**Auckland Health Research Ethics Committee (AHREC)**

**Application Form, version 1.4**

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| **For Administrative use only:** | |
| **AHREC Application No.:** | Click here to enter text. |
| **Date received at RO:** | Click here to enter a date. |
| **Review method:** | Choose an item. |

AHREC undertakes the review of health and disability research studies that fulfil all of the following criteria:

1. The study is **not** eligible for review for ethics approval by a Health and Disability Ethics Committee (HDEC).

The following studies require HDEC review:

* Any intervention study
* Research involving participants or using identifiable health information without consent
* Research using human tissue in an identifiable form
* Research involving vulnerable participants *excluding research limited to retrospective clinical record review*
* Studies that withhold standard care

The following studies do **not** require HDEC review:

* Research wholly for the attainment of a qualification at masters level or below
* Using identifiable health information without consent for audit or related activities
* Research using health information in a de-identified form

**For fuller details of which studies require HDEC review, see:** [**http://ethics.health.govt.nz/home**](http://ethics.health.govt.nz/home)

AND

1. The study involves human participants from within the geographic region served by the Auckland District Health Board (Auckland DHB) and/or from within non-Auckland DHB areas where the Auckland DHB is a clinical service provider in the area of practice for the research proposed. For multi-site applications that meet these criteria, applicants are to seek ethics approval either from AHREC or from another HRC-approved ethics committee.

AND

1. The study involves health research conducted by Auckland DHB employees, and/or employees and/or students of the University of Auckland.

# AHREC uses the HDEC definition of health and disability research as “research that aims to generate knowledge for the purpose of improving health and independence outcomes.”

Further information is available at:

Faculty of Medical and Health Sciences: <https://www.auckland.ac.nz/en/about/research/re-ethics.html>

Auckland DHB: [www.adhb.govt.nz/ResearchOffice/](http://www.adhb.govt.nz/ResearchOffice/)

Requirements for applications

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| Step 1 | Complete the application form and prepare all relevant documents (study protocol, Participant Information Sheet, Consent Form, advertisements, etc.). |
| Step 2 | Obtain a science review of the proposed study from a peer or senior consultant. For grant funded studies, include the grant award letter. Refer to section H of this form for more information about requirements of a science review. Obtain appropriate sign-off from a Head of Department or similar. |
| Step 3 | Submit the completed application package to the following email address: [ahrec@auckland.ac.nz](mailto:ahrec@auckland.ac.nz) |

Receipt of the application will be acknowledged within 3 days and you will be notified of the application number and review pathway (expedited or full committee review).

Please note: The research may not start until approval from AHREC has been obtained.

# Section A: Applicants

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| **A1** | **Auckland DHB Project Number (if known):** Click here to enter text. |
| A2 | Full project title: Click here to enter text. |
| A3 | Principal Investigator: Click here to enter text. |
| A4 | PI Contact details:  Click here to enter text.  Phone: Click here to enter text.  Emergency Number: Click here to enter text.  E-mail: Click here to enter text.  Auckland DHB Service Area (if relevant): Click here to enter text.  University Department or School (if relevant): Click here to enter text. |
| **A5** | **Contact details for communication if not via Principal Investigator:**  Click here to enter text. |
| **A6** | **For University of Auckland employees, please provide name of Auckland DHB contact person, if relevant**  **Auckland DHB Contact Name:** Click here to enter text.  **Contact details, including Department:**  Click here to enter text.  **Work phone:** Click here to enter text.  **Emergency phone:** Click here to enter text.  **E-mail:** Click here to enter text.  **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **A7** | **List all other investigators (apart from students) and their affiliation(s):**   |  |  |  |  | | --- | --- | --- | --- | | Name | Email | Affiliation | Role in the project | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | |
| A8 | Will this research form part of a degree or other qualification?  Yes  No    **Is this a summer studentship?**  Yes  No  Student name: Click here to enter text.  Student ID: Click here to enter text.  Degree/Qualification: Click here to enter text.    University Department/School: Click here to enter text.  Email: Click here to enter text. |
| **A9** | **For student projects (summer, masters and doctoral), please provide name of Auckland DHB clinical supervisor, if different from the contact person (above):**  **Auckland DHB Clinical Supervisor Name:** Click here to enter text.  **Contact details:**  Click here to enter text.  **Work phone Number:** Click here to enter text.  **E-mail:** Click here to enter text.  **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| A10 | Curriculum vitae:  Please attach the CV of the principal investigator to this application. An HRC/MBIE standard CV format is acceptable.  **Summarise the principal investigator’s qualifications and experience relating to conducting studies of this nature** (<200 words)**:**  Click here to enter text. |

# Section B: Eligibility and Location

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| **B1** | **Indicate how this study meets the AHREC eligibility criteria (see page 1 of this form), including why it is not eligible for HDEC review**  Click here to enter text. |
| **B2** | **Where will the research take place?**  Click here to enter text. |
| **B3** | **Does the study involve Auckland DHB patients or staff?**  Click here to enter text. |

# Section C: Study Description

Attach a copy of the study protocol to this application

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| **C1** | **What is the principal question or hypothesis the study will address?**  Click here to enter text. |
| **C2** | **Describe the scientific background of the study** (<300 words):  Click here to enter text. |
| **C3** | **How will the study contribute to new knowledge and/or improve health outcomes?**  Click here to enter text. |
| **C4** | **Provide a plain English summary of your study** **and the design used** (<300 words):  Click here to enter text. |
| **C5** | **Describe in detail what taking part in the study will involve for participants:**  Click here to enter text. |
| **C6** | **C6a: What are the inclusion and exclusion criteria for participants in the study?**  Click here to enter text.  **C6b: How many participants do you intend to recruit?**  Click here to enter text.  **C6c: How was this number determined?**  Click here to enter text.  **C6d: What are the age(s) of the participants?**  Click here to enter text.  **C6e: Is a formal power calculation appropriate – if so, please provide this:**  Click here to enter text. |
| **C7** | **Will any population groups be specifically targeted for recruitment into the study?**  Yes  No  **If “Yes”,**   * **indicate which groups:**   Click here to enter text.   * **briefly describe how these populations have been or will be consulted:**   Click here to enter text.   * **briefly describe how the study may benefit these populations:**   Click here to enter text.   * **describe any on-going involvement of the groups(s) consulted:**   Click here to enter text. |
| **C8** | **Provide the dates on which you plan to commence and conclude the study:**  Planned commencement date: Click here to enter a date.  Planned conclusion date: Click here to enter a date.  Please note that the standard length of AHREC approval is three years. If you want to request a different length of approval, please indicate the duration of approval you request in years:  Click here to enter text. |
| **C9** | **Describe any impact upon Auckland DHB resources (e.g., use of staff time, premises, facilities, consumables) and, if no DHB budget is supplied, justify this:**  Click here to enter text. |

# Section D: Responsiveness to Māori

Māori responsiveness review should be undertaken within either the University or DHB depending on where the research is based and whether it involves DHB participants. These reviews will be organised by the Auckland DHB Research Office for Auckland DHB employees after the application has been submitted. University staff and students who are unfamiliar with University’s requirements may seek advice from the [Office of the Tumuaki](https://www.fmhs.auckland.ac.nz/en/faculty/tkhm/office-of-tumuaki.html) (R2M@auckland.ac.nz) or access the resources provided to students to facilitate this process.

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| **D1** | **Describe whether and how your study may advance Māori health outcomes and Māori health workforce:**  Click here to enter text. |
| **D2** | **Will participants’ ethnicity status be collected as part of the study?**  Yes  No  **If “No”, please explain why:**  Click here to enter text.  *Standard ethnicity data protocols for the Health and Disability Sector are available at:*  [**http://www.health.govt.nz/publication/ethnicity-data-protocols-health-and-disability-sector**](http://www.health.govt.nz/publication/ethnicity-data-protocols-health-and-disability-sector) |
| **D3** | **Is an analysis (or sub-analysis) of outcomes by Māori ethnicity planned?**  Yes  No  **If “Yes”, describe, if “No”, please explain why:**  Click here to enter text. |
| **D4** | **How many Māori participants are expected to be involved in the study (% and absolute numbers)?**  Click here to enter text.  *These links may help you find Māori health statistics for the health issue you are researching:*  Ministry of Health: <http://www.health.govt.nz/nz-health-statistics>  Statistics NZ: <http://www.stats.govt.nz/infoshare/?gclid=CMWcuqfZorUCFct7QgodkSgAVQ> |
| **D5** | **Might this study contribute to reducing inequalities in health outcomes between Māori and other New Zealanders?**  Yes  No  **Please explain why:**  Click here to enter text. |
| **D6** | **D6a: Describe how Māori participants will be recruited (where, how, by whom):**  Click here to enter text.  **D6b: Outline steps to ensure adequate participation:**  Click here to enter text. |
| **D7** | **Identify the main cultural issues that may arise for Māori who participate in the study and explain how these issues will be managed**. Examples of research processes with cultural issues for Māori include genetic testing, tissue banking, collective informed consent, privacy and confidentiality of personal information.  Click here to enter text.  *Links to guidelines:*  HRC Guidelines for Researchers on Health Research involving Māori:<http://www.hrc.govt.nz/sites/default/files/Te%20Ara%20Tika%20Guidelines%20for%20Maori%20Research%20Ethics.pdf> |
| **D8** | **How will the study results be communicated to Māori?**  Click here to enter text. |

# Section E: Human Tissue

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| **E1** | *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)*.* Use of tissue in an identifiable form or without existing informed consent for use requires approval from HDEC, not AHREC. HDEC may decline jurisdiction in the case of a masters or other student project, in which case AHREC will assess the proposal.  **Will human tissue be collected and/or used in this study?**  Yes  No  If No, then move directly to the section F. |
| **E2** | **What types of human tissue will be collected and/or used in this study?**  Click here to enter text. |
| **E3** | **Will your study involve:**  human tissue collected from participants?  existing stored human tissue samples? |
| **E4** | **How and from where will you obtain these existing stored human tissue samples?**  Click here to enter text. |
| **E5** | **Will any human tissue samples used in your study be imported from outside New Zealand?**  Yes  No |
| **E6** | **Please briefly explain why it is appropriate to use imported human tissue in your study.**  Click here to enter text. |
| **E7** | **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 |
| **E8** | **Explain how human tissue samples will be stored during your study, and how the privacy of donors and participants will be protected.**  Click here to enter text. |
| **E9** | **Will human tissue collected in New Zealand be sent overseas as part of your study?**  Yes  No |
| **E10** | **Explain why it is necessary and appropriate that human tissue samples be sent overseas as part of this study.**  Click here to enter text. |
| **E11** | **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.health.govt.nz/system/files/documents/publications/guidelines-use-of-human-tissue-may07.pdf)**) that has been 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)**?**  Yes  No  **If “No”, please explain:**  Click here to enter text. |
| **E12** | **What tests or analyses will be carried out on human tissue as part of the study?**  Click here to enter text. |
| **E13** | **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  **Please briefly explain your answer:**  Click here to enter text. |
| **E14** | **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?**  Click here to enter text. |

# Section F: Risks & Benefits

|  |  |
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| **F1** | **Describe any benefits the study may have for participants** (<200 words):  Click here to enter text. |
| **F2** | **Describe any wider/other benefits of the study** (<200 words):  Click here to enter text. |
| **F3** | **Describe any risks associated with the study**. (<400 words).  (Do not describe procedures that will be undertaken as part of normal clinical care regardless of participation in your study, or the risks of such procedures. If research involves accessing individual health information without consent, consider risks of loss of privacy or confidentiality).  Click here to enter text. |
| **F4** | **Will the study involve the administration of ionising radiation that is not needed for participants’ normal clinical management?**  Yes  No  **If Yes, describe the form(s) in which ionising radiation will be administered:**  Click here to enter text.  **If Yes, provide a statement from a medical physicist of the effective doses of radiation, together with an appraisal of their appropriateness and safety.**  Click here to enter text. |
| **F5** | **F5a: During the study, who will have access to health information used in the study?**  Click here to enter text.  **F5b: Explain how you will ensure the confidentiality of this health information during the study:**  Click here to enter text. |
| **F6** | **F6a: Will the study involve interviews?**  Yes  No    *Attach a copy of the interview questions or discussion topics.*  **F6b: Will your study involve focus groups?**  Yes  No  *Attach a copy of the focus group questions or discussion topics.*  **F6c: Will your study involve the use of surveys or questionnaires?**  Yes  No  *Attach a copy of these surveys or questionnaires.*  **F6d: Will your surveys or questionnaires be anonymous?**  Yes  No  Not applicable |
| **F7** | **F7a: In what form will data from the study be stored after the study has finished?**  identified  potentially identifiable  partially de-identified  de-identified  anonymous  other (specify): Click here to enter text.    *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.*  **F7b: For how long will information generated in this study be stored?**  Click here to enter text. |
| **F8** | **Will the results of your study be published in a form that identifies (or could reasonably be expected to identify) individual participants?**  Yes  No |
| **F9** | **Will the participants be audio-recorded, video-recorded or recorded by any other means?**  Yes  No |
| **F10** | **F10a: Will the recordings be transcribed?**  Yes  No  **If yes, please identify who will transcribe the recordings:** Click here to enter text.  **F10b: Will the recordings be translated?**  Yes  No  **If yes, please identify who will translate the recordings:** Click here to enter text.  *If a person not part of the research team is going to transcribe or translate the recordings, please attach a copy of the confidentiality agreement that will be used.* |
| **F11** | **If recordings are transcribed, will participants be offered the opportunity to edit the transcript of the recording?**  Yes  No  Not applicable  **If not, please explain why not:**  Click here to enter text. |
| **F12** | **Will participants be offered their recordings or digital files of their recording (or a copy thereof)?**  Yes  No |
| **F13** | **Will participants receive any payments, reimbursement of expenses or any similar benefits or incentives for taking part in the study?**  Yes  No    **Please describe these, and explain why they are appropriate:**  Click here to enter text. |
| **F14** | **F14a: 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  **F14b: Briefly describe how the risk of a conflict of interest between the research and clinical roles of such investigators will be managed:**  Click here to enter text.  **F14c: Briefly describe any other potential conflicts of interest that may arise for researchers in the study, and describe how they will be managed:**  Click here to enter text. |
| **F15** | **Might the study adversely impact on the provision of health and disability services?**  Yes  No    **If “Yes”, how will this possibility be managed?**  Click here to enter text. |
| **F16** | **Is this application related to one or more previous applications reviewed by an ethics committee?**  Yes  No    **If yes, please explain the relationship, giving name of the reviewing ethics committee and the ethics reference number(s) of the previous application(s):**  Click here to enter text. |
| **F17** | **Has an application for this study (or a substantially similar study) previously been declined by an ethics committee in New Zealand or overseas?**  Yes  No |
| **F18** | **Provide a summary of the main ethical issues that you believe the study raises and justify any risks in relation to the study’s benefits** (<200 words):  Click here to enter text. |

# Section G: Information & Consent

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| **G1** | **Will all participants in the study give their informed consent to participate?**  Yes  No  **If “No”, explain why it is appropriate that the study involve non-consenting participants:**  Click here to enter text. |
| **G2** | **Explain the process by which potential participants will be provided with information on the study, have the opportunity to ask questions, and be asked to give their informed consent (**<200 words):  Click here to enter text. |
|  | *The documents that you will provide to potential participants must be attached to this application. These may include a Participant Information Sheet, Consent Form, Assent Form, advertisement, email invitation, confidentiality agreement, etc.*  *Suggested template for these documents can be found here:*  [*https://ethics.health.govt.nz/*](https://ethics.health.govt.nz/)  *Please adjust these forms to comply with AHREC requirements as outlined in the AHREC Applicants’ Manual:*  [*https://www.auckland.ac.nz/en/about/research/re-ethics/auckland-health-research-committee.html*](https://www.auckland.ac.nz/en/about/research/re-ethics/auckland-health-research-committee.html) |
| **G3** | **Does your study involve deliberately withholding or concealing information from participants?**  Yes  No  **If “Yes”, please explain:**  Click here to enter text. |
| **G4** | **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  **If “No”, please explain:**  Click here to enter text. |
| **G5** | **G5a: Will you offer participants the opportunity to receive the results of the study?**  Yes  No  **G5b: Please either explain how you will inform participants, or why you do not intend to do so** (<100 words):  Click here to enter text.  **G5c: In which of the following forms will the results from the study be published or otherwise disseminated?**  Journal publication  Conference presentation  Thesis/dissertation  Other publications  Hui, public meetings  Other – provide more details: Click here to enter text. |

# Section H: Science Review

Applicants are responsible for providing proof of independent peer review.

### **For research supported by funding from competitive internal (Auckland DHB / University of Auckland) or external funding sources:**

Proof of a peer-reviewed funding award will be sufficient.

### **For unfunded projects:**

Applicants are required to provide an independent science review. This should address the importance of the scientific question, the appropriateness of the methodology, study power, feasibility, the track record of the applicant(s), and a global assessment of the study’s scientific merit.

### ***3. For applications concerning student projects at or below masters level:***

The main supervisor may instead provide an explicit assessment of the research merit of the project, paying attention to the issues indicated above, but recognising that benefits for student learning may be part of the justification for a project and properly balanced against such things as scope and significance of health outcomes of the proposed research. For doctoral student projects, an independent science review (or competitive funding grant) is required.

Attach the science review to this application.

# Section I: Funding

|  |  |
| --- | --- |
| **I1** | **I1a: How will this study be funded?**  Click here to enter text.  *If applicable, please provide the study budget*  **I1b: In which institution will the budget be held?**  Click here to enter text.  **I1c: Who will authorise expenditure from this budget?**  Click here to enter text.  **I1d: Does the principal investigator, any co-investigator, or any direct member of their families have any commercial interest or any financial relationship to the study sponsor or funder(s) that may influence his or her conduct in the study?**  Yes  No  **If yes, please briefly describe the nature of this interest or relationship, and how the risk of a conflict of interest will be minimised and managed:**  Click here to enter text.  **I1e: Will the funder have the potential to influence the analysis or any resulting publication?**  Click here to enter text.  **I1f: Who will own the intellectual property rights to the study results?**  Click here to enter text. |

# Section J: Approvals

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| --- |
| **Auckland DHB Departmental sign-off**  **(for research taking place within Auckland DHB. If research is to be undertaken by more than one Auckland DHB department, obtain additional signatures as appropriate)** |
| **Service Clinical Director :**   * *I agree that the study aligns with department/service area interests and access to patients/staff/health information is justified*   *YES / NO / NA*   * *I agree that access to care for non-study patients will not be adversely affected*   *YES / NO / NA*   * *I agree that the study is feasible and clinically appropriate*   *YES / NO / NA*   * *I agree that staff workload is acceptable and PI and team are suitably qualified and experienced*   *YES / NO / NA*     * *I agree that the potential group of patients/clients is not over researched already*   *YES / NO / NA*   * *I agree that the recruitment target is achievable*   *YES / NO / NA*   * *I agree that the department/service area can manage the research in the time frame suggested*   *YES / NO / NA*  *I agree that there are no conflict of interest issues that need declaring/addressing*  *YES / NO / NA* |
| |  |  |  | | --- | --- | --- | | Name  Click here to enter text. | Dept/Service Area  Click here to enter text. | Job title  Click here to enter text. | | Comments or qualification about the study?  Click here to enter text. | | | | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Do not sign if any of above are *NO*, if you are an investigator or supervisor, or you are not authorised to do so | | Date: Click here to enter a date. |  |  |  |  | | --- | --- | --- | | Name  Click here to enter text. | Dept/Service Area  Click here to enter text. | Job title  Click here to enter text. | | Comments or qualification about the study?  Click here to enter text. | | | | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Do not sign if any of above are *NO*, if you are an investigator or supervisor, or you are not authorised to do so | | Date: Click here to enter a date. | |
| **University sign-off**  **(for research hosted by the University of Auckland)** |
| **Head of Department or School :**   * *I approve of this research being conducted from my Department/School* |
| |  |  |  | | --- | --- | --- | | Name  Click here to enter text. | Department/School  Click here to enter text. | Position  Click here to enter text. | | Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | Date: Click here to enter a date. | |

Management approvals:

1.         AHREC will provide University of Auckland management approval and Auckland DHB approval (on behalf of the Auckland DHB Research Review Committee) for studies that fulfil the eligibility criteria for AHREC review and DO NOT require ADHB Research Review Committee assessment.

2          The Auckland DHB Research Office will organise Auckland DHB Research Review Committee assessment if there is an Auckland DHB budget or potential operational impact.

3.         Multi-site applications: It remains the responsibility of applicants to obtain local management approvals for other DHB(s) or other health providers.

4. If the study requires a University budget, then approval of the appropriate Department, School or Faculty manager should be obtained.

# Section K: Supporting Documents Checklist

Some or all of the following are required, as applicable. Please indicate which documents have been submitted:

Study protocol

Participant information sheet

Consent form

Science review

Māori responsiveness review

Interview questions or topics

Focus group questions or discussion topics

Surveys or questionnaires

Assent form

Advertisement(s)

email invitations

Confidentiality agreement

Statement from a medical physicist (for studies using ionising radiation)

Budget

CV for PI

**Section L: Checklist for determining Expedited Review**

Please select Yes or No for each of the following questions:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **A.** | **Risk of Harm** | | | |
|  | 1. | Does the research involve situations in which the researcher may be at risk of harm? | Yes | No |
|  | 2. | Does the research involve the use of any method, whether anonymous or not, which might reasonably be expected to cause discomfort, pain, embarrassment, psychological or spiritual harm to the participants? | Yes | No |
|  | 3. | Does the research involve processes that are potentially disadvantageous to a person or group, such as the collection of information which may expose the person/group to discrimination? | Yes | No |
|  | 4. | Does the research involve collection of information about illegal behaviour(s) which could place the researcher or participants at risk of criminal or civil liability or be damaging to their financial standing, employability, professional or personal relationships? | Yes | No |
|  | 5. | Does the research involve any form of physically invasive procedure on participants, such as the collection of blood, body fluids, tissue samples, DNA, human tissue from a tissue bank, exercise or dietary regimes or physical examination? | Yes | No |
|  | 6. | Does the research involve any intervention administered to the participant, such as drugs, medicine (other than in the course of standard medical procedure), placebo, environmental conditions, food/drink? | Yes | No |
|  | 7 | Does the research involve processes that involve EEG, ECG, MRI, TMS, MRI, EMG, radiation, invasive or surface recordings? | Yes | No |
|  | 8. | Is the research considered a clinical trial? | Yes | No |
|  | 9. | Does the research involve physical pain beyond mild discomfort? | Yes | No |
| **B.** | **Informed and Voluntary Consent** | | | |
|  | 1. | Does the research involve participants giving oral consent rather than written consent?  (If participants are anonymous, the response is “No”). | Yes | No |
|  | 2. | Does the research involve participation of children under sixteen years of age? | Yes | No |
|  | 3. | Does the research involve participants who are in a dependent situation, such as people with a disability, residents of a hospital, nursing home or prison, or patients highly dependent on medical care? | Yes | No |
|  | 4. | Does the research involve participants who are being asked to comment on employers? | Yes | No |
|  | 5. | Does the research involve participants whose capacity to give informed consent is in doubt? | Yes | No |
|  | 6. | Does the research use previously collected information or biological samples for which there was no explicit consent? | Yes | No |
|  |  | | | |
| **C.** | **Privacy and confidentiality issues** | | | |
|  | 1. | Does the research involve evaluation of University of Auckland or Auckland DHB services or organisational practices where information of a personal nature may be collected and where participants may be identified? | Yes | No |
|  | 2. | Does the research involve University of Auckland or Auckland DHB staff or students where information of a personal nature may be collected and where participants may be identified? | Yes | No |
|  | 3. | Does the research involve matters of commercial sensitivity? | Yes | No |
|  | 4. | Does the research involve Focus Groups? | Yes | No |
| **D.** | **Deception** | | | |
|  | 1. | Does the research involve deception of the participants, including concealment or covert observations? | Yes | No |
| **E.** | **Conflict of interest** | | | |
|  | 1. | Does the research involve a conflict of interest or the appearance of a conflict of interest for the researcher (for example, where the researcher is also the lecturer/teacher/treatment provider/colleague or employer of the participants, or where there is a power relationship between researcher and participants)? | Yes | No |
| **F.** | **Cultural sensitivity** | | | |
|  | 1. | Does the research raise any specific ethnic or cultural issues? | Yes | No |
| **G.** | **Requirements imposed from outside The University of Auckland or Auckland DHB** | | | |
|  | 1. | Does the research involve a requirement imposed by an organisation outside The University of Auckland or Auckland DHB? | Yes | No |