**Research Ethics (Health) Application Form**

Updated July 2023

**Human ethics applications must be submitted as one PDF and emailed by the deadline date to**: **humanethics@otago.ac.nz**

**Does your study require Health and Disability Ethics Committees (HDEC) review?** If your research project is within HDEC scope you must apply to HDEC rather than to the University of Otago Human Ethics Committee (Health). If you are in any doubt, please complete the *HDEC – Scope of Review Form* available at: [**http://ethics.health.govt.nz/applying-review/how-do-i-apply**](http://ethics.health.govt.nz/applying-review/how-do-i-apply).

**More information is available from the University of Otago website under the heading *Does your research require HDEC approval*?:**

[**http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html**](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html)

You may also wish to consult the Standard Operating Procedures for Health and Disabilities Ethics Committees and the [National Ethics Advisory Committee (NEAC) National Ethical Standards](https://neac.health.govt.nz/) for guidance on ethical issues related to health and disability research and services.

##

## Section 1 - Details of investigators, including student investigators and title of study

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| **Title of Study:** |  |

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

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

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| **Department:** |  |

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| **Email:**  |  |

* 1. **Co-investigators**

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

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

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

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

* 1. **Student investigator(s)**

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| **Name:** |  | **Level of study:** |  |

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| **Name:** |  | **Level of study:** |  |

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

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

**All researchers must complete PART A and PART C.**

If your study includes human participants recruited in their capacity as …

* ***Consumers of health and disability support services or***
* ***Relatives or caregivers of such consumers or***
* ***Volunteers in clinical trials***

… you are also required to complete **PART B**.

**PART A**

## Section 2 – Protocol and summary

 ***A protocol must be attached to this application before submission to the committee.***

**2.1** **Provide a plain English description of the proposed project including what the principal study question (hypothesis) that the study will test.** *You can refer to page numbers of your study’s protocol for further detail if you need to.* *\*It is essential that question 2.1 is completed in simple understandable lay language that a non-expert could understand*

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**2.1.1 Study background - describe the background for the study** (including, where appropriate, brief discussion of previous research). *You can refer to page numbers of your study’s protocol for further detail if you need to.*[<200 words]

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**2.1.2** **Inclusion and exclusion criteria**

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**2.1.3 Describe the impact, if any, of the exclusions on the generalisability of results**

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**2.1.4 Study design - describe and justify the design of your study,** including, if appropriate, the power calculation on which the number of participants is based. Provide power calculation if not explicitly stated in the protocol. **[<200 words]**

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**2.1.5** **How will the study contribute to new knowledge or improve health outcomes**.[<100 words]

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**2.1.6 Research teams’ qualifications and experience relating to conducting studies of this nature** *(include information regarding the principal investigator (or supervisor), co-investigators and students (if relevant) involved with the project*)**:**. [<200 words]

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**2.2** Ethical Issues - *(All human participant research projects have some ethical considerations so please do not leave this question unanswered.)*Provide a summary of the main ethical issues that you believe your study may raise as well as detailing your approach or strategy for dealing with them. (This information would also normally be reflected in the participant information sheet under the heading [*‘Is there any risk of discomfort or harm from participation’*](#Is_there_any_harm) **)** [<200 words] *A “not applicable” response is not acceptable.*

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**2.3** **Provide the dates on which you plan to commence and conclude your study.**

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| Planned commencement date: |  |
| Planned conclusion date: |  |

**Note**: At the conclusion (final write up) of the study **a Final Report must be submitted to the Committee**. The Final Report template can be found on the[**Human Ethics Web Page**](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html)

## Section 3 - Sponsors

**3.1 *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?

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| --- | --- | --- | --- |
| [ ]  | University of Otago | [ ]  | other government agency |
| [ ]  | another academic institution | [ ]  | pharmaceutical company |
| [ ]  | collaborative research group | [ ]  | medical device company  |
| [ ]  | district health board (DHB) |  |  |
| [ ]  | other (e.g. non-governmental organisation (NGO), or contract research organisation) |

 Please specify:

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## Section 4 - Localities and participants

Locality authorization is required from the establishment (hospital, health centre, surgery, etc.) from which the procedures outlined in the protocol are to be conducted. This authorisation confirms that the locality, if outside the University of Otago, has addressed research governance issues that may arise as a result of the study. Should this be the case, written confirmation from the locality is required. (see 4.1)

Other organisations involved in studies may prefer or require that their involvement in studies be recorded as an authorisation. You should check with these organisations before proceeding with your study.

**4.1** **At which localities in New Zealand do you intend to conduct your study?**

Written support is essential, whether your study is conducted in New Zealand or overseas and should be either attached to this application or forwarded to the Committee once ethical approval has been granted. The locality needs to be aware of the University’s protocol, governance and ethical issues.

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| [ ]  | tertiary education institution  | [ ]  | district health board (DHB) |
| [ ]  | primary health care organisation | [ ]  | private organisation |
| [ ]  | Other: |  |  |
| Specify: |  | provide details: |  |

**4.2 Age range of participants**

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**Note:** *For research involving children, the Committee suggests that the* [*Ethical Research Involving Children Guidelines*](https://childethics.com/) *(ERIC) is consulted.*

**4.3** **Approximately how many participants do you intend to recruit:**

In New Zealand?

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1-50  |  | 51-100  |  | 101-150  |  | 151-200 |  | Over 200 |  |

Overseas?

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1-50  |  | 51-100  |  | 101-150  |  | 151-200 |  | Over 200 |  |

|  |  |
| --- | --- |
| Grand total number of participants: |  |

**4.4** **If overseas, state all countries where you intend to recruit**:

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4.4.1 Is permission, or ethical approval, required to conduct the research in the country or countries to be visited?

YES / NO – if **YES** evidence will be required for the committee’s records prior to commencing the research

*(For research which involves student overseas travel, a Student Overseas Travel Plan needs to be attached to the application).*

## Section 5 - Prior review

**5.1** **Is this application related to one or more previous applications to any ethics committee?**

 [ ] yes [ ]  no

If yes, explain the relationship, giving the ethics reference number(s) of the previous application(s).

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**5.2** **Has an application for this study (or a substantially similar study) previously been declined approval by any other ethics committee in New Zealand or overseas?**

[ ] yes [ ] no[(go to section 6)](#_Section_6_–)

*If yes, provide a copy of the letter from the ethics committee communicating its decision to decline the previous application,* ***and***

*a covering letter explaining how this application addresses the issues identified by the previous ethics committee in declining approval.*

## Section 6 – Study Design

**6.1** **Is your study:**

[ ] an intervention study - Go to section 6.1.1
[ ] an observational quantitative or laboratory study - Go to section 6.1.2
[ ] a mixed methods study - Use appropriate sections of 6.1

[ ] a qualitative study - Go to section 6.1.3

**6.1.1** **Which of the following best describes your intervention study?**

**Blinding:**

[ ] open-label [ ] single-blind [ ] double-blind

**Arms**:

[ ] two-arm [ ] multi-arm

**Design**:

[ ] parallel [ ] crossover [ ] dose-ranging [ ]  cluster [ ] factorial

**Control**:

[ ] placebo-controlled [ ] active-controlled [ ]  uncontrolled

**Randomisation**:

[ ] randomised [ ] non-randomised

**Aim**:

[ ] superiority [ ] equivalence [ ] non-inferiority

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| [ ]  none of the above | Explain: |  |

**6.1.2 Which of the following best describes your observational quantitative or laboratory study?**

[ ] case control study [ ]  cohort study [ ]  cross-sectional study

[ ] case report [ ] case series

[ ] audit or related activity [ ] device usability assessment

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| [ ]  other | Explain: |  |

**6.1.3 Which qualitative methodology provides the main basis for your study design?**

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| [ ] phenomenology | [ ]  ethnography | [ ]  grounded theory  |
| [ ]  Discourse Analysis | [ ] action research | [ ]  Narrative analysis |
| [ ] other (describe) |  |

**Which of the following data collection methods will you use in your study? (select as many as apply).**

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| --- | --- | --- |
| [ ] direct observation  | [ ]  audio-visual recording  | [ ] participant observation  |
| [ ]  interviews | [ ]  focus groups | [ ]  document review  |
| [ ] Survey  | [ ] other (describe) |  |

**6.2 Scientific review**

**Evidence of two scientific reviews using the template provided must be attached to this application including your response to any recommended changes**. These responses will be expected to have been implemented in the project submitted. The application cannot be considered without the reviews. The peer reviews should specifically address the project presented in this application.

**Exception**: The only exception is if you have received a Marsden or Health Research Council (HRC) review.  The full Marsden or Health Research Council reviews must be attached.

[ ]   I have attached two peer reviews and my response to any recommended changes

[ ]   I have attached a Marsden or Health Research Council review

**6.3** **How do you intend to report or disseminate the results of your study?**

[ ]  article(s) in peer-reviewed scientific journals [ ]  internal reports

[ ]  conference presentations [ ]  publication on website

[ ]  submission to regulatory authorities (e.g. Medsafe, TGA, FDA, EMA)

[ ]  other publications

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| [ ] other | Explain: |  |

**6.4** **Will any restrictions be placed (for example, by your study’s sponsor or funder) on the publication of the results of your study?**

[ ] yes [ ] no

If yes, briefly describe these restrictions, and explain why they are in place.[<200 words]

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**6.5** **Might data generated in your study, but not reported, be made available for use in future research (e.g. for inclusion in an individual data meta-analysis)?**

[ ] yes [ ] no

*If so, you should explain this clearly to potential participants.*

Which of the following best describes the form in which data generated by your study will **be published, stored, and, if consent for future use has been given, might be made available to other researchers?**

[ ] identified [ ] potentially identifiable

[ ] partially de-identified [ ] de-identified

[ ] anonymous

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| [ ] other | Describe: |  |

## Section 7 - Use of human tissue, including blood and other body fluids

**7.1** *The use of human tissue in New Zealand is regulated by the* [*Human Tissue Act 2008*](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) *and the* [*Code of Health and Disability Services Consumers’ Rights 1996*](http://www.hdc.org.nz/the-act--code/the-code-of-rights)*.*

**Will human tissue be collected and/or used in your study?**

[ ] yes [ ] no **If “no”** [**go to Section 8**](#Section_8)

**7.2 What types of human tissue will be collected and/or used in your study?** [<100 words]

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**7.3 Will your study involve:**

[ ] human tissue collected from participants during this study? Go to [7.6](#section7_6)

[ ] existing stored human tissue samples?

**7.4 How and from where will you obtain these existing stored human tissue samples?** [<100 words]

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**7.5 Will donors of existing stored human tissue samples used in your study be able to be identified by you or your research team?**

[ ] yes [ ] no
If yes, briefly explain why the use of existing stored human tissue samples in a form that may allow the donor(s) to be identified is necessary in your study. [<100 words]

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**7.6** **Will any human tissue samples used in your study be imported from outside New Zealand?**

[ ] yes [ ] no

If yes, explain why it is appropriate to use imported human tissue in your study. [<100 words]

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**7.7 Briefly explain how human tissue samples will be stored during your study, and how the privacy of donors and participants will be protected.** [<100 words]

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**7.8 Will human tissue collected in New Zealand be sent overseas as part of your study?**

[ ] yes [ ] no

If yes, you should explain this clearly to participants.

**Briefly explain why it is necessary and appropriate that human tissue samples be sent overseas as part of your study.**[<100 words]

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**7.9** **Will the use of all human tissue in your study be in accordance with the informed consent (including consent to** [**future unspecified research**](http://www.moh.govt.nz/moh.nsf/indexmh/guidelines-use-human-tissue)**) that has been or will be obtained from participants, donors of existing stored human tissue, or other persons entitled to give informed consent under the** [**Human Tissue Act 2008**](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html)**?**

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| [ ] yes go to [7.10](#section7_10)   | [ ] no |

**7.9.1 Insofar as your study involves the storage, preservation or use of human tissue without informed consent, does a statutory exemption to the need to obtain such consent apply?**

Statutory exemptions are set out at section 20(f) of the [Human Tissue Act 2008](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) and Right 7(10)(c) of the [HDC Code of Rights](http://www.hdc.org.nz/the-act--code/the-code-of-rights).

[ ] yes [ ] no

**7.9.1.1** Under section 20(e) of the [Human Tissue Act 2008](http://www.legislation.govt.nz/act/public/2008/0028/latest/DLM1152940.html) and Right 7(10)(b) of the [HDC Code of Rights](http://www.hdc.org.nz/the-act--code/the-code-of-rights), ethics committees may approve the use of human tissue without consent in research. Approval may be given where it is not practicable to obtain informed consent, and/or where the benefits of the research outweigh the very strong need to protect an individual’s right to consent.

**Briefly justify the storage, preservation or use of human tissue without consent in your study.** [<300 words]

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**7.10 Is consent being sought for future unspecified use?**

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| [ ]  Yes | if so specify the general terms of the additional research |  |

[ ] no

 Notes:

1. A new application will need to be submitted to gain approval of any additional research or testing on samples taken for the current study which is outside the scope of the current specified study.
2. Consent for the particular research project should be obtained separately from the consent for the future unspecified use of the tissue. This could be achieved by two separate consent forms or a separately detailed statement on the same consent form. Attach consent form(s).

**7.11 What types of tests or analyses will be carried out on human tissue as part of your study?**

[<100 words]

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**7.12 What will happen to human tissue at the end of your study, or if participants withdraw consent for its use in this study?**

[ ]  disposal

[ ]  return to donor, whānau, or family member

[ ]  return to current holder of existing stored human tissue (e.g. a tissue bank)

[ ]  transfer to another tissue bank

[ ]  storage by the research team for use in another study

[ ] storage by the research team as part of a new tissue bank

[ ]  other

**7.13 Briefly explain your answer above.** [<100 words]

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**7.14 Will any human tissue collected or otherwise obtained from participants in this study but not used in the current study be stored and potentially used in unspecified future research?** *You should explain this clearly to potential participants.*

[ ] yes [ ] no

## Section 8 - Risk of physical harm to participants

**8.1 Briefly and in plain English, describe the risks inherent in the** **procedures to be undertaken by participants in your study and how these risks will be minimised. Including:**

* **risk minimisation by use of health questionnaires**
* **participant exclusion criteria**
* **monitoring during procedures**
* **training of research staff and availability of resuscitation equipment if appropriate**
* **use of EEG, ECG, MRI, TMS, FMRI, EMG, radiation, invasive or surface recordings.** *[<200 words]*

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*Ensure that any risks associated with these procedures that potential participants may reasonably wish to be informed of are included in the participant information sheet.*

**8.2 Will your study involve the administration of ionising radiation that is not needed for participants’ normal clinical management?**

[ ] yes [ ] no – [go to 8.](#quest8_5)3

**8.2.1 Briefly describe the form(s) in which ionising radiation not needed for normal clinical management will be administered**. [<100 words]

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**8.2.2 Provide the name(s) of the person(s) licenced under the** [**Radiation Protection Act 1965**](http://legislation.govt.nz/act/public/1965/0023/latest/DLM372539.html) **under whose supervision ionising radiation not needed for clinical management will be administered to participants in your study; and confirm that a medical physics expert has verified that accurate effective doses have been calculated for this ionising radiation.**

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**8.3** Arrangements for monitoring serious adverse events

*Note that a record of adverse events should be kept, and a summary provided to the ethics committee at the conclusion of the study. Serious adverse events should be reported to the ethics committee.*

**How will serious adverse events occurring in your study be monitored?**

[ ] independent data safety monitoring committee

[ ] internal data safety monitoring committee

[ ] other data safety monitoring arrangements

[ ] no formal data safety monitoring arrangements

**8.4 Briefly explain** *either:*

1. the monitoring arrangements in place for your study, and explain why they are appropriate (including reference to your study’s protocol where appropriate), *or*
2. why you do not consider formal monitoring arrangements to be necessary for your study. [<100 words]

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**8.5 If this is an intervention study, briefly outline the criteria for its termination, including reference to your study’s protocol where appropriate**. [<100 words]

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## Section 9 - Risks to participants other than physical risks of an intervention

**9.1 Could participation in the study, or reporting of the findings, risk psychological harm to participants?**

[ ] yes [ ] no

If yes, how this risk will be minimised and managed. [<100 words]

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**9.2 Could participation in the study, or reporting of the findings, risk stigmatising individuals or population groups**, **or punishment/ harassment for participation?**

[ ] yes [ ] no

If yes, how this risk will be minimised and managed. [<100 words]

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## Section 10 - Risk of potential conflict of interest

**10.1** Funding and remuneration

**Briefly describe the main source(s) of funding for your study**.[<100 words]

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**10.2 Does the Principal Investigator, any co-investigator, or any direct member of their families have any commercial interest in the intervention(s) to be studied, or any financial relationship to the study sponsor or funder(s), that may inappropriately influence his or her conduct in the study?**

[ ] yes [ ] no

**10.3 Will the Principal Investigator or any co-investigator be remunerated for their involvement in the study in a way that may inappropriately influence his or her conduct in the study (for instance, bonuses for favourable results or high recruitment rates)?**

[ ] yes [ ] no

**10.4** Other potential conflicts of interest

**Will any researchers in the study face other conflicts of interest (e.g. academic dependence, personal belief)?**

[ ] yes [ ] no

**10.5 Briefly describe how the risks of any conflict of interest, described in sections 10.1 to 10.4 above, will be minimised and managed.**[<100 words]

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## Section 11 - Risk of breach of privacy and confidentiality

***Compliance with The Privacy Act 2020 and the Health Information Privacy Code 2020 imposes strict requirements concerning the collection, use and disclosure of personal information.***

**11.1** Before the study:

**Will your study involve reviewing or screening health information, for example in order to identify potential participants?**

*The term “health information” is defined in the* [*Health Information Privacy Code*](http://privacy.org.nz/health-information-privacy-code/)*.*

[ ] yes [ ] no

If yes, briefly explain how you will ensure the confidentiality of this health information before the study. [<100 words]

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**11.2 Will your study involve the use of surveys or questionnaires?**

[ ] yes [ ] no

*Copies of these surveys or questionnaires should be provided with this application.*

## Section 12 - Risks to researchers and third parties

**12.1 Briefly indicate whether your study may pose any significant risks to researchers and/or third parties, and briefly explain how such risks will be minimised and managed**. [<100 words]

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## Section 13 - Informed Consent

**13.1 Will all participants in your study be competent to, and asked to, provide their informed consent to participate?**

[ ] yes, all participants will be competent to, and asked to give informed consent - If yes [go to 13.2](#_Section_13_-)

[ ] no, one or more participants may not be competent to, or will not be asked to give informed consent

**13.1.1 If no, indicate the groups to which non-consenting participants in your study belong**:

[ ] individuals from whom information or biological samples have been stored, with or without explicit consent

[ ] adults with serious intellectual disability or mental illness

[ ] children and young people (under the age of 16) who are not competent to give informed consent

[ ] other potentially vulnerable people – that is, people who may have a restricted ability to make independent decisions about their participation.

**13.1.2 Explain why you believe it is appropriate that your study involve such participants who are unable to, or not offered the opportunity to, provide informed consent.**

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**13.1.3 Will you seek the informed consent of parents, guardians, relatives or other persons who are able to advise on the presumed wishes of participants who will not be competent to, or not be asked to provide consent?**

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| [ ] yes- [go to 13.2](#section_13_2)  | [ ] no |

**13.1.4 If no, explain and justify why you will not obtain such consent, and what steps you will take to provide non-consenting participants with information about the study, and to consider their wishes and feelings about participating?**

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**13.1.5 Is it possible that non-consenting participants’ ability to give informed consent could change during your study?**

[ ] yes - If yes, how would such changes be managed in your study’s informed consent process? Incorporate the explanation in the Information Sheet.

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[ ] no

**13.2** **Does the research involve participants giving oral consent rather than written consent?**

[ ] yes [ ] no

If yes, explain and justify and incorporate the justification in the Information Sheet.

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**13.3 Briefly explain the process by which potential participants in your study will be identified, approached, provided with an Information Sheet written in language appropriate to the intended participants, have the opportunity to ask questions, and be asked to give their informed consent free from undue influence. Identify the person or persons who will conduct the process**.

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**13.4 Will consent be recorded by signature on an individual consent form?**

[ ] yes [ ] no

If no, explain how participants’ informed consent will be recorded, and incorporate this information in the Information Sheet.

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**13.5 Does the research involve deception, covert observations, or other ways in which information is deliberately withheld or concealed from participants ?**

[ ] yes [ ] no

If yes, explain why it is felt appropriate to withhold or conceal information from participants in your study. [<100 words]

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**13.6 How will you ensure that participants receive information that becomes available during the study (for example, an unexpected incidence of adverse events in your study, or information from elsewhere) that may be relevant to their continued participation?**

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**13.7 Will you inform participants of the results of your study?**

[ ] yes [ ] no

Either explain how you will inform participants or explain why you do not intend to do so.

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**13.8 Will participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in your study?**

[ ] yes [ ] no

If yes, describe these, and explain why they are appropriate.

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**13.9 Will you seek consent from participants to inform health practitioners with responsibility for their health care that they are taking part in your study?**

[ ] yes [ ] no

## Section 14 - Consultation with Māori

**Māori should be consulted in the design and conduct of research that is of relevance to them.**

**14.1 Describe whether and how your study may benefit Māori, and identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed.**[<200 words]

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**14.2 According to the Health Research Council’s** [**Guidelines for Researchers on Health Research Involving Māori**](http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL%5B1%5D.pdf)**, is formal consultation with Māori required for your study**?

[ ] yes [ ] no

**14.3 The University of Otago has a Policy for Research Consultation with Māori.** **Have you, or will you, 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 (e.g. the research is being undertaken overseas):

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## Section 15 - Consultation with other population groups

 **15. 1 Does your study require consultation with other population groups?**

[ ]  yes – if yes, go to question 15.2 below[ ] no

15.2 **Describe the population group chosen; how your study may benefit the selected group; identify the main cultural issues that may arise for those participants who may participate in your study, and explain how these issues will be managed.**

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 **Please note that the University of Otago has a Pacific Research Protocol which is a guide for university researchers who wish to undertake research with Pacific peoples.**

**PART B**

**To be completed if your study includes human participants recruited in their capacity as:**

* ***Consumers of health and disability support services or***
* ***Relatives or caregivers of such consumers or***
* ***Volunteers in clinical trials***

## Section 16 - Compensation for injury to participants

**16.1** **Will the proposed research be conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out?**

[ ] yes - submit a **Form B\*** with your application.

[ ] no – go to Section 17

The **Form B** template can be found on the [Human Ethics Committees](http://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html) webpage under the heading ‘Forms and submitting your application’.

## Section 17 - Risk of unexpected clinically significant findings

**17.1 Might any aspect of your study produce findings that may be both unexpected and clinically significant for participants, donors of existing stored human tissue, or their families?**

[ ] yes [ ] no

If yes, what might these findings be, and how will participants, donors of existing stored human tissue, or their families be informed of them?[<100 words]

|  |
| --- |
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##

## Section 18 - Privacy and confidentiality of health information

***As noted in Section 11, both the Privacy Act 2020 and the Health Information Privacy Code 2020 impose strict requirements concerning the collection, use and disclosure of personal information. Please ensure your research is complaint with both the Act and HIPC.***

**18.1** During the study

During your study, who will have access to health information used in your study?

[<100 words]

|  |
| --- |
|  |

**18.2 Briefly explain how you will ensure the confidentiality of this health information during the study.** [<100 words]

|  |
| --- |
|  |

**18.3** *The* [*Health (Retention of Health Information) Regulations 1996*](http://legislation.govt.nz/regulation/public/1996/0343/latest/DLM225616.html) *require that* ***some*** *health information be retained for a period of ten years.*

**For how long will health information generated in your study be stored?**[<100 words]

|  |
| --- |
|  |

## Section 19 - Health or disability support service providers

**19.1 Will the Principal Investigator or any co-investigator also be the usual health or disability support service provider for one or more participants in your study?**

[ ] yes [ ] no

**19.2 Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?**

[ ] yes [ ] no

|  |  |
| --- | --- |
| If yes, how much and why is it necessary? |  |

## Section 20 - Impact on the provision of health and disability services

**20.1 Might your study adversely impact on the provision of health and disability services?**

[ ] yes [ ] no [ ] not applicable

If yes, how will this possibility be minimised and managed? [<100 words]

|  |
| --- |
|  |

**PART C** – Signatures

|  |  |
| --- | --- |
| **Signature of Applicant (Principal Investigator):** |  |

|  |  |
| --- | --- |
| **Name: (please print)**  |  |

|  |  |
| --- | --- |
| **Date:**  |  |

**Departmental approval:** I have read this application and believe it to be scientifically and ethically sound. I confirm that the peer reviews obtained for the study was appropriate reflecting the risk and intended purpose of the proposal and was by means of one of the following:

[ ]  Peer reviewed by a peer review committee, and external peer reviewing body or an internal reviewing body;

[ ]  Peer reviewed by at least two peers reviewing confirming scientific validity;

[ ]  Peer review by one other reviewer confirming scientific validity.

I approve the research design. 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 University of Otago Human Ethics Committee (Health) with my recommendation that it be approved.

|  |  |
| --- | --- |
| **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.**

Attach copies of the Information Sheet and Consent Form

## Check List

## Please go through this check list to ensure you have completed all relevant sections:

|  |
| --- |
|[ ]  Part A – To be completed by all applicants |
|[ ]  Study protocol attached. |
|[ ]  Two peer reviews attached including the peer reviewers comments AND your response to any recommended changes. |
|[ ]  Part B – To be completed if your study includes human participants recruited in their capacity as: consumers of health and disability support services, relatives or caregivers of such consumers or volunteers in clinical trials. |
|[ ]  Part C – Signature page. Signed by the Principal Investigator and the Head of Department before submitting for review. |
|[ ]  Attach evidence of Māori Consultation |
|[ ]  Participant Information Sheet |
|[ ]  Participant Consent Form |
|[ ]  Advertisement for the recruitment of participants |
|[ ]  If applicable, Form B - Declaration of provision of compensation for injury for participants in a research study for a pharmaceutical company or any other company involved in health research |
|  | **Submitting to the Committee:** |

Once fully signed by the Principal Investigator and Head of Department, the application and all attachments must be compiled as one PDF and emailed by the deadline to **humanethics@otago.ac.nz**

Notes

1. Proposals submitted to the Committee will only be considered if they are submitted in typed or word-processed format.
2. It is helpful if applicants use a font different to the default font on the electronic application form (Times 12 point) as this helps to distinguish the applicant's entries from the standard headings and guideline notes which appear throughout the application form. Please do not use all capital letters or italics.
3. Use language which is, as far as possible, free from jargon and is comprehensible to lay people, or children if applicable. Ensure your Consent Form, Information Sheet and Advertisement have been carefully proof-read; the institution as a whole is likely to be judged by them.

**Note:** Not all of the templates below will necessarily apply to all projects; for some projects, additional information may also be required.

## Information Sheet and Consent Form Templates

The Information Sheet and Consent Form must be separate documents, as the Information Sheet is kept by participants, whereas they sign and hand in their Consent Form.

The following templates should be used as 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 these templates will necessarily apply to all projects.

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 potential participants need in order to make an informed decision about whether or not they wish to participate in the research.

The Information Sheet 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. in an anonymous survey.

The Information Sheet and Consent Form templates should be written in appropriate language for your participants. In most cases both should be free from jargon and comprehensible to lay people, and children if applicable.

The Information Sheet and Consent Form you submit with your application should be the final versions you intend to use. All traces of the prompts from the Human Ethics Committee (Health) to the researcher should be removed and it should be carefully proof-read for grammatical accuracy and consistency and correct spelling.

**Informed consent**

***Attach*** *the information sheet and the consent form to this application.* ***The information sheet and consent form must be separate****.*

 At a minimum the Information Sheet must describe in lay terms:

• the nature and purpose of the research;

• the procedure and how long it will take;

• any risk or discomfort involved;

• who will have access and under what conditions to any personal information;

• the eventual disposal of data or tissue collected;

• the name and contact details of the staff member responsible for the project and an invitation to contact that person over any matter associated with the project;

• details of remuneration offered for participation and compensation payable in the event of harm (Please see [forms A and B](#forms_A_B));

• Exclusion criteria for the project if applicable including health concerns;

 and any other relevant matters.

The Information Sheet must conclude with the statement: "This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email humanethics@otago.ac.nz). Any issues you raise will be treated in confidence and investigated, and you will be informed of the outcome.”

 The Consent Form must make it clear that a participant:

• understands the nature of the proposal;

• has had all questions satisfactorily answered;

• is aware of what will become of the data or tissue at the conclusion of the project;

• knows that he or she is free to withdraw from the project before its completion (specify a date if necessary);

• is aware of risks, remuneration and compensation;

• is aware that the data may be published;

• is aware that a third party (i.e. transcriber) may have access to the data;

• is aware that every attempt will be made to ensure that participants will not be identified unless the participant gives an express waiver, which must be in addition to and separate from this consent form.

*(Applicants should use the pro forma Information Sheet and Consent Form provided by the University of Otago Human Ethics Committee (Health), with appropriate adaptation, unless a case is made and approved that these formats would be inappropriate for the specific project;*

*Research or teaching involving children or young persons under 16 years of age require written consent from both the child or young person AND the parent/guardian unless an adequate justification is provided.)*

**Academic Committee and Services Office contacts:**

Gary Witte gary.witte@otago.ac.nz 64 3 479 8256

Jo Farron de Diaz jo.farrondediaz@otago.ac.nz

Paulette Milnes paulette.milnes@otago.ac.nz on 64 3 479 6531

##

## **Participant Information Sheet** (enter further details if necessary e.g. for Parents/Guardians, for child participants etc)

|  |  |
| --- | --- |
| **Study title:** |  |
| **Principal investigator:** | **Name****Department****Position** | Contact phone number:……………………………… |

**Introduction**

Thank you for showing an interest in this project. Please read this information sheet carefully. Take time to consider and, if you wish, talk with relatives or friends, 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 this research project?**

*State the rationale and aims for the project. Explain how your study will contribute to new knowledge, or improve health or social outcomes.*

**Who is funding this project?**

*Indicate the source of any funding provided for this study e.g. a national Research Council, another Government Agency, a local or national Research Trust, University departmental funds, or a commercial organisation engaged in manufacturing or distribution.*

**Who are we seeking to participate in the project?**

*Explain how the sampling frame for potential participants has been defined, listing and justifying the inclusion and exclusion criteria. If the research involves a group (such as students in a class), members of which may decline to participate, indicate what these non-participants will do while the research is being conducted and indicate how the anonymity of non-participants will be preserved.*

**If you participate, what will you be asked to do?**

*Explain in plain English the procedures in which the participants will be involved, and the frequency and duration of time involvement.*

*If there is any dependent relationship between the researcher and potential participants (e.g. the researcher is also providing clinical care, or is seeking participants who are students in the same department) there must be an explicit statement that no aspect of care, or of grades/ academic relationships will be affected by either refusal or agreement to participate. It should be made clear that participation is voluntary.*

*Reimbursement of expenses for participation, e.g. for expenses of participation or for travel is permitted; the terms and conditions should be clearly stated.*

**Is there any risk of discomfort or harm from participation?**

*If the research involves any procedure that might cause physical, psychological, or social discomfort or harm, the nature and size of the risk should be made clear. The steps taken by the research team to minimise risk, and to manage any adverse event, should be described.*

**What specimens, data or information will be collected, and how will they be used?**

*Explain how, where, and for how long any body fluids or other tissue specimens will be stored, and what the arrangements will be for their disposal. If it is proposed that such materials will be retained beyond the completion of this project, and may be used for future research as yet unspecified, explain how participants will have the opportunity to consent, or refuse consent, for that to happen.*

*Explain how, where, for how long and in what format data will be stored and subsequently destroyed. Give participants the choice of disposal with a Karakia (M*ā*ori Prayer). If data will be retained beyond the completion of the research for which it was collected, explain why. State if data is to be transferred to a public repository.*

*If audio, video, electronic, or other means of recording are involved this should be indicated. If such recording is optional, explain how participants will have the opportunity to consent, or refuse consent, for that to happen.*

**What about anonymity and confidentiality?**

*If it is intended that a participant’s recordings (audio, video, or pictures) can be reviewed by the participant, the researcher should explain the process.*

*Explain how the reporting of the completed research will strive throughout to preserve confidentiality and anonymity, by the use of code numbers and secure data management.*

*If third parties are involved (for example, in transcription, translation, editing or cultural comment), indicate who will view the data, for what purpose, and how confidentiality of information and participation will be preserved.*

**If you agree to participate, can you withdraw later?**

*If participants are to be named or identified, they must give an express waiver in addition to, and separate from, the Consent Form.*

*You may withdraw from participation in the project before its completion (specify a date if necessary).*
*The information sheet will need to explain if there is a specific time after which the participant cannot withdraw (i.e. de-identified information is already integrated into the study.)*

**Any questions?**

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

|  |  |
| --- | --- |
| **Name****Position****Department** | Contact phone number:……………………………… |
| **Name****Position****Department** | Contact phone number:……………………………… |
| **Name****Position****Department** | Contact phone number:……………………………… |

*This study has been approved by the University of Otago Human Ethics Committee (Health). If you have any concerns about the ethical conduct of the research you may contact the Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email humanethics@otago.ac.nz). Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.*

*This Consent Form template should be used as a prompt for the development of your final Consent Form. Not all of the suggestions on this template will necessarily apply to all projects. Appropriate deletions and additions will need to be made.*



**Title of the project**

***Principal Investigator: Dr/Professor …………..*** (e-mail address and telephone number)

## **CONSENT FORM FOR PARTICIPANTS**

Following signature and return to the research team this form will be stored in a secure place for ten years.

Name of participant:…………………………………………..

1. I have read the Information Sheet concerning this study and understand the aims of this research project.
2. I have had sufficient time to talk with other people of my choice about participating in the study.
3. I confirm that I meet the criteria for participation which are explained in the Information Sheet.
4. All my questions about the project have been answered to my satisfaction, and I understand that I am free to request further information at any stage.
5. I know that my participation in the project is entirely voluntary, and that I am free to withdraw from the project before its completion *(specify a date if necessary).*
6. I know that as a participant I will...

(*detail the expectations in respect of provision of information including access to medical records, completion of questionnaires, undergoing measurements of physical or mental function, and of donation of tissue, blood or other body fluid as listed in the information sheet)*

1. I know that the (*questionnaire, interview etc)* will explore the *(briefly describe the question line)* and that if 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 disadvantage of any kind.
2. I understand the nature and size of the risks of discomfort or harm which are explained in the Information Sheet.
3. I know that when the project is completed all personal identifying information will be removed from the paper records and electronic files which represent the data from the project, and that these will be placed in secure storage and kept for at least ten years.
4. I understand that the results of the project may be published and be available in the University of Otago Library, but that either (i) I agree that any personal identifying information will remain confidential between myself and the researchers during the study, and will not appear in any spoken or written report of the study [ ]  or (ii) I agree to be named or identified in the study and will sign a waiver form. [ ]
5. I know that there is no remuneration offered for this study, and that no commercial use will be made of the data.
6. I understand that the (*tissue, blood or other body fluid)* samples will be (*provide details of storage, and disposal with opportunity to ask for karakia if appropriate).*

|  |  |  |
| --- | --- | --- |
| Signature of participant: |  | Date: |
|  |  |  |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| Name of person taking consent |  | Date: |
|  |  |  |

[The advertisement which will be used to recruit participants should 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.

 Please note: The University’s Marketing Services encourages researchers to contact the [Marketing Advisory teams](https://www.otago.ac.nz/marketing-services/marketing-and-advisory/) within the relevant Division regarding advertisements of the research once the application and the draft 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. 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 University of Otago Human Ethics Committee, (Health). Reference: ##/###]**

Title of research project

Contact details of principal investigator

Title of research project

Contact details of principal investigator

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Title of research project

Contact details of principal investigator

***[Evidence of peer review must be attached*** *to this application* ***including responses to any recommended changes.****These responses will be expected to have been implemented in the project submitted. The application cannot be considered without this. The peer review template below can be used for this purpose.]*

**Department of: ­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# 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.] | **Researcher response** |
| 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  |  |  |