

**Minimal Risk Health Research Application Form**

**Updated July 2023**

**Submit applications to**: **humanethics@otago.ac.nz**

**This document describes the circumstances when ethics review is permissible for Minimal Risk Health Research. It also describes the process and provides the application form for approval.**

Explanation

There are two situations to which this process applies:

1. **When the previously collected and stored health data is de-identified.**

Where the study only uses information that cannot be linked to an identifiable individual *(see the Health Information Privacy Code, Rule 11 (2) (c) (i)* )

1. **When identifiable health information is being used for audit of health provision, process or outcomes and there is no health information being obtained through contact with patients. (Where researchers are making direct contact with patients and asking them to do anything outside of their normal routine management, a full Health and Disability Ethics Committee application or a University of Otago Human Ethics Committee (Health) application form is required).**

While ethics review may not be required for clinical audit, ethics review should be considered:

* where there is any doubt that the audit also constitutes research, i.e. creating new knowledge;
* and also may be advisable when it is anticipated or intended that this activity will lead to any publication which has a requirement for ethics approval.

Even though ethics approval may be given this does not preclude the need for:

* Locality authorisation from the Health Agency[[1]](#footnote-1) involved as in (B) above;
* Permission(s) from the Health Agency which is providing the de-identified information as in (A) above;
* Research consultation with Māori;
* A confidentiality agreement between the researcher and the Health Agency describing requirements for confidentiality of health information where this is not already included as part of locality authorisation.

**The research may not commence until these approvals and agreements are in place and formal ethical approval has been granted by the subcommittee of the University of Otago Human Ethics Committee (Health).**

Process

1. **Complete the form**
* Use language which is, as far as possible, free from jargon and is comprehensible to lay people, or children if applicable.
* Ensure, if applicable, that the Consent Form and Information Sheet have been carefully proof-read; the institution as a whole is likely to be judged by them.
* If being used in electronic form, the various sections of this application form should be expanded or contracted to suit the length of the information to be entered.
* It is helpful if applicants use a font different to the default font on the electronic application form as this helps to distinguish the applicant's entries from the standard headings. Please do not use all capital letters or italics.
1. **Submit the completed form and attachments to your Head of Academic Department for approval and signing.**
2. **Submit the signed application and any attachments as one PDF to the University of Otago Human Ethics Committee (Health) to humanethics@otago.ac.nz**
3. **Final approval will be confirmed by letter to the Principal Investigator from the Manager, Academic Committees and Services.** Minimal Risk Health Research studies are reviewed outside the normal meeting cycle by a subcommittee of the University of Otago Human Ethics Committee (Health) (UOHEC (H)). **Please note the research may not start until approval from UOHEC (H) has been obtained.**

Academic Committees & Services Contacts:
Gary Witte gary.witte@otago.ac.nz Tel: 03 479 8256, or
Jo Farron de Diaz jo.farrondediaz@otago.ac.nz

**1. Title of Study:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Investigators**

 **Principal Investigator** (University of Otago staff member responsible for project)

**Name:**   **Title:**

**Department/School:**   **Email:**

**Co-investigators**

**Name:**   **Title:**

**Department/School:**  **Email:**

**Name:**  **Title:**

**Department:** **Email:**

**Student investigator**

**Name:** **Level of Study:**

**Department/School:**  **Email:**

 ***Where there are more co-investigators or student investigators, insert details on a separate sheet.***

1. **Study Description:**
	1. Briefly and in plain English describe the proposed study and the relevant background
	2. Please attach the study protocol

1. **Peer review**

 **Has Peer Review been carried out? (**[***Peer review template***](#peer_review)***)***

[ ]  Yes - Please attach peer review

[ ]  No - **Please provide explanation**

1. **Funding Body/Sponsor**

***The sponsor is the organisation with overall responsibility for the initiation, management and financing arrangements of a study.***

**Which of the following best describe the sponsor(s) of your study?**

 [ ] University of Otago [ ]  another academic institution

[ ] collaborative research group [ ] district health board (DHB)

[ ] other government agency [ ] pharmaceutical company

[ ] medical device company [ ] other (e.g. non-governmental organisation (NGO), or contract research organisation)

1. **Is your study based on de-identified data which has been previously collected in a database**

[ ]  Yes - go to question 10

 [ ]  No - go to next question

1. **Does your study include access to health information where individuals are identifiable and is an audit of health provision, process and/or outcome.** [ ]  Yes - go to question 8

[ ]  **No - a full University of Otago Human Ethics (Health) application is required. The Application Form can be found on the University of Otago Human Ethics web page. Please do not proceed with this conditional ethics review form.**

1. **If your study seeks access to identifiable health information collected for another purpose, will you be seeking informed consent?**

[ ]  Yes - Attach a Participant Information Sheet and Consent Form (Templates can be found on the [University of Otago Human Ethics Committees web page)](https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html) - go to question 9[ ]  No - New Zealand law has mechanisms where it is permissible to waive consent for use of health information collected for another purpose for research purposes. Researchers must clearly justify why they need to apply that waiver. Provide this justification below and clearly outline this in the study protocol that you have attached.

1. **Where identifiable health information is being accessed:**
2. You must receive **authorisation** allowing you to access the information from the Health Agency where the information is held.

[ ]  I have ALREADY obtained authorisation (Attach a copy of the authorisation)

[ ]  I will be obtaining authorisation before commencing the research

[ ]  As a clinical leader I already have the appropriate authority
 Briefly explain your role:

1. A **confidentiality agreement** is required (if not included in the locality authority) confirming that patient confidentiality will be maintained at all times by all those using this information. ([Confidentiality agreement template](#Confidentiality_agreement)).
2. **Where de-identified information is being accessed, the agency from which the information is being obtained may need to provide authorisation for the use of the information for the study.**

[ ]  We have ALREADY obtained (attach a copy of the authorisation)

[ ]  We will be obtaining authorisation before commencing the research

[ ]  We do not need authorisation for this information (Please provide an explanation)

1. **The University of Otago has a Policy for Research Consultation with Māori**. Have you already completed, or do you propose to undertake Māori consultation?

(Please see http://www.otago.ac.nz/research/maoriconsultation/index.html).

[ ] Yes, we have ALREADY undertaken consultation (attach a copy of your completed Research Consultation with Māori Form)

[ ]  No - If no, provide a brief outline of reasons why not

 Signatures

**Researcher statement**I confirm that:

* I have read the Health Information Privacy Code, specifically Rule 10 Limits on Use of Health Information and Rule 11 Limits on Disclosure of Health Information and my proposed research complies with both Rules;
* the information contained in this form is true and accurate;
* I will not commence this research without the required authorisations and agreements being in place before the study commences.

**Applicant signature (Principal Investigator): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name: (please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Departmental Approval**

I have read this application and believe it satisfies the criteria as outlined above and I further acknowledge that the study being proposed complies with established ethical standards set out in the guidelines from the National Ethics Advisory Committee and the Health Information Privacy Code, specifically Rule 10 Limits on Use of Health Information and Rule 11 Limits on Disclosure of Health Information. The research proposed in this application is compatible with the University of Otago policies and I give my consent for the application to be forwarded to the subcommittee of the University of Otago Human Ethics Committee (Health) with my recommendation that it be approved. I will also ensure that all authorisations and agreements described in the application will be in place before the study commences.

**Signature of \*Head of Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Name: (please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**\*In cases where the Head of Department is also a member of the research team then the appropriate Dean or Pro-Vice-Chancellor must sign.**

Check list

[ ]  If peer review has been undertaken (question 4) please attach.

[ ]  Has the Principal Investigator signed (page 5)?

[ ]  Has the application been signed and approved by the Head of Department (page 5)?

[ ]  If applicable, (see Question 7) attach a Participant Information Sheet and Consent form.

[ ]  If applicable, (see question 9) attach a signed authorisation

[ ]  If applicable, (see question 9 (b)) attach confidentiality agreement

[ ]  If applicable, (see question 11) attach Research Consultation with Maori form

*Peer review template.*

**Department of xxxxxx**

# SCIENTIFIC PEER REVIEW: Reviewer template

Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Research Title\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Researcher Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer’s role \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Reviewer’s institution \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reviewer signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Recommendation: Approve / Revise minor / Revise major / Decline

|  |  |  |
| --- | --- | --- |
| **REVIEW GUIDELINE** | **GUIDELINE PROMPTS** | **COMMENTS** [Please note that the ethics committee greatly appreciates and carefully considers comments made by peer reviewers when assessing the scientific validity and consequentially the ethics of the applications.] |
| Relative merit of the research | * Important, worthwhile and justifiable.
* Addresses a health issue that is important for health and/or society.
* Aims, research questions and hypotheses build on and address gaps in existing knowledge.
 |  |
| Design and methods | * Quality of study design
* Robustness of the methods used.
* Includes a description of sample recruitment and characteristics (including number, gender and ethnicity where relevant) proposed methods of data analysis.
* Timelines for the research included
 |  |
| Feasibility of the research | * Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project.
* Likely to improve scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions.
* Achievable within the specified timeframe
* Researcher/research team has the appropriate experience and expertise
 |  |
| Presentation of the application | * Appropriate overall presentation, including structure, ‘understandability’, clarity and readability
* In general the way in which the application reads and gets the message across reflects well planned and conceived research.
 |  |
| Other comments | Any reviewer observations that are not covered in the points above  |  |

*Confidentiality Agreement template, please adapt to suit the study.*



**CONFIDENTIALITY AND DATA USE AGREEMENT**

**Study title:**

**Principal Investigator:**

**Department:**

I understand that the information I am dealing with is confidential and must not be disclosed to, or discussed with, anyone other than the researcher.

I agree to take reasonable measures to keep all information in any form or format, digital or paper files (e.g. WAV files, VOB files, CDs, transcripts physical copy, etc) secure while it is in my possession in accordance with the follow:

1. Specific conditions of use for this project/dataset
2. Approval(s) given by the relevant ethics committee(s)
3. Privacy Act 2020 and Health Information Privacy Code 2020

I agree to return all research information in any form or format to the researcher in a secure method.

If I find any information I see or hear is affecting me personally in such a way that it is in my interest to talk to someone, I agree to discuss this with a member of the research team.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** |  | **Witness** |  |
| **Signature** |  | **Signature** |  |
| **Date** |  | **Date** |  |

1. *Please refer to the* [*Health Information Privacy Code 2020*](https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/) *subclause 4 (2) for a full definition of what constitutes a service defined as a ‘Health Agency’.* [↑](#footnote-ref-1)