Department of Public Health:
Guide to University of Otago Ethics Applications

This document is designed to help you navigate the University of Otago internal ethics system as a researcher within the Department of Public Health, University of Otago, Wellington.

It starts with points about overcoming the most common problems encountered by investigators ('Before You Start'), and gives some guidance regarding the four types of ethics applications within our system ('Types of Committees and Applications'). It has a flow chart which shows you the submission and approval process for each of the four applications ('Approval Process in Our Department'), and finishes with links to some helpful online resources and templates ('Online Resources').

Contents

Before You Start

Do you need ethical approval?
- Some studies do not need ethical approval (see *Examples of Exempt Studies)*. If you are in doubt, contact gary.witte@otago.ac.nz or jo.farrondediaz@otago.ac.nz and ask for advice.
- If you are just seeking an amendment to an existing approval from a University of Otago Committee, see *Seeking an Amendment to an Existing Study* for more information.

Are you sure you don't need to do an HDEC application?
- Some health research studies need to be considered by one of the national Health and Disability Ethics Committees (HDEC). For example, if identifiable health information is being used, HDEC will need to approve these projects (see *Online Resources* for a handy flow-chart).
- Studies accessing the **Stats NZ Integrated Data Infrastructure (IDI)** usually require an 'out-of-scope' letter from HDEC, which you'll need to include with your University ethics application.

Do you know which application you need to fill out?
- Applications are occasionally sent back from the Committees because the study does not suit the type of application. The *Types of Committees* and *Online Resources* sections might help you decide which application to fill-out. If you're still in doubt, contact gary.witte@otago.ac.nz or jo.farrondediaz@otago.ac.nz.

Do you have the latest version of the application form?
- Forms are constantly being updated. Be sure you are using the latest version. You should always download a fresh version from the University's website (see *Online Resources*), rather than re-using an old one.

Have you prepared all your 'accessory' documents?
- Depending on your study, you may need additional documents such as a study protocol, evidence of Peer Review, Participant Information Sheets, Consent Forms, Assent Forms, and brochures. If applicable, these need to be submitted with your application.

Do you need to have your study peer-reviewed?
- If your study is being reviewed by the University of Otago Human Ethics Committee (Health), then Peer Review may be required. Check out *Online Resources* for links and templates.

Have you allowed enough time?
- Investigators often underestimate how much time it will take to fill out applications, and for them to be processed by the Department and the relevant Committee. You should allow at least 3 days for applications to be processed by the Department – so if the application is due in Dunedin on a certain day, you need to allow for these days.

Do you know who to send the completed application to?
- All applications should be sent <u>electronically in **one PDF file**</u> to Andrea Farquharson (andrea.farquharson@otago.ac.nz) in the first instance, who will forward them on to the Research Portfolio Leader and/or the Head(s) of Department.

Examples of Exempt Studies

Some studies don't need ethical approval. Below are some examples of studies that are likely to be exempt.

- Studies of **public behaviour** that are purely observational (non-invasive and non-interactive).
- Studies with no element of intervention in **established educational settings**, involving normal educational practices, researching current instructional strategies; or research on the effectiveness of instructional techniques, curricula, or education management.
- Testing within **normal educational requirements** and in accordance with a host institution's normal practices and approvals.
- **Quality assurance/audit projects** that do not involve access to or collection of private, sensitive or health data.

Remember, if you are in any doubt, contact gary.witte@otago.ac.nz or jo.farrondediaz@otago.ac.nz with a brief summary of your study (including methods), and ask for advice.

Types of Committees and Applications

Some studies need to be submitted to the national Health and Disability Ethics Committee (HDEC). If you have established that your study is 'out of scope' for HDEC (see *Online Resources* for links), then you will need to go through the University of Otago system.

There are four separate types of ethics applications within the University of Otago system, which are considered by two separate ethics committees. The two committees have separate membership with different areas of expertise and separate meetings.

The two University of Otago committees, along with the types of ethics applications that they consider, are:

University of Otago Human Ethics Committee	University of Otago Human Ethics Committee (Health)
• Category A applications	• Research Ethics (Health) applications
• Category B applications	• Minimal Risk Health Research applications

Broadly speaking, if your study involves patients who are recruited in their capacity as consumers of health care services, then it needs to be approved by the University of Otago Human Ethics Committee (Health); if your study does not involve patients, then it needs to be approved by the University of Otago Human Ethics Committee. Also, studies that do not involve patients, but do involve the collection of health information, will likely need to be approved by the University of Otago Human Ethics Committee (Health). The key difference lies in which ethics committee is likely to have the expertise required to give your study full consideration. If you are in doubt, contact the Manager of Academic Committees gary.witte@otago.ac.nz or the Research Ethics Administrator jo.farrondediaz@otago.ac.nz, and ask for advice.

A summary of the guidelines for each of the application types is shown in the pages below, and there is more detailed information for each of the applications on the University's website (see *Online Resources* for links).

University of Otago Human Ethics Committee

Category A Ethics Applications

What type of study? Category A applications are for studies that involve human participants, but are not considered clinical health research and do not involve patients.

Who approves it? After being approved by the Department, Category A applications are approved by the University of Otago Human Ethics Committee at a formal meeting in Dunedin. This committee meets once per month (see *Online Resources* for links to meeting times).

Any tips? The easiest way to fill-out your Category A application is to use your study protocol or funding application to complete the relevant sections. Once the application has been approved by the Department, a single electronic PDF copy of all your documents will be sent to Dunedin. As a Wellington-based Department, we don't need to send the standard 18 copies.

Category B Ethics Applications

What type of study? Category B applications are for low-risk studies that do not involve patients, identifiable data, collection of biospecimens, participation of children or other vulnerable participants, and other factors that might involve some risk to the participants.

Who approves it? Category B applications are approved by the Head of Department or a nominated senior staff member, then submitted to the ethics committee for recording and auditing. In our Department, the Research Portfolio Leader usually approves these applications. Once approved by the Research Portfolio Leader the application is sent to the ethics committee. Category B applications are audited on a monthly basis by the Committee in Dunedin. All applicants will be written to formally following the audit confirming approval. Should any issues or questions arise, then the Principal Investigator will be notified at this time.

Any tips? Category B applications are more straight-forward than Category A applications, because of the low-risk nature of the research. However, it's important to know if you should apply for Category B or one of the other applications. For example, if your study involves patients or patient data, then you should be submitting a Minimal Risk Health Research application.

The difference between Category A and Category B applications

One of the most common reasons that an ethics application within our Department is not approved is because a Category B application was submitted when a Category A application is more appropriate. This causes delays in the approval process for your study, so it's important to get this right the first time. The University has a handy guide to help you tell the difference between Category A and Category B (see *Online Resources*, as well as the back of the Category B application form). In short, Category B applications are only appropriate when:

- The data from your study involves no identifiable personal information in its final form
- Your study involve no physical or psychological stress for the participants
- Your study involves no situations that might be unsafe for researchers or participants
- Your study does not involve vulnerable participants (including children)
- Your study does not have the potential for conflicts of interest
- Your study does not involve deceiving participants
- Your study is not being undertaken overseas by students

University of Otago Human Ethics Committee (Health)

Research Ethics (Health) Applications

What type of study? Research Ethics (Health) applications are for studies that involve patients or use of clinical data, but fall outside the scope of needing approval from the national Health and Disability Ethics Committee (HDEC; see *Online Resources* for links). Also, studies that do not involve patients, but do involve the collection of health information, will likely need to be approved by the University of Otago Human Ethics Committee (Health). If you are in doubt, contact gary.witte@otago.ac.nz or jo.farrondediaz@otago.ac.nz and ask for advice.

Who approves it? After being approved by the Head of Department, Research Ethics (Health) applications are approved by the University of Otago Human Ethics Committee (Health) at a formal meeting in Dunedin. This committee also meets once per month (see *Online Resources* for links to the meeting times).

Any tips? Similar to a full HDEC application, the Research Ethics (Health) application is relatively lengthy and requires some time investment to put together. If working with health care services, you will need to secure Locality Authorisation from the relevant DHB(s). Normally DHBs will require ethical approval before granting Locality Authorisation. You will need to provide evidence that your study has been independently peer-reviewed (see *Online Resources* for links). Once the application has been approved by the Department, a single electronic PDF copy of all your documents will be sent to Dunedin. As a Wellington-based Department, we don't need to send the standard 18 copies.

Minimal Risk Health Research Applications

What type of study? Minimal Risk Health Research applications are for low-risk health research studies that involve patients or use of clinical data, but either a) do not involve identifiable information, or b) only involve identifiable information in the context of a clinical audit. The second of these is rare in our Department.

Who approves it? After being approved by the Research Portfolio Leader or Head of Department (see *Approval Process in Our Department*), Minimal Risk Health Research applications are approved as they arrive by a subcommittee of the University of Otago Human Ethics Committee (Health).
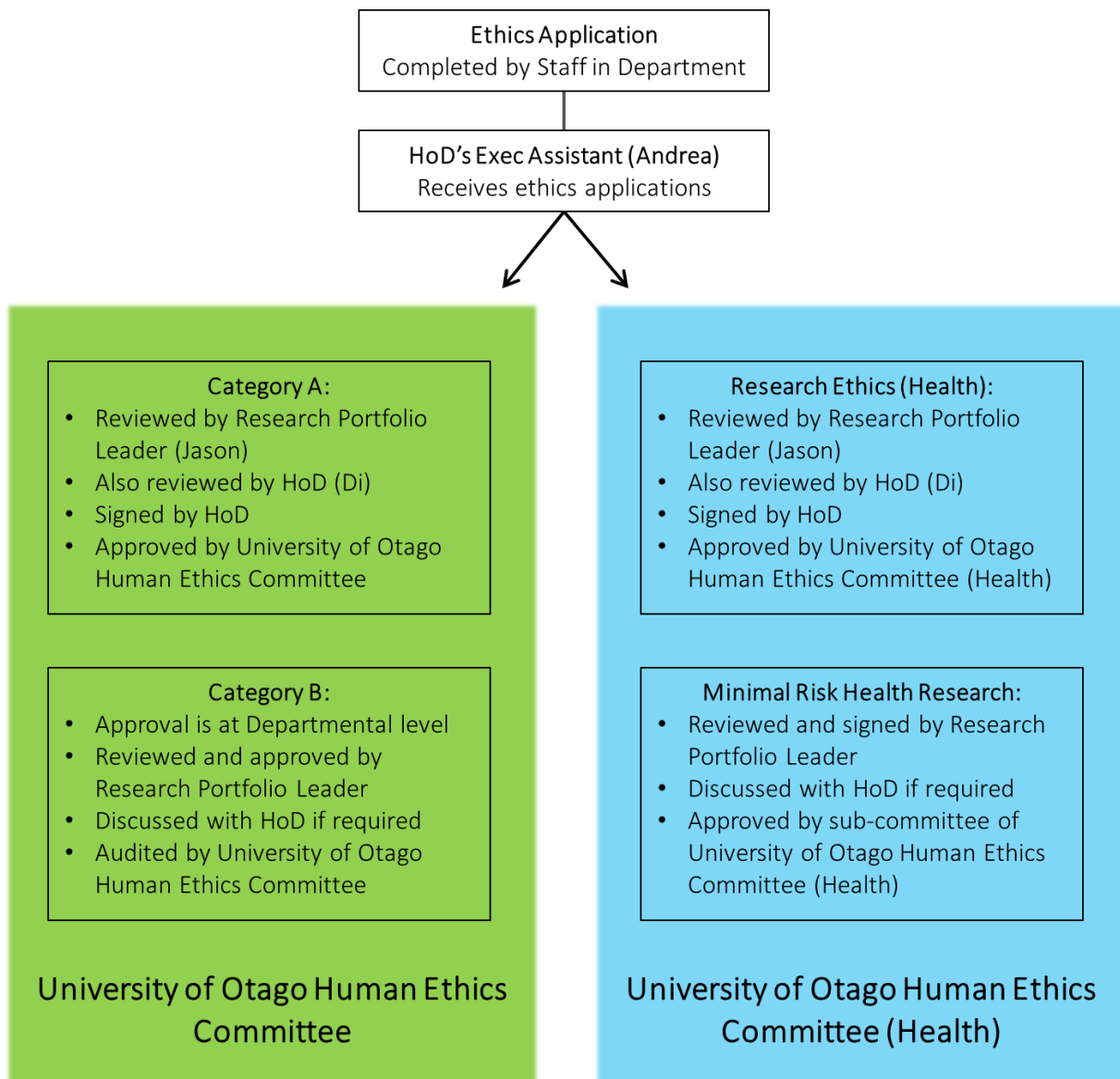
Any tips? Like the Research Ethics (Health) application, you will need to provide evidence that your study has been independently peer-reviewed. This type of application is relatively common in our Department, mainly because many of our staff are involved in analysing de-identified data that has been collected by others (e.g. Cancer Registry data, hospitalisation data, NZ Health Survey, etc.) and the data collection has already been subject to an ethics review/consent process where that is required. The use of this data may not require ethical review by the University Committee provided the following conditions are met:

- There are no expectations from the data custodian that there be ethical approval to use the data;
- The data is de-identified;
- The researcher has determined that the data used has been collected following an appropriate process of ethical review and approval where required;
- The data is publically accessible – i.e. can be accessed by any legitimate user who fulfils the requirements the data custodian sets for access;
- The researcher adheres to any requirements about secure and safe use set by the data custodian.

However, if you are in doubt about whether your study requires ethical approval, contact gary.witte@otago.ac.nz or jo.farrondediaz@otago.ac.nz and ask for advice.

Approval Process in our Department

The flow chart below shows the process with which ethics applications are dealt with in the Department, as agreed with the Committees in Dunedin.

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                    ┌─────────────────────────────────┐
                    │       Ethics Application        │
                    │  Completed by Staff in Department│
                    └─────────────────────────────────┘
                    ┌─────────────────────────────────┐
                    │   HoD's Exec Assistant (Andrea)  │
                    │    Receives ethics applications  │
                    └─────────────────────────────────┘
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Category A:
- Reviewed by Research Portfolio Leader (Jason)
- Also reviewed by HoD (Di)
- Signed by HoD
- Approved by University of Otago Human Ethics Committee

Category B:
- Approval is at Departmental level
- Reviewed and approved by Research Portfolio Leader
- Discussed with HoD if required
- Audited by University of Otago Human Ethics Committee

University of Otago Human Ethics Committee

Research Ethics (Health):
- Reviewed by Research Portfolio Leader (Jason)
- Also reviewed by HoD (Di)
- Signed by HoD
- Approved by University of Otago Human Ethics Committee (Health)

Minimal Risk Health Research:
- Reviewed and signed by Research Portfolio Leader
- Discussed with HoD if required
- Approved by sub-committee of University of Otago Human Ethics Committee (Health)

University of Otago Human Ethics Committee (Health)

Seeking an Amendment to an Existing Study

If you have already received ethical approval for a study from one of the University of Otago ethics committees, and are just seeking an amendment to that study, you might not need to apply for new ethics approval. For example, you may be seeking a time extension to the study, or changing the way you are recruiting participants, or expanding the study in a relatively-minor way.

To seek an amendment to an existing study, you will need to write a formal letter (e.g. in Microsoft Word) to the Committee, explaining the situation and outlining the specific amendment that you would like to make to your study. Send this letter via email to gary.witte@otago.ac.nz and jo.farrondediaz@otago.ac.nz (you do not need to send a hard copy). This letter does **not** need to be approved by the Department – it is up to you to communicate directly with the Committee in this case. The Committee will assess your request, and inform you via return letter whether it has been approved or not. This process is usually complete within a week, but allow yourself additional time just to be safe.

Online Resources

General information and latest application forms. The University of Otago Human Ethics Committees website has a lot of information about our system. It also has the latest version of the four applications, and the dates that applications are due for the monthly meetings: http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html

The University also has an excellent page which talks about ethical practices in research and teaching involving human participants, and includes helpful explanations (like the difference between a Category A and a Category B application): http://www.otago.ac.nz/administration/academiccommittees/otago015522.html

Peer review. The University has a number of guidelines regarding peer review: http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html#peer_review

The Health and Disability Ethics Committee (HDEC) also has a template for peer review, which you can use and/or adapt for your own purposes: https://ethics.health.govt.nz/system/files/documents/pages/HDEC-Peer-Review-Template.docx

Do you need HDEC approval instead? The following link will take you to a handy flow-chart which may help you decide whether you need to submit your application to the national committee (HDEC) rather than the University: http://ethics.health.govt.nz/system/files/documents/pages/HDEC%20scope%20summary.pdf

You can also complete a series of screening questions about your study on HDEC's Online Forms site, which will tell you whether you need to apply for HDEC approval or not (you will need to setup an Online Forms account): https://nz.ethicsform.org/SignIn.aspx