

Health Research South

Te Whatu Ora – Southern and Dunedin School of Medicine

All research conducted in Te Whatu Ora - Southern and Dunedin School of Medicine (DSM) is required to have Locality Authorisation (LA).

LA is a means of ensuring that

- All compliance requirements for the research are in place (e.g. legal, ethics review, peer review, SCOTT approval).
- All resources that will be required for the research have been identified and the costs covered in some way.
- The research has been discussed with all relevant staff in the Te Whatu Ora - Southern and DSM to identify and manage any (risk) issues or concerns that might arise e.g. as a result of involving patients, staff and resources of the Te Whatu Ora - Southern.

As well as Te Whatu Ora and DSM requiring confirmation that all of the above have been covered, ethics committees also require that localities have reviewed and approved research projects prior to their implementation.

Health Research South is the body charged with overseeing research in the Te Whatu Ora - Southern and DSM and implementing the LA process.

LA is customised according to the type of research project and the best way to be sure you understand the requirements for any particular research project is to visit the HRS Office.

However, there are key areas that need to be addressed and these can be prepared in advance.

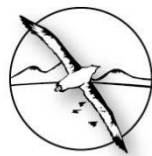
All research in the DSM and Te Whatu Ora - Southern requires the following seven areas to be addressed:

1. Registration. All clinical research studies must be registered with the Health Research South Research Office. Please see the “Locality Authorisation application form” or “Minimal Risk Locality Authorisation application form” under *Registration* on the HRS website www.otago.ac.nz/hrs

2. Scientific Peer Review. Peer Review of the **study protocol** for DSM staff members is carried out by the Departmental Peer Review Committees. Peer Review for researchers external to the DSM will need to check with the HRS Office. The Peer Review process is described under *Peer Review* on the HRS website www.otago.ac.nz/hrs

3. Ethics. Ethical review is carried out by either Health and Disabilities Ethics Committees (HDEC) or the University of Otago Human Ethics Committee (Health). The choice of committee depends on the type of research you are doing. For further information please check with the HRS office or the HDEC website <http://ethics.health.govt.nz/>

4. Māori Consultation. Māori consultation is required by the University of Otago. Details of this process can be found on the University of Otago website www.otago.ac.nz/research/maoriconsultation/



5. Research Costs and Funding. All research uses resources (staff, procedures, equipment, admin supplies etc). Te Whatu Ora - Southern is not funded to carry out research and all costs must be identified and covered. In general:

- If the funding for the research is a grant, the costing must be carried out on a UoO costing worksheet (CCW). You will need to contact your Research Advisor to work through this.
- If the research is a commercial trial the costing will be carried out on Te Whatu Ora - Southern approved NZACREs costing template. You will need to contact the HRS Office to work through this.
- If the funding comes from elsewhere (e.g. internal departmental funds) you can develop your own costing layout.
- If there will be no cost to Te Whatu Ora – Southern, this must be clearly explained on the LA form

6. Contracts. Contracts between the UoO or Te Whatu Ora - Southern and Sponsors for grants and commercial trials must be handled by the HRS Office (Te Whatu Ora - Southern commercial trials) or your Research and Enterprise Research Advisor (UoO grants and commercial trials).

7. Consultation with Te Whatu Ora - Southern and DSM Staff. It is important that Te Whatu Ora - Southern staff know what research is happening in their area so they can decide how to accommodate for the resources required. There are some key people who **MUST** be informed (Te Whatu Ora - Southern Clinical Leader and/or other relevant professional leader, DSM Academic Leader, Te Whatu Ora - Southern General Manager) but other “on the ground” staff will need to know about your project. HRS can help you identify who these people are but, as a minimum, the Te Whatu Ora - Southern Service Manager should be approached if the project is taking place within the Te Whatu Ora - Southern.

Audit and Quality Improvement

An audit is part of Quality Improvement (QI) in the healthcare service. **Locality Authorisation is not required for audits or QI.** However, we do recommend applying for an Ethics approval from University of Otago Human Ethics Committee (Health) for an audit as this is often required for publication or presentation of your findings.

Any doubts? Please check with Health Research South.

Where can you find us?

Visit our office: First floor, Dunedin Hospital

Visit our website: www.otago.ac.nz/health-research-south

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