

RESEARCH MANUAL

University of Otago, Christchurch

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Introduction

The aims of this manual are three-fold. Firstly, it has been written to help emerging researchers establish a research profile at the University of Otago, Christchurch. Secondly, it provides a repository for information, especially for new staff, on the various forms and procedures required when undertaking a research project. Thirdly, it aims to be a general reference document for all administration and compliance aspects of research undertaken at the University of Otago, Christchurch (UOC).

This manual will be an "active" document and will be updated as new procedures are put in place. As such, we hope it will be a very useful tool.

Manuals have been customised for the various Schools within the Division of Health Sciences. This manual has been customised for UOC. There are separate manuals for the Dunedin and Wellington Schools of Medicine and a manual for the Otago School of Medical Sciences and the Schools of Physiotherapy, Dentistry and Pharmacy. If you require a manual for a different School please contact Dr Michele Coleman at michele.coleman@otago.ac.nz.



Preface for Emerging Researchers:

Prior to starting the new job!

As an emerging researcher, it is likely you have recently finished (or are in the process of finishing) your post-doctoral fellowship or clinical research training. There are a number of important things you should consider prior to starting your new appointment. These include identifying: a) what your specific research focus will be; b) what you need in the way of equipment to be able to start your research; c) any experienced and established researchers who you may be able to collaborate with; d) a well-established person who is willing to act as a 'mentor'; and e) the most relevant grants for you to apply for. These points are considered in more detail below.

- a) Research Focus: Although your research direction may change upon appointment, the identification of an initial research focus will help to determine what resources you will need (i.e. equipment and funding) and who you may want to collaborate with.
- b) Equipment Needs: The equipment you have (or have access to) will dictate to a large extent your research focus. Your grant application will need to reflect both the skills you have and the equipment available to you in order to address the aims of your grant proposal.
- c) Collaborators: Initially, it may be of benefit to have some experienced and established researchers to collaborate with. Such collaborations will allow better access to equipment, new techniques, different patients, etc. Successful collaborations can enable you to carry out quality research, research that may not otherwise be possible on your own.
- d) Mentorship: Having a good mentor is invaluable. This person does not necessarily need to be an expert in your research area. It is more important that they should be experienced in attracting external funding, or be in a position to offer advice on all aspects of your progression (e.g. Head of Department). They should be willing to offer some informal mentorship and have the time to provide feedback on your grant applications. If you are also able to run your applications by an 'expert' in your particular field then clearly this will be very helpful. However, be aware that 'good science' is unlikely to get funded if your grant application is of poor quality. Constructive advice on grant writing is critical.
- e) Relevant Grants: It is very useful to have a good 'feel' for the range of grants available and for those that are most relevant to you and your field of research. There are now also specific grants available for emerging researchers with both the HRC and the Marsden Foundation. Other smaller internal (less competitive) sources of funding should also be considered since these can enable you to get some of your projects up and running and/or provide funds for research staff in the interim.

The Research Office

The purpose of the UOC Research Office is to provide high quality, professional research support to researchers in the Health Sciences relating to all applications and contracts for staff at the UOC.

University of Otago, Christchurch Research Office

Staff

Research Manager	Rebecca Coombes	Rebecca.Coombes@otago.ac.nz
Kaitohutohu Rangahau Hauora	Karen Keelan	Karen.Keelan@otago.ac.nz
Māori		
R & E (Christchurch) Research	Karen Chaney	Karen.Chaney@otago.ac.nz
Advisor		
R & E (Christchurch) Research	Kosta Tabakakis	Kosta.Tabakakis@otago.ac.nz
Advisor		
R & E (Christchurch) Senior	Jen Dreaver	Jen.Dreaver@otago.ac.nz
Research Administrator		
UOC Research Office Generic		research.uoc@otago.ac.nz
Email		

Physical Address

Research Office Level 5 University of Otago, Christchurch 2 Riccarton Avenue Christchurch

Postal Address

Research Office University of Otago Christchurch PO Box 4345 Christchurch 8140

Office Hours and Contact Details

Monday - Friday, 8:30 am - 5:00 pm

Phone: 03 364 0237

Email: research.uoc@otago.ac.nz

The Research Advisors

The Research Advisors are Karen Chaney and Kosta Tabakakis (Research & Enterprise). They will help you with any queries you have in relation to research at the UOC and should be your first point of call when you are thinking of submitting a proposal or needing advice.

Karen is responsible for providing support to the following departments: *Medicine, Psychological Medicine, Orthopaedic Surgery and Musculoskeletal Medicine, the Deans Department, the Centre for Postgraduate Nursing Studies and MIHI.*

Kosta is responsible for providing support to the following departments: *Paediatrics, Radiology and the Centre for Bioengineering, Pathology, Population Health, Obstetrics and Gynaecology, General Practice, Surgery and Anaesthesia.*

Role: To provide high quality, professional research proposal support to researchers in the Health Sciences relating to all applications and contracts for staff at the UOC

Kaitohutohu Rangahau Hauora Māori

Karen Keelan

Email: <u>Karen.Keelan@otago.ac.nz</u>

Phone: (03) 364 1658 Mobile 021 993 489

Office Hours

Monday 8.30am to 4.30pm Thursday 8.30am to 4.30pm Alternate Fridays

About Karen

Nei rā te mihi koutou. Ko Hikurangi te maunga, Ko Waiapu te awa, Ko Te-Aitanga-a-Materoa te hapu, Ko Te Aowera te marae, Ko Ngāti Porou te iwi. Ko Karen Keelan tōku ingoa.

Kia ora, my name is Karen Keelan. My role as Māori Research Advisor is to manage and increase the responsiveness of research undertaken at the University of Otago, Christchurch to meet the needs and aspirations of Māori.

Other facets of my role include maintaining, building and bridging relationships between Māori (Ngai Tahu and Mataa Waka), the University and researchers. I have a strong interest in Māori health, particularly health inequalities research.

Much of my employment history has been based working for and in health and social service sectors.

Research and Development Manager

Rebecca Coombes

Email: Rebecca.Coombes@otago.ac.nz

Phone: (03) 364 038

Role: to oversee developing research in UOC and CDHB and the running of the combined research office. She supports the function of the Research Advisors to meet and assist researchers individually with their work and any issues within the research office that require escalation come to Rebecca.

Rebecca is focused on

- risk mitigation
- strategic and process improvements
- ethics queries
- networking of researchers and funders
- o developing our research abilities and culture

Rebecca also manages the Summer Studentship programme, secretary for the UOC and CDHB research committees and is active in the area of research management in DHBs and Clinical Trials throughout NZ.

Associate Dean of Research University of Otago, Christchurch

Professor Margreet Vissers

Email: margreet.vissers@otago.ac.nz

Phone: (03) 364 1524

Role: The Associate Dean (Research; ADR) is responsible for providing strategic leadership and overall coordination for research development at UOC.

The Research Email List

UOC staff who wish to receive regular research information by email should send an email to: research.uoc@otago.ac.nz with the subject heading "SUBSCRIBE". No message is necessary.

(To unsubscribe send an email with the subject heading "UNSUBSCRIBE")

Research Websites

Information about research funding, together with application forms, costing sheets and guidelines are presented in this manual but can also be found on the University of Otago, Christchurch, Research Office website.

www.otago.ac.nz/christchurch/research/researchoffice/

The Division of Health Sciences Research Committee supports a number of funded opportunities, including provision of PhD Travel Funds and Postdoctoral Fellowships. http://healthsci.otago.ac.nz/research/index.html

Research Procedures

The flow chart on the following page summarises the procedures you need to go through when intending to undertake research at the UOC.

Each bold heading in the flow chart is book marked so if you want to know more, just click on the heading. Alternatively, you can just read the notes following the flow chart.

Important!

Who is the Host institution for the Project?

- The host institution is the institution that employs the Principal Investigator (PI). Under exceptional circumstances, and with approval from all relevant institutions, exceptions to the rule may be granted.
- The host institution is responsible for ensuring that the project has been peerreviewed and budgeted appropriately (pre-award stage), ethics and other regulatory approvals have been obtained, Maori consultation has occurred, and providing support in the form of basic facilities for research and the services necessary for its fulfilment.
- Any services or work carried out in another institution will be formalised through a subcontract between the institution and the host institution, with appropriate locality assessment approval as required.



Research Procedures at the UOC Flow Chart

Approached by an organisation to conduct some research or wanting to respond to a request for proposal (RFP) or a Call for applications

Original Research Idea

Discuss the project with your Mentor / Head of Department and discuss key questions

Apply online for a <u>Maori Consultation</u> with Karen Keelan http://www.otago.ac.nz/christchurch/research/researchoffice/maoriconsultation/index.html

Contact the appropriate Research Advisor

Check the <u>Indicatory Contract</u> with the Research Advisor and fill out the **RFP**.

Send electronic copy to Research Advisor for checking, signing, copying and sending Identify Sources of funding and fill out Application Form(s)

http://www.otago.ac.nz/research/forms Send electronic copy to Research Advisor

for checking, signing, copying and sending

Fill in a Costings and Consents Worksheet (CCW) http://www.otago.ac.nz/research/forms/1 COSTINGS CONSENTS CCW/

Send electronic copy to Research Advisor for checking and signing.

Fill in (if required) a <u>Memorandum of Understanding</u> (<u>MoU</u>) with assistance from Research Advisor. Form available from Research Advisor.

If required, obtain ethics approval from either HDEC or UO Ethics (Human and/or Animal):

UO Human:

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

UOC Animal: information and forms (including IARMS)

HDEC: https://nz.ethicsform.org/SignIn.aspx

- Is your HOD aware of your research ideas?
- What personnel will be involved in the research, internal staff, students, external other University personnel, contractors?
- Where will the research be sited?
- What resources will you need to complete research budget, space?
- What are your options for funding?

Return to flow chart

Research Advisor

Always make sure you contact the **Research Office** to advise them that you are intending to submit a proposal. They can provide advice and guidance now, which may well save you time later.

Karen Chaney Research Advisor, R & E Tel: 03 364 1593

Email: <u>Karen.Chaney@otago.ac.nz</u>

Kosta Tabakakis Research Advisor, R & E Tel: 03 378 6370

Email: Kosta.Tabakakis@otago.ac.nz

Return to flow chart (procedures)

Return to flowchart (contracts)

Funding Application Form(s)

For original research, you will need to identify the possible **sources of funding** for your project (e.g. Cancer Foundation, Health Research Council (HRC), Heart Foundation etc.) and obtain the application form(s) for these organisations. Note down the closing deadlines and the application requirements. The following web page provides a list of possible funding sources and their application forms;

http://www.otago.ac.nz/christchurch/research/researchoffice/fundingcalendar/index.

The list of Funders is vast. Some of the names on the list give you an obvious clue as to what type of research they may fund e.g. "Cancer Society" for cancer research, but there are also many that are not so obvious e.g. "FRST" or "Marsden". This is one of the reasons you should contact the Research Advisor early on as they have a good understanding of who may fund what. This will save you a lot of time in the long run.

When you have decided on which funders you might like to apply to for funding, just click on their name and this will take you to another index which should include their application form to download as well as any other information that may be useful.

Obviously, it is beyond the scope of this research manual to go through each funder and describe how to fill in the application form. Most application forms will come with quidelines and often it is just a case of providing them with the information they need.

For tips on writing grants, visit the following webpage; http://www.otago.ac.nz/research/proposals/otago004485.html

You need to send an electronic copy of your application to the Research Advisor at least 10 business days before the funder's closing date, as the Research Advisor needs to have time to check your application, prepare the number of copies required by the funder, get the forms signed by the Dean and courier them to the funder. Please refer to the **funding calendar** for the internal deadlines:

http://www.otago.ac.nz/christchurch/research/researchoffice/fundingcalendar/index.html

IMPORTANT: Should your application be successful, recognise that the Funder may not wish to purchase all research you offer in your application. If you are offered reduced money, be prepared to negotiate reduced research (revised objectives). Return to flow chart

Request for Proposal

A Request for Proposal (RFP) is an invitation for providers of a product or service (in this case, research) to bid on the right to supply that product or service to the individual or entity that issued the RFP.

RFP's are regularly advertised by many agencies such as ACC, Ministry of Health, etc. The following website lists all Government agencies RFP's and has a daily tender watch notification system.

http://www.gets.govt.nz

The UOC Research Advisor receives these notifications and can gain access to this website. If you would like to receive these notifications, contact a Research Advisor to obtain access.

Return to flow chart

Tender Document

Prepare the **RFP/ tender document** as per the prescription given. Discuss this with a Research Advisor. The RFP is signed and the Research Advisor submits this, usually by courier.

Return to flow chart

Indicatory Contract

Some Request for Proposal's (RFP's) come with an **Indicatory Contract**. The Research Advisor needs to check this thoroughly with you to ensure that everyone is happy with the conditions proposed in this contract. Sometimes, this will be the only chance to ensure clauses that don't suit are amended, added or deleted.

As well as timeframes proposed, special consideration needs to be given to CLIPPE.

C onfidentiality
L iability
I ntellectual property
P ublication
P ublicity
E xclusion

Return to flow chart

Costing and Consents Worksheet (CCW)

The CCW serves several functions: (1) To aid in the preparation of your budget, (2) to act as a template for the eventual contract between the University and the Funding Agency, and (3) will determine your eventual account details for the research contract. The CCW form can be downloaded from the website:

http://www.otago.ac.nz/research/forms

Please note that there are 2 **costing sheets** – the standard one and one for scholarships/travel/equipment only. Please make sure you download the correct CCW.

All applications and formal proposals must be accompanied by a University of Otago Costing and Consents Worksheet. As well as costing information, this worksheet includes the checklist covering statutory and regulatory consents and approvals.

Please note that this is an **internal document only**. It is never to be referred to or made public to anyone.

The costing sheet is also used to set up the contract account for the project if it is funded.

University of Otago Full Cost Recovery Policy

The University applies the principle of full cost recovery for externally funded research. An explanation of full cost recovery principles and their application at the University of Otago is available on the following website;

http://www.otago.ac.nz/administration/policies/otago003192.html

The full cost of research must be identified in all contracts even where there are situations where it is not possible for the University to recover the full cost of the research. In any proposal to waive a proportion of the costs, the difference between the full cost and recovered income becomes a direct charge on the Department or School and requires formal recommendation and approval by the Head of Department/Cost Centre Manager, the Dean of School or Pro-Vice-Chancellor and approval by the Deputy Vice-Chancellor (Research).

The CCW looks very daunting when first approached, but it has in fact become a very user-friendly document over the years as it has been worked and re-worked to make it as easy as possible to use. To save time and to make sure you get things correct at the very start, it is suggested that you ask one of the Research Advisors to show you how to fill in the CCW form.

General Consents and Costings Worksheet (CCW)

The following gives you detailed information on how to complete out the CCW. Please remember that this document is your best guess on the day and is unlikely to be 100% accurate.

Structure and Completing the General CCW

There are **12** tab pages in this workbook. Researchers are required to liaise with their dedicated Research Advisor when completing the CCW.

Tab page 1 "Printing" enables the user to print the desired pages in the CCW by clicking on the appropriate button(s). If you are unable to print, click on the "Enable Content" button and try again.

Tab page 2 "Summary" is where the project specific details are entered (i.e. PI, Project Title, Start and End Dates). Many of the cells contain drop-down menus that enable you to populate the cell with the required information. This page also includes a table that summarises information previously entered in the applicable tab pages (e.g., indirect salaries, operating expenses).

Specifically, all the previously entered details are automatically pasted to this page and both the Full Cost and Price column are automatically filled in. If the full cost is not being requested, then amendments are made to the Price Column by overtyping the figures. For example, perhaps you are not asking the funder to fund a special piece of equipment as you have received funding for that elsewhere you would then alter the Price column accordingly leaving the cost without that piece of equipment. Some funders do not pay overheads (e.g., Charitable Organisations) and therefore, the price to them would be the full cost minus the overheads, so you would remove the overhead figure in the pricing column. **Important**: Once the field has been overwritten the formula will be lost! So only do this when the full cost has been calculated. Any alteration to the full cost should be justified in the "comments" section.

Overhead Rate. Overheads cover all the indirect costs to a project. For example, the cost of the desk you work at, the lights, the heating and Human Resources. The default value is 105% but 124% should be entered for commercial contracts (services or consultancy work). If you are not sure about this, then check with the Research Advisor.

Tab page 3 **"Finances"** This provides an itemised summary of all the costings and is calculated based on the entries in the relevant cells within each tab (i.e., indirect salaries, operating expenses etc.).

Tab page 4 "Indirect Staff"

Indirect staff are the staff who have a full-time commitment to clinical services or teaching and for whom 'buy-out' time is required. You need to know their grade and the department, how much they earn each year of the project. You will need a summary of how many full-time equivalent (FTE) staff time are working on this project.

You also need to know if they are receiving superannuation and if so, under which scheme (Government or University; each has a different rate). To get this information you can try asking them, but most people unfortunately do not know their salary grade so you need to ask the Research Advisor to source this. Once you know someone's grade, you can calculate their salary by looking at the salary charts available at: http://www.otago.ac.nz/research/forms/2 SALARY%20SCALE%20PROJECTIONS/

Note: When inserting salary information into the CCW, please use projected salaries for the time of the project, taking any likely promotions into account.

General staff figures are only available for the current year, so you should add a reasonable increase (we suggest 2%) for each successive year of the project (please note that this percentage figure is NOT University policy but an estimate of what may happen in negotiations between staff and the University). Remember to look at the side of each chart where normal progression is listed.

It is also necessary to build in promotions that are likely to occur. These should be discussed with each staff member individually.

Medical pay scales are very different to general staff pay scales so make sure you are looking at the right scale.

To calculate full time equivalents (FTE's), simply use the FTE calculator on the side of the form and it will automatically calculate the FTE once you give it the hours and weeks the person will be working on the project.

REMEMBER: Projects starting on 1 July or after, use the following year's pay scale.

Superannuation and ACC

There is a dropdown menu in the Super cell which allows you to populate the appropriate Super scheme (Uni, Govt, Kiwi or None). The form will automatically calculate Superannuation and ACC contributions for you.

Tab page 5 "Direct Staff" Direct staff are those who receive wages directly from this project. Information on direct staff salaries and salary related expenses is entered in the same way as for the indirect staff.

Casuals

Enter the salary amount for all casuals in the box provided. Holiday pay of 8% and ACC will be automatically calculated.

Tab page 6 "Ethics and Consents" This page is for the researcher to indicate whether the relevant consents and approvals information has been gained or is still needed for the project. Make sure you send copies of all required approvals with the CCW (if you have them).

Tab page 7 "Subs-Students" This is where you enter information pertaining to subcontracts and postgraduate students.

Subcontractors

Those outside the University working on the project. The name and institution or company should be recorded, as well as each yearly payment required. The unprinted space to the right of this box will give GST and ex-GST totals useful for checking Memorandums of Understanding (MOUs). (Remember that each of these people/institutions will need a MoU written for them which the Research Advisor will help you with).

Important: If you are unsure about whether someone is an employee or a subcontractor, please refer to the Otago University Human Resources website for guidelines. This is VERY important as there are Tax and employment issues involved! If you are still unsure, contact the Research Advisor.

http://www.otago.ac.nz/administration/policies/otago003037.html

Postgraduate Students

The postgraduate details are entered in the appropriate boxes. Stipends vary according to the funder and research programme (Masters or PhD). Please liaise with your RA to get the correct figures.

For a PhD student, the stipend and fees are for the full three years and the thesis costs for the final year. Indicative thesis cost (2016) - \$700.

For a Masters student, the stipend, fees and thesis costs are only in the research year.

Note: Some Funder's do not pay for fees or thesis costs.

Important: Please allow for a 5% annual increase in tuition fees in successive years.

Tab page 8 "OP Expenses" This is where those general operating expenses are entered. This page is used to split up each dissection's costs into more usable figures e.g., instead of having just one amount to cover photocopying and printing, you can split up this area into photocopying, printing and publishing. Consolidated yearly totals are automatically populated to the finances summary sheet (tab page 3).

It is often very hard to estimate how much operating expenses you will need over the length of the project and unfortunately, this is usually just a case of having your best guess. Be generous but not outlandish!

Tab page 9 "Equipment" This refers to purchases over \$2,000 (or \$5,000 for Marsden) and any computer purchases. Quotes should be attached for equipment purchases. Please note that very few Funders will allow you to purchase any but the most minor equipment. If you need specialised expensive equipment, you should investigate hiring it for the project term and put this down as a direct cost under "operating expenses". If new equipment is purchased for the project, but not paid for by the Funder, then it is reasonable to attribute depreciation towards the project.

Equipment Depreciation

Most people will put the computers used for the project in this section. The Asset Description will be the number of the computer (or other specialised piece of equipment). This number is usually found on a sticker on the side of the machine.

Tab pages 10 and 11 "ISR" and "Multi-Dept Split" are used by the Research Advisors.

Tab page 12 "Foreign \$" This sheet automatically displays the totals from the applicable tab pages converted to another currency, if the correct conversion rate is entered where required.

Commercial Profit

For commercial projects you have the opportunity to include a profit margin. This amount is added at the end in the price column. Ask the Research Advisor for advice on this.

What to do with the CCW

Once you have completed the Costing Worksheet, please email it to your dedicated Research Advisor for checking well BEFORE THE INTERNAL DEADLINE.

Signatures

Once the document has been checked by the Research Office it can be printed out and signed by the relevant parties (The Research Advisor will obtain the necessary Host Organisation signatures). Please note it is only necessary to print out the "Summary" and not the rest of the document. Please email a final copy of the CCW to the Research Advisor.

Return to flow chart

Travel/Equipment/Scholarships CCW

Travel

Please insert the costs into the appropriate cell within the CCW. Ensure that you have used the correct dissection (drop-down menu) next to each itemised cost using the key to the right of the tab page as a guide.

Equipment

Again, please insert the cost of the equipment into the appropriate cell and select the dissection that applies (8846 for Equipment or 8848 for Computers)

Scholarships

The postgraduate details are entered in the appropriate boxes. Stipends vary according to the funder and research programme (Masters or PhD; PhD: \$20,000-\$30,000; Masters: \$10,000-\$20,000). Please liaise with your RA to get the correct figures.

For a PhD student, the stipend and fees are for the full three years and the thesis costs for the final year. Indicative thesis cost (2016) - \$700.

For a Masters student, the stipend, fees and thesis costs are only for the research year. Indicative thesis cost (2016) - \$400.

Fees are inserted for the full three years. The fee schedule can be found at the following website:

http://www.otago.ac.nz/study/fees/

Important: Please allow for a 5% annual increase in tuition fees in successive years.

Note: Some Funder's do not pay for fees or thesis costs

"Ethics and Consents" tab page – This page is for the researcher to indicate whether the relevant consents and approvals information has been gained or is still needed for the project. Make sure you send copies of all required approvals with the CCW (if you have them).

Memorandum of Understanding

If you are going to be working with an external organisation or person (e.g. someone from another University or agency), then you will also need to fill in a **Memorandum of Understanding form (MoU)** to go with the costing worksheet (CCW). The Research Advisor will assist you with completing this form. Please contact the Research Office for the form and advice.

A Memorandum of Understanding (MoU) is a document that identifies the intended collaborators in a research project i.e. people or organisations that you will be working with outside of the University.

It is signed by the University of Otago and the external organisation, indicating an intention to collaborate should the project be funded. A Memorandum of Understanding must be signed at the time the research application is submitted. It will form the basis of your Subcontract if the application is successful.

A MoU includes the following;

- Which objectives the external organisation will be involved with
- FTE and salary costs of all subcontracted personnel
- Total consumable costs
- Overheads (if the funding body funds full cost recovery)
- The intended level of funding to the subcontractor for the period of the grant (subject to the funding provided by the sponsor)
- Specifies if the agreement is GST inclusive or exclusive

The MoU could also contain:

- A description of how the funding would change if the full amount of funding requested is not awarded
- A description of how Intellectual Property would be treated should the contract be successful

The MoU must be signed by the authorised signatory of the subcontracting organisation and be included with your grant application. **NOTE:** This signature cannot be accepted electronically and therefore you must allow time to have the MoU drawn up and then

sent to the collaborator, signed and then returned to you **before** the Research Office deadline.

Return to flow chart

Maori Consultation

The University of Otago has a commitment to partnership with Māori consistent with the Treaty of Waitangi and the University's stated objectives.

The Policy for Research Consultation with Māori provides the framework for an appropriate and relevant consultation process with Māori for research. It ensures an effective and efficient mechanism for managing the consultation process while acknowledging the needs and aspirations of Ngāi Tahu for Māori development and benefit the Ngāi Tahu Vision 2025.

This process is available to University of Otago researchers only. **Note:**

- 1. Appropriate consultation is required before you begin work on research proposals
- 2. Consultation is required for all areas of research
- 3. Consultation may take time so start well in advance of preparing your proposal

The consultation process asks researchers to submit a Research Consultation with Māori Form with information on your research proposition, which is then assessed for consultation requirements. The form as well as further information on the research consultation with Māori Policy is available from the following websites:

Form

http://www.otago.ac.nz/christchurch/research/researchoffice/maoriconsultation/otag o080683.html

Policy

http://www.otago.ac.nz/research/maoriconsultation/

You will be contacted for an appointment with Karen Keelan, Kaitohutohu Rangahau Hauora Māori, University of Otago, Christchurch after you submit your form online.

The HRC has produced a useful set of guidelines for researchers on health research involving Maori. This can be downloaded from:

http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori = %20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL%5B1%5D.pdf

Return to flow chart

Human Ethics Committee Approval

Projects involving research which involve human participants or the use of personal information must obtain permission from an Ethics Committee.

There are two Human Ethics Committees that are used for research at the UOC. The University of Otago Human Ethics Committee and the Health and Disability Ethics Committee (HDEC). The University of Otago Human Ethics Committee is independent from HDEC and each has its own application form and administration processes.

Health and Disability Ethics Committee(s)

When does a study require HDEC review?

To establish if your proposal requires HDEC approval, please work through the questions at the following website or contact the appropriate ethics Administrator; http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.ht ml

Additional information about whether your study may need HDEC approval is provided in the appendices.

It is often prudent to work through the ethics committee application at the same time as the other forms so that if you obtain funding you can submit an ethics application at the very next meeting and thus not have to postpone starting the project.

To complete and submit an application please go to the following website: https://nz.ethicsform.org/SignIn.aspx

The Online Forms website tells you everything you need to know about submitting an application. If you haven't already, you will need to "Create and Account". Once you have created an account, you can register a project and follow the requisite process.

The University of Otago Human Ethics Committee

This is an Institutional Ethics Committee accredited by the Health Research Council.

When does a study require UOHEC review?

You should apply to the University of Otago Human Ethics Committee when teaching or research proposals involving human participants do **NOT** come within the terms of reference of HDEC.

If you have a health related proposal which involves District Health Board (DHB) patients, the records of patients, or any other health providers employed by the DHB you should apply to HDEC.

If you are in doubt about which committee your research falls under, you should contact the University of Otago Human Ethics Committee (Gary Witte 03 479 8256; Gary.Witte@otago.ac.nz) or the HDEC (hdecs@moh.govt.nz).

The University of Otago Human Ethics Committee has two categories of application; Category A and Category B. Category A applications are considered by the Committee whereas Category B Reporting Sheets are audited by the Committee after having been approved by the Head of Department on the Committee's behalf. The Human Ethics Committee has delegated authority to Heads of Department to approve low risk research involving human participants. Research falling under Category B is considered to be approved once the relevant Head of Department has signed it but should be sent to the Ethics Committee after the Head of Department approves it but before research commences. The Committee normally does not comment on Category B Reporting Sheets unless it sees a misunderstanding of the criteria between Category A and Category B or there is a point of clarification or query about the research.

For more information on the University of Otago Human Ethics Committee and the forms required, refer to the website;

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

Note: The closing dates for the ethics committee meetings and remember that your completed form will need to be delivered to the research office at least two working days prior to this date to enable it to be photocopied and couriered to the Ethics Committee. **Please note that the Research Office does not check ethics applications.**

Remember to advise the Ethics Committee Administrator (in writing when you submit your application) if you wish to attend the Ethics Committee meeting in person or by teleconference. The administrator will contact you to advise on how to attend.

You will receive notification of the Committee's decision within 7-10 days of the meeting at which your application is discussed. The decision on your application will not be available informally from the Committee Administrator prior to this.

Please ensure that copies of any correspondence with the Ethics Committees are given to the Research office.

Note: You will need to indicate on your Costing and Consents Worksheet (CCW) that you require ethical or regulatory consents for your proposal. If you are successful, you will need to obtain the appropriate approvals and forward copies of them to the Research and Enterprise Office via the Research Office **before** your research account will be activated.

Ethics Committee Progress Reports

HDEC approval requires researchers to submit annual reports and a final report. Once completed, these reports should uploaded on the Online Forms portal.

Please note that it is the researcher's responsibility to ensure annual reports are provided to the ethics committee and that ethical approval may be withdrawn if reports are not received.

Return to flow chart (procedures)

Return to flowchart (contracts)

Statutory and Regulatory Consents

If you are intending to do clinical research where hazardous substances will be used, animals may be involved, genetic material will be handled, or drugs may be prescribed, you will also need to obtain **Statutory and Regulatory Consents and Approvals**. Refer to the website:

http://www.otago.ac.nz/christchurch/research/researchoffice/ethics/index.html

If your application is for research or innovative treatment involving assisted human reproduction, you will need to apply for ethical approval from ECART (Ethics Committee on Assisted Reproductive Technology). In this case, your research will not also need to be reviewed by a health and disability ethics committee.

Refer: http://ecart.health.govt.nz/

If your application is for research involving the manipulation of human genetic material, as in gene therapy, you will need to apply for approval from the <u>Gene Technology Advisory Committee (GTAC)</u> of the Health Research Council.

Refer:

http://www.hrc.govt.nz/about-us/committees/gene-technology-advisory-committeegtac

Also, check the section on "special case research" in this manual for further information.

Return to flow chart (procedures)

Return to flowchart (contracts)

Special Case Research

Clinical Trials

Approvals

If your application is for research involving a clinical trial of a pre-registration medicine, you will also need to apply to the **Standing Committee on Therapeutic Trials** (**SCOTT**). SCOTT is a committee of the Health Research Council. It is convened to provide recommendations to the Director-General of Health on the scientific validity of applications for clinical trials on new medicines. All clinical trials involving pre-registration medicines will need the approval of SCOTT to proceed.

The SCOTT application form and details about where to send it are available from; http://www.medsafe.govt.nz/regulatory/forms.asp

Details on the Terms of Reference and Membership for SCOTT can be located here: http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott

If you need assistance with this, please contact a Research Advisor.

Indemnity and Insurance for Clinical Trials

ACC Protection

(Injury Prevention, Rehabilitation and Accident Act 2001)

Clinical Trials which ARE NOT conducted principally for the benefit of a manufacturer or distributor, are covered under the Accident Compensation Corporations (ACC) legislation (refer to Section 32 of the Act) for 'Treatment injury' arising from the clinical trial on a no fault basis. An exception to the ACC cover is where the participant did not agree, in writing, to participate in the trial hence the importance of complying with this requirement.

Note: The ACC cover does not include pure mental injury i.e. ACC only covers mental injury resulting from physical injury.

In the situation where ACC provide cover, a declaration is required from the Principal Investigator at the time of submitting a HDEC Committee approval application.

Insurance Protection

For all other Clinical Trials, these will be conducted principally for the benefit of a manufacturer or distributor and accordingly no cover is available under the Accident Compensation legislation.

In these situations, the Sponsor should be responsible for arranging adequate insurance cover, which will require approval by HDEC The insurance cover should normally be in the form of a No Fault Clinical Trials Insurance coverage and is the responsibility of the Sponsor. If possible, the University of Otago and the Investigator should request to be added to the Sponsor's insurance coverage arranged.

To facilitate this and the negotiation of the Contract Agreement and Sponsor Indemnity all documentation must be forwarded to the Research Office for review and finalisation with the Sponsor.

If the situation arises where the Clinical Trial involves no Sponsor but rather the University of Otago is conducting the Clinical Trial at their instigation, then there is the possibility the University of Otago could be deemed to be a 'manufacturer or distributor' under the ACC legislation and hence no ACC cover applies

Any Clinical Trials of this nature must be forwarded to the Research Office for review and if required, arrange adequate insurance for the participants.

Clinical Trials Register

The International Committee of Medical Journal Editors (ICMJE) announced that member publications would only consider clinical trials for publication if the trial had been registered on a trials registry before recruitment of the first participant. Member journals of ICMJE include many major medical publications overseas (such as New England Journal of Medicine, Lancet and JAMA) as well as the New Zealand Medical Journal.

New trials should register before the first participant is randomised. The Australian New Zealand Clinical Trials Registry is free of charge, meets the ICMJE criteria and is now live and accepting online registrations at http://www.anzctr.org.au. New Zealand trials will be identifiable within the register to facilitate research on New Zealand entries.

Research Involving Animals

If you wish to use animals in research, testing or teaching you will need to:

- Obtain written approval from the Christchurch Animal Ethics Committee
- Order animals from the centralised animal facility
- Obtain details of costs for the purchase and housing of animals
- Attend Module 1 of the Animal Welfare Office Training Programme if you are a new user of experimental animals
- Read the Code of Ethical Conduct for The Use of Live Animals for Teaching and Research

If you wish to administer anaesthetic, analgesic or antibiotic veterinary or human medicines to animals you will need to:

- Obtain a veterinary prescription (Institutional Drug Administration order)
- Place an order for veterinary medicines or human medicines used in animals

For forms and further information please refer to the Animal Ethics Committee website:

https://www.otago.ac.nz/council/committees/committees/otago000865.html or liaise with the Secretary of the Christchurch Animal Ethics Committee (research.uoc@otago.ac.nz).

Research Involving Hazardous Substances

According to the Code of Practice for CRI and University exempt Laboratories, a hazardous substance means, unless expressly provided otherwise by regulations, any substance:

- 1. With one or more of the following intrinsic properties:
 - Explosiveness
 - Flammability
 - A capacity to oxidize
 - Corrosiveness
 - Toxicity
 - Ecotoxicity, with or without bio-accumulation; or
- **2**. Which on contact with air or water (other than air or water where the temperature or pressure has been artificially increased or decreased) generates a substance with any one or more of the properties specified in paragraph (1) of this definition.

A statutory and Regulatory consents and approvals form must be completed for all projects (last sheet of the costing and consents worksheet). For advice on whether your research requires such approvals (Hazardous Substances and New Organisms (HSNO) approval, the Ministry of Primary Industries (MPI) approval, the Environmental Protection Agency (EPA, formerly the Environmental Risk Management Authority or ERMA), please contact the Laboratory Manager on 0274128120.

Post–Doctoral Fellows, Research Fellows, Research Assistants, PhD Students, Masters Students, 4th Year Honour Students and Technicians must have their projects involving hazardous substances approved by the Laboratory Supervisors and Laboratory Manager in order to become an authorised Laboratory User.

Research involving hazardous substances also requires a risk assessment and other procedures to be put in place before the research commences (HSNO Act). There is a manual available from the Laboratory Manager which contains information on how to comply with the Code of Practice requirements within the University environment. Please contact the Laboratory Manager for a copy of this.

Generic information on HSNO compliance can be found at; http://www.otago.ac.nz/healthandsafety/hazardmanagement/hsno.html

Laboratory Procedures and Training

All laboratories at the UOC are HSNO exempt and therefore have specific requirements in order to meet this exemption. All staff and students working in HSNO exempt laboratories must have completed the standard training course on working in these laboratories. Please contact the Laboratory Manager for information about this training on 0274128120

Research Involving Genetically Modified Organisms

Any research requiring the development, importation or transport of a genetically modified organism requires special approval by EPA. Please contact the Laboratory Manager for the forms and advice on 0274128120.

Obtaining a Research Contract

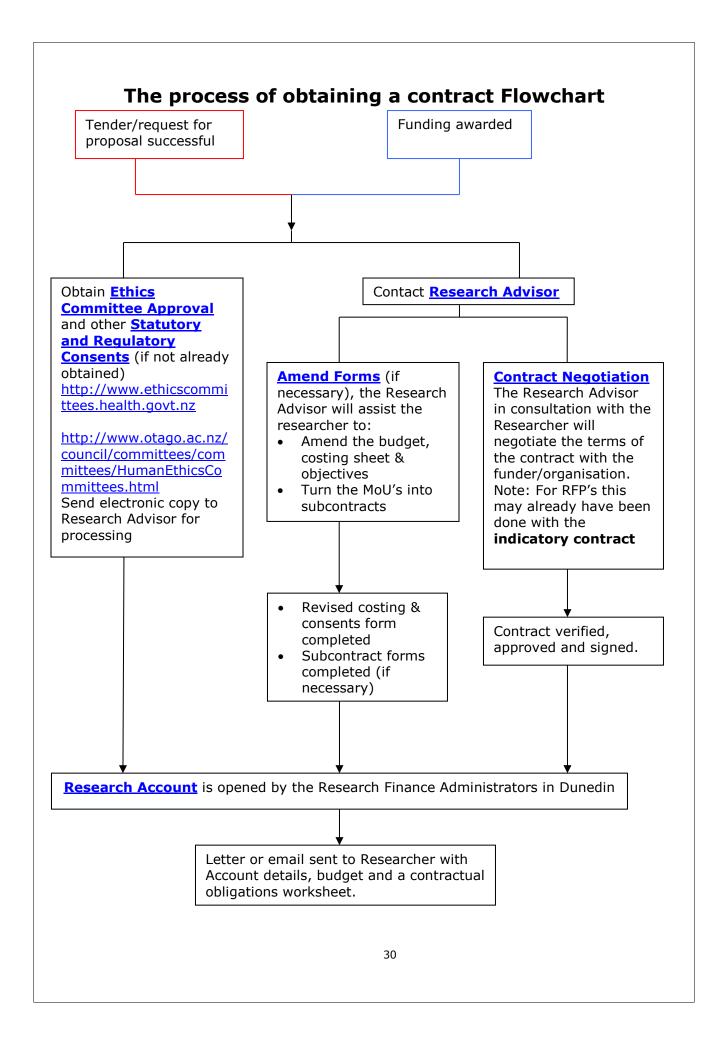
A contract between the funding body and the University of Otago is negotiated when either funding for a research project has been awarded for a grant application or an external funder requests the University of Otago to undertake a specified research project. This applies whether you have a contract directly with a funding body or are a subcontractor on someone else's funded project.

If you are notified directly by the funding body that your application is successful, you MUST contact the Research Office and advise them of your success. You should enquire if they have received copies of any letters from the funding body (and if not, send a copy to the Research Office). Once the Research Office knows you are successful they can start the process of getting the contract organised and a research account set up.

The following flow chart summarises the procedures you need to go through to obtain a research contract and open an account. Each bold heading in the flow chart is book marked so if you want to know more, just click on the heading. Alternatively, you can read the following notes.

Once your contract has been fully signed off, you will receive a copy from the Research Office.





Amending the Forms

Often, an applicant is awarded less money than was requested. In this case they may be asked to provide a revised budget and revised research objectives. As a general rule, if you are awarded less money you should provide less research than was proposed in the application. You will also be required to complete a revised Costing and Consents Worksheet (CCW) as part of the contracting process. The Research Advisor will be able to help you with this process.

At this time, Memorandum of Understanding forms are processed into subcontracts. The Research Advisor will send you the subcontract form with most of it already populated for your consideration.

Return to flowchart

Contract Negotiations

The Research Office will work with staff to set up these contracts and make sure they adequately protect such things as confidentiality, liability, intellectual property (IP) and publication rights.

The Research Office acts as the primary intermediary for communications with external contractors. A contract is normally forwarded to the University by the research purchaser when a decision has been made by a funding body to purchase research. Sometimes the University is asked to prepare the draft contract.

The contract is read and reviewed by the Research Advisor and the Principal Investigator(s). After any modifications are made, a final version of the contract is signed by a representative of the purchasing body and the Deputy Vice-Chancellor (Research), or an authorised delegate, on behalf of the University. Normally, the funding body will provide its own form.

Contracts should contain as a minimum requirement;

- Full contact details for all parties to the contract
- Statements on the ownership of intellectual property and publication rights
- Statement relating to thesis submission (especially if a student is involved)
- A statement of confidentiality
- A statement of governing law
- A statement allowing either party to withdraw from the contract under appropriate circumstances
- A statement on liability

Schedules should contain;

- Instructions as to the reporting procedure to the funding body during the course of the contract
- The date for the submission of the final report
- The name(s) of the principal investigator(s) or director of the project as well as the name(s), if available, of others engaged in the research and the Department to which each belongs
- Details of the budget (including whether the funding is to be exclusive or inclusive of GST)
- Method of payment and payment schedule (including invoice dates, if appropriate and any requirements for payment e.g. submission of report(s))
- Description of service or research being processed

Important Additional Comment

The University of Otago (not an individual staff member) is the binding signatory on all research and commercial contracts and as such, is required to ensure that any report(s) or product(s) is delivered in accordance with the contract. A failure by employees to abide by contract conditions may place the University in breach of its contractual obligations.

The University requires students to sight and/or sign the contractual agreement if they are involved in the work.

Return to flowchart

Variations to the Contract

By its nature, ongoing research may require an alteration to protocols, procedures, timelines, milestones, objectives, etc. contained in the original research contract. Any changes may require the University to notify the research purchaser by letter and to enter into a revision of the research contract. All re-negotiations of contracts must be handled by the Research Office.

Most funding bodies accept that circumstances can change, causing unforeseen delays or changes to the research programme. In this case, a contract variation or an extension can be organised. You must go through the Research Advisor or Business Development Manager to notify the funding body of any changes. The Research Advisor/Business Development Manager will notify the funding body on your behalf and put forward a request for an extension or variation to your contract.

A new CCW may also need to be completed to take into account the extra time required or other changes. This, along with the letter of variation, goes to the Finance Associate (Financial Services Division; FSD) in Dunedin and they arrange to extend the "life" of the research account so that you can continue to use it.

Note: If you are needing an extension, then make sure the project is still covered by ethics approval for the extra period of time required.

Obtaining Payment from the Funder

Payment is recovered in one of three ways;

- 1. Research and Enterprise sends invoices to the Funder
- 2. The Departmental Administrator sends invoices to the Funder
- 3. The Funder pays automatically (e.g. The HRC)

If invoices are to be issued by your Department, it will be stated in the letter from the Research and Enterprise Office. Contact your Department Administrator if this is the case.



Setting up a Research account

Obtaining an Account

When a signed research contract or a grant approval letter with appropriate ethical approval is received by the Finance Associate (FSD) in Dunedin, a research account will be set up in the University's General Ledger.

The Research Office will notify you (the researcher) of the account code by email (with a copy to your departmental administrator). The account will be available for use (subject to the budget split information being provided) once loaded by the FSD.

The account notification letter or e-mail contains the following information;

- Account code
- Funding body
- Funding body reference number (if any)
- Overhead deduction schedule
- The budget template (an excel spreadsheet with monthly splits for you to check and respond to if necessary)
- Payment method by the funding body (e.g. direct credit, invoice and by invoicing who is responsible for issuing the invoice)
- Project start date and end date
- Notification as to when the account will become available

Account Codes

There are a number of different account codes and the type of account depends on the type of research being undertaken. A few of the main ones are listed below.

"P" account	These are for reciprocal research grants i.e. where there is a requirement to the funder e.g. a report must be written (most research falls into this category).
"Q" account	These are for non-reciprocal research grants i.e. where there is limited or no obligations to the funder e.g. donations.
"E" account	Commercial and applied research
"R" account	Otago University Research Grant account

Dissections

Dissections are the numbers given to each part of the budget. For example, dissection 2111 is for Academic salaries, 2211 is for general salaries, 2441 is for superannuation and 3241 is for chemicals. A total list of all these dissections can be found on:

The Budget and Budget Template

Budgets are required for research activities and a budget (monthly split) template has been developed to assist in providing this information. The budget is the financial plan for the research project, as submitted in the grant application and approved by the funding body. This should be split over the term of the grant based on your research plan as to when you anticipate incurring the expenditure. It is your best guess based on the information you have available at the time. Actual expenditure may differ from your plan and a variance will result. This indicates that for whatever reason you varied from the original plan and in order to complete within the time frame and budget, a revision of that plan may be needed.

The Associate Finance (FSD) will email the template to the Principal Investigator and Departmental Administrator for verification after the account is set up. Amounts that are known from the CCW will be completed by the R & E Office, for example, income budgets, overhead charges, equipment depreciation and indirect salary.

You (the Researcher) are required to notify the Research Office/Associate Finance if you believe the template is incorrect. The account will not be available for use until the budget template has been loaded. Budgets are loaded at the end of the month the account is opened in. The following year's budget will be loaded automatically at the beginning of each year and can be revised at any time of the year. Please contact the Research Office if you wish to revise your research account budget.

Monthly Financial Reports

Each month the Financial Services Division sends a monthly financial report for each account to your department. From these reports you are able to monitor your financial performance against your budget (some researchers will have access to the University's financial software "Finance One" which can give you up to date information on your accounts).

On these monthly reports is a column called Variance. This is the difference between what you budgeted for and what you actually spent. Since the budget was often just your "best guess" at the time, some variance is expected, but if the variance is too big you may need to adjust the CCW. You can initiate this through your Research Advisor at any time.

Paying Direct Staff and Scholarships

For staff that are paid directly from a research account (listed under "Direct Salary" on the CCW), it is the department's responsibility to liaise with Human Resources to ensure the salary payment is made from the correct account.

For students (PhD or Masters) whom are paid directly from a research account, the researcher (i.e. the supervisor of the student) needs to fill out a "Setting up a Research Grant Scholarship" form and forward a signed version to the Research Higher Degrees Postgraduate Scholarship Office. The form can be obtained from the Research Office or Manager, Academic Programmes, UOC.

Subcontracting External Agencies/Contractors

If you submitted a MoU then this now needs to be put into subcontract form. A subcontract is a contract that the University of Otago has with a collaborating organisation for them to work on one of our research projects. If you receive funding for a research project which involves collaboration with another organisation, a subcontract agreement must be entered into (this follows on from the MoU you completed at the time of grant application).

The Research Advisor will ask the Principal Investigator (PI) to fill in the project details of the agreement from a template provided (based on the original MoU you filled in). It will be sent to you with highlighted yellow parts which are the only parts to be filled in.

Note: It is the responsibility of the Research Advisor to negotiate subcontract agreements on behalf of the University with the subcontracting organisation (not the individual PI).

If the funding awarded is less than that applied for, the Research Advisor, in consultation with the PI and the subcontractor, will determine the reallocation of funds. This could be done to maintain equity in the funding of the project, or whatever is agreed to in the MoU. The Research Office will also liaise with the subcontractor in regards to other terms of the agreement such as publication rights, student involvement and ownership of intellectual property.

Once the terms of the subcontract have been agreed to by all parties concerned, the Research Advisor will arrange for the authorised signatures on the agreement. The original of the agreement will be held in the Research Office and an electronic copy sent to the Principal Investigator.

Note: No subcontract can be signed until the prime contract is signed.

Preparing Financial Statements of Account

Financial reports may be required by some funding bodies. These should be prepared in collaboration with the Finance Associates (FSD) and Research Office. If you are approached by the funding body for a financial statement, please contact the Research Advisor at UOC and they will in turn contact a Financial Associate in FSD, Dunedin.

Closing Accounts

Using the information you supplied on the CCW and reflected on the contract, your account will be closed approximately <u>two months</u> after the nominated expiry date. The nominated expiry date is the date you initially believed your project would be completed, i.e. final report provided and no further obligation on behalf of the University.

If the work is going to continue beyond the nominated expiry date (i.e. period specified in the contract), the Research Advisor will need to negotiate a variation to the contract with the client and a new CCW may be required (refer to the "Variations to the Contract" section in this manual for further information on this).

The Finance Associate (FSD) will contact you to remind you of the closure date. This date can be extended until such time that your project is fully completed. Please make sure you reply to this email if the date is not as you expected. The closing of an account is a big job for the staff of the Research and Enterprise Office in Dunedin and it involves many hours of work.

Surplus Funds

Should you have a surplus of funds remaining in your account after the completion of the research project, these funds need to be transferred from the account before it can be closed. In some cases this may mean returning funds to the funding bodies. Where no such clause is in the contract, these funds can be transferred to a departmental account as agreed with the Head of Department.

Note: Final transfer of surplus funds is not done until after all charges against the account in that period have gone through.

Your research grant should only be used for the purpose it was set up for. Once the research is completed, the account needs to be closed.

If you have any queries regarding your research account please contact the Research Advisor.

Reporting Requirements

In most cases you will be required to complete progress and/or final reports for your project. Reporting processes vary between funding bodies but it could be every six months, annually or at the end of your contract. In some cases continued funding of the project will depend on reporting being met. Reports are to be submitted through the Research Office.

Note: More and more research income is based on milestones, which are often reports. If reports are not completed as required by agreement, then your research project will not receive the income. In some cases, failure to report could lead to a breach of the agreement with the funder.

Remember, Ethics Committee approval requires researchers to submit annual reports and a final report. Once completed, these reports should be uploaded to the HDEC portal as a post-approval form (PAF).

Please note that it is the researcher's responsibility to ensure annual reports are provided to the ethics committee and that ethical approval may be withdrawn if reports are not received.

Return to flowchart



You and Your Research

Intellectual Property

To facilitate the creation and protection of commercially valuable Intellectual Property, a staff member should immediately advise the Research and Enterprise Office (RAs or David Grimmett (Business Development Manager); David.Grimmett@otago.ac.nz) when research activity generates results that are novel and have potential commercial applicability.

Please read the Otago University Policy for Intellectual property rights on the following web page;

http://www.otago.ac.nz/administration/policies/otago003229.html

Note: Any student involved in a research project with: (1) third parties involved, (2) third party obligations, or (3) projects that have potentially valuable IP needs to sign a student Intellectual Property agreement, which essentially formalises their rights as if they were a staff member. These forms are available from the Research Advisor or Business Development Manager.

Copyright

The University does not claim copyright in work or material produced by University staff in furtherance of their general employment obligations to teach and to undertake scholarly research and agrees that copyright in such work or material is owned by the University staff members who produce it.

For further information on copyright licence and restriction, please refer to the following webpage;

http://www.otago.ac.nz/administration/policies/otago003229.html

Confidentiality Agreements

These should be discussed directly with the Research Advisor/Business Development Manager.

Material Transfer Agreements

These should be discussed directly with the Research Advisor/Business Development Manager.

Publishing Your Research

Most journals will require you to conform to the "Uniform requirements for manuscripts submitted to biomedical journals":

http://www.icmje.org/index.html

Each journal however, will have subtle differences in the way it requires manuscripts to be presented, so always read the "Instructions for authors" section for the intended journal and also look through recent issues of that journal to get an idea of how that journal likes the research to be presented.

Authorship

The "Uniform requirements for manuscripts submitted to biomedical journals" has a section on authorship and contributorship (see above website).

Generally, authorship credit should be based on;

- 1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data
- 2. Drafting the article or revising it critically for important intellectual content
- 3. Final approval of the version to be published.

Authors should meet conditions 1, 2 and 3.

The Ethical Behaviour Committee

The University's policy, processes for action and procedures for ethical behaviours can be found at:

http://www.otago.ac.nz/administration/policies/otago003161.html

The objective of this policy is to promote ethical dealings between members of the University community and to provide an environment of safety, respect and dignity so members can participate fully in all aspects of University life.

Unethical behaviour includes, but is not limited to, sexual harassment, racial harassment, discrimination, personal harassment and bullying, or the abuse of supervisor authority.

PBRF

The Performance Based Research Fund (PBRF) has become the mechanism for funding research in the tertiary education sector. Funding for research will no longer be allocated to institutions according to student enrolments. Instead, research funds will be allocated through the PBRF according to the quality of the research produced in each institution. The system will take into account the quality of researchers, research degree completions and external research income.

The quality of researchers is judged by information supplied by staff at each institution. This information called an "evidence portfolio" will be evaluated then externally assessed by a panel at the Tertiary Education Commission (TEC) and awarded a grade.

Further information on PBRF can be found at the following website; http://www.otago.ac.nz/research/pbrf/

Contact Details

For help at any time with the PBRF process please contact the PBRF Section

Donna Hendry

Publications/Outputs Team Leader Tel 03 479-5391 Email donna.hendry@otago.ac.nz Email pbrf@otago.ac.nz

For help at any time with development of a PBRF Evidence Portfolio within the Division of Health Sciences contact;

Dr Michele Coleman

Research and Development Manager Division of Health Sciences Tel 03 479-3076 Email michele.coleman@otago.ac.nz

More Grant Information

University of Otago Research Grants

Applications for University of Otago Research Grants, administered centrally by the Research Committee, are invited once per year for requests in excess of;

- \$2,500 for Humanities disciplines
- \$5,000 for Social Sciences disciplines
- \$5,000 for the Life, Human and Biomedical, Physical and Clinical and Public Health Sciences (non lab/field-based)
- \$10,000 for the Life, Human and Biomedical, Physical and Clinical and Public Health Sciences (lab/field-based)

Applications are considered by panels established by the Research Committee, taking into account the excellence of the research proposed, the research record of applicants and the overall research perspectives of the University. The Research Committee will give special consideration to grants which enable eligible staff to develop a research profile to the extent that they become better able to compete for externally funded grants and also to support excellence in research and scholarship for which external funds are not readily available. Grants are generally for one year but a small portion of the money is available for two and three year projects.

The Committee gives special consideration to applications from early career staff and new career confirmation staff compared with applications from more established members of staff.

The application round for these grants occurs annually in around **May**. Please see the Research Forms site for the forms and guidelines; http://www.otago.ac.nz/research/forms/

Note: If you are successful in gaining a University of Otago Research grant, an "R" account will be opened for you. Please note that these expire on the $31^{\rm st}$ March unless prior approval for an extension by the Otago University Research Committee is received. Any money left in an "R" account cannot be transferred to another account.

University of Otago Out of Season Research Grants

It is recognised that there are, from time to time, exceptional reasons why it might be appropriate to consider requests for research funding at times other than during the normal annual round of applications.

Out of season UORG applications must meet all the criteria of the standard UORG scheme and be assessed to have been of sufficient quality to have been funded in the previous round. In addition to the standard criteria, an out of season UORG application must present a very strong and compelling justification which;

- Identifies the "one-off" research opportunity which will be lost if the funding is not available as soon as possible, before the beginning of the next calendar year.
- Emphasises the extraordinary reason, with respect to timing, for the request
- Explains why the request could not have been submitted in the subsequent round.

Any such application should be submitted to the Otago Research Committee, via the UOC Research Office, on the special "Out of Season Otago Research Grant" application form and be endorsed by the head of Department. Please refer to the following web page for a copy of the form and guidelines;

http://www.otago.ac.nz/research/forms/

Major Equipment Grants

The announcement of a new round is sent out electronically to the Vice-Chancellor, Assistant Vice-Chancellors, Heads of Resource Responsibility Centres and others as appropriate.

Major equipment grant forms are available from the Index of Research Forms, which can be accessed from the UOC Research Office website under "Application Forms for Grants":

http://www.otago.ac.nz/christchurch/research/researchoffice/Forms/index.html

HRC Grants

The Health Research Council (HRC) is the major government funded agency responsible for purchasing and coordinating health research and fostering the health research workforce in New Zealand. Their website has details of their funding opportunities, as well as their funding and purchase strategy; http://www.hrc.govt.nz

The HRC offer funding opportunities in the following categories;

Researcher Initiated Proposals

Projects

Researchers should aim to make a significant improvement in, or develop knowledge that contributes to, health outcomes. The HRC offers contracts worth up to \$400,000 per year, to a maximum contract value of \$1.2M. The cap for clinical trials is \$1.44M.

Programmes

Collaborative research is encouraged, and programmes should have a strategic, long-term vision that will contribute to significant improvement in health outcomes. The HRC will offer programme contracts worth up to \$5 million over five years.

Feasibility Studies

Feasibility Study applications might address appropriate choice of methodologies, the likelihood of obtaining valid results, or acceptability in a population. The topic, aims and scope of the larger study must be identified. Biomedical research studies are not eligible for Feasibility Study contracts. Up to \$250,000 is available over 12 months.

Emerging Researcher First Grants

Research proposals should represent an independent research stream in which the applicant will undertake overall responsibility for the research. There is no salary component available and up to \$250,000 is available over three years for research expenses.

Explorer Grants

Explorer grants support transformative research ideas that have a good chance of making a revolutionary change to how we manage New Zealanders' health. They are available in any health research discipline and are worth \$150,000 for a term of up to 24 months.

Requests for Proposals

Requests for Proposals (RFPs) are calls for research in areas of strategic importance. They include, but are not limited to research that will contribute to an evidence-base for policy and planning. RFPs are released by the HRC as funding opportunities occur throughout the year.

Career Development Awards

Career development awards help to foster the health research workforce in New Zealand. A range of awards is available to support the career development of emerging health researchers, including Māori and Pacific health researchers undertaking postgraduate qualifications.

Maori Health Research

Māori health research is research that values Māori world views and builds Māori research capacity and leadership.

Pacific Health Research

The primary role of Pacific health research is to generate knowledge and understanding of Pacific peoples that will improve their health outcomes.

Other Research Activities at the UOC

Postgraduate Study

There are many options for postgraduate study at the UOC including Masters Degrees, the degree of Doctor of Philosophy (PhD) and various diplomas and certificates. For further information on the qualifications offered see; http://www.otago.ac.nz/christchurch/study/

For further information regarding postgraduate study at UOC please contact:

Ruth Helms
Manager, Academic Programmes
University of Otago, Christchurch
P O Box 4345
Christchurch
New Zealand
Tel 03 364-3664
Email ruth.helms@otago.ac.nz

Scholarships

The scholarships database has details of scholarships and awards and can be accessed at; http://www.otago.ac.nz/study/scholarships/index.html

For any help required in filling these out, please contact the Research Office.

Summer Studentships

About the Studentships

Each year the University of Otago, Christchurch (UOC) hosts a Summer Studentship programme that is made up of a number of research projects.

Participating students can get an introduction to research methods in one of the following fields:

- Public Health
- Clinical
- Laboratory

The studentships are of 10 weeks' duration, from early November until the end of January (allowing for 2 weeks break over Christmas/New Years). Participating students are paid an educational grant of \$5,000. The aim is to encourage the most promising students to take up a research career. The programme is open to staff and students of any tertiary academic institution in New Zealand.

Sponsors

Each project programme is generously sponsored by a charitable or business organisation. Sponsors' contributions are paid directly to students as an educational grant

Prospective Supervisors

- Supervisors are expected to read the Summer Studentship handbook and understand the rules of the programme and their obligations.
- Prospective supervisors are invited to submit projects for the programme to the Research Committee of the University of Otago, Christchurch.
- Projects must be in a health-related field.
- Project applications from potential supervisors who are external to the University of Otago, Christchurch (UOC) and Canterbury District Health Board (CDHB) will only be accepted where they represent a genuine collaboration in a joint supervisor capacity between external staff and staff of the UOC or CDHB.

Ethics

- Supervisors must seek ethical approval when they submit their project application.
- Full ethical approval must be obtained before the project is advertised to students and
- A copy of the current letter of ethical approval must be provided to the Research Office.

For more information about the Summer Studentship Programme (including forms) go to the following webpage:

https://www.otago.ac.nz/christchurch/research/researchoffice/studentships/

Queries

Research Office 5th Floor, 2 Riccarton Avenue University of Otago, Christchurch PO Box 4345 Christchurch 8140

Telephone: +64 3 364 0237

Email: summer.studentship@otago.ac.nz

The Library

The Canterbury Medical Library is located on the sixth floor of the University of Otago, Christchurch building. The Library has a good collection of materials in a broad range of medical, nursing and health-related topics. The Library system incorporates the Central library, which has a number of collections (Audio-visual, Historical, Loan, Reference, and Student Reserve), the Burwood Hospital library, the Princess Margaret Hospital library and the Hillmorton Hospital library (Sunnyside Hospital library) which is owned and operated by Canterbury District Health Board.

The following link will take you to the library's homepage which has information on location, catalogues, databases, opening hours and services offered. http://www.otago.ac.nz/christchurch/library/

Commercialisation of Research

The University of Otago is committed to commercialising its intellectual property and building research links with the private sector. To facilitate this process three entities exist.

Research and Enterprise

The Research and Enterprise (R & E) Office acts as the conduit for fostering and encouraging research links between business and University researchers, it also has the objective of identifying and protecting commercially viable intellectual property owned by the University.

http://www.otago.ac.nz/research/index.html

Centre for Innovation

The Centre for Innovation provides the physical resource and stimulus for collaboration between University researchers and commercial entities on projects commercialising technology research outcomes. Within the Centre for Innovation is the Dunedin City New Venture Suites offering customised business counselling to start up and emerging enterprises.

http://www.cfiotago.com

Otago Innovation Limited

Otago Innovation Limited is a University owned company with the purpose of negotiating and agreeing the arrangements for commercialisation of intellectual property owned by the University.

http://www.otagoinnovation.com

NOTE: If you have any queries regarding commercialisation of research, please discuss this first with a Research Advisor or Business Development Manager from the R & E Office who will then be able to direct you to the appropriate contact in R & E or Otago Innovation Limited.

Expertise Databases

There are currently two expertise databases available for use.

The <u>Media Expertise database</u> is a guide to specialised knowledge at Otago, with a particular focus on serving the needs of print or broadcast media professionals seeking stories, comment, interviews, or background.

The <u>Health Sciences Expertise Database</u> enables you to search for expertise within the Division of Health Sciences.

For any other queries on expertise please contact the Research and Enterprise Office directly.

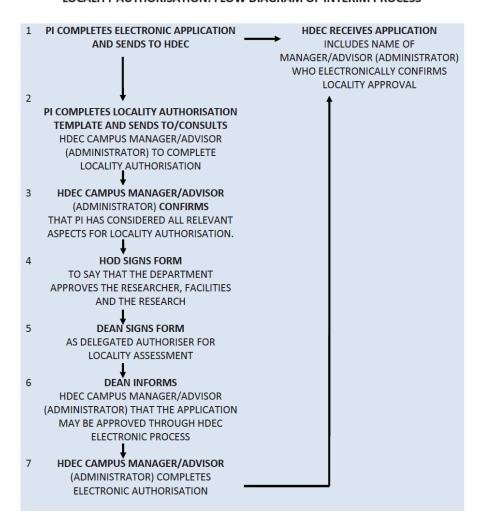


Obtaining Locality Approval for UOC

UOC Locality approval should be applied for when University of Otago applications sent to the Health and Disability Ethics Committees (HDEC) are not conducted through a District Health Board (i.e., projects using UO controlled or owned localities)

The interim locality assessment review template, guidelines and policy for research not conducted through a DHB can be obtained from the UOC Research Office.

LOCALITY AUTHORISATION: FLOW DIAGRAM OF INTERIM PROCESS



FLOW-HoD_HDEC Manager Interim Process-9Aug2012

Conducting Research in the CDHB

Please be aware that the Research Processes ("Procedures") for conducting research within each institution may be different.

When does my project need CDHB approval?

If your project involves CDHB staff, patients and/or resources you will be required to obtain Locality Authorisation, regardless of whether or not you need HDEC approval.

Locality Authorisation can be obtained by first registering your project with the CDHB Research Office via this link:

http://www.otago.ac.nz/christchurch/research/researchoffice/otago085425.html

CDHB Research Approval Process

Enquiries about the CDHB Research Office process can be directed to their office:

Phone (03) 364 1513

Email: cdhb.researchoffice@otago.ac.nz



Appendix One: When does my study need HDEC review?

All research requires ethical approval. Any research on humans or their tissues should in the first instance go to HDEC for review. If HDEC deem the research to be 'out of scope', then the investigative team needs to have the project reviewed by the University of Otago Human Ethics Committee (Health). All animal research needs to be reviewed by the UO Animal Ethics Committee (Christchurch).

When does a study require HDEC review?

Main criteria

- 1. Health and disability research requires HDEC review only if it involves one or more of the following:
 - 1.1. **human participants** recruited in their capacity as:
 - 1.1.1. consumers of health or disability support services, or
 - 1.1.2. relatives or caregivers of consumers of health or disability support services, or
 - 1.1.3. volunteers in clinical trials (including, for the avoidance of doubt, bioequivalence and bioavailability studies)
 - 1.2. the use, collection or storage of **human tissue** (as defined by the Human Tissue Act 2008), unless:
 - 1.2.1. informed consent (which may include informed consent to future unspecified research) has been obtained for such use, and tissue will not be made available to researchers in a form that could reasonably be expected to identify the individual(s) concerned, or
 - 1.2.2. one or more of the statutory exceptions to the need to gain informed consent set out at section 20(f) of the Human Tissue Act 2008 (or Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996) applies
 - 1.3. the use or disclosure of **health information** (as defined by the Health Information Privacy Code 1994), unless:
 - 1.3.1. this use or disclosure has been authorised by the individual(s) concerned, or
 - 1.3.2. health information will not be disclosed to researchers in a form that:
 - 1.3.3. could identify, or could reasonably be expected to identify, the individual(s) concerned, or
 - 1.3.4. would allow for the information to be matched with other data sets (for example, through the use of

non-encrypted identifiers such as National Health Index numbers).

Exemptions to main criteria

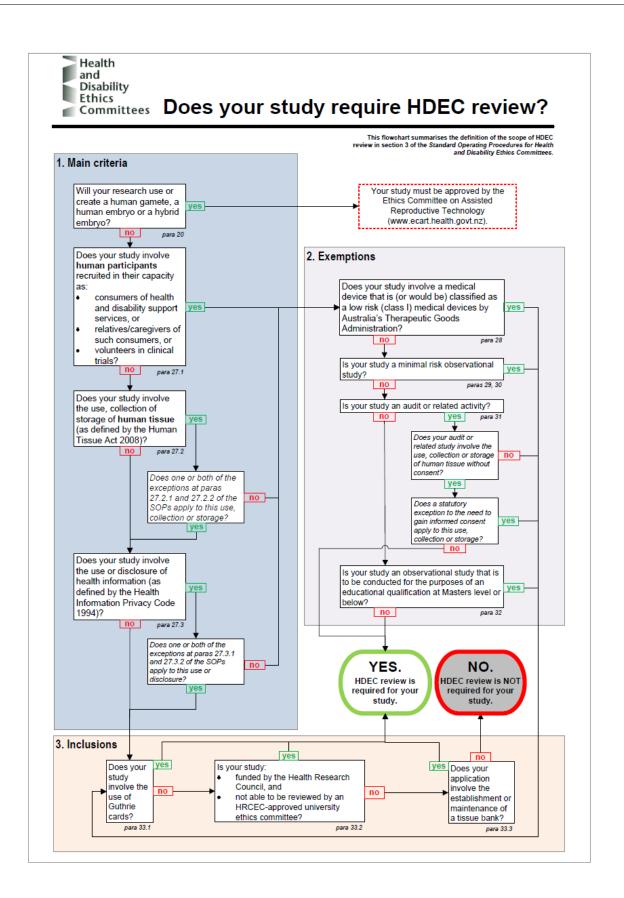
- Studies on low-risk devices: A study involving a medical device does not require HDEC review if the device is (or would be) classified as a low-risk (class I) medical device by Australia's Therapeutic Goods Administration (TGA).¹
- 3. **Minimal-risk observational studies:** An observational study requires HDEC review only if the study involves more than minimal risk (that is, potential participants could reasonably be expected to regard the probability and magnitude of possible harms resulting from their participation in the study to be greater than those encountered in those aspects of their everyday life that relate to the study).
- 4. For the avoidance of doubt, an observational study always involves more than minimal risk if it involves one or more of the following:
 - 4.1. one or more participants who will not have given informed consent to participate, or
 - 4.2. one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study),² or
 - 4.3. standard treatment being withheld from one or more participants, or
 - 4.4. the storage, preservation or use of human tissue without consent, or
 - 4.5. the disclosure of health information without authorisation.
- 5. **Audits and related activities:** An audit or related activity requires HDEC review only if it involves the use, collection or storage of human tissue without consent, other than in accordance with a statutory exception (set out at section 20(f) of the Human Tissue Act 2008 and Right 7(10)(c) of the Code of Health and Disability Services Consumers' Rights 1996).
- 6. **Student-led research:** From 1 January 2013, a study conducted wholly or principally for the purposes of an educational qualification requires HDEC review only if it:
 - 6.1. is an intervention study, or
 - 6.2. is not conducted at or below Master's level.

¹ The TGA's guidance on device classification can be found from page 77 of the Therapeutic Goods Administration's 2011 <u>Australian regulatory guidelines for medical devices</u>, available from the TGA's website at http://tga.gov.au/pdf/devices-argmd.pdf.

² This term is defined more fully in the *Ethical Guidelines for Intervention Studies*.

Inclusions

- 7. Regardless of the exemptions to the main criteria outlined above, a study requires HDEC review if it:
 - 7.1. involves the use of human tissue samples taken as part of New Zealand's Newborn Metabolic Screening Programme (known as 'Guthrie cards'), or
 - 7.2. is funded by the Health Research Council of New Zealand (HRC) and is not able to be reviewed by an institutional ethics committee approved by the HRC's Ethics Committee (HRCEC).
 - 7.3. involves the establishment or maintenance of a tissue bank (see section 13).



What is the full review pathway, and what should be reviewed by it?

- 8. The full review pathway involves an HDEC reviewing a new application, substantial amendment or other item of business at a meeting held in accordance with the provisions set out in this section.
- 9. The full review pathway is appropriate for any intervention or observational study that is within the scope of HDEC review and that involves one or more of the following:
 - 9.1. a new medicine (as defined by the Medicines Act 1981), or
 - 9.2. an approved medicine being used for a new indication or through a new mode of administration, or
 - 9.3. a medical device that is or would be classified as a class IIb, class III or active implantable medical device by the TGA,³ or
 - 9.4. a new surgical intervention, or
 - 9.5. one or more participants who will not have given informed consent to participate, or
 - 9.6. one or more participants who are vulnerable (that is, who have restricted capability to make independent decisions about their participation in the study),⁴ or
 - 9.7. standard treatment being withheld from one or more participants, or
 - 9.8. the storage, preservation or use of human tissue without consent.
- 10. Full review is also appropriate for substantial amendments to previously approved studies that were themselves reviewed by this pathway. However, the chair of an HDEC may direct that the HDEC review any such amendments through the expedited review pathway.

What is the expedited review pathway, and what should be reviewed by it?

- 11. In the expedited review pathway, a subcommittee of an HDEC reviews an application, substantial amendment or other item of business in accordance with the provisions set out in this section.
- 12. The expedited review pathway is appropriate for:
 - 12.1. all new applications for which full review is not required (including studies of class IIa medical devices, where none of the other features making full review appropriate are present)

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³ The TGA's guidance on device classification can be found from page 77 of the Therapeutic Goods Administration's 2011 <u>Australian regulatory guidelines for medical devices</u>, available from the TGA's website at http://tga.gov.au/pdf/devices-argmd.pdf.

⁴ This term is defined more fully in the *Ethical Guidelines for Intervention Studies*.

- 12.2. all substantial amendments to approved studies that were reviewed through the expedited review pathway
- 12.3. any substantial amendments to other studies, at the discretion of the chair
- 12.4. all annual progress reports and final reports
- 12.5. all protocol deviations or violations
- 12.6. all notifications of the conclusion or early termination of a study.

Source:

Ministry of Health (2014). Standard operating procedures for health and disability ethics committees. Wellington: MOH.