Nursing Research – Guide to Ethics

The Research Ethics and Governance (REG) department oversees research that is conducted in or by the Melbourne Children’s Campus. They ensure that high quality research is being produced while protecting the safety, rights and autonomy of research participants. To find out more information on the REG department, please refer to their intranet website: https://www.rch.org.au/ethics/

Please note: When searching the intranet for the Ethics website, look under ‘R’ in Departments and Services for ‘Research Ethics and Governance’.

Most research projects supervised by Nursing Research are either Quality Improvement (QI), Clinical Audit or Low and Negligible Risk (LNR) projects. These three project types will be described in more detail further in this document.

The Nursing Research team also has templates and guides to write your own research protocol. If you would like any help or assistance with developing your research protocol, please contact Nursing Research (Nursing.Research@rch.org.au).
Quality Improvement (QI):

Quality Improvement (QI) projects generally involve one ward or department and the activity is conducted within existing resources that pose no major risk relating to the implementation of the project.

For more information on QI projects please visit the Project Management website on the RCH intranet: [https://www.rch.org.au/project-management/](https://www.rch.org.au/project-management/)

Please note: When searching the intranet for the QI projects, look under ‘P’ in Departments and Services for ‘Project Management’. Quality Improvement projects are not located within the Ethics department.

There is a ‘screening’ survey on the intranet to help you determine whether your project is a QI project which can be found here: [https://secure.rch.org.au/survey/index.php/623688?lang=en](https://secure.rch.org.au/survey/index.php/623688?lang=en)
The survey can also be found under the ‘Getting Started’ tab:

Then scroll down the bottom to Step 2.
Your QI project can also be registered here (Step 4).

---

**Step 2: Is my work Quality Improvement (QI) or research?**

Research projects require ethics approval and QI do not. Use the following screening tool to determine whether the proposed project is research or QI:


**Step 3: Is my work local or organisational projects?**

Use the local or organisational screening tool to determine if your work is a local or an organisational project.

Local or organisational project: [http://projectregister.rch.org.au](http://projectregister.rch.org.au)

The project charter is embedded in the project register (link above)

**Step 4: Register your project**

The Local or Organisational survey is part of the RCH Online Project Register, based on your result, please register your project on the RCH Online Project Register and refer to the appropriate section on the Project Management page to assist you in completing your project
If you remain unsure whether your project is a QI project or not, then there is a ‘risk assessment checklist’ on the Research and Ethics Governance website that you can download and complete. This ‘Application Coversheet’ is designed to guide you to determine whether your project is a High Risk, Low Risk or a Quality Improvement application: [https://www.rch.org.au/ethics/new-applications/](https://www.rch.org.au/ethics/new-applications/)

**APPLICATION COVERSHEET**

**RESEARCH ETHICS & GOVERNANCE**

**HREC Reference Number**

Obtained prior to submission: [PRE-SUBMISSION FORM](https://www.rch.org.au/ethics/new-applications/)

**Project Title**

**SECTION A: Does the research project involve ANY of the following? (Tick all that apply)**

<table>
<thead>
<tr>
<th></th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Use of a product (drug or device) that is not registered with the Therapeutic Goods Administration (TGA)</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Use of a drug or device in a clinical trial, when the product is being used in the trial for an unapproved indication, in an unapproved age group or at an unapproved dose</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Use of a drug or device in a clinical trial, when such use in the trial is to gain further information about an approved use (e.g. pharmacokinetic or pharmacodynamic research)</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>A randomised and/or control group trial assessing an intervention(s) i.e. drug/device, clinical, surgical, diagnostic, public health or mental health (consider NS 3.3)</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Targeted recruitment of Aboriginal or Torres Strait Islander people (consider NS 4.7)</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Targeted recruitment of vulnerable groups e.g. children in the ICU, people with mental illness or those who may have been involved in criminal activities (consider NS 4.3 &amp; 4.4)</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Invasive procedures outside of standard care e.g. collection of blood or tissue samples</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Audit:

A Clinical Audit project accesses data that already exists (for example, EMR) and then analyses and evaluates this data in order to improve the workplace or clinical practice. The data accessed should remain private and confidential, and the researchers should have rightful access to the data (i.e. employees of the RCH).

For more information on clinical audit projects, search for the ‘Clinical Audit’ link under the ‘New Applications’ tab on the REG intranet website: https://www.rch.org.au/ethics/new-applications/Clinical_audits/

For your completed clinical audit application you will need:
- Your research protocol
- Completed ‘Application Form Clinical Audit’ (https://www.rch.org.au/ethics/new-applications/Clinical_audits/)
These documents will then need to be submitted through the Ethics departments online management system entitled ‘Ethics Review Manager’ (ERM) https://au.forms.ethicalreviewmanager.com/Account/Login.

You will require an RCH login to be able to register for ERM and create an ERM account.

You will be able to complete all the required documentation for your online submission by opening up the ‘Information’ hyperlink (circled in red in image above). You will also be able to upload your completed documents here.

Once your Clinical Audit project is submitted via ERM, the Ethics department will review your research protocol and then approve your project if appropriate.
Low and Negligible Risk (LNR):

A Low and Negligible Risk (LNR) project is a research project that involves collecting data prospectively with minimal risk to the participants of the project.

For more information on LNR projects, search for the ‘Low and Negligible Risk Research’ link under the ‘New Applications’ tab on the REG intranet website:
https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/
Prior to your LNR submission, you will need to register your project to receive a reference number. To do so, please complete the pre-submission form found here: 


---

#### Research Governance and Ethics

**Single-site research**

For the purposes of HREC review, the Melbourne Children’s Campus is considered one site. Therefore, research conducted at or by RCH, MCRH and/or The University of Melbourne Department of Paediatrics is eligible for single-site review. This includes home based, school based and community based studies.

Please note that single-site research may also be classified as ‘Low or Negligible Risk’ (LNR). To determine if your research can be classified as LNR, please complete the checklist within the REG mediation cover sheet and proceed to the Low and Negligible Risk Research page for submission advice. Please note Major Victorian Hospitals (including RCH) do not accept the Vic LNR NEAF, please complete the HREA for all studies.

**Pre-submission process:**

All studies must be pre-registered as soon as possible prior to submission. This is done by completing the [pre-submission form](https://www.rch.org.au/ethics/new-applications/Single-site_research/). Within 24 hours of submitting the form, you will be allocated a reference number. This number is required to communicate with REG, as well as all supporting service departments on campus.

**Single-site submission process:**

Please review the Meeting Dates/Deadlines page for submission deadlines.

All single-site submissions to the RCH HREC (including single-site clinical trials), must include the following documents (as applicable):

<table>
<thead>
<tr>
<th>Document</th>
<th>Number of Copies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-submission form</td>
<td>Complete prior to Submission</td>
</tr>
<tr>
<td>RCH DFG Application Cover Sheet</td>
<td>One electronic copy</td>
</tr>
<tr>
<td>Peer Review Proforma</td>
<td>One electronic copy</td>
</tr>
<tr>
<td>Participant Information Statement and Consent Form</td>
<td>One electronic copy</td>
</tr>
<tr>
<td>Participant Information Statement and Consent Form</td>
<td>One electronic copy</td>
</tr>
</tbody>
</table>

---

**Peer Review:**

All LNR projects require to be peer reviewed to ensure the research methods are rigorous, valid and adequate to answer the research question proposed. The peer reviewer should be independent to your project and have knowledge and experience regarding research design and methods. Once you have found a dedicated peer reviewer, send them a copy of your research proposal and the ‘Peer Review Proforma’ to complete, sign and send back to you. The link to the Peer Review Proforma can be found here: 


(The location of the document is also circled in red in the image above)
Head of Department Declaration:
For your project to be approved, you will also be required to meet with your NUM/Department Manager/Head of Department and provide them with a copy of your research protocol and ask for them to approve your project i.e. that they are happy for the project to occur on the ward or within the department you plan to conduct the research project in.

The Head of Department (HoD) Declaration form can be found on the REG intranet website, under the ‘Researcher Resources’ side tab and then under the link entitled ‘Forms and Templates’ here:

https://www.rch.org.au/ethics/researcher-resources/Forms_and_templates/
For your completed LNR application you will need:

- Your research protocol
- All information statement and consent forms (as applicable). Templates can be found here: [https://www.rch.org.au/ethics/new-applications/Single-site_research/](https://www.rch.org.au/ethics/new-applications/Single-site_research/)
- Other forms and templates can be found here: [https://www.rch.org.au/ethics/research-resources/Forms_and_templates/](https://www.rch.org.au/ethics/research-resources/Forms_and_templates/)
- Other documents required for the project (for example, survey questionnaires, flyers and emails for advertisement and recruitment)
- Signed ‘Head of Department Declaration’ form
- Signed Peer Review Proforma (and if applicable, any letters in response to the Peer Reviewer’s comments made on the proforma)

These documents will then need to be submitted through the Ethics departments online management system entitled ‘Ethics Review Manager’ (ERM) [https://au.forms.ethicalreviewmanager.com/Account/Login](https://au.forms.ethicalreviewmanager.com/Account/Login). You will require an RCH login to be able to register for ERM and create an ERM account.

Once your LNR project has been created on ERM, you will need to complete the Human Ethics Research Application (HREA) form online. This form asks some in-depth and tricky questions. Please just provide basic answers, or copy and paste parts of your research protocol into the appropriate sections. This HREA form is a state requirement, and all the information that the ethics department requires to approve your project is within your research protocol and the supporting documents, so please do not stress over or over-complicate your answers in the HREA form.

The HREA form can also be quite tedious as each link will have to be opened up individually and completed (the numerous links can be seen in the image above).
Alternatively, you can work through each of these pages of the HREA form by clicking on the next button (highlighted in red in the image below):

As you work through the form, different sections will become open or grey out depending on your answers. A more in-depth guide to assist you to navigate ERM can be found here: https://www.rch.org.au/uploadedFiles/Main/Content/ethics/ERM%20%E2%80%93%20User%20guide%20-%20V2%2026.10.2018.pdf

Otherwise, the Nursing Research Team are always eager and more than happy to help or provide support. Contact us anytime at Nursing.Research@rch.org.au

All the best with your research project 😊

Nursing Research Team
Fiona, Sharon, Bianca and Meaghan.