****

Form Updated: November 2018

**UNIVERSITY OF OTAGO HUMAN ETHICS COMMITTEE
APPLICATION FORM: CATEGORY B**

**(Departmental Approval)**

*Please ensure you are using the latest application form available from:* [*http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html*](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html)

**1. University of Otago staff member responsible for project:**

*Surname First Name Title (Mr/Ms/Mrs/Dr/Assoc. Prof./Prof.)*

**2. Department/School:**

**3. Contact details of staff member responsible** *(always include your email address)***:**

**4. Title of project:**

**5. Indicate type of project and names of other investigators** **and students**:

**Staff Research Names**

**Student Research Names**

*Level of Study**(e.g. PhD, Masters, Hons)*

 **External Research/ Names**

**Collaboration**

 *Institute/Company*

**6.** **When will recruitment and data collection commence?**

**When will data collection be completed?**

**7. Brief description in lay terms of the aim of the project, and outline of the research questions that will be answered** (approx. 200 words)**:**

**8. Brief description of the method.** Include a description of who the participants are, how the participants will be recruited, and what they will be asked to do and how the data will be used and stored *(Note: if this research involves* ***patient data or health information*** *obtained from the Ministry of Health, DHBs etc please refer to the [UOHEC(H) Minimal Risk Health Research - Audit and Audit related studies )](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html%22%20%5Cl%20%22minimal_risk)*[:-](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html%22%20%5Cl%20%22minimal_risk)

**9. Disclose and discuss any potential problems and how they will be managed**: (For example: medical/legal problems, issues with disclosure, conflict of interest, safety of the researcher, safeguards to participant anonymity if open access to data is proposed etc)

**\*Applicant's Signature:** .............................................................................

***Name (please print):*** ………………………………………………………*.*

 **Date:** ................................

*\*The signatory should be the staff member detailed at Question 1.*

***ACTION TAKEN***

Approved by HOD Approved by Departmental Ethics Committee

 Referred to UO Human Ethics Committee

**Signature of \*\*Head of Department*:***..........................................................................

***Name of HOD (please print):*** ………………………………………………………*.*

 ***Date:***.....................................................

\*\*Where the Head of Department is also the Applicant, then an appropriate senior staff member must sign on behalf of the Department or School.

**Departmental approval:** *I have read this application and believe it to be valid research and ethically sound. I approve the research design. The research proposed in this application is compatible with the University of Otago policies and I give my approval and consent for the application to be forwarded to the University of Otago Human Ethics Committee (to be reported to the next meeting).*

**IMPORTANT NOTE**: As soon as this proposal has been considered and approved at departmental level, the completed form, together with copies of any Information Sheet, Consent Form, recruitment advertisement for participants, and survey or questionnaire should be forwarded to the Manager, Academic Committees and Services, (Ground Floor, Clocktower Building,) gary.witte@otago.ac.nz, or Senior Administrators Jo Farron de Diaz, jo.farrondediaz@otago.ac.nz or Ruth Sharpe ruth.sharpe@otago.ac.nz .

**INFORMATION SHEET TEMPLATE: NOTES FOR APPLICANTS**

***(Delete all notes and prompts before providing to Human Ethics Committee)***

The template on the following pages is a guide for providing information to potential participants before they agree to take part in the research project. Not all of the suggestions or headings on this template will necessarily apply to all projects. Delete those that do not apply and/or make the necessary amendments. An Information Sheet is written in the form of a customised letter of invitation to each target group of research participants. It must contain all the information they need in order to make an informed decision about whether or not they wish to participate in your research. What are they asked to do? What will they experience?

An Information Sheet is expected to be submitted with the application for ethical approval in all Category A applications and most Category B Reporting Sheets. The Information Sheet template can be used as a prompt for a cover letter introducing the research even in cases where a formal written Consent Form is not used, e.g. an anonymous survey.

The Information Sheet should be written in simple, clear language (free from jargon and technical terms) that is age and culture appropriate for your participants, so that they can fully understand what they will be doing and experiencing. This is the principle of Informed Consent.

The Information Sheet you submit with your application should be the final version you intend to provide to your participants. All traces of the prompts in italics from the Human Ethics Committee to the researcher should be removed and it should be carefully proof-read for spelling, grammar and formatting.

[Reference Number: *as allocated upon approval by the Human Ethics Committee*]

 [*Date*]

****

***TITLE OF PROJECT***

**INFORMATION SHEET FOR PARTICIPANTS**

Thank you for showing an interest in this project. Please read this information sheet carefully before deciding whether or not to participate. If you decide to participate we thank you. If you decide not to take part there will be no disadvantage to you and we thank you for considering our request.

**What is the Aim of the Project?**

*Provide a brief summary of the project.* *Provide* a *clear and concise explanation, in lay terms, of the major aim(s) of the project. Mention if the project is part of a specific course: e.g. This project is being undertaken as part of the requirements for [name of student’s] Postgraduate Diploma in Science.*

**What Types of Participants are being sought?**

*Provide a* *statement of the types of participants being sought which includes information about the following:*

* *Recruitment method*
* *Method of obtaining participant names (where relevant)*
* *Selection criteria (where relevant)*
* *Exclusion criteria (where relevant)*
* *Number of participants to be involved*
* *Details of compensation/reimbursement of expense/payments offered for participation (where relevant)*
* *Description of any benefit or access to information which the participant will have access to as a result of participating in the research*

**What will Participants be asked to do?**

Should you agree to take part in this project, you will be asked to

[*Clear and concise explanation in lay terms of:*

* *The procedures in which the participants will be involved*
* *The time commitment required*
* *Any support or health and safety processes in place to deal with adverse physical or psychological risks associated with participating in the research*
* *Description of discomforts, risks or inconvenience to participants as a result of participation.*]

Please be aware that you may decide not to take part in the project without any disadvantage to yourself.

**What Data or Information will be collected and what use will be made of it?**

*[There is a distinction between the raw data or information collected by the researcher and the data/information that is set out in the completed research. The potential participant has a reasonable expectation to know:*

* *What raw data or information will be collected?*

*-Will participants be audio taped? How will the tapes be used?*

*-Will participants be video taped? How will the tapes be used?*

*-What personal information will be collected?*

*-What are the purposes for which the data or information are being collected?*

*-What use will it be put to?*

* *Who will have access to the data or information?*

*-Participants should be made aware of those who will have access to the data or information including researchers, supervisors, research assistants, typists, transcribers, staff making photocopies, outside organisations, including funding entities.*

*-If the research is externally funded, will there be any commercial use of the data?*

* *How will data or information be securely managed, stored and destroyed?*

*Participants should be made aware of the data and information which will be stored for possible future scrutiny in secure storage and what data and information will be destroyed at the end of the project. A statement should be included on the Information Sheet setting this out:*

The data collected will be securely stored in such a way that only those mentioned below will be able to gain access to it. Data obtained as a result of the research will be retained for **at least 5 years** [*or at least 10 years for health research*] in secure storage. Any personal information held on the participants [*such as contact details, audio or video tapes, after they have been transcribed etc.,*] may be destroyed at the completion of the research even though the data derived from the research will, in most cases, be kept for much longer or possibly indefinitely.

* *An increasing number of journals and funders are requesting that there be more* ***open access to data****. If you are intending that data collected from this research project is going to be open access, you must inform participants in the Information Sheet of this prior to obtaining their consent:*

No material that could personally identify you will be used in any reports on this study. Results of this research may be published. The data from this project will be publicly archived so that it may be used by other researchers.

* *What data or information will be reflected in the completed research?*

*-Some research projects protect anonymity, others do not. The important factor is that the participant be made aware of whether or not they will be identified. No participant should be identified without their consent. It is the duty of the researcher to make clear to the participant the extent to which their participation will be known to others.*

*-Sometimes anonymity is not preserved despite the best efforts of researchers. Absolute claims to guarantee anonymity should therefore be avoided. Will there be an attempt to preserve anonymity? If so, a statement to this effect, but stopping short of providing an absolute guarantee, should be included in the Information Sheet such as:*

The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve your anonymity.

*-If anonymity cannot or will not be preserved a statement to this effect should be made on the Information Sheet such as:*

 Due to the nature of the research whereby …(give reasons why anonymity cannot or will not be preserved) it will not be possible/desirable (choose one) for your anonymity to be preserved in the completed research.

*-For some types of research, it is entirely appropriate to reveal the identity of the participant. If anonymity will not be preserved, participants need to be informed of this and they must consent to it and this should be reflected in the Information Sheet and the Consent Form.*

*-Some research projects may offer a choice to participants regarding their anonymity. If so the Information Sheet and Consent Form should reflect this, with the Information Sheet including a statement such as:*

On the Consent Form you will be given options regarding your anonymity. Please be aware that should you wish we will make every attempt to preserve your anonymity. However, with your consent, there are some cases where it would be preferable to attribute contributions made to individual participants. It is absolutely up to you which of these options you prefer.

* *Remember to include tick boxes on the Consent Form to give choices for anonymity.*
* *Will the participants have the opportunity to correct or withdraw the data/information?*

*-Will participants be given the opportunity to view the data or information that relates to them either before or after the completion of the research? At what stage will this opportunity be given to them?*

*- Some types of research such as oral history and documentary film making etc. are appropriate for storage for the purposes of posterity. If this is the case, the research might involve transfer to a public repository and should include an agreement, for example, a separate release form, with the participants which clarifies the placement and access to the recorded material.*

* *Will participants be provided with the results of the study? If so they should be informed of this.*
* *If the project involves any form of open questioning technique, i.e. where the questions have not been prescribed in advance and consequently not reviewed by the HOD or Department Committee, a statement along the lines of that set out below should be included in the Information Sheet. The Information Sheet should include the general line of questioning even if the precise questions are unknown.*

 This project involves an open-questioning technique. The general line of questioning includes…**[insert topics here]**. The precise nature of the questions that will be asked have not been determined in advance, but will depend on the way in which the interview develops. Consequently, although the Department of …. is aware of the general areas to be explored in the interview, the Committee has not been able to review the precise questions to be used.

In the event that the line of questioning does develop in such a way that you feel hesitant or uncomfortable you are reminded of your right to decline to answer any particular question(s).

**Can Participants change their mind and withdraw from the project?**

*Participants should normally be given the opportunity to withdraw themselves and their data or information from the project. The information sheet should include a statement such as:*

You may withdraw from participation in the project at any time [*explain the final point of withdrawal if appropriate]* and without any disadvantage to yourself*.*

**What if Participants have any Questions?**

If you have any questions about our project, either now or in the future, please feel free to contact either:-

*Name of Student Researcher* and *Name of Supervisor*

Department of … Department of …

University Telephone Number:- ... University Telephone Number:- …

Email Address … Email Address …

*[Home contact details of student researchers should not be included unless a special case has been made.]*

This study has been approved by the Department stated above. However, if you have any concerns about the ethical conduct of the research you may contact the University of Otago Human Ethics Committee through the Human Ethics Committee Administrator (ph +643 479 8256 or email gary.witte@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

****

*[Delete any clauses that are not required and ensure the numbering is correct]*

***TITLE OF PROJECT***

CONSENT FORM FOR

***PARTICIPANTS***

I have read the Information Sheet concerning this project and understand what it is about. All my questions have been answered to my satisfaction. I understand that I am free to request further information at any stage.

I know that:-

1. My participation in the project is entirely voluntary;

2. I am free to withdraw from the project at any time without any disadvantage;

3. Personal identifying information [*specify e.g.* *video-tapes/audio-tapes etc*] will be destroyed at the conclusion of the project but any raw data on which the results of the project depend will be retained in secure storage for at least five years;

[***Open data alternative***]

[3. The data from this project will be publicly archived so that it may be used by other researchers, but any information that could identify you will be removed or changed*.*]

4. *If an open-questioning technique is to be used, include the following statement, otherwise delete this question*:

 This project involves an open-questioning technique. The general line of questioning includes…**[insert topics here]**. The precise nature of the questions which will be asked have not been determined in advance, but will depend on the way in which the interview develops and that in the event that the line of questioning develops in such a way that I feel hesitant or uncomfortable I may decline to answer any particular question(s) and/or may withdraw from the project without any disadvantage of any kind.

5. [*mention of any discomfort or risks*];

6. [*mention of any reimbursement, or any external funding, or commercial use of the data*];

7. The results of the project may be published and will be available in the University of Otago Library (Dunedin, New Zealand) but every attempt will be made to preserve my anonymity.

I agree to take part in this project.

............................................................................. ...............................

 (Signature of participant) (Date)

.............................................................................

 (Printed Name)

[*Options for Anonymity: in the case where your participants are public figures, artists, musicians, politicians or government officials, and it is anticipated that they will be identified/identifiable, you can offer the following options, which should match the paragraph in the Information Sheet which states “On the Consent Form you will be given options regarding your anonymity. Please be aware that should you wish we will make every attempt to preserve your anonymity. However, with your consent, there are some cases where it would be preferable to attribute contributions made to individual participants. It is absolutely up to you which of these options you prefer.”]*

[8. I, as the participant: a) agree to being named in the research, OR;

 b) would rather remain anonymous.]

 [The advertisement which will be used to recruit participants should also be attached to the application for ethical approval. This template can be used to develop the advertisement. Please ensure the standard of the written material is of the highest quality, with correct spelling and grammar. You may wish to include an image to increase your advertisement’s appeal.

 The University’s Marketing and Communications Division encourages researchers to contact them regarding the printing of advertisements once the application and the advertisement are approved by the Human Ethics Committee.]

****

**[Title of Project]**

[Brief description of project: including the purpose, research aims, questions the research will attempt to answer, etc. Please include a statement outlining that it is “research for an investigation”, or include ‘research study’ somewhere in the title]

[Brief summary of criteria that will be used to determine eligibility for the study (inclusion/exclusion criteria)]

[Brief list of benefits to participants (if any) reasonably stated. Outsized fonts emphasising money should not be used]

[The time commitment that will be required]

[Contact Details: Name, address, phone number and email address of principal investigator]

[**This project has been reviewed and approved by the Department of** (insert name)**,** **University of Otago**]

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

**IMPORTANT NOTES/CHECK LIST: Category B Reporting Sheets**

Detach this page of notes *before* making the copies to be forwarded to the University of Otago Human Ethics Committee.

1. This form should only be used for proposals which are **Category B**, as defined in the policy document "Policy on ethical practices in research and teaching involving human participants", and which may therefore be properly considered and approved at departmental level. **These proposals should not be health research or involve patients/patient data.**

2. A proposal can only be classified as Category B if **NONE** of the following is involved:-

• Personal information - any information about an individual (e.g. name, contact details, position etc,) who may be identifiable from the data once it has been recorded in some lasting and usable format, or from any completed research;\**see note below*

 (Note: this does not include contact details needed for a limited time for practical purposes but which are unlinked to research data and destroyed once the details are no longer needed.)

• Any form of physical or psychological stress;

• Situations which might place the safety of participants or researchers at any risk;

• A potential conflict between the applicant’s activities as a researcher, clinician or teacher and their interests as a professional or private individual;

• The participation of minors or any other vulnerable individuals;

• Any form of deception.

• The research is being undertaken overseas by students.

\**Exception*: Please note that Category B applications can be used where you are interviewing a public figure (s) about their work/profession (e.g. writer, artist, musician, politician, government official). Public figures can expect to be interviewed and quoted about their professional practice, so this is considered minimal risk. However the public figure needs to be offered the opportunity to give informed consent to be interviewed named and quoted.

**If any of the above is involved**, then the proposal is **Category A**, and must be submitted to the **University of Otago Human Ethics Committee** using the standard Category A application form, before the teaching or research commences.

If the research involves the following, the proposal should be submitted to the **University of Otago Human Ethics Committee (Health)** on the **health** application form:

* Participants are recruited from health services (patients)/patient data is to be examined;
* The taking or handling of any form of tissue or fluid sample from humans or cadavers;
* Any form of physical or psychological stress;
* The administration or restriction of food, fluid or a drug to a participant;

If your research involves an audit of **patient data**, and/or access to any health information/data obtained from the Ministry of Health, District Health Boards, or Pharmac etc, please refer to the **[University of Otago (Health) Minimal Risk Health Research – Audit and audit related studies form](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html%22%20%5Cl%20%22minimal_risk)**

3. Ensure the application is in the name of and signed off by a University of Otago staff member (and not, for example, the student researcher).

4 Ensure the Consent Form, Information Sheet, Advertisement and any survey or questionnaire have been carefully proofread for spelling, grammar and formatting, as the institution as a whole is likely to be judged by them.

4. A Category B proposal may commence as soon as departmental approval has been obtained; however it is best practice to plan ahead to ensure the Committee has time to audit your proposal and respond to you (the audit happens the week prior to the Human Ethics Committee meeting). Should the Committee have any concerns about the proposal, you will be notified in writing.

5. Please submit a Category B Reporting Sheet together with copies of any Information Sheet, Consent Form, recruitment advertisement for participants, and survey or questionnaire **immediately after it has been signed by the Head of Department** to the Human Ethics Committee, via:

The Manager, Academic Committees and Services, Gary Witte, (Ground Floor, Clocktower Building,) gary.witte@otago.ac.nz, or Senior Administrators Jo Farron de Diaz, jo.farrondediaz@otago.ac.nz or Ruth Sharpe ruth.sharpe@otago.ac.nz .