Metro North Research

# Introduction to Clinical Research Principles 2021

## Update on Ethics and Governance Approval Processes in Metro North Health

04 May 2021 | Live via Microsoft Teams

Facilitated by Professor Janet Davies
Metro North Research
MetroNorthResearch@health.qld.gov.au

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Metro North Research

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# Agenda

**Topics covered:**

- Overview of HREC ethical review processes
- Processes for parallel ethical and governance submissions
- Review of current MNHHS research governance processes

**Ann-Maree Gordon**
**HREC Coordinator**
**Royal Brisbane & Women's Hospital**

- Coordinator for the RBWH Human Research Ethics Committee (HREC) for the past eight years and was the Assistant Coordinator prior to that.
- Has worked in Queensland Health for over thirteen years (twelve and a half years in the Research Ethics Office).
- Has vast experience providing advice to researchers on ethical topics, HREC applications and processes.

**Rebekah Steele**
**Research Governance Manager**
**Metro North MNHHS**

- Research background in physical activity behaviour and epidemiology; completed post-doctoral research program with the Medical Research Council, Cambridge, UK
- Has worked in a number of Queensland Health departments to lead and drive change to improve internal efficiencies, build stakeholder support, engage consumers and improve patient-centred care.

**Panel Discussion (10 min)**

What's next & session close

*Please do not mention any confidential details of patients or research.*

**Teams Virtual session,**

**Facilitated by Prof Janet Davies, MNHHS Office of Research MNHHS-Research@health.qld.gov.au**

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# Research Ethics Approval Processes in Metro North Health

Ann-Maree Gordon
Coordinator, Human Research Ethics Committee
Royal Brisbane & Women's Hospital, Metro North Health

V1 Effective: 05/2021

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## Metro North HRECs

- There are 2 HRECs in Metro North Health:
  - ➢the Royal Brisbane & Women's Hospital (RBWH) HREC
  - ➢The Prince Charles Hospital (TPCH) HREC.

- The RBWH HREC meets on the 2nd Monday of every month and TPCH HREC meets usually on the 4th Thursday of every month

- Meeting dates, HREC memberships, Terms of Reference and Standard Operating Procedures can be accessed on the Metro North Ethics and Governance webpage**.

- ** https://metronorth.health.qld.gov.au/research/ethics-and-governance/human-research-ethics-committee



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## ETHICS REVIEW MANAGER (ERM)

- All submissions to the HREC require uploading into Ethics Review Manager (ERM) - https://au.forms.ethicalreviewmanager.com/:
  - ➢New HREAs (for both greater than low risk studies and low risk studies) and the LNR form for requests for Exemption from HREC review for QA/Audit projects
  - ➢Post approval documents, e.g. Amendments, Progress Reports (Annual/Final/Notifications), Safety Reports, SUSARs, SAEs, DSURs, Protocol Deviations, Investigator's Brochures, Commencement Forms etc.
  - ➢Responses to HREC reviews

- For any ERM issues, please contact the relevant HREC office:
  - RBWH HREC: 3647 1007
  - TPCH HREC: 3139 4500

  **OR** for technical support - HIIRO_Reg@health.qld.gov.au
  - Helpdesk@infonetica.net



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## SUBMISSION GUIDANCE

- The MNHHS Ethics & Governance website provides guidance for submitting to the RBWH HREC and TPCH HREC: https://metronorth.health.qld.gov.au/research/ethics-and-governance

- The RBWH Research website is another useful resource tool and provides step-by-step instructions on ERM submission processes, as well as links to guidance documents: https://metronorth.health.qld.gov.au/rbwh/research/ethics



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## Ethical Review

- The HREC reviews applications in accordance with the National Statement** principles of Research Merit & Integrity, Justice, Beneficence and Respect.

- Ethical considerations include:
  - the aims, design and methodology of the study *(Research Merit)*
  - the experience and qualifications of researchers *(Integrity)*
  - the identification of participants and how and by whom they will be recruited *(Justice)*
  - Risks and how they will be managed *(Beneficence)*
  - Information provided to participants to afford informed consent *(Respect)*

** *https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018*



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## STUDY DESIGN / PROTOCOL

- A Protocol should be submitted with every application (whether a research study or Quality Assurance [QA] project).
- To address ethical concerns, it is important that a Research Protocol is clear and robust.
- A guideline on what is required in a Protocol can be accessed on both the MNHHS Ethics & Governance website (https://metronorth.health.qld.gov.au/research/ethics-and-governance/ethics-approval) **and** the RBWH Research website (https://metronorth.health.qld.gov.au/rbwh/research/ethics/pre-approval)
- Other useful website links for Protocol information and templates are:
  - ❖The Equator Network (SPIRIT) website - https://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/
  - ❖Metro North Allied Health website - https://qheps.health.qld.gov.au/metronorth/allied-health/research/research-resource-map/protocol-proposal

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## SUBMISSION REQUIREMENTS

- **All** study documentation must be uploaded into the application in ERM, e.g. Cover Letter, Protocol, Participant Information Sheets & Consent Forms (PICFs), Surveys, Data Collection Sheets, Investigator Brochures, CVs, etc.
- All documents need identifiers in the footers, i.e. document identifier, version number, date and page numbers (page 1 of 6, page 2 of 6, etc.).
- The application should clearly list the sites for approval, details of the Coordinating Principal Investigator and Principal Investigators.
- If requesting a waiver of consent for the confidential use of health information in a research project, please justify the request in the application in accordance with the National Statement section 2.3.10 **
- For multi-centre studies, only 'Master' documents should be submitted to the HREC. Site-Specific documents (based on the approved Master documents) are submitted to the relevant Research Governance Office.

** *https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018*

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## *SUBMITTING RESPONSES TO HREC REVIEW*

- Responses to the HREC review for new studies are to be uploaded into the original HREA.
- Any amended documents (tracked and clean copies with new versions and dates in the footers) should also be uploaded into the original application.
- Once responses and amended documents are uploaded into the HREA, resign the application and then press 'Submit'.
- Responses will not be accepted if they are submitted via the Correspondence tab. Similarly, do not submit responses via the amendment tab in 'Create a sub-Form'.

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## Research vs Quality Improvement / Audit Activities

- A Research project is designed to gain new knowledge, understanding and insights.
- A Quality Improvement (QI) project is to monitor and evaluate local practice and the results will be used by local staff to improve healthcare and service delivery.
- Audit projects measure against a pre-determined (existing) standard.
- For guidance on QI/Audit activities, please refer to the NHMRC publication on Ethical Considerations in Quality Assurance and Evaluation Activities (*https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities*)

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## EXEMPTION SUBMISSION PROCESS

- Exemption requests for Quality Improvement / Audit / Service Evaluation projects and Case Reports, are to be submitted on the Qld Health Exemption Form via ERM.
- The Metro North Ethics and Governance webpage** provides relevant information regarding requests for exemption, as well as a link to 'Requesting an exemption from HREC review guideline'.
- The RBWH Research website# also provides guidance and links, specific to requests to the RBWH HREC.
- A Site-Specific Assessment (SSA) is not required for Quality Improvement activities – SSAs are only required for 'research' studies.
- Institutional approval procedures must be followed for quality improvement and evaluation activities.

- ** https://metronorth.health.qld.gov.au/research/ethics-and-governance/ethics-approval/request-exemption-hrec-review
- # https://metronorth.health.qld.gov.au/rbwh/research/ethics/pre-approval

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## REVIEW PROCESSES

- The RBWH and TPCH HRECs provide an expedited review process for low risk research projects. [A project is 'low risk' where the only foreseeable risk is discomfort, e.g. minor side effects of medication; discomforts relating to measuring blood pressure; anxiety induced by an interviewer. Where the risk is more than discomfort, the research is **not** low risk *(NS** 2.1.6)*].
- Greater than low risk studies are submitted for a closing date, however, the RBWH HREC has introduced a process whereby greater than low risk research applications are sent out to HREC reviewers as soon as they are submitted. This has the advantage of questions and responses being able to be actioned prior to the HREC meeting. This process reduces the number of days to approval for greater than low risk research studies.

- ** *https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018*

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## WHO NEEDS TO SIGN MY APPLICATION?

- The HREA should be signed by the Coordinating Principal Investigator (CPI).
- If the CPI is a student, the HREA should also be signed by the CPI's supervisor/s.
- More signatures will be required when submitting your Site-Specific Assessment (SSA) to the Research Governance Office.**
- ** Metro North Research Governance & Site Authorisation webpage: https://metronorth.health.qld.gov.au/research/ethics-and-governance/research-governance

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## *WHERE IS MY APPLICATION?*

- There have been occasions where the HREC has not received an application in the Ethics Work Area on ERM. This could be related to 2 things:
  - 2 different HRECs have been chosen in the application – firstly early on in the application under *'Select the committee that your ethics application will be submitted to'* and then later in the application at *Question 4.3*.
    If the response at these 2 questions is not the same, the application will appear to have been submitted, but will have been submitted to a 'Default Committee' and will not go anywhere. Ensure that the HREC listed is **exactly** the same at the two places.
  - The researcher has not pressed 'Submit' when the application is complete.

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## *INFORMATION CLINICS*

- Metro North Research provides weekly Information Clinics to assist researchers with their pending submissions. These clinics provide clarification on requirements for submission to both the HREC and RGO. It is recommended that researchers attend an Information Clinic prior to the submission to the HREC and RGO.

- Researchers have the opportunity of meeting for a 30-minute face-to-face consultation.
  2 x 30-minute timeslots are available from 9.00am on a Monday and Tuesday morning each week.

- Appointments can be made through the Metro North Research Governance Office (Telephone: 3647 1004 – Email: MNHHS-RGO@health.qld.gov.au)

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## Research Governance and Site Specific Assessment

**Rebekah Steele, Research Governance Manager**
**Metro North Hospital and Health Service**

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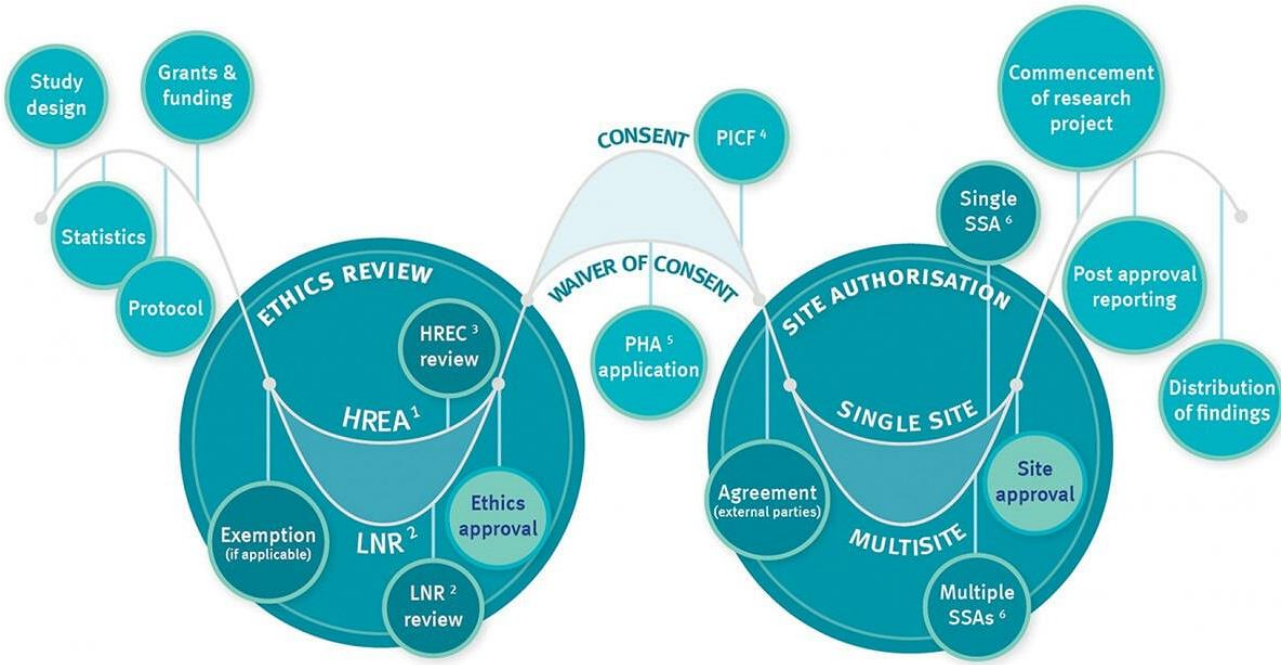


Note: the above diagram does not represent proporational time speant in each stage. [1] Human Research Ethics Application (HREA), [2] Low or negligible risk (LNR), [3] Human Research Ethics Committee (HREC), [4] Participant Information and Consent Form (PICF) - requires ethics review, [5] Public Health Act (PHA), [6] Site Specific Assessment (SSA).

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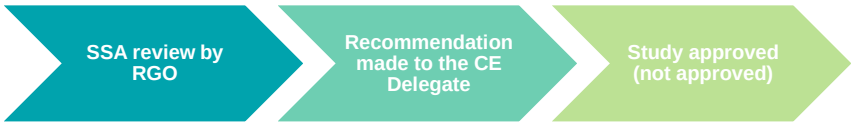
## Site Specific Assessment

- The HREC considers the ethical acceptability of the study
- Site-specific authorisation ('governance') considers the appropriateness of conducting the research project at the site:
  - Resource implications (financial, human, equipment, infrastructure)
  - Expertise & experience of the researchers
  - Legal requirements (Need for research contracts with external collaborators eg: universities)
  - Regulatory approvals, including compliance of the research project with relevant laws, policies & codes of conduct

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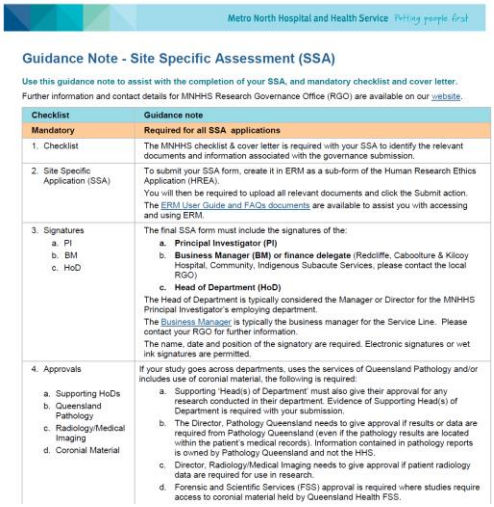
# SSA submission requirements



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**Guidance Note - Site Specific Assessment (SSA)**

**Use this guidance note to assist with the completion of your SSA, and mandatory checklist and cover letter.**

Further information and contact details for MNHHS Research Governance Office (RGO) are available on our website.

| Checklist | Guidance note |
|---|---|
| **Mandatory** | **Required for all SSA applications** |
| 1. Checklist | The MNHHS checklist & cover letter is required with your SSA to identify the relevant documents and information associated with the governance submission. |
| 2. Site Specific Application (SSA) | To submit your SSA form, create it in ERM as a sub-form of the Human Research Ethics Application (HREA).<br>You will then be required to upload all relevant documents and click the Submit action.<br>The ERM User Guide and FAQs documents are available to assist you with accessing and using ERM. |
| 3. Signatures<br>a. PI<br>b. BM<br>c. HoD | The final SSA form must include the signatures of the:<br>a. **Principal Investigator (PI)**<br>b. **Business Manager (BM) or finance delegate** (Redcliffe, Caboolture & Kilcoy Hospital, Community, Indigenous Subacute Services, please contact the local RGO)<br>c. **Head of Department (HoD)**<br>The Head of Department is typically considered the Manager or Director for the MNHHS Principal Investigator's employing department.<br>The Business Manager is typically the business manager for the Service Line. Please contact your RGO for further information.<br>The name, date and position of the signatory are required. Electronic signatures or wet ink signatures are permitted. |
| 4. Approvals<br>a. Supporting HoDs<br>b. Queensland Pathology<br>c. Radiology/Medical Imaging<br>d. Coronial Material | If your study goes across departments, uses the services of Queensland Pathology and/or includes use of coronial material, the following is required:<br>a. Supporting 'Head(s) of Department' must also give their approval for any research conducted in their department. Evidence of Supporting Head(s) of Department is required with your submission.<br>b. The Director, Pathology Queensland needs to give approval if results or data are required from Pathology Queensland (even if the pathology results are located within the patient's medical records). Information contained in pathology reports is owned by Pathology Queensland and not the HHS.<br>c. Director, Radiology/Medical Imaging needs to give approval if patient radiology data are required for use in research.<br>d. Forensic and Scientific Services (FSS) approval is required where studies require access to coronial material held by Queensland Health FSS. |

**Key elements**

- Completed SSA via ERM
- Signatures/approvals
- HREC Approval
- HREC Approved documentation
- Budget
- Agreement (if involving external entities)
- Public Health Act approval (if waiver of consent)
- Other regulatory documents (e.g for clinical trials)

https://metronorth.health.qld.gov.au/research/ethics-and-governance/research-governance

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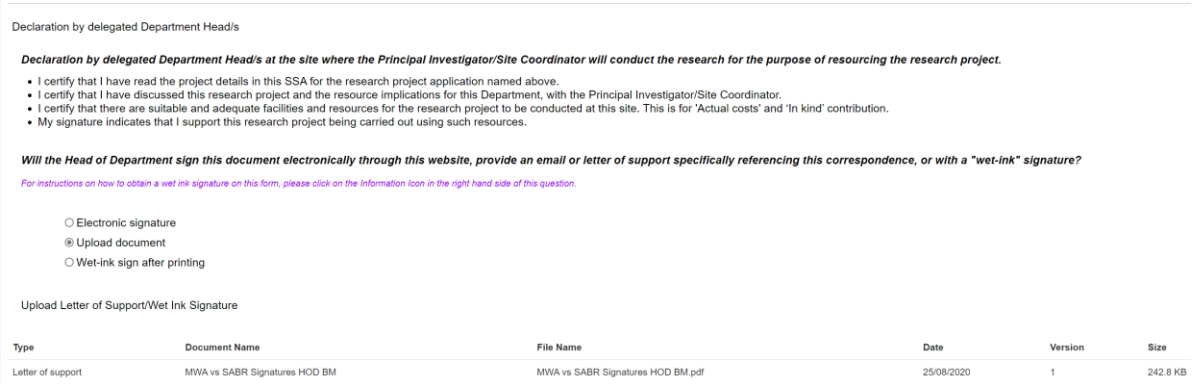
## # 1 Who needs to review and approve the SSA application?

- Principal Investigator (PI)
- Head of Departments (HoD)
  - Department that 'hosts' the study
  - Department of the PI
- Supporting departments (sHoD)
  - Pathology, Medical Imaging, Pharmacy
- Business Manager (BM)



Declaration by delegated Department Head/s

***Declaration by delegated Department Head/s at the site where the Principal Investigator/Site Coordinator will conduct the research for the purpose of resourcing the research project.***

- I certify that I have read the project details in this SSA for the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator/Site Coordinator.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site. This is for 'Actual costs' and 'In kind' contribution.
- My signature indicates that I support this research project being carried out using such resources.

***Will the Head of Department sign this document electronically through this website, provide an email or letter of support specifically referencing this correspondence, or with a "wet-ink" signature?***

*For instructions on how to obtain a wet ink signature on this form, please click on the Information Icon in the right hand side of this question.*

○ Electronic signature
◉ Upload document
○ Wet-ink sign after printing

Upload Letter of Support/Wet Ink Signature

| Type | Document Name | File Name | Date | Version | Size |
|---|---|---|---|---|---|
| Letter of support | MWA vs SABR Signatures HOD BM | MWA vs SABR Signatures HOD BM.pdf | 25/08/2020 | 1 | 242.8 KB |

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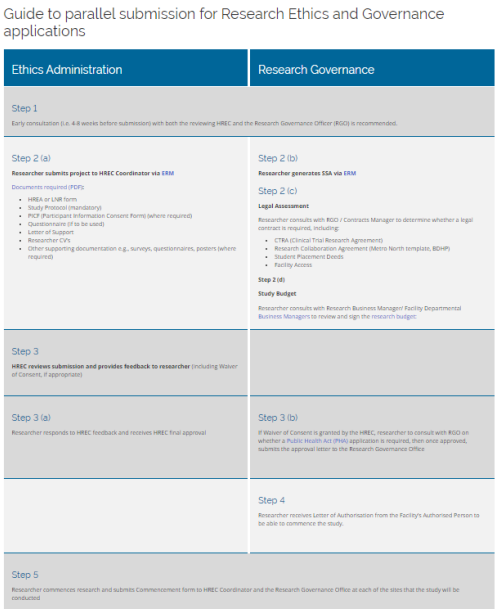
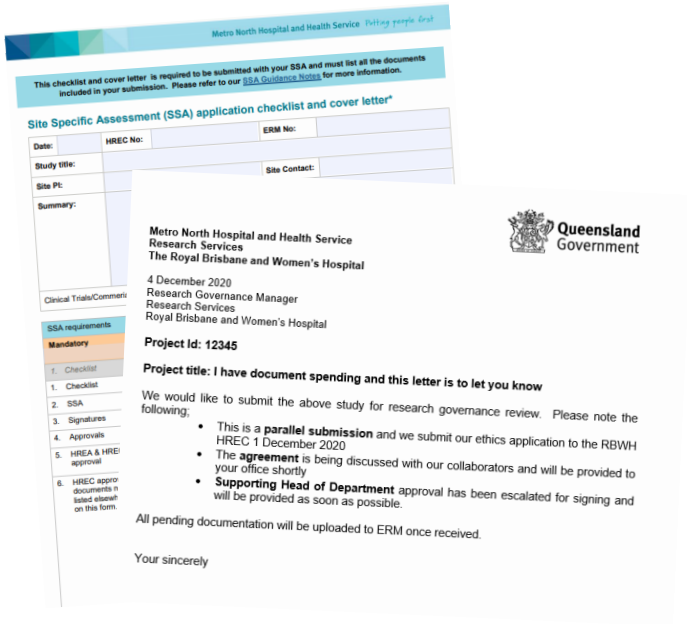
## # 2 Can I submit my SSA with documents still pending?



Guide to parallel submission for Research Ethics and Governance applications

| Ethics Administration | Research Governance |
|---|---|
| Step 1<br>Early consultation (i.e. 4-8 weeks before submission) with both the reviewing HREC and the Research Governance Officer (RGO) is recommended. | |
| Step 2 (a)<br>**Researcher submits project to HREC Coordinator via ERM**<br>Documents required (PDF):<br>• HREA or LNR form<br>• Study Protocol (mandatory)<br>• PICF (Participant Information Consent Form) (where required)<br>• Questionnaire (if to be used)<br>• Letter of Support<br>• Researcher CVs<br>• Other supporting documentation e.g., surveys, questionnaires, posters (where required) | Step 2 (b)<br>**Researcher generates SSA via ERM**<br>Step 2 (c)<br>**Legal Assessment**<br>Researcher consults with RGO / Contracts Manager to determine whether a legal contract is required, including:<br>• CTRA (Clinical Trial Research Agreement)<br>• Research Collaboration Agreement (Metro North template, BDHP)<br>• Student Placement Deeds<br>• Facility Access<br>**Step 2 (d)**<br>**Study Budget**<br>Researcher consults with Research Business Manager/ Facility Departmental Business Managers to review and sign the research budget. |
| Step 3<br>**HREC reviews submission and provides feedback to researcher** (including Waiver of Consent, if appropriate) | |
| Step 3 (a)<br>Researcher responds to HREC feedback and receives HREC final approval | Step 3 (b)<br>If Waiver of Consent is granted by the HREC, researcher to consult with RGO on whether a Public Health Act (PHA) application is required, then once approved, submits the approval letter as the Research Governance Office |
| | Step 4<br>Researcher receives Letter of Authorisation from the Facility's Authorised Person to be able to commence the study. |
| Step 5<br>Researcher commences research and submits Commencement form to HREC Coordinator and the Research Governance Office at each of the sites that the study will be conducted. | |



Metro North Hospital and Health Service

This checklist and cover letter is required to be submitted with your SSA and must list all the documents included in your submission. Please refer to our SSA Guidance Notes for more information.

**Site Specific Assessment (SSA) application checklist and cover letter***

Date:
HREC No:
ERM No:
Study title:
Site Contact:
Site PI:
Summary:

Clinical Trials/Commerci

SSA requirements
Mandatory
1. Checklist
1. Checklist
2. SSA
3. Signatures
4. Approvals
5. HREA & HRE approval
6. HREC appro documents n listed elsewh on this form.

Queensland Government

**Metro North Hospital and Health Service**
**Research Services**
**The Royal Brisbane and Women's Hospital**

4 December 2020
Research Governance Manager
Research Services
Royal Brisbane and Women's Hospital

**Project Id: 12345**

**Project title: I have document spending and this letter is to let you know**

We would like to submit the above study for research governance review. Please note the following;

- This is a **parallel submission** and we submit our ethics application to the RBWH HREC 1 December 2020
- The **agreement** is being discussed with our collaborators and will be provided to your office shortly
- **Supporting Head of Department** approval has been escalated for signing and will be provided as soon as possible.

All pending documentation will be uploaded to ERM once received.

Your sincerely

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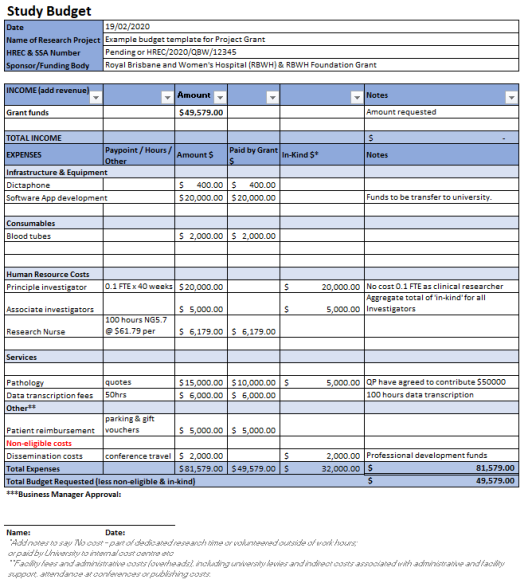
## # 3 I am doing this study on my own time do I need a budget?

- Cash contributions
- **In-kind contributions (during QH hours/donated time)**
  - For example, if you anticipate spending 20 hours on a research project during work hours as a Principal Investigator and Metro North Hospital and Health Service employee, you need to quantify the in-kind contribution (e.g. 20 hours x hourly salary) for the SSA study budget.



**Study Budget**

| | |
|---|---|
| **Date** | 19/02/2020 |
| **Name of Research Project** | Example budget template for Project Grant |
| **HREC & SSA Number** | Pending or HREC/2020/QBW/12345 |
| **Sponsor/Funding Body** | Royal Brisbane and Women's Hospital (RBWH) & RBWH Foundation Grant |

| **INCOME [add revenue]** | | **Amount** | | | **Notes** |
|---|---|---|---|---|---|
| Grant funds | | $49,579.00 | | | Amount requested |
| | | | | | |
| **TOTAL INCOME** | | | | | $ - |
| **EXPENSES** | **Paypoint / Hours / Other** | **Amount $** | **Paid by Grant $** | **In-Kind $*** | **Notes** |
| **Infrastructure & Equipment** | | | | | |
| Dictaphone | | $ 400.00 | $ 400.00 | | |
| Software App development | | $20,000.00 | $20,000.00 | | Funds to be transfer to university. |
| | | | | | |
| **Consumables** | | | | | |
| Blood tubes | | $ 2,000.00 | $ 2,000.00 | | |
| | | | | | |
| | | | | | |
| **Human Resource Costs** | | | | | |
| Principle investigator | 0.1 FTE x 40 weeks | $20,000.00 | | $ 20,000.00 | No cost 0.1 FTE as clinical researcher |
| Associate investigators | | $ 5,000.00 | | $ 5,000.00 | Aggregate total of 'in-kind' for all investigators |
| Research Nurse | 100 hours NG5.7 @ $61.79 per | $ 6,179.00 | $ 6,179.00 | | |
| | | | | | |
| **Services** | | | | | |
| Pathology | quotes | $15,000.00 | $10,000.00 | $ 5,000.00 | QP have agreed to contribute $50000 |
| Data transcription fees | 50hrs | $ 6,000.00 | $ 6,000.00 | | 100 hours data transcription |
| **Other**** | | | | | |
| Patient reimbursement | parking & gift vouchers | $ 5,000.00 | $ 5,000.00 | | |
| **Non-eligible costs** | | | | | |
| Dissemination costs | conference travel | $ 2,000.00 | | $ 2,000.00 | Professional development funds |
| **Total Expenses** | | $81,579.00 | $49,579.00 | $ 32,000.00 | $ 81,579.00 |
| **Total Budget Requested [less non-eligible & in-kind]** | | | | | $ 49,579.00 |

***Business Manager Approval:**

**Name:** **Date:**

*Add notes to say 'No cost – part of dedicated research time or volunteered outside of work hours; or paid by University to internal cost centre etc

**Facility fees and administrative costs [overheads], including university levies and indirect costs associated with administrative and facility support, attendance at conferences or publishing costs.

***Business Manager Approval can be wet ink signature on the budget, electronic signature or email approval.

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# # 4 Do I need a PHA?

## Data / PHA Requests

Where a researcher wants to use confidential identifiable or potentially re-identifiable health information without the consent of the participant or substitute decision maker (e.g NOK) for research purposes (i.e the HREC has granted a waiver of consent) there are two ways that this may occur:

### 1. Approval under Chapter 6 Part 4 of the *Public Health Act 2005* (Qld) ("PHA Approval")

Any researcher applying for access to identifiable or potentially re-identifiable data held by the Royal Brisbane and Women's Hospital (RBWH), who is unable to obtain participant consent, must make an application under the Public Health Act 2005 (PHA) and receive approval from the Director General of Queensland Health.

Read more

### 2. Permission under Section 150 of the *Hospital and Health Boards Act 2011* ("Section 150 Permission")

Section 150 of the Hospital and Health Boards Act 2011 provides that a 'designated person' may disclose 'confidential information' to another 'designated person' if the disclosure is for the purpose of 'evaluating, managing, monitoring or planning health services'.

Read more

## Approval under Chapter 6 Part 4 of the Public Health Act 2005 (Qld) (PHA Approval)

Any researcher applying for access to identifiable or potentially re-identifiable data held by the Royal Brisbane and Women's Hospital (RBWH), who is unable to obtain participant consent, must make an application under the Public Health Act 2005 (PHA) and receive approval from the Director General of Queensland Health.

Researchers can apply for the release of confidential information for the purposes of research under s280 Public Health Act 2005 (Qld). In assessing applications consideration given to whether the disclosure is in the public interest: s284(2) and (3) Public Health Act 2005 (Qld).

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Royal Brisbane and Women's Hospital

### Data custodian approval checklist

This checklist is to be used when;

1. you are requesting data for a clinical audit and have received Human Research Ethics Committee (HREC) Exemption - Complete page 1 and sign on page 2. **OR**
2. you have been granted a waiver of consent from HREC and are seeking access to data for research under *Section 150 of the Hospital and Health Boards Act 2011**. Please complete all pages and sign. **You will need to provide this approval to the Research Governance Office with your Site-Specific Assessment application.**

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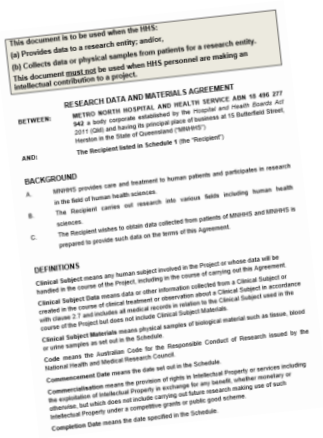
# # 5 Do I need an agreement?



This document is to be used when the HHS:
(a) Provides data to a research entity; and/or,
(b) Collects data or physical samples from patients for a research entity.
This document must not be used when HHS personnel are making an intellectual contribution to a project.

RESEARCH DATA AND MATERIALS AGREEMENT

BETWEEN: METRO NORTH HOSPITAL AND HEALTH SERVICE ABN 16 496 277 942 a body corporate established by the *Hospital and Health Boards Act 2011* (Qld) and having its principal place of business at 15 Butterfield Street, Herston in the State of Queensland ("MNHHS")

AND: The Recipient listed in Schedule 1 (the "Recipient")

BACKGROUND

A. MNHHS provides care and treatment to human patients and participates in research in the field of human health sciences.

B. The Recipient carries out research into various fields including human health sciences.

C. The Recipient wishes to obtain data collected from patients of MNHHS and MNHHS is prepared to provide such data on the terms of this Agreement.

DEFINITIONS

Clinical Subject means any human subject involved in the Project or whose data will be handled in the course of the Project, including in the course of carrying out this Agreement.

Clinical Subject Data means data or other information collected from a Clinical Subject or created in the course of clinical treatment or observation about a Clinical Subject used in the with clause 2.2 and includes all medical records in relation to the Clinical Subject used in the course of the Project but does not include Clinical Subject Materials.

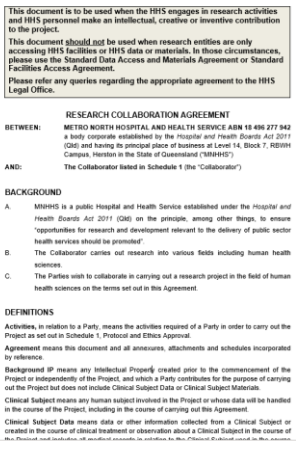
Clinical Subject Materials means physical samples of biological material such as tissue, blood or urine samples as set out in the Schedule.

Code means the Australian Code for the Responsible Conduct of Research issued by the National Health and Medical Research Council.

Commencement Date means the date set out in the Schedule.

Commercialisation means the provision of rights in Intellectual Property or services including the exploitation of Intellectual Property in exchange for any benefit, whether monetary or otherwise, but which does not include carrying out future research making use of such Intellectual Property under a competitive grants or public good scheme.

Completion Date means the date specified in the Schedule.



This document is to be used when the HHS engages in research activities and HHS personnel make an intellectual, creative or inventive contribution to the project.

This document should not be used when research entities are only accessing HHS facilities or HHS data or materials. In those circumstances, please use the Standard Data Access and Materials Agreement or Standard Facilities Access Agreement.

Please refer any queries regarding the appropriate agreement to the HHS Legal Office.

RESEARCH COLLABORATION AGREEMENT

BETWEEN: METRO NORTH HOSPITAL AND HEALTH SERVICE ABN 16 496 277 942 a body corporate established by the *Hospital and Health Boards Act 2011* (Qld) and having its principal place of business at Level 14, Block 7, RBWH Campus, Herston in the State of Queensland ("MNHHS")

AND: The Collaborator listed in Schedule 1 (the "Collaborator")

BACKGROUND

A. MNHHS is a public Hospital and Health Service established under the *Hospital and Health Boards Act 2011* (Qld) on the principle, among other things, to ensure "opportunities for research and development relevant to the delivery of public sector health services should be promoted".

B. The Collaborator carries out research into various fields including human health sciences.

C. The Parties wish to collaborate in carrying out a research project in the field of human health sciences on the terms set out in this Agreement.

DEFINITIONS

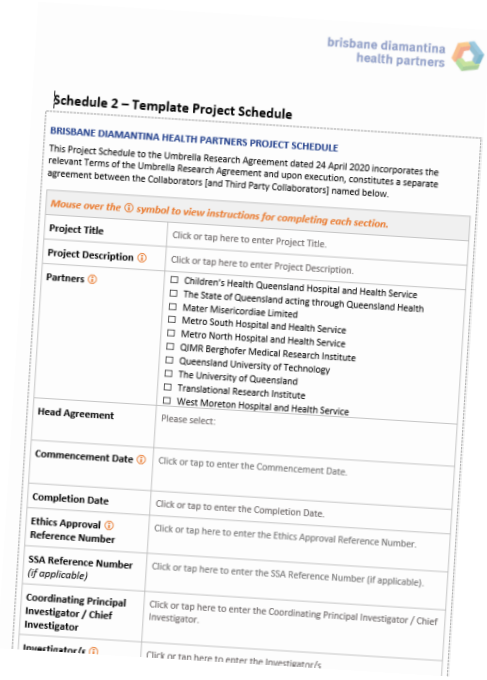
Activities, in relation to a Party, means the activities required of a Party in order to carry out the Project as set out in Schedule 1, Protocol and Ethics Approval.

Agreement means this document and all annexures, attachments and schedules incorporated by reference.

Background IP means any Intellectual Property created prior to the commencement of the Project or independently of the Project, and which a Party contributes for the purpose of carrying out the Project but does not include Clinical Subject Data or Clinical Subject Materials.

Clinical Subject means any human subject involved in the Project or whose data will be handled in the course of the Project, including in the course of carrying out this Agreement.

Clinical Subject Data means data or other information collected from a Clinical Subject or created in the course of clinical treatment or observation about a Clinical Subject in the course of



brisbane diamantina health partners

Schedule 2 – Template Project Schedule

BRISBANE DIAMANTINA HEALTH PARTNERS PROJECT SCHEDULE

This Project Schedule to the Umbrella Research Agreement dated 24 April 2020 incorporates the relevant Terms of the Umbrella Research Agreement and upon execution, constitutes a separate agreement between the Collaborators [and Third Party Collaborators] named below.

*Mouse over the ⓘ symbol to view instructions for completing each section.*

| | |
|---|---|
| **Project Title** | Click or tap here to enter Project Title. |
| **Project Description** ⓘ | Click or tap here to enter Project Description. |
| **Partners** ⓘ | ☐ Children's Health Queensland Hospital and Health Service<br>☐ The State of Queensland acting through Queensland Health<br>☐ Mater Misericordiae Limited<br>☐ Metro South Hospital and Health Service<br>☐ Metro North Hospital and Health Service<br>☐ QIMR Berghofer Medical Research Institute<br>☐ Queensland University of Technology<br>☐ The University of Queensland<br>☐ Translational Research Institute<br>☐ West Moreton Hospital and Health Service |
| **Head Agreement** | Please select: |
| **Commencement Date** ⓘ | Click or tap to enter the Commencement Date. |
| **Completion Date** | Click or tap to enter the Completion Date. |
| **Ethics Approval** ⓘ **Reference Number** | Click or tap here to enter the Ethics Approval Reference Number. |
| **SSA Reference Number** *(if applicable)* | Click or tap here to enter the SSA Reference Number (if applicable). |
| **Coordinating Principal Investigator / Chief Investigator** | Click or tap here to enter the Coordinating Principal Investigator / Chief Investigator. |
| **Investigator/s** ⓘ | Click or tap here to enter the Investigator/s |

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# #6 I am doing my study across multiple MNHHS sites – do I need to submit multiple SSA?

***1.1 What is the name of the site (or satellite site if you chose o***

RBWH; TPCH; Herston Biofab Institute; STARS

***1.2 To which Queensland Health Research Governance Office***

Metro North HHS - RBWH RGO



## Single Site-Specific Assessment (SSA) Factsheet

This factsheet describes the process for obtaining Research Governance approval for research projects being conducted at more than one Metro North Hospital and Health Service (MNHHS) facility or service

### Background

In 2019/2020 a trial was conducted in Metro North which enable submission of a single SSA to one Research Governance Officer (RGO), for studies being conducted at more than one MNHHS facility. This was conducted to reducing duplication and enhance consistency of research governance review. This trial received positive feedback and accordingly, is now being implemented as standard practice in MNHHS.

### What do I do?

For studies involving more than one MNHHS facility, complete a single (one) SSA for a MNHHS research project in Ethical Review Manager (ERM) and submit to the lead MNHHS site. If there is no lead site, please select the site you are located. Please note this will change in the foreseeable future as the process is rolled out further.

### What changes?

The main change for researchers is the reduced number of SSAs required to be submitted for multi-site research in MNHHS. One research governance approval letter will be issued for multi-site research projects in MNHHS, listing all MNHHS sites involved.

Single site research projects are still processed through the facility RGO as per standard processes.

### What if my project begins at one MNHHS site and then other sites are added on later?

Please submit the SSA to the RGO who reviewed the initial site. The first site will be approved, and other sites may be added at a later stage. If this occurs, please submit the budget, head of department signatures and any other relevant documentation pertaining to the new sites to the same RGO who initially approved the study.

### Post approvals

Please submit all post approval amendments and reports to the approving RGO of the single SSA. Only one submission is required.

### Who do I contact for questions, concerns, queries and feedback?

To provide feedback on the single SSA process, please contact your site RGO.

**Royal Brisbane and Women's Hospital**

P: 3646 8579

E: RBWH-RGO@health.qld.gov.au

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# #7 How do I get help?

Home / Research / Ethics and governance / Research Ethics & Governance Information Clinics

## Research Ethics & Governance Information Clinics

Are you thinking of starting a research project at Metro North? Before you begin the submission process, come to an Information Clinic to obtain advice on ethical and governance requirements. Staff from the Human Research Ethics Committee (HREC), Research Governance Office (RGO) and Finance Section are available to provide advice.

The Clinics are held on a Monday and a Tuesday morning each week, with 2 x 30 minute timeslots available on both days, beginning at 9.00am.

Appointments can be made by calling 3647 1002 or 3647 1001.

https://metronorth.health.qld.gov.au/research/ethics-and-governance/clinics

## Contact Us

### Metro North Office of Research

The Metro North Office of Research provides strategic oversight and direction for research in Metro North Hospital and Health Service through operational implementation of the Metro North Research Strategy. The Metro North Office of Research works collaboratively with the Metro North Executive and leadership team, Research Directors, Administrators and Managers across the Health Service, external academic partners and with researchers to support and enable research excellence.

+ Contact Details

### Metro North Research Governance Office

− Contact Details

- Research Governance Manager, Rebekah Steele
  Phone: Monday/Tuesday (07) 3647 9550 ; Wednesday-Friday (07) 3646 8579
- Research Governance Officer, Ascar Yu
  Phone: Monday/Tuesday (07) 3646 5033; Wednesday-Friday (07) 3139 4407
- Research Governance Officer, Vanessa Constable
  Phone: Monday/Tuesday (07) 3646 5047; Wednesday-Friday (07) 3883 7243

Email: MNHHS-RGO@health.qld.gov.au

### Human Research Ethics Committee (HREC)

https://metronorth.health.qld.gov.au/research/ethics-and-governance/clinics

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## Other frequently asked questions….

- **I need help with ERM?**
  - Health, Investment and Research Office website: https://www.health.qld.gov.au/hiiro/html/regu/regu_home/erm-ethics-review-manager
- **Multisite studies - PICF version control – what is required?**
  - Local details of the site PI, RGO details for complaints
  - The site version and date must be in the footer and reference the master version and date
    - *MNHHS Site Specific PICF v1.0 30/01/2020 based on Master PICF v4.0 25/03/2019*
- **How long will the review and approval take?**
  - SSA approval is typically received within 2-4 weeks of a valid application
- **Are there any fees associated with my SSA?**
  - There are fees for site authorisation of commercially sponsored research. A fee template signed by the sponsor should be submitted with your SSA. The fee template is available on the MNHHS website
  - https://metronorth.health.qld.gov.au/research/ethics-and-governance/research-governance

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