RBWH Research Services Update

February 2020

In this issue

- Stay tuned Research Services along with the RBWH Research Council is committed to improving the research experience and access to facilities and infrastructure at RBWH. As such, we will be sending out a short survey in the near future to help us understand what we are doing well and areas for improvement.

Safety Monitoring and Reporting

- New Safety Monitoring and adverse event reporting. We have recently updated our Safety Reporting advice for MNHHS researchers (please see attached). The advice will be published here: https://metronorth.health.qld.gov.au/research/ethics-and-governance/post-approval-reporting and attached with this electronic update. For clarification, where there is a commercial sponsor for a study, MNHHS Ethics and Governance do NOT require the following to be reported:
  - Single Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Adverse Events (AEs) that do not affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.
  - External SUSARs or device/non-therapeutic good equivalents
  - Six monthly line listings

Where MNHHS is the sponsor, all safety events for all sites for which MNHHS is responsible should be reported to the relevant MNHHS Research Governance Office.

Research Mentors

Have you considered being a mentor to staff undertaking research? Register your interest in being a research mentor at: https://metronorth.citizenspace.com/rbwh-intensive-care-services/8d1606d5; or contact Therese Starr, Research Coordinator-Research Services, for more information. As a research mentor you will be asked to provide an overview of your research background. This will be placed on the RBWH Internet page for potential mentees to contact you.

Good Clinical Practice (GCP) Training

- The National Safety and Quality Health Service (NSQHS) Standards (2nd ed) are now in place.
- Complementary to the NSQHS Standards is the National Clinical Trials Governance Framework.
- As part of accreditation, RBWH will be assessed on compliance with researcher GCP training
- Good clinical practice (GCP) is the international standard for conducting clinical research and provides a framework for ensuring participants' rights, safety and well-being are protected and the data generated is credible.
- Originally developed for pharmaceutical trials, this guidance has now become known as the "Good Clinical Practice" (GCP) guideline and has been widely adopted as the standard for all clinical research, not just clinical trials.
- From 1 January 2020, all researchers conducting **clinical trials** at RBWH must undertake formal GCP training. Evidence of this will be requested at the RBWH Research Governance submission.

- A free online ICH GCP training program can be accessed here: https://gcp.nidatraining.org/ or contact us for further information.
- Evidence of industry sponsored GCP training will also be accepted. It is also recommended that any researchers conducting other clinical research should undertake formal GCP training.

Research Ethics and Governance FAQs

The MNHHS Research Office last year published an FAQ on "What are Research Study "In-kind" Expenses?". This is one of the Site-Specific Assessment (SSA) application items that we continually have to request further information on from the applicant, which in turn delays your SSA application. We know many RBWH researchers do not have any funding and you often do work in your own hours, however, as a health service we still need to acknowledge these contributions.

What are Research Study "In-kind" Expenses?

It is important to understand and capture the full cost of a Research Study, in terms of non-cash (or "in-kind" contributions) and actual cash expenses. It is also important to understand the amount of time that people contribute towards the successful completion of a study, and the overall duration of a study, in order to ascertain its full impact on Metro North.

Research "in-kind" expenses do not just quantify the cost or impact, it is about recognising investment made by Metro North to support research endeavours and to understand the true value of Research. Therefore both "in-kind" and cash expenses are captured in the Research Study Budget.

In order to help understand the difference between these two types of costs further, the following definitions and examples may be of use:

- "In-Kind" costs: these are the costs, services, supplies and time which Metro North contributes towards supporting the outcome of the Research Study for which no invoices are raised and no actual costs are charged to the study. The primary example is labour costs where a QH employee gives their time to support a study. This time can either be during normal working hours, with the consent of their manager, or in their own time, for example evenings or at weekends. This time is therefore recorded in both hours and at a notional labour cost, including all on-costs in the Study Budget.
- Cash costs: these are the costs, services, supplies and time associated with a Research Study, where actual services or supplies are used during the study for which invoices will be paid, or costs will be actually incurred. Examples of such costs are Research Coordinators labour costs, pathology costs, imaging costs, pharmacy fees or clinical supplies. Funding and revenue to support the study should ordinarily be sufficient to cover the cash expenses, thus, as a minimum, the study should normally break-even financially.
- An important note with "in-kind" labour is that the rates used, and the approval given in the Study Budget, are calculated on normal labour rates for each person involved at their individual pay-point including all on-costs, not using overtime or penalty costs. The Study Budget does not approve overtime for a staff member to work on the project.

Observing at the RBWH Ethics Committee meeting

Do you want to know what happens during an ethics committee meeting? The RBWH HREC would like to offer research staff the opportunity of attending HREC meetings as observers. This would help staff to gain an appreciation and understanding of the purpose of the ethical review process and observe the discussions which take place at meetings. For more information, or to express an interest in observing, please contact the HREC Coordinator (telephone: 07 3646 5490 or email: RBWH-Ethics@health.qld.gov.au).

Researcher members needed for RBWH Human Research Ethics Committee (HREC)

There are currently vacancies for researchers on the RBWH Human Research Ethics Committee (HREC). These members provide input into the review of an application from the perspective of scientific merit and integrity. If you are interested in contributing once every two months, please contact the HREC Chairperson (Dr Gordon McGurk – email: gordon.mcgurk@health.qld.gov.au; or telephone: 07 3346 0331)

HREC Annual Reporting Requirements

Please note that, as from 01 January 2020, Annual Reports for **all** approved research studies should be submitted by 30 April each year. Therefore, to ensure ongoing ethical approval for your study, please submit an Annual Report for this year by 30 April 2020. Your next annual report due date will then be 30 April 2021 and so on.

As the HREC no longer has any expiry dates for research studies, requests for extension are no longer required to be submitted, however, ongoing ethical approval is contingent upon the submission of an annual report to be received by the due date, i.e. by 30 April each and every year.

Implementation of the Human Rights Act 2019 (Qld)- effect on research

The Human Rights Act 2019 (Qld) ('the Act') commenced in Queensland on 1 January 2020. The main objects of the Act are to:

- protect and promote human rights;
- help build a culture that respects and promotes human rights; and
- help promote a dialogue about the nature, meaning and scope of human rights.

The Act protects 23 fundamental human rights drawn from international human rights law. These are:

- Recognition and equality before the law
- Right to life
- Protection from torture and cruel, inhuman or degrading treatment
- Freedom from forced work
- Freedom of movement
- Freedom of thought, conscience, religion and belief
- Freedom of expression
- Peaceful assembly and freedom of association
- Taking part in public life
- Property rights
- Privacy and reputation
- Protection of families and children
- Cultural rights—generally
- Cultural rights—Aboriginal peoples and Torres Strait Islander peoples
- Right to liberty and security of person
- Humane treatment when deprived of liberty
- Fair hearing
- Rights in criminal proceedings
- Children in the criminal process
- Right not to be tried or punished more than once
- Retrospective criminal laws
- Right to education
- Right to health services.

As of 1 January 2020, all applications for research that are reviewed through the RBWH Human Research Ethics Committee process must consider whether any human rights may be limited; how any limitations may be justified; and how the application respects, protects and promotes human rights. This means that in addition to the application, applicants must provide further information for consideration. However, it is most likely that very few human rights may

be infringed during research and as such the workload for researchers is not expected to be significant, though as it is a legislative requirement, it is necessary.

The following table can be used to summarise:

1. Which human right may be impacted by the research?
2. What the impact/ limitation is
3. Whether it is justified (the factors that must be considered are:
    a. the nature of the human right;
    b. the nature of the purpose of the limitation, including whether it is consistent with a free and democratic society based on human dignity, equality and freedom;
    c. the relationship between the limitation and its purpose, including whether the limitation helps to achieve the purpose;
    d. whether there are any less restrictive and reasonably available ways to achieve the purpose;
    e. the importance of the purpose of the limitation;
    f. the importance of preserving the human right, taking into account the nature and extent of the limitation on the human right;
    g. the balance between the matters mentioned in paragraphs (e) and (f).
4. If necessary, and an amendment to the research is proposed, explain the amendment.

Step 1 – Identification of document and human right impact	Step 2 – Identification of specific limitation	Step 3 – General limitation (section 13 of Act)	Step 4 – Consider amendments
[Insert the human right impacted]	*[Does a specific or express limitation apply?* *If yes, record the provision in the Act that provides for this and stop here.* *If no, continue to step 3.]*	*[Is the limit justified under s 13?* *If yes, explain the justification with reference to s 13 and stop here.* *If no, continue to step 4.]*	*[If it is decided an amendment is required, explain the amendment here.* *If it is decided an amendment is not required, explain the reason here.]*

Contact Us:

Human Research Ethics Office
Phone: 07 3646 5490 / 3646 6132
Open: Monday-Friday, 8.00am – 3.00pm
Email: RBWH-Ethics@health.qld.gov.au

Research Governance Office
Phone: 07 3646 4301
Open: Monday-Friday, 7.45am – 3.45pm
Email: RBWH-RGO@health.qld.gov.au

**** Research Ethics & Governance Information Clinics****
Do you, or someone you know, need assistance with Ethics and SSA application(s)? Come to our Research Clinics!
To book an appointment, phone: 3646 4301. For more information see our website:
https://metronorth.health.qld.gov.au/research/ethics-and-governance/clinics