

# Research processes in the Department of Women's and Children's Health

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This document is designed to guide the researcher through the process when commencing a research project within the Department of Women's and Children's Health.

Students should work with their supervisors throughout this process.

The Research Administrator for Women's and Children's Health, Sarah-Jane Robertson [wch.research@otago.ac.nz](mailto:wch.research@otago.ac.nz) provides administrative support for the Department of Women's and Children's Health research programmes.

## Research Projects require:

1. Protocol development
2. Ethics Application (either HDEC or University of Otago)
3. Peer Review
4. Maori Consultation
5. Budget and funding
6. Locality assessment and approval
7. Head of Department sign off
8. Study registration
9. Reporting to Ethics and Ngāi Tahu Research Consultation Committees and funding bodies
10. Dissemination of findings

The Department of Women's and Children's Health sits within [the Health Research South](#), Dunedin School of Medicine who is in partnership with Southern District Health Board in Research. The office of Health Research South facilitates the research approval process. Consultation with Health Research South advisors should occur early in the research development process.

## 1. Protocol development

Prior to commencing the research approval process development of a robust study protocol is required. See the below link for template.

<http://www.otago.ac.nz/dsm-wchealth/otago124803.docx>

It is strongly recommended to ensure early consultation with all the necessary researchers at the time of protocol development, this may for example include a statistician or health economist.

## 2. Ethics Approval

To establish which ethical committee you will need to apply to review

<http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>

And

<http://ethics.health.govt.nz/system/files/documents/pages/HDEC%20scope%20summary.pdf>

UOHEC	UOHEC (Health)	HDEC
<p><b>Research involving:</b> Human participants but which falls outside the jurisdiction of the University of Otago Human Ethics Committee (Health) and the Health and Disability Ethics Committee (HDEC) (i.e. is not considered health research, does not involve patients.)</p> <p> <a href="#">UOHEC - application form</a></p> <p>Departmental Ethical Approval</p> <p><a href="#">&gt; Deadlines &amp; meeting dates</a></p>	<p><b>Research involving:</b> Health Research (observational and intervention studies) involving <b>consumers of health and disability services</b> (patients) but deemed <b>exempt from HDEC review</b> (see list below)</p> <p>Health Research (observational and intervention studies) involving <b>healthy participants who are not recruited as patients.</b> (This would include methodologies which require blood and other tissue samples.)</p> <p> <a href="#">UOHEC (Health) - application form</a></p> <p> <a href="#">UOHEC(H) Minimal Risk Health Research - Audit and audit related studies</a></p> <p><a href="#">&gt; Deadlines &amp; meeting dates</a></p>	<p><b>Research involving:</b> Human participants recruited in their capacity as: consumers of health and disability support services or relatives or caregivers of such consumers or volunteers in clinical trials.</p> <p><a href="#">HDEC - How to apply</a></p>

For either of these committees you will require protocol development, peer review and Maori consultation.

HDEC Meeting Dates: <https://ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes#2020>

Both HDEC and UoO ethics have templates for Participant Information Sheet and Consent Form

### 3. Peer review

Peer review is required to review the research protocol to ensure the research design is optimal – this should be seen as an opportunity to gain an independent review on your research. ALL research requiring human participants should undergo peer review. Forms should be sent to the [Chairperson of the WCH Department's Peer Review Committee](#)

WCH Department Peer Review Template Instructions and Application Form:  
<http://www.otago.ac.nz/dsm-wchealth/otago123834.docx>

HDEC Peer Review Template: <http://www.otago.ac.nz/dsm-wchealth/otago123835.docx>

### 4. Maori Consultation

Where your research involves Maori participants ensure there is consultation at the time of protocol development.

- a) In the Department of Women's and Children's Health Hine Forsyth provides Ngāi Tahu consultation. Appointments should be booked with Sarah-Jane Robertson [wch.research@otago.ac.nz](mailto:wch.research@otago.ac.nz)
- b) A University of Otago Maori consultation application MUST also be completed at <https://www.otago.ac.nz/research/maoriconsultation/>

Dates for the Ngāi Tahu research committee meetings are also found on the above page.

## 5. Budget and Funding

If the work is University initiated Budgets should be completed using the [http://www.otago.ac.nz/research/forms/1\\_COSTINGS\\_CONSENTS\\_CCW/](http://www.otago.ac.nz/research/forms/1_COSTINGS_CONSENTS_CCW/)

Funding resources are advertised <http://www.otago.ac.nz/research/otago004140.html>

Consideration should be made of any cost implications of dissemination when applying for funding.

The [Health Research South advisors](#) are able to provide information and advice about funding.

If the work is SDHB initiated or commercial please contact Health Research South.

## 6. Locality assessment and approval

All clinical research studies should be registered with the Health Research South Research Office. It is advised that all health research is discussed with the Health Research South Research Office to gain advice.

See the below link for the Clinical Research Approval Form

<http://www.otago.ac.nz/dsm-wchealth/otago124802.docx>

## 7. Head of Department sign off

Ethics and funding applications will require sign off from the Head of Department.

Ensure that all documents are given to Sarah-Jane and that all documents are in at least **one week** before the due date, to allow time for the HOD to read the material.

Sarah-Jane will arrange for the necessary signatures and will be in contact only if there is an issue.

Before you submit to the HOD please check you have:

- ✓ Provided evidence of your Research Protocol (e.g. Information Sheets, Consent Forms)
- ✓ Completed the Ethics Application

- ✓ Completed the peer review process (if needed) and provided evidence of this
- ✓ Completed Departmental Maori Consultation (if needed) and University Maori Consultation and provided evidence of this
- ✓ Completed the Health Research South Locality Approval Form (if needed)

## **8. Study registration if indicated e.g. RCT**

Many journals will not publish studies which are not prospectively registered.

<https://clinicaltrials.gov/>

<http://www.anzctr.org.au/>

<http://www.isrctn.com/>

## **9. Reporting**

During and at completion of the study reporting may be necessary to the bodies which have approved and /or funded your research.

During the ethical approval process it may be necessary to state whether you are happy to share the data from your study. Please make sure you refer back to this to check what you've agreed on.

## **10. Dissemination of findings**

An essential component of research is dissemination of the study findings this may be at local meetings, conferences or publication. Consideration should be made of any cost implications of dissemination when applying for funding.