

RBWH Research Services Update



December 2019

Dear Researchers,

From all in Research Services we wish you an awesome festive season. Here are a few early presents for you to consider.

The HREC and Research Governance Offices will be closed for the Christmas period as from Monday, 23.12.2019 and will re-open for business on Monday, 06.01.2020.

HREC Submissions:

- The closing date for submission of all new Low Risk applications and all Amendment submissions, for review this year, is 09.12.2019.
- The closing date this year for the review of all responses to requests for further information is 16.12.2019.
- HREC applications will commence being sent out to reviewers on the week commencing 13.01.2020.
- The HREC closing and meeting dates for 2020 are in the attached Flyer.

Some of the things we've done in the last year:

- You may recall that we conducted a survey to listen to your concerns about Ethics and Governance. We listened, we heard, and we've acted. Here are some things that we have done over the last year to try and improve how we do things:
 - Did a webinar to try and clarify research from what isn't research (this is available via the Metro North website)
 - Made all applications electronic. This has removed the need for copious reams of paper. Submission is now via ERM with a parallel submission to the Ethics email account until we are certain that all studies are received on ERM.
 - A single application form for **all research** studies. These should be submitted on the HREA.
 - The **LNR form** is now only to be used for the submission of requests for exemption from HREC review, i.e. Quality Assurance, Audit, Service Evaluation, Case Report projects. However, the LNR form will be replaced with a specific QA application form next year.

Our Statistics for the 2019 Calendar Year:

HREC Submissions:

The HREC received the following submissions:

- 95 Greater than Low Risk studies
- 155 Low Risk studies
- 204 Requests for Exemption from HREC Review

The average number of days to approval is:

- 18 days for low risk research studies
- 20.5 days for greater than low risk research
- 10 days for exempt projects

RGO Submissions:

The RGO received the following submissions:

- 249 Site Authorisations
- 91 Contracts
- 44 Clinical Trials

The average number of days until site authorisation was 29 days.

Some thoughts for 2020 – how we will continue to improve:

- In 2020, we will be looking at changing our HREC process to seek responses from you before the meeting so that the application may be able to go through quicker and in a more responsive manner. **Stay tuned**
- We will be looking to redevelop the annual reporting form to be more of an exception report form, as it used to be, in order to save time and to collect only essential information.
- We are working on internal process flows to improve the reporting of SAE's via ERM, particularly for clinical trials in relation to HREC and RGO requirements. **Stay tuned**

- We strongly encourage you to submit your Ethics application and your Site-Specific Assessment (SSA) application at the same time. A parallel review and submission process have been shown to decrease the average commencement time of clinical trials by more than 100 days.
- We are committed to producing training and research user guides and videos.
- We will continue to conduct Ethics and Governance Clinics for all researchers. Please encourage any new researchers to attend. Experience and feedback have demonstrated that these clinics are very beneficial.

Research Clinical Trial Financial Management:

- The Royal Brisbane & Women's Hospital (RBWH) Foundation has made the decision that Research Clinical Trial financial management is no longer part of their core business. The Foundation intends to redirect their efforts towards philanthropic fund-raising. The RBWH Foundation will transfer the overall management of externally funded Clinical Trials to the RBWH in a staged approach:
 - For new trials this will be as of 1st February 2020
 - For existing trials this will be by 30th June 2020
 - Over the past 12 months consultations & working groups have occurred to ensure a smooth transition
- The Research Service Line's BAS Team will provide a central support service which includes the payment of expenses, patient reimbursements and invoice requests.
- For further information please contact Emma Raymond, the Research Business Manager - Emma.Raymond@health.qld.gov.au or on (07) 3646 2123

** Changes to Annual HREC Research Reporting Requirements**

Metro North Hospital and Health Service has introduced a new process relating to the submission of Annual HREC Reports. There is now a single date for the submission of all annual reports and removal of the need to seek an extension to HREC approval for projects, as long as a complete annual report is provided by the due date.

As of 1 January 2020, the Principal Investigator will be required to report to the respective HREC annually **by 30 April in that year** in the format specified from time to time in the Metro North Ethics and Governance webpage at: <https://www.health.qld.gov.au/metronorth/research/ethics-governance/post-approval-reporting/default.asp>

Continuation of Ethical approval will now be contingent upon the receipt of a complete Annual Report, as well as meeting the requirements as set out in the original approval letter. Submission dates for Annual Reports will be as follows:

Report due date	Submission date
1 July 2019 - 31 December 2019	Submit by due date
1 January 2020 - 31 December 2020	Submit by 30 April 2020
1 January 2021 - 31 December 2021	Submit by 30 April 2021

For further information or clarification regarding the Annual Reporting process, please contact the HREC Coordinators at either: RBWH: RBWH-Ethics@health.qld.gov.au Ph: 07 3646 5490; TPCH: ResearchTPCH@health.qld.gov.au; Ph: 07 3139 4500.

** 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>

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