



# **Administrative Section**

## **1. TITLE AND SUMMARY OF PROJECT**

### **1.1. Title**

#### **1.1.1 What is the formal title of this research proposal?**

\*DEMONSTRATION\* Research involving Aboriginal and/or Torres Strait Islander Peoples

#### **1.1.2 What is the short title / acronym of this research proposal (if applicable)?**

\*test\*

### **1.2. Description of the project in plain language**

#### **1.2.1 Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve those aims.**

\*test\*

## 2. RESEARCHERS / INVESTIGATORS

### 2.2. Principal researcher(s) / investigator(s)

2.2.0 How many principal researchers / investigators are there? 1

#### 2.2.1. Principal researcher / investigator 1

##### 2.2.1. Name and contact details

Name: Mr \*test\* \*test\*

Address: \*test\*  
\*test\* ACT \*test\*  
\*test\*

Organisation: \*test\*

Area: \*test\*

Position: \*test\*

Contact (Bus) \*test\* (AH) -  
(Mob) - (Fax) -

Email: \*test\*

2.2.2... Summary of qualifications and relevant expertise [NS 4.8.7](#) [NS 4.8.15](#)  
\*test\*

2.2.2... Please declare any general competing interests  
\*test\*

2.2.2... Name the site(s) for which this principal researcher / investigator is responsible.  
\*test\*

2.2.3 Describe the role of the principal researcher / investigator in this project.  
\*test\*

2.2.4 Is the principal researcher / investigator a student? Yes

2.2.4...What is the educational organisation, faculty and degree course of the student?

Organisation \*test\*  
Faculty \*test\*  
Degree course \*test\*

2.2.4... Is this research project part of the assessment of the student? Yes

2.2.4... Is the student's involvement in this project elective or compulsory? Compulsory

2.2.4... What training or experience does the student have in the relevant research methodology?  
\*test\*

2.2.4... What training has the student received in the ethics of research?  
\*test\*

2.2.4... Describe the supervision to be provided to the student. [NS 4.8.8](#)  
\*test\*

2.2.4... How many supervisors does the student have? 1

#### 2.2.4...Supervisor 1

2.2.4...Provide the name, qualifications, and expertise, relevant to this research, of the students' supervisor

Title A/Prof  
First Name \*test\*  
Surname \*test\*  
Summary of qualifications and relevant expertise \*test\*

## 2.3. Associate researcher(s) / investigator(s)

2.3.1 How many known associate researchers are there? (You will be asked to give contact details for these associate researchers / investigators at question 2.3.1.1) 0

2.3.2 Do you intend to employ other associate researchers / investigators? Yes

## 2.4. Contact

Provide the following information for the person making this application to the HREC.

### 2.4.1. Name and contact details

Name: Dr \*test\* \*test\*

Address: \*test\*  
\*test\* ACT \*tes

Organisation: \*test\*

Area: \*test\*

Position: \*test\*

Contact (Bus) \*test\* (AH) -  
(Mob) - (Fax) -

Email: \*test\*

## 2.5. Other personnel relevant to the research project

2.5.1 How many known other people will play a specified role in the conduct of this research project? 1

2.5.1... Describe the role, and expertise where relevant (e.g. counsellor), of these other personnel.  
\*test\*

2.5.2 Is it intended that other people, not yet known, will play a specified role in the conduct of this research project? Yes

## 2.6. Certification of researchers / investigators

2.6.1 Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research? Yes

2.6.1... Describe the certification, accreditation or credentialing requirements.  
\*test\*

2.6.1... Specify and advise whether the chief researcher / investigator, principal researcher / investigator or any of the associate researchers / investigators have been so certified and/or accredited or credentialed.  
\*test\*

## 2.7. Training of researchers / investigators

2.7.1 Do the researchers / investigators or others involved in any aspect of this research project require any additional training in order to undertake this research? Yes

2.7.1... What is this training?  
\*test\*

2.7.1... How and by whom will the training be provided?  
\*test\*

2.7.1... How will the outcome of the training be evaluated?  
\*test\*

### 3. RESOURCES

#### 3.1. Project Funding / Support

##### 3.1.1. Indicate how the project will be funded

###### 3.1.1... Type of funding.

[Please note that all fields in any selected funding detail column (with the exception of the code) will need to be completed.]

	External Competitive Grant
Name of Grant / Sponsor	*test*
Amount of funding	*test*
Confirmed / Sought	Confirmed
Detail in kind support	*test*
Indicate the extent to which the scope of this HREC application and grant are aligned	*test*

###### 3.1.1... How will you manage a funding shortfall (if any)?

\*test\*

###### 3.1.2 Will the project be supported in other ways eg. in-kind support/equipment by an external party eg. sponsor

Yes

###### 3.1.2... Describe the support and indicate the provider.

\*test\*

#### 3.2. Duality of Interest

##### 3.2.1 Describe any commercialisation or intellectual property implications of the funding/support arrangement.

\*test\*

##### 3.2.2 Does the funding/support provider(s) have a financial interest in the outcome of the research?

Yes

###### 3.2.2... Describe the interest.

\*test\*

###### 3.2.2... Do you consider the funding/support arrangement constitutes:

[X] a potential conflict of interest

###### 3.2.2... Provide an explanation.

\*test\*

##### 3.2.3 Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research?

Yes

###### 3.2.3... Describe affiliation(s) and/or interest(s).

\*test\*

###### 3.2.3... Do you consider the relationship between the research team and the funding/support provider constitutes:

[X] a potential conflict of interest

###### 3.2.3... Provide an explanation.

\*test\*

##### 3.2.4 Does any other individual or organisation have an interest in the outcome of this research

Yes

###### 3.2.4... Indicate the interested party and describe the interest.

\*test\*

##### 3.2.5 Are there any restrictions on the publication of results from this research?

Yes

###### 3.2.5... Describe these restrictions.

\*test\*

## 4. PRIOR REVIEWS

### 4.1. Ethical review

#### 4.1.0. Duration and location

4.1.0... In how many Australian sites, or site types, will the research be conducted? 1

4.1.0... In how many overseas sites, or site types, will the research be conducted? 0

Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted

#### 4.1.0...Site / Site Type 1

4.1.0... Site / Site Type Name  
\*test\*

4.1.0... Site / Site Type Location  
\*test\*

4.1.0...Provide the start and finish dates for the whole of the study including data analysis

Anticipated start date 21/08/2009

Anticipated finish date 21/08/2010

4.1.0... Are there any time-critical aspects of the research project of which an HREC should be aware? Yes

4.1.0... Describe the time-critical aspects.  
\*test\*

4.1.1 To how many Australian HRECs (representing site organisations or the researcher's / investigator's organisation) is it intended that this research proposal be submitted? 1

#### 4.1.1...HREC 1

4.1.1... Name of HREC Alfred Hospital Ethics Committee (EC00315)

4.1.1...Provide the start and finish dates for the research for which this HREC is providing ethical review.

Anticipated start date or date range 22/08/2009

Anticipated finish date or date range 22/08/2010

4.1.1... For how many sites at which the research is to be conducted will this HREC provide ethical review? 1

#### 4.1.1...Site 1

4.1.1... Name of site \*test\*

4.1.1... Which of the researchers / investigators involved in this project will conduct the research at this site?

Principal Researcher(s)

Associate Researcher(s)

Mr \*test\* \*test\*

4.1.2 Have you previously submitted an application, whether in NEAF or otherwise, for ethical review of this research project to any other HRECs? Yes

4.1.2... To how many other HRECs have you submitted a proposal relating to this research project. 1

#### 4.1.2...HREC 1

4.1.2... Name of HREC Australian Hearing Human Research Ethics Committee (EC00109)

4.1.2... Status of this review Rejected

4.1.2... Please explain why this proposal was rejected.  
\*test\*

4.1.2... Explain why an application for ethical review was submitted to the HREC/s identified in answer to question 4.1.2.1, eg. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.

\*test\*

### **4.3. Peer review**

**4.3.1 Has the research proposal, including design, methodology and evaluation undergone, or will it undergo, a peer review process?** [NS 1.2](#) Yes

**4.3.1... Provide details of the review and the outcome. A copy of the letter / notification, where available, should be attached to this application.**

\*test\*

# Ethical Review Section

## Summary

### Applicant / Principal Researcher(s)

**Dr \*test\* \*test\***

*\*test\*, \*test\**

**Mr \*test\* \*test\***

*\*test\**

***Potential conflicts of interest***

*\*test\**

### Other Relevant Personnel

**A/Prof \*test\* \*test\***

*\*test\**

## 5. PROJECT

### 5.1. Type of Research

5.1.1 Tick as many of the following 'types of research' as apply to this project. Your answers will assist HRECs in considering your proposal. A tick in some of these boxes will generate additional questions relevant to your proposal (mainly because the National Statement requires additional ethical matters to be considered), which will appear in Section 9 of NEAF.

This project involves:

Research using quantitative methods, population level data or databanks, e.g survey research, epidemiological research [NS 3.2](#)

5.1.2 Does the research involve limited disclosure to participants? [NS 2.3](#) No

5.1.3 Are the applicants asking the HREC / review body to waive the requirement of consent? [NS 2.3.5](#) No

### 5.2. Research plan

5.2.1 Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal, eg. previous studies, anecdotal evidence, review of literature, prior observation, laboratory or animal studies (4000 character limit). [NS 1.1](#)

\*test\*

5.2.2 State the aims of the research and the research question and/or hypotheses, where appropriate.

\*test\*

5.2.3 Has this project been undertaken previously? Yes

### 5.3. Benefits/Risks

5.3.0 Does the research involve a practice or intervention which is an alternative to a standard practice or intervention? Yes

5.3.0... Explain how the practice or intervention differs from standard practice or intervention.

\*test\*

5.3.1 Describe how the research demonstrates an understanding of and respect for and engages with the knowledge systems, cultural practices, heritage, beliefs, experiences and values of Aboriginal or Torres Strait Islander individuals and communities. Include, as appropriate:

- how the proposal responds to the diversity between communities eg. Different languages, cultures, histories, decision-making and perspectives (refer to Chapter 4.7 of the National Statement, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, and the AIATSIS Guidelines for Ethical Research in Indigenous Studies),
- how the proposal contributes to and does not erode social and cultural bonds among Aboriginal and Torres Strait Islander participants and communities,
- how the research respects the values based expectations and identity and protects and promotes cultural distinctiveness of Aboriginal and Torres Strait Islander people participants,

\*test\*

5.3.2 What expected benefits (if any) will this research have for the wider community?

\*test\*

5.3.3 What expected benefits (if any) will this research have for participants? [NS 2.1](#)

\*test\*

5.3.4 Are there any risks to participants as a result of participation in this research project? [NS 2.1](#) No

5.3.5 Explain how the likely benefit of the research justifies the risks of harm or discomfort to participants. [NS 1.6](#)

\*test\*

5.3.8 Are there any other risks involved in this research? eg. to the research team, the organisation, others Yes

5.3.8... What are these risks?

\*test\*

5.3.8... Explain how these risks will be negated/minimised/managed.

\*test\*

5.3.8... Explain how these risks will be monitored.

\*test\*

**5.3.8... Explain how any harm to participants, resulting from these risks, will be reported.**

\*test\*

**5.3.9 Is it anticipated that the research will lead to commercial benefit for the investigator(s) and or the research sponsor(s)?** Yes

**5.3.9... Is it intended that participants will share in these benefits?** Yes

**5.3.11 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?** Yes

**5.3.11... Describe the risk and explain how it will be managed.**

\*test\*

## **5.4. Monitoring**

Refer to NS 3.3.19 - 3.3.25

**5.4.1 What mechanisms do the researchers / investigators intend to implement to monitor the conduct and progress of the research project? [NS 5.5](#)**

\*test\*

## 6. PARTICIPANTS

### 6.1. Research participants

6.1.1 The National Statement identifies the need to pay additional attention to ethical issues associated with research involving certain specific populations.

This question aims to assist you and the HREC to identify and address ethical issues that are likely to arise in your research, if its design will include one or more of these populations. Further, the National Statement recognizes the cultural diversity of Australia's population and the importance of respect for that diversity in the recruitment and involvement of participants. Your answer to this question will guide you to additional questions (if any) relevant to the participants in your study.

**6.1.1 Tick as many of the following 'types of research participants' who will be included because of the project design, or their inclusion is probable, given the diversity of Australia's population. If none apply, please indicate this below.**

	a) Primary intent of research	c) Design specifically excludes
People whose primary language is other than English (LOTE)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Women who are pregnant and the human foetus <a href="#">NS 4.1</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Children and/or young people (ie. <18 years) <a href="#">NS 4.2</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
People in existing dependent or unequal relationships <a href="#">NS 4.3</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
People highly dependent on medical care <a href="#">NS 4.4</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
People with a cognitive impairment, an intellectual disability or a mental illness <a href="#">NS 4.5</a>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Aboriginal and/or Torres Strait Islander peoples <a href="#">NS 4.7</a>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
People who may be involved in illegal activity	<input type="checkbox"/>	<input checked="" type="checkbox"/>

### 6.2. Participant description

6.2.1 How many participant groups are involved in this research project?

1

6.2.2 What is the expected total number of participants in this project at all sites?

1

#### 6.2.3. Group 1

6.2.3... Group name for participants in this group

\*test\*

6.2.3... Expected number of participants in this group

\*test\*

6.2.3... Age range

\*test\*

6.2.3... Other relevant characteristics of this participant group

\*test\*

6.2.3... Why are these characteristics relevant to the aims of the project?

\*test\*

**6.2.4. Your response to questions at Section 6.1 - Research Participants' indicates that the following participant groups are excluded from your research. If this is not correct please return to section 6.1 to amend your answer.**

People whose primary language is other than English (LOTE)

Children and/or young people (ie. <18 years)

People with an intellectual or mental impairment

People in existing dependent or unequal relationships with any member of the research team, the researcher(s), and/or the person undertaking the recruitment/consent process (eg. student/teacher; employee/employer; warden/prisoner; officer, enlisted soldier; patient/doctor)

Women who are pregnant and the human foetus

People highly dependent on medical care

**6.2.4... Have any particular potential participants or groups of participants been excluded from this research? In answering this question you need to consider if it would be unjust to exclude these potential participants.** [NS 1.4](#)

\*test\*

### **6.3. Participation experience**

**6.3.1 Provide a concise detailed description, in not more than 200 words, in terms which are easily understood by the lay reader of what the participation will involve.**

\*test\*

### **6.4. Relationship of researchers / investigators to participants**

**6.4.1 Specify the nature of any existing relationship or one likely to rise during the research, between the potential participants and any member of the research team or an organisation involved in the research.**

\*test\*

**6.4.2 Describe what steps, if any, will be taken to ensure that the relationship does not impair participants' free and voluntary consent and participation in the project.**

\*test\*

**6.4.3 Describe what steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher / investigator or organisations.**

\*test\*

**6.4.4 Will the research impact upon, or change, an existing relationship between participants and researcher / investigator or organisations.?** Yes

**6.4.4... Explain how the risk will be managed if the relationship is changed or impacted upon**

\*test\*

### **6.5. Recruitment**

**6.5.1 What processes will be used to identify potential participants?**

\*test\*

**6.5.2 Is it proposed to 'screen' or assess the suitability of the potential participants for the study?** Yes

**6.5.2... How will this be done?**

\*test\*

**6.5.3 Describe how initial contact will be made with potential participants.**

\*test\*

**6.5.3... Do you intend to include both males and females in this study?** Yes

**6.5.3... What is the expected ratio of males to females that will be recruited into this study and does this ratio accurately reflect the distribution of the disease, issue or condition within the general community?**

\*test\*

**6.5.4 Is an advertisement, e-mail, website, letter or telephone call proposed as the form of initial contact with potential participants?** Yes

**6.5.4... Provide details and a copy of text/script.**

\*test\*

**6.5.5 If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?** Yes

**6.5.5... What are the risks or disadvantages?**

\*test\*

**6.5.5... How will these issues be addressed?**

\*test\*

### **6.6. Consent process**

- 6.6.1 Will consent for participation in this research be sought from all participants? Yes
- 6.6.1... Will there be participants who have capacity to give consent for themselves? Yes
- 6.6.1... What mechanisms/assessments/tools are to be used, if any, to determine each of these participant's capacity to decide whether or not to participate?  
\*test\*
- 6.6.1... Are any of the participants children or young people? Yes
- 6.6.1... Explain how will the children or young people's vulnerability and capacity to consent be judged.  
\*test\*
- 6.6.1... Are there any children not of sufficient maturity to consent to participation? Yes
- 6.6.1... Is the research likely to advance knowledge about the health or welfare or other matters relevant to children or young people? Yes
- 6.6.1... Explain how this research is intended to advance knowledge.  
\*test\*
- 6.6.1... Will there be participants who do not have capacity to give consent for themselves? Yes
- 6.6.1... Specify why these participants do not have capacity to give consent for themselves.  
\*test\*
- 6.6.1... By whom will consent for these participants be given?  
\*test\*
- 6.6.1... On what basis is it believed that these people have legal authority to give consent for these participants?  
\*test\*
- 6.6.1... Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project.  
\*test\*
- 6.6.1... If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision? [4.6.6 - 4.6.7](#)  
\*test\*
- 6.6.1... Might individual participants be identifiable by other members of their group, and if so could this identification could expose them to risks?  
\*test\*
- 6.6.1... If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent?  
\*test\*
- 6.6.1... Specify the nature and value of any proposed incentive/payment (eg. movie tickets, food vouchers) or reimbursement (eg travel expenses) to participants.  
\*test\*
- 6.6.1... Explain why this offer will not impair the voluntary nature of the consent, whether by participants' or persons deciding for their behalf. [NS 2.2.10 - 2.2.11](#)  
\*test\*
- 6.6.3 Do you propose to obtain consent from individual participants for your use of their stored data/samples for this research project? Yes

## 8. CONFIDENTIALITY/PRIVACY

### 8.1. Do privacy guidelines need to be applied in the ethical review of this proposal?

8.1.1 Indicate whether the source of the information about participants which will be used in this research project will involve:

collection directly from the participant

#### 8.1.1... Information which will be collected for this research project directly from the participant

8.1.1... Describe the information that will be collected directly from participants. Be specific where appropriate.

\*test\*

8.1.1... The information collected by the research team about participants will be in the following form(s). Tick more than one box if applicable.

individually identifiable

8.1.1... Give reasons why it is necessary to collect information in individually identifiable or re-identifiable form.

\*test\*

### 8.2. Using information from participants

8.2.1 Describe how information collected about participants will be used in this project.

\*test\*

8.2.2 Will any of the information used by the research team be in identified or re-identifiable (coded) form? Yes

8.2.2... Indicate whichever of the following applies to this project:

Information collected for, used in, or generated by, this project will not be used for any other purpose.

8.2.4 List ALL research personnel and others who, for the purposes of this research, will have authority to use or have access to the information and describe the nature of the use or access. Examples of others are: student supervisors, research monitors, pharmaceutical company monitors .

\*test\*

### 8.3. Storage of information about participants during and after completion of the project

8.3.1 In what formats will the information be stored during and after the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, videotape, film)

\*test\*

8.3.2 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during and after the research project? (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)

\*test\*

8.3.5 The information which will be stored at the completion of this project is of the following type(s). Tick more than one box if applicable.

individually identifiable

8.3.5... Give reasons why it is necessary to store information in identifiable or potentially identifiable (coded) form.

\*test\*

8.3.6 For how long will the information be stored after the completion of the project and why has this period been chosen?

\*test\*

8.3.7 What arrangements are in place with regard to the storage of the information collected for, used in, or generated by this project in the event that the principal researcher / investigator ceases to be engaged at the current organisation?

\*test\*

### 8.4. Ownership of the information collected during the research project and resulting from the research project

8.4.1 Describe how the research will respect and acknowledge the contribution of Aboriginal or Torres Strait Islander peoples to the research.

Include, as appropriate:

- acknowledgement of cultural property rights in relation to knowledge, ideas, cultural expressions and cultural materials,
- acknowledgement of the sources of information and those who have contributed to the research
- a description of any agreement (preferably written) between the researchers / investigators and the community regarding research intentions, methods and potential results.

\*test\*

**8.4.2 Who is understood to own the information resulting from the research, eg. the final report or published form of the results?**

\*test\*

**8.4.3 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?** No

## **8.5. Disposal of the information**

**8.5.1 Will the information collected for, used in, or generated by this project be disposed of at some stage?** Yes

**8.5.1... At what stage will the information be disposed?**

\*test\*

**8.5.1... How will information, in all forms, be disposed?**

\*test\*

## **8.6. Reporting individual results to participants and others**

**8.6.1 Is it intended that results of the research that relate to a specific participant be reported to that participant?** Yes

**8.6.1... Specify in what form the results will be reported to participants.**

\*test\*

**8.6.1... How will the results be communicated to participants? eg telephone call, individual letter, copy of publication, consultation with a medical practitioner or other**

\*test\*

**8.6.1... Who will be responsible for communicating the project results to participants?**

\*test\*

**8.6.2 Is the research likely to produce information of personal significance to individual participants?** No

**8.6.3 Will individual participant's results be recorded with their personal records?** Yes

**8.6.4 Is it intended that results that relate to a specific participant be reported to anyone other than that participant?** No

**8.6.5 Is the research likely to reveal a significant risk to the health or well being of persons other than the participant, eg family members, colleagues** Yes

**8.6.5... How will this information be used?**

\*test\*

**8.6.6 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities?** No

**8.6.7 How is it intended to disseminate the results of the research? eg report, publication, thesis**

\*test\*

**8.6.8 Will the confidentiality of participants and their data be protected in the dissemination of research results?** Yes

**8.6.8... Explain how confidentiality of participants and their data will be protected in the dissemination of research results**

\*test\*

## 9. PROJECT SPECIFIC

### 9.7. Research Involving Aboriginal and Torres Strait Islander Peoples

You have indicated that the research involves Aboriginal and/or Torres Strait Islander peoples. You should refer to relevant guidelines as appropriate eg. Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research <http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>, National Statement Chapter 4.7 and AIATSIS Guidelines for Ethical Research in Indigenous Studies.

**9.7.1 What is the estimated proportion of Aboriginal and Torres Strait Islanders peoples in the population from which participants will be recruited?**

\*test\*

**9.7.2 Will the Aboriginal or Torres Strait Islander status of participants be recorded?** Yes

**9.7.2... Explain why the Aboriginal or Torres Strait Islander status of participants will be recorded**

\*test\*

**9.7.3 Will there be or has there been a process of consultation and negotiation between Aboriginal or Torres Strait Islander peoples and the researchers / investigators regarding the proposed research?** Yes

**9.7.2... Describe this process of consultation and negotiation. Include, as appropriate:**

- how the consultation process and the research proposal demonstrates the integrity of the researcher
- negotiation of the aims, anticipated outcomes and priorities of the research,
- consultation regarding community and individual consent to participation in the research,
- the process for negotiating ongoing advice as the research progresses, to monitor ethical standards and minimise unintended consequences,
- how the processes show engagement with the values and processes of participating communities, and
- the process of negotiating access to, and /or control of the results of the research.

\*test\*

**9.7.4 Has there been a role for Aboriginal or Torres Strait Islander peoples in the development of the research and or will there be a role for Aboriginal or Torres Strait Islander peoples in the implementation of the research proposal.** [NS 4.7](#) Yes

**9.7.4... Describe the role of Aboriginal or Torres Strait Islander peoples in the development and or implementation of the research.**

**Include, as appropriate:**

- whether any or all of the researchers / investigators are Aboriginal or Torres Strait Islander people,
- how Aboriginal or Torres Strait Islander peoples from the community involved in, or affected by, the research have collaborated in the development of the research,
- whether the participating communities have expressed satisfaction with the research agreement, potential benefits and their distribution,
- the extent to which reciprocal obligations, responsibilities and benefits is demonstrated between the researchers / investigators and the community

\*test\*

**9.7.7 Describe how the research will provide benefits to the Aboriginal and Torres Strait Islander peoples. Include, as appropriate:**

- a description of how the research relates to the health priorities and needs of participant communities,
- a description of benefits for participants and the communities, including establishment and/or enhancement of capacities, opportunities and outcomes beyond the project,
- a description of how the research shows an intent to contribute to the advancement of the health and well being of participants and their communities

\*test\*

# 10. DECLARATIONS AND SIGNATURES

## 10.1 Project Title

\*DEMONSTRATION\* Research involving Aboriginal and/or Torres Strait Islander Peoples

## 10.2 Human Research Ethics Committee to which this application is made

Alfred Hospital Ethics Committee (EC00315)

Australian Hearing Human Research Ethics Committee (EC00109)

## 10.3 Signatures and undertakings

### Applicant / Principal Researchers (including students where permitted)

I/we certify that:

- All information is truthful and as complete as possible.
- I/we have had access to and read the National Statement on Ethical Conduct in Research Involving Humans.
- the research will be conducted in accordance with the National Statement.
- the research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal NS 5.5.3 including:
  - serious or unexpected adverse effects on participants;
  - proposed changes in the protocol; and
  - unforeseen events that might affect continued ethical acceptability of the project.
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion NS 5.5.6 see NS 5.5.8(b);
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

### Applicant / Chief Researcher(s) / Principal Researcher(s)

Dr \*test\* \*test\*  
\*test\*

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Signature Date

Mr \*test\* \*test\*  
\*test\*

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Signature Date

### Supervisor(s) of student(s)

I/we certify that:

- I/we will provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above;
- I/we will ensure that training is provided necessary to enable the project to be undertaken skilfully and ethically.

A/Prof \*test\* \*test\*

\_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
Signature Date

### Heads of departments/schools/research organisation

I/we certify that:

- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

\_\_\_\_\_  
Title

\_\_\_\_\_  
First name

\_\_\_\_\_  
Surname

\_\_\_\_\_  
Position

\_\_\_\_\_  
Organisation name

\_\_\_\_/\_\_\_\_/\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## 11. ATTACHMENTS

This page and all pages that follow don't need to be submitted to your HREC.

### 11.1 List of Attachments

<b>Core Attachments</b>	<b>Attachments which may be required/appropriate.</b>
Recruitment/invitation	Copy of advertisement, letter of invitation etc
Participant Information	Copy or script for participant Copy or script for parent, legal guardian or person responsible as appropriate
Consent Form	Copy for participant For parent, legal guardian or person responsible as appropriate For, optional components of the project eg. genetic sub study
Peer review	Copy of peer review report or grant submission outcome
HREC approvals	Copy of outcome of other HREC reviews

<b>Attachments specific to project or participant group</b>	<b>Attachments which may be required/appropriate.</b>
Epidemiological research	Evidence of support/permission from database custodian for proposed access / use of data
People whose primary language is other than English (LOTE)	English translation of participant information/consent forms
Children and/or young people (ie. <18 years)	Information/consent form for parent, legal guardian or person responsible
People with an intellectual or mental impairment	Information/consent form for legal guardian or person responsible
People highly dependent on medical care	Information/consent form for legal guardian or person responsible
Aboriginal and/or Torres Strait Islander peoples	Evidence of support / permission of elders and/or other appropriate bodies
Peer Review	If appropriate also provide copies of previous grants, reports or project proposals that are directly applicable to this ethics application.

## 11.2 Participant information elements

### Core Elements

Provision of information to participants about the following topics should be considered for all research projects.

Core Elements	Issues to consider in participant information
About the project	Full title and / or short title of the project Plain language description of the project Purpose / aim of the project and research methods as appropriate Demands, risks, inconveniences, discomforts of participation in the project Outcomes and benefits of the project Project start, finish, duration
About the investigators / organisation	Researchers conducting the project (including whether student researchers are involved) Organisations which are involved / responsible Organisations which have given approvals Relationship between researchers and participants and organisations
Participant description	How and why participants are chosen How participants are recruited How many participants are to be recruited
Participant experience	What will happen to the participant, what will they have to do, what will they experience? Benefits to individual, community, and contribution to knowledge Risks to individual, community Consequences of participation
Participant options	Alternatives to participation Whether participation may be for part of project or only for whole of project Whether any of the following will be provided: counselling, post research follow-up, or post research access to services, equipment or goods
Participants rights and responsibilities	That participation is voluntary That participants can withdraw, how to withdraw and what consequences may follow Expectations on participants, consequences of non-compliance with the protocol How to seek more information How to raise a concern or make a complaint
Handling of information	How information will be accessed, collected, used, stored, and to whom data will be disclosed Can participants withdraw their information, how, when Confidentiality of information Ownership of information Subsequent use of information Storage and disposal of information
Unlawful conduct	Whether researcher has any obligations to report unlawful conduct of participant
Financial issues	How the project is funded Declaration of any duality of interests Compensation entitlements Costs to participants Payments, reimbursements to participants Commercial application of results
Results	What will participants be told, when and by whom Will individual results be provided What are the consequences of being told or not being told the results of

<b>Core Elements</b>	<b>Issues to consider in participant information</b>
	research How will results be reported / published Ownership of intellectual property and commercial benefits
Cessation	Circumstances under which the participation of an individual might cease Circumstances under which the project might be terminated

**Research Specific Elements**

Provision of information to participants about the following topics should be considered as may be relevant to the research project.

<b>Specific to project or participant group</b>	<b>Additional issues to consider in participant information</b>
Aboriginal and/or Torres Strait Islander peoples	describe consultation process to date and involvement of leaders whether ATSI status will be recorded