Health Research South

October 2022

RESEARCH IN THE DUNEDIN SCHOOL OF MEDICINE AND TE WHATU ORA HEALTH NEW ZEALAND – SOUTHERN CODE OF CONDUCT FOR CLINICAL RESEARCH

A. CONDUCTING CLINICAL RESEARCH IN THE SHARED RESEARCH ENVIRONMENT OF TE WHATU ORA - SOUTHERN AND DUNEDIN SCHOOL OF MEDICINE

1) Conduct of Clinical Research
   a) This document defines the expectations of the **Health Research South** with regard to the conduct of clinical research in Te Whatu Ora - Southern and the Dunedin School of Medicine (DSM).
   b) Geographical scope / limit of this document: The content of this document is limited to Te Whatu Ora – Southern which covers the geographical area that Southern DHB previously represented under the New Zealand Public Health and Disability Act 2000.

2) Research Encompassed by this Policy
   a) The term "Clinical Research" for the purposes of this policy document is used in a broad context to refer to any of the conditions below.
   b) Research studies involving patients and consumers of Te Whatu Ora - Southern, including its sites at Dunedin Hospital, Wakari Hospital, Southland Hospital, Lakes District Hospital, and the Southern Blood and Cancer Service. This includes any recruitment activities within Te Whatu Ora – Southern targeting patients of Te Whatu Ora - Southern.
   c) Research studies involving use of the staff, facilities or any resources of Te Whatu Ora - Southern

d) Research studies involving access to patient records

e) All research targeting women who are pregnant and accessing Queen Mary facilities including "f.5." below.

f) This policy does **not** cover:

(1) Audit or clinical case study activities which are for the purposes of learning or improvement of personal or organisational process.

(2) research conducted by University of Otago (UoO) staff that does not involve staff, patients, facilities or resources of Te Whatu Ora - Southern; this will be managed in accordance with UoO procedure through the Research and Enterprise Office.

(3) research which is conducted outside the direct governance of Te Whatu Ora - Southern. This includes Dunstan, Waitaki, Clutha, Lawrence, Maniototo and Gore hospitals or any Primary Health Organisations whether or not these are funded by Te Whatu Ora - Southern.

(4) research which is carried out by Principal Investigators in their capacity as private consultants, that is, working with patients in their private practice.

(5) research conducted by external (non Te Whatu Ora - Southern or DSM) researchers which is recruiting participants as members of the public rather than through Te Whatu Ora - Southern clinics, lists, records etc. but advertised via fliers and notifications in Te Whatu Ora - Southern hospitals

3) Approval to carry out Clinical Research in Te Whatu Ora - Southern

a) Written approval must be gained from **Health Research South** before any clinical research can be carried out in Te Whatu Ora – Southern .

b) The Health Research South Research Office administers the approval process under delegation from its Board.

c) Researchers are required to register any intended clinical research through the Health Research South Research Office.

d) Health Research South will advise investigators and facilitate approval processes as necessary.

e) Health Research South will ensure all processes required for approval have been completed.

f) Health Research South is responsible to the Board to ensure all requirements have been met.

g) Approval will be given by the Health Research South Research Office (under delegation from the HRS Board) once all requirements have been met.

h) Written approval is provided when all approval requirements have been carried out. This includes fulfilling the requirements for

   i) Ethical approval for human research including scientific peer review,

   ii) Māori consultation,

   iii) legislative and privacy regulations,

   iv) internal Te Whatu Ora - Southern /DSM approvals,

   v) budgeting

   vi) funding

4) Responsibilities of Principal Investigator

   a) Each project must have a Principal Investigator (PI). An appropriate PI must:

      i) be a professional employee of Te Whatu Ora - Southern or the DSM and

      ii) be able to demonstrate that they have appropriate research skills and

      iii) be an individual who can be held accountable for the completion of the research and

      iv) not be a temporary staff member in a department.

   b) The PI is responsible for ensuring all aspects of Locality Authorisation Approval have been completed including ensuring:

      i) the principles of Good Clinical Practice are adhered to (see ICH E6 Good Clinical Practice) as appropriate

      ii) design, and conduct of the research project is relevant and appropriate

      iii) ethical approval has been obtained (including scientific peer review)

      iv) costs of carrying out the research have been identified and a budget prepared

      v) agreed funding arrangements are in place

      vi) Māori consultation has been carried out in accordance with University of Otago requirements

      vii) relevant DSM and Te Whatu Ora - Southern staff have been engaged with (see "d" below)

      viii) any other matters of compliance have been identified and attended to.

c) The PI is responsible for ongoing conduct of the study including ensuring:
   i) ethical standards are maintained
   ii) patient safety and confidentiality are maintained
   iii) any reporting requirements are fulfilled
   iv) sound financial management of the project
d) PIs must consult with the appropriate DSM Academic Departmental Head, Te Whatu Ora - Southern General Manager and Te Whatu Ora - Southern Clinical Leader (or equivalent professional leader) to ensure that patient safety and cost issues are satisfactorily addressed.
e) PIs who are not DSM or Te Whatu Ora - Southern employed must arrange for a "site" PI to take responsibility. The "site" PI has the same responsibilities as the PI (above)
f) **Health Research South** will determine any exceptions to the above on a case by case basis.

5) Role of Te Whatu Ora - Southern Management and DSM Heads of Academic Departments
   a) Approval to conduct research requires evidence that the appropriate DSM Academic Head, Te Whatu Ora - Southern Clinical Leader (or other discipline, as appropriate) and Te Whatu Ora - Southern General Manager have all reviewed the research study. Evidence of review takes the form of a signature in the appropriate place in the Locality Authorisation Approval form.
   b) Approvals for research taking place in Southland Hospital, Lakes District Hospital are the same as for Dunedin Hospital.
   c) The **Clinical Leader, or equivalent Allied Health, Nursing or Midwifery professional** is responsible for reviewing the research, patient safety and clinical service impact on behalf of Te Whatu Ora - Southern. Where the Clinical Leader (or equivalent) has a conflict of interest, or is the PI, review and sign off should be by the appropriate Medical Director or a Clinical Leader from another Service area. Where the research spans multiple Services the researcher should contact HRS for advice regarding appropriate signatories.
   d) The **General Manager** is responsible for oversight of financial and resource considerations on behalf of Te Whatu Ora - Southern. Specifically the General

Manager is responsible for ensuring there are no resource implications over and above those that are already covered off by Health Research South or the other signatories.

e) The **Academic Leader** has responsibility for ensuring there are no DSM resourcing issues. In addition, review of a proposed project should include consideration for its scientific value and feasibility. While the Scientific Peer Review process ensures methodology is satisfactory, even though these clinical studies are not conducted in DSM, it is still important to ensure a DSM perspective to help protect against the unexpected within the **shared research environment**. Where the Academic Leader is the PI or there is a conflict-of-interest HRS may direct an applicant to the most suitable Academic Leader. If there is no DSM involvement, the Dean of the DSM will sign as Academic Leader.

6) Roles of the Te Whatu Ora - Southern District Director and the DSM Dean

The Te Whatu Ora - Southern District Director and the Dean of the DSM are jointly responsible for research in the **shared research environment** of the DSM and Te Whatu Ora - Southern. Their responsibility is to consider the research from a broad organisational perspective and approve the research (subject to ethical approval) on behalf of their respective organisations.

7) Ethical Standards of Research

a) The standards that apply to research involving human participants, tissue, fluids or records, are contained in the Ministry of Health, NEAC National Ethical Standards for Health and Disability Research and Quality Improvement (December 2019) or as updated from time to time.

b) All human research carried out in the shared research environment of the DSM and Te Whatu Ora - Southern must have undergone ethical review and been approved by either the Health and Disabilities Ethics Committees or the University of Otago Human Ethics Committee (Health). Researchers should refer to the guidelines, and/or seek advice from both ethics approval bodies to ensure the correct ethical approval is gained.

c) Researchers from Te Whatu Ora - Southern may also access the University of Otago Human Ethics Committee (Health) under the Deed addressing this between the University of Otago and Southern District Health Board, July 2015.

d) Professional associations and various granting bodies may have additional policies that should be consulted as appropriate.

8) Consultation with Māori

a) The University of Otago and Te Whatu Ora - Southern have a commitment to partnership with Māori consistent with the Treaty of Waitangi and both organisations' stated objectives.

b) A Policy for Research Consultation with Māori provides the framework for an appropriate and mandated consultation process with Māori for research. Researchers from the University of Otago must follow this process.

c) The policy is available on the University of Otago website along with the requirements for the consultation process. Proposals should be submitted online for the consideration of the Ngāi Tahu Research Consultation Committee via www.otago.ac.nz/research/maoriconsultation/

d) Researchers from Te Whatu Ora - Southern may also access this consultation process as part of shared DSM and Te Whatu Ora - Southern research arrangements.

9) Financial Administration of Research

a) Clinical research studies fall into three broad categories for the purposes of financial administration: commercial clinical research, externally funded investigator led (public good) research and internally funded investigator led (public good) research.

b) Commercial clinical research is

i) research which is conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled as stated in Accident Compensation Act 2001, Section 32, and determined by Health and Disability Ethics Committee review (Standard operating Procedures for Health and Disability Ethics Committees, Version 3.0, December 2019)

ii) to be contracted through Te Whatu Ora - Southern and must have an approved and dedicated Research Project Account. All commercial clinical research must be fully cost recoverable including overheads and must operate in accordance with the policy document "Managing Research Project Accounts and Research Group Accounts held by The Southern District Health Board"

c) All other externally funded (investigator-led) research should be administered through the University of Otago using an approved and dedicated University research account. Any exemptions for full cost recovery including overheads will be determined via University of Otago processes.

d) Exceptions to the contractual and financial administration outlined above occur when

   i) a UoO/DSM-only employee is PI for a commercial trial, or

   ii) a Te Whatu Ora - Southern-only employee is PI for a non- commercial, externally- funded study.

   In these cases the contracting will be with the organisation with which the PI is employed.

e) Regardless of contracting or financial route, any Te Whatu Ora - Southern related resource required by any research study must be clearly identified and cost recovery carried out as agreed with Te Whatu Ora - Southern. Health Research South will advise on the arrangements needed.

f) Where there is any doubt as to the nature of the research, its administration path or other financial and/or contracting aspects, the HRS Board will determine on a case by case basis whether any exemptions are warranted

g) Subcontracting and other payment arrangements between DSM and Te Whatu Ora - Southern for staff and services:

   i) From time to time staff and services of Te Whatu Ora - Southern may be required to carry out DSM research projects and vice versa.

   ii) It is important that there is clarity around whether and how costs will be paid between the two organisations. While there is an agreement to share a research environment, the financial systems are separate.

   iii) In the case of staff where employment conditions, responsibilities and payment need to be clear, a subcontract or a fully executed Master Service Agreement and an associated Statement of Work are required . However in

some cases, where the staffing requirement is small e.g. a few hours periodically, Te Whatu Ora - Southern Service Managers may arrange for staff to carry out UoO research project work on a quid pro quo basis. Similarly, Managers of UoO Research Nurses may do likewise for Te Whatu Ora - Southern research projects. Either arrangement must be in writing and clear communication is vital. HRS will assist in the setting up of these arrangements.

iv) In the case of other services, there are various mechanisms for recouping costs depending on the nature of the resource used e.g.:

- Subcontract, supported by Resource Request Forms as required for major resources and services. Resource Request Forms serve as a quote and confirm that a request has been approved and costed by the provider of the resource or service.
- Resource Request Forms only may be used for small cost, easily invoiced services provided between the UoO and Te Whatu Ora - Southern, or for services provided within Te Whatu Ora - Southern where journaling of funds is the most efficient process for recouping costs.
- Quid quo pro / informal unpaid arrangements where the service provided can be easily incorporated into the organisations daily running and will not create a resourcing issue.

v) In all cases, clear communication, confirmed in writing (email etc) is vital to ensure both organisations are clear about the extent of the service being provided and the payment arrangements.

10) Financial Accountability for Research

a) The PI is responsible for ensuring a budget has been prepared which reflects, as nearly as possible, the real costs of the research project, including all relevant overheads. The PI is also responsible for ensuring the day to day financial and administrative management of approved research projects had been attended to.

b) A budget must be prepared for all clinical research studies. Budgeting for commercial clinical research must be prepared using a *HRS approved Clinical Study Costing Sheet (unless exception 9d above)*. Budgeting for a DSM investigator-led externally funded research studies must be prepared using a *University of Otago Costing and Consents Worksheet (unless exception 9d above)*. Exceptions use

the appropriate organisational budget template. Internally funded research project budgets should be prepared in a format appropriate to the size of the project and the costs.

c) For details of financial management policies and practice refer to
   i) "Managing Research Project Accounts and Research Group Accounts held by Southern District Health Board" and "Budget and Costing & Consents Worksheet (CCW)", both can of which can be accessed through the Health Research South website: **www.otago.ac.nz/hrs**
   ii) University of Otago Financial Services policies and procedures

11) Monitoring of Research Projects

a) External grant funding bodies usually require regular reports. These reports should be submitted through the appropriate pathway e.g. UoO Research and Enterprise or HRS Research Office who will forward them to the relevant funding body. Internal funds may also require reports. Reporting requirements are usually indicated along with call for applications or letter of award. HRS can advise on the timing and format of reporting.
b) Commercial clinical trials and collaborative/cooperative clinical trials must comply with contractual and protocol requirements.

12) Completing the research project

a) Once the research project is completed, a number of obligations must be fulfilled. These may include:
   i) Making the results of the research public through journal article, report etc
   ii) Providing final reports and copy of any published materials to funder/s
   iii) Closing down research accounts in accordance with the appropriate policy and process
   iv) Final report to the Ethics committee

13) Variations to an Approved Research Project

a) When substantial variations to an approved project, requiring ethical re-approval, extension of the period of data collection, or review of funding arrangements, are

proposed, the PI must advise HRS in writing. No research affected by the changes may take place until approved by HRS. Requests for extension of the approved period of data collection should be made two months in advance of the scheduled termination.

b) Variations to commercial clinical research must be negotiated through HRS

14) Designated Authority for Signing Research Contracts and other legal documents

a) Legal documents including, but not limited to, contracts, indemnities, data sharing agreements and non-disclosure agreements, with sponsors of research (e.g. pharmaceutical companies and grant bodies) require the signature of designated officers of the institution operating the research account and reporting process. Individual Researchers, Departmental Heads, Group Managers and Clinical Leaders do not have this authority. Obtaining appropriate signatures after legal review and scrutiny of the legal document is the responsibility of HRS.

15) Conduct of Research at Other Institutions

Staff of Te Whatu Ora - Southern /DSM conducting research at another institution must abide by the policies and procedures of that institution, but should notify the HRS of their participation.

16) Disputes

a) If a dispute arises over the approval process or the conduct of research, resolution will be facilitated through HRS, in the first instance by the Chair of the HRS Board, and referred to the Te Whatu Ora - Southern District Director, or the Dean of DSM or both, as appropriate.

17) Authority to Defer, Suspend or Terminate Research

a) The Te Whatu Ora - Southern District Director or, where appropriate, the Dean of the DSM may defer or suspend a project, including withdrawing HDEC Locality Authorisation, at any time in the interests of safety of patients or staff, or where financial risk to either institution becomes apparent. The advice of the **Health Research South** will be taken into account before any decision to terminate a project is taken.

B. CONDUCTING NON-CLINICAL RESEARCH IN THE SHARED RESEARCH ENVIRONMENT

18) While HRS has an interest in and oversight over all research in the DSM and Te Whatu Ora - Southern, not all research is required to undergo Locality Authorisation Approval.

19) DSM research which does not require Locality Authorisation Approval should follow the processes required by the relevant DSM Department

20) Te Whatu Ora - Southern research which does not require Locality Authorisation Approval should be forwarded to Health Research South where arrangements will be made on a case by case basis for approval from, or liaison with, relevant managers and other Te Whatu Ora - Southern staff as appropriate, and for meeting any compliance requirements.

C. ACCOMPANYING DOCUMENTS.

a) HRS – Terms of Reference
b) Locality Authorisation Approval - forms and guideline
c) Managing Research Project Accounts and Research Group Accounts held by Southern District Health Board (SDHB)
d) Peer Review
e) Privacy Impact Assessment form

ADDENDUM 1: MINIMAL RISK LOCALITY AUTHORISATION FORM

In order to simplify the Locality approval process for "Minimal Risk Clinical Research" projects in June 2020 a new Minimal Risk Locality Authorisation form was created.

A "Minimal Risk Clinical Research" project may involve staff, facilities and any Te Whatu Ora - Southern resources or access to Te Whatu Ora - Southern de-identified patient's records. It excludes projects involving patients of Te Whatu Ora - Southern.

Written Locality authorisation approval will be provided only once all approval requirements have been meet. These requirements are:

i) Obtaining Ethical approval based on a Minimal Risk Health Research Ethics Application, including confirmation of scientific peer review,
ii) Completing Māori consultation submission,
iii) Complying to all legislative regulations,
iv) Completing all Te Whatu Ora - Southern /DSM approvals processes,
v) Submitting a budget,
vi) Demonstrating that funding has been granted,
vii) Submitting evidence of consultation with the following, taking the form of a signature:

1) DSM Academic Leader (relevant to DSM staff or joint clinical staff),
2) Te Whatu Ora - Southern Clinical Leader, (or other discipline, as appropriate),

3) Te Whatu Ora - Southern Service Manager.

The Service Manager is responsible for ensuring that there are no financial or resource implications over and above those that are already covered by Health Research South or the other signatories. These should be expected to be minimal or insignificant given the minimal risk nature of the research project.

The Service Manager is to liaise with the relevant General Manager, if financial and resource considerations are considered to be significant.

The Te Whatu Ora - Southern General Manager, the Te Whatu Ora - Southern District Director and the Dean of the DSM are to be notified of the research project once the Minimal Risk Locality Approval has been granted by the HRS.