Clinical Trials Pharmacist prior to site specific application to discuss arrangements for drug dispensing and or other drug management services.

Diagnostic Services

- Blood Collections are available from 830-1630 Monday to Friday (non public holidays).
- Following and as a result of discussions during the Planning Meeting, the Pathology Services Manager will supply the project specific request form that each and every patient on that study must present with at Pathology. Agreement to fully support a study will not proceed until the Pathology Services Manager has liaised and received agreement with the relevant Diagnostic Services Heads responsible for areas that will be directly involved in this study. This is to ensure all the analyses and procedures required by the study can be performed within the constraints of relevant departmental resources, staff and funding
- If the trial is a sponsored trial and the sponsor has supplied a pathology request form, this may be used for bookings but must first be shown to the Pathology Services Manager at the planning meeting to ensure it is not ambiguous, confusing or erroneous.

Note: any clinical trial patients or specimens that present for blood collection or processing that there has been no agreement met /no contract signed, will be turned away from Pathology.

Blood and Marrow Transplant Services

- Bookings will be made via the Bone Marrow Transplant (BMT) Unit after consultation with The BMT Unit Head.

Allied Health

- Contact the CARPA Clinical Program Director for instructions on booking.

Nursing

- For nursing in wards other than Turner Unit, contact the Nurse Unit Manager of that ward.

Additional Roles and Responsibilities

Turner Unit

Staff in Turner Unit are primarily responsible for patient safety and the general well-being of all patients and their families. They are not responsible for monitoring study/trial protocols, recording study specific patient information or the overall management and coordination of the trial/study. These responsibilities are, of course, ultimately the responsibility of the Principal Investigator and/or Sponsor of the trial. They may be delegated to another study team member. They may be delegated to a member of Turner Unit but this must be by prior written agreement and never assumed. Study/Trial Coordinators should not write instructions for Turner staff to perform research-related tasks on patient charts without prior written consent from the NUM.

Whenever research is required to be undertaken in any other ward or involves specific nurses, communication with relevant Nursing Unit Managers is essential. The paragraph above relating to staff on Turner Unit applies to all wards at CHW.

Nuclear Medicine

For all Research Projects, the Researcher is responsible for:

1. Observing Good Clinical Practice.
2. Providing Electronic Orders or Medical Imaging Request forms.
3. Organising appointments.
4. Confirmation of appointments with subjects.
5. Consenting subjects. If required, copies of Patient Information and Consent Forms can be provided by Nuclear Medicine for these procedures.
6. Subject preparation
    i. Inform subjects about the procedures.
    ii. Ensure subjects are appropriately prepared and dressed.
    iii. Obtain the date of last menstruation and provide pregnancy testing (if applicable).

7. Sedation (if required). This includes:
    i. Supply and administration of medication.
    ii. Medical supervision of sedated subjects.
    iii. Booking a bed / room where sedation will take place.
8. Feedback of examination results to subjects
9. Informing Nuclear Medicine staff of any changes to protocol that impacts on Nuclear Medicine's role or responsibilities e.g. changes to the number of subjects or scans performed, changes to commencement date or study duration, or if the project is paused for an extended period of time as they will need to confirm that extension/continuation of project is possible.
10. All relevant data management, scan shipments and protocol-specific documentation.

Allied Health and Nursing Division

The Division of Allied Health/Nursing staff may be involved in research as a chief investigator, co-investigator, project coordinator or as a data collector as negotiated with the research team. In most instances, at least one member of an allied health discipline/nurse should be an investigator when this discipline is involved in the research project.

If existing information, including assessment/test data, collected by allied health/nursing staff is requested for analysis in a research project, the information will only be released under the following circumstances:

i. The project has been planned in consultation with the allied health/nursing departments involved
ii. The project has received HREC approval
iii. The Head of the respective Department has approved release of the data
iv. At least one member from allied health/nursing is involved as a co-investigator and co-author on any papers arising out of the research.

Schedule of Fees

- All investigators should review any schedules of fees provided by the relevant Department/Ward/Unit/Division. Contact the Clinical Research Centre Manager for access to these.
- It is necessary to levy these fees and charges to ensure that there are adequate resources for the efficient provision of clinical research services and support. The charges levied are not for revenue raising purposes but to meet some of the costs incurred in the provision of the service.
- Please note that these fees are separate and in addition to the Policy for **Fees for the Review of Ethics and Site Specific Applications**: http://chw.schn.health.nsw.gov.au/o/documents/policies/policies/2014-9044.pdf

- Investigators should ensure that all relevant fees and charges are reflected in the clinical trials agreement (contract) with the Sponsor (if appropriate).
- For Sponsored studies, funding for all resources related to the clinical study must be provided by the Sponsor, including reimbursement for human resources.
- Investigator-driven trials will have to be self-funded or paid for by their own research fund. The charges will be negotiated depending on the work-load, complexity of the trial and the amount of external support, if any, provided. All relevant clinical trial costs must be recognised through collaboration with the supporting Department prior to Ethics submission.
- Investigator-driven trials will be charged to the nominated research costs centre.

Pharmacy

- The Pharmacy Clinical Trials Service is reimbursed for drug costs, dispensing, labelling, IP handling, storage, accountability, archiving etc.
- Discussion with the Clinical Trials Pharmacist about the intended study requirements and pharmacy fees involved should happen prior to the submission of the study applications to HREC and Governance, to ensure adequate resources are available for the efficient provision of the service.
- The fees set for Pharmacy are in accordance with the NSW Association of Directors of Pharmacy University Teaching Hospital "Schedule of Fees for Clinical Trials". The CHW Pharmacy Schedule of fees is reviewed and updated yearly.
- The Pharmacy fees may vary depending from the study complexity and services required.
- A copy of the newest schedule of pharmacy's fees is obtained by contacting the Clinical Trials Pharmacist directly.
- Investigator or Sponsor should fill in the required sections of the provided schedule and return it to the Clinical Trials Pharmacist for review and /or discussion if required.
- The finalised and signed schedule of fees then will become an Agreement of Trial Fees.
- The fees quoted do not include GST, which will be charged as applicable
- The Clinical Trials Pharmacist invoices the sponsor or investigator directly for clinical trials fees.

Turner Unit

- Supervision or training of external CRNs or CTCs will incur extra costs.

Allied Health

Research funding may be used to employ additional allied health staff for a project or, alternatively, to employ staff to backfill an existing position to allow a staff member to participate in a research project. The Division of Allied Health may undertake to partially fund projects that are highly merited, closely linked and beneficial to clinical practice, and where the allocation of staff and resources is not detrimental to existing departmental services and activities.

Diagnostic Services

- The Diagnostic Services is reimbursed for venepunctures, specimen processing, specimen storage, packing and transport of specimens which is listed in the quotation.
- The Diagnostic Services is reimbursed for administrative costs of setting up and continuing the study which is listed in the quotation.
- Discussion with the Pathology Services Manager about the intended study requirements.
- The Pathology fees may vary depending from the study complexity and services required
- A quote will be sent to the coordinator or other nominated study member for approval and signature to agree to the costs to be charged for the work to be performed by Pathology for the study.
- The signed quotation of fees will then become an agreement of Trial Fees.
- The fees quoted do not include GST, which will be charged as applicable
- Any additions or alterations to the original quoted work must be requoted before progressing.
- The cost of any Pathology collection equipment e.g. blood tubes, urine jars that are not to be used for specimens to be analysed at CHW but forwarded onto an external laboratory will be charged for even though they may have not been included as part of the quote.
- The cost of other items such as required e.g. eskies, dry ice for transport of specimens to an external laboratory will be charged for if there is no general transport charge already listed and levied in the quote.

Administration of Fees

- Clinical trials fees will only apply for the services actually provided in the clinical trial
- The fees negotiated in the planning meeting may have to be revised if the workload and affiliated costs are much greater than anticipated. In this situation the details of any additional workload will be specified and provided to the investigator.
- The fees quoted do not include GST, which will be charged as applicable.
- The charges will be levied on establishment of the Clinical Trial, and then at negotiated intervals and at the closure of the trial. These fees are retrospective and reflect the actual use of resources. These regular invoices will be sent to the person nominated in the planning meeting to be responsible for accounts payable. This may be the Principal Investigator, a Department Accounts Manager/ Research Manager or a contact person in a company for Sponsored trials.

- Schedules of fees will be reviewed annually. If the trial hasn't started one year after the planning meeting it may be necessary to revise the project budget if fees have increased.
- Any fee policy will be administered by Finance as follows:
  - If fees are being sought directly from the Sponsor, Finance will be requested to issue a GST compliant tax invoice for the company by the service Department/Ward
  - If fees are being sought from the investigator, a journal transfer to the relevant cost-centre will be requested. **NOTE: It is advisable that all research funds be managed in a research cost centre that is separate to a Department's operating cost centre. This allows for transparency and easier auditing of research funds**.
- For Pathology, each trial is given a unique trial number to be used for booking and invoicing.
- Pharmacy administration fees for drug company trials will be charged directly to the Sponsor by Pharmacy.
- Any issues that the researcher/Sponsor has regarding the fee policy should be discussed at first instance with the contact people listed below for the relevant department. Outstanding issues should then be forwarded to the Research Development Manager or the Director of the supporting department.

Contacts

Clinical Research Centre

- Manager: Email clinicaltrials.schn@health.nsw.gov.au , 9845 3505

Pharmacy

- Clinical Trials Pharmacist: Phone 9845 0459, pager 7315

Nuclear Medicine

- Senior Scientist (Bone Mineral Density): Phone 9845 2897
- Chief Nuclear Medicine Scientist: Phone 9845 2897
- Department Head: Phone 9845 2904
- Radiation Safety Officer: Phone 9845 1892

Medical Imaging

- Chief Radiographer: Phone 9845 2909

Diagnostic Services

- Pathology Services Manager: Phone 9845 2204, pager 6332

Turner Unit

- Nurse Unit Manager: Phone 9845 1231, pager 6208

Blood and Marrow Transplant Services

- Senior Staff Oncologist: Phone 9845 2143, pager 6246

Community, Ambulatory, Rehabilitation, Population & Allied Health (CARPA)

- Clinical Program Director: Phone 9845 2765

References

1. The NSW Association of Directors of Pharmacy University Teaching Hospital: Policy: Schedule of Fees for Clinical Drug Trials NSW Teaching Hospitals Pharmacy Departments. 2014-2015
2. SHPA Standards of Practice for Pharmacy Investigational Drugs Services. JPPR. 2006, 36(1) 46-53
3. Therapeutic Good Administration. Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm#.VCDzel1xmUk

Summary

Check list

Prior to Ethics or Site Specific Application or Grant Submission

☐ Schedule a Planning Meeting with the relevant Manager (see contact list above) of each Department impacted by the study.

☐ Provide all the relevant study details and the Protocol and study aims to the supporting Department or Ward prior to the Planning Meeting.

☐ Agree on resource availability, fees and delegation of task responsibilities at the Planning Meeting.

☐ Wait for feedback from supporting Department/Ward staff confirming methodology, safety, resource availability and fee structure if this was not finalised at the Planning Meeting.

☐ Obtain signature of each Department/ Ward for a Site Specific Application (if appropriate).

After Ethics/Site specific approval:

☐ Supply a copy of final research protocol (if amended) & proof of Ethics approval (letter or approval number as required by each Department).

☐ Contact the Department/Ward to discuss project commencement date.