

National Ethics Application Form

Version 2008 - V2.0

Proposal title: *DEMONSTRATION* Clinical Trials

For submission to:
Barwon Health Research and Ethics
Advisory Committee (EC00208)

Name: **Ms *test* *test***

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

Contact: (Bus) ***test***

(AH) -

(Mob) -

(Fax) -

Proposal status: **Complete**

Proposal description:

test

Previously submitted to:

Behavioural & Social Sciences Ethical Review Committee (EC00176)

Administrative Section

1. TITLE AND SUMMARY OF PROJECT

1.1. Title

1.1.1 What is the formal title of this research proposal?

DEMONSTRATION Clinical Trials

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

DEMONSTRATION Clinical Trials

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

2.1. Chief researcher(s) / investigator(s)

2.1.0 How many chief researchers / investigators are there? This question only applies to multi-centre research. If your research is not multi-centre, please enter 0 (zero) here. See Guidance Text (G) for the definition of a Chief Researcher. 1

2.1.1. Chief researcher / investigator 1

2.1.1. Name and contact details

Title	Prof
First Name	*test*
Surname	*test*
Mailing Address 1	*test*
Suburb/Town	*test*
State	ACT
Postcode	*test*
Organisation name	*test*
Faculty/department/school or centre name as appropriate (optional)	*test*
Position in organisation	*test*
Business Hours Phone Number	*test*
Email Address	*test*
Is this person the contact person for this application?	No

2.1.2... Summary of qualifications and relevant expertise
test

2.1.2... Please declare any general competing interests
test

2.1.2... Name the site(s) for which this chief researcher / investigator is responsible.
test

2.1.3 Describe the role of the chief researcher / investigator in this project.
test

2.1.4 Is the chief researcher / investigator a student? No

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:	Dr *test* *test*
Address:	*test* *test* ACT *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)

1

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

Yes

2.3.1...Associate Researchers / Investigators 1

2.3.1...Name and contact details

Name: Dr *test* *test*

Address: *test*
test ACT *test*

Organisation: *test*

Area: -

Position: *test*

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

Email: *test*

2.3.1... Summary of qualifications and relevant expertise [NS 4.8.7](#) [NS 4.8.15](#)

test

2.3.1... Please declare any general competing interests

test

2.3.1... Description of the role of the associate researcher / investigator in this project.

test

2.3.1... Name the site at which the associate researcher / investigator has responsibility.

test

2.3.1... Is this associate researcher / investigator a student?

No

2.4. Contact

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

2.4.1. Name and contact details

Name: Ms *test* *test*

Address: *test*
test ACT *tes

Organisation: *test*

Area: -

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

3.1.3... Is this a study where capitation payments are to be made, and will participants be made aware of these payments to clinicians or researchers / investigators? [NS 3.3.18b](#)

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:

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:

a potential duality 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? 1

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...Site / Site Type 2

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 Barwon Health Research and Ethics Advisory Committee (EC00208)

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)

Dr *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 Behavioural & Social Sciences Ethical Review Committee (EC00176)

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

Chief Researcher(s)

Prof *test* *test*
test*, *test

Applicant / Principal Researcher(s)

Ms *test* *test*
test

Dr *test* *test*
test

Potential conflicts of interest
test

Associate Researcher(s) / Investigator(s)

Dr *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:

Clinical research [NS 3.3](#)

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

5.3.2 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](#) Yes

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

5.4.2 Please detail your DSMB and its nominee for this trial.

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.

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

Aboriginal and/or Torres Strait Islander peoples

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? No
- 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
- collection from another person about the participant
- use or disclosure of information by an agency, authority or organization other than your organisation
- use of information which you or your organisation collected previously for a purpose other than this research project

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

8.1.1... Information which will be collected for this research project from another person about the participant

8.1.1... Describe the information which will be collected from another person about 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).

- re-identifiable

8.1.1... Give reasons why it is necessary to collect information in identified or potentially identifiable (coded) form.

test

8.1.1... Will consent be sought from participants (or for participants from persons with legal authority) for the collection and use of information about them? Yes

8.1.1... Indicate the number of databases, from which you will be collecting information, held by any of these categories of agencies.

8.1.1... Indicate the number and identity of agencies, authorities or organisations, which will be using or disclosing information, the names of the databases (where applicable), the data items and their degree of identifiability and, where applicable, the reasons for using identifiable or re-identifiable data.

Commonwealth	1
State/Territory	1
Private Sector	1

8.1.1... Organisation Database

Agency Type	Name of agency / organisation	Name/description of the database	Describe the information that will be collected. List all data items	The information collected by the research team about participants will be in the following form(s). NS 3.2	Give reasons why it is necessary to collect information in identified or potentially identifiable (coded) form.
Commonwealth 1	*test*	*test*	*test*	[X] individually identifiable	*test*
State/Territory 1	*test*	*test*	*test*	[X] re-identifiable	*test*
Private Sector 1	*test*	*test*	*test*	[X] non-identifiable	*test*

8.1.1... Information which will be used for this research project which you or your organisation collected previously for a purpose other than this research project

8.1.1...Indicate from which of the following you will be collecting information for this research project and indicate how many databases from each source.

Commonwealth	1
State/Territory	1
Private Sector	1

8.1.1... Organisation Database

Agency Type	Name of agency / organisation	Name/description of the database	Describe the information that will be collected. List all data items.	The information collected by the research team about participants will be in the following form(s). NS 3.2	Give reasons why it is necessary to use information in identified or potentially identifiable (coded) form.
Commonwealth 1	*test*	*test*	*test*	[X] individually identifiable	*test*
State/Territory 1	*test*	*test*	*test*	[X] re-identifiable	*test*
Private Sector 1	*test*	*test*	*test*	[X] non-identifiable	*test*

8.1.1... Guidelines Under Section 95 of the Privacy Act 1988 - Do they apply to this project?

You have indicated in question set 8.1.1.4.0 that you are collecting and/or using personal information from a Commonwealth Government department or agency without obtaining consent from participants or their legal representatives. If this is not correct please reconsider your answers at question set 8.1.1.4.0. If this is correct Commonwealth privacy regulation may affect the conduct and the review of your project.

It is your responsibility to ensure that the proposal complies with all relevant legislation and that you provide the HREC with relevant information to assess such compliance [NS 18.1]. The following references and websites may be assistance:

Guidelines Under Section 95 of the Privacy Act 1988

Privacy Act 1988 (Cwth)

Office of the Federal Privacy Commissioner (OFPC) website

8.1.1... Will the information be used in medical research? Yes

8.1.1... State/territory privacy related legislation or regulation - Does it apply to this project?

You have indicated in question set 8.1 that you are collecting and/or using personal information from a state/territory public sector agency without obtaining consent from participants or their legal representatives. If this is not correct please reconsider your answers at question set 8.1. If this is correct, state/territory law may affect the conduct and the review of your project.

It is your responsibility to ensure that the proposal complies with all relevant legislation and that you provide the HREC with relevant information to assess such compliance. The additional information may be provided as an attachment which must provide the HREC to whom you are submitting your proposal with all the information it will need to fulfil the tasks that it has under State and Territory legislation.

The following references and websites may be assistance:

ACT NT NSW TAS

Queensland
Department of Justice and Attorney-General - Privacy

Queensland Health - Privacy

Victoria
Office of the Victorian Privacy Commissioner

Office of the Health Services Commissioner

8.1.1... Does this application include an attachment relevant to state/territory privacy legislation. Yes

8.1.1... Guidelines Approved Under Section 95A of the Privacy Act 1988 - Do they apply to this project?

You have indicated in question set 8.1 that you are collecting and/or using personal information from a private sector organisation without obtaining consent from participants or their legal representatives. If this is not correct please reconsider your answers at question set 8.1. If this is correct Commonwealth privacy regulation may affect the conduct and the review of your project.

It is your responsibility to ensure that the proposal complies with all relevant legislation and that you provide the HREC with relevant information to assess such compliance. NS 18.1 The following references and websites may be assistance:

Guidelines Approved Under Section 95A of the Privacy Act 1988

Privacy Act 1988 (Cwth)

Office of the Federal Privacy Commissioner (OFPC) website

8.1.1... Is the information health information? Yes

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:

[X] 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

Given the this research involves a proposed waiver of consent and the intent of exposing illegal activity [see NS 4.6.1] the HREC must be satisfied that your response to this question has justified that there is sufficient protection of the privacy of the participants.

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

8.4.2 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? Yes

8.4.3... Specify any limitations on publication.

test

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? Yes

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?** Yes
- 8.6.4... To whom will the results be reported other than the participant?**
test
- 8.6.4... Explain why the results will be reported to a person other than the participant?**
test
- 8.6.4... Will the participant be told that their results will be reported to another person?** Yes
- 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?** Yes
- 8.6.6... Describe the risk and explain how it will be managed.**
test
- 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

9.1. Type of research/trial

9.1.1 The administration of a drug / medicine (includes a complementary / alternative medicine) Yes

9.1.2 The use of a medical device Yes

9.1.3 The administration of human somatic cell gene therapy Yes

9.1.4 The use of a xenotransplant Yes

9.1.5 The use of stem cells (adult or embryonic) as therapy Yes

9.1.6 Other Yes

9.1.6... Describe the type of study to be conducted.
test

9.1.7. The project will be conducted as follows:

9.1.7... Under the Clinical Trial Notification Scheme (CTN) Yes

9.1.8. Provide the following details for the clinical trial protocol:

9.1.8... Protocol name
test

9.1.8... Protocol version number
test

9.1.8... Protocol version date 22/08/2009

9.1.8... If you intend to/have registered this trial in a publicly accessible register, please provide the details of it here [NS 3.3.12](#)
test

9.1.9. Provide the following details for the investigator's brochure/product information (as relevant):

9.1.9... Title of Investigator's Brochure
test

9.1.9... Investigator's brochure version number
test

9.1.9... Investigator's brochure version date 22/08/2009

9.1.1... Use of a medical device under the CTN/CTX scheme

9.1.1... Describe the trial phase for the medical device.
test

9.1.1... How many devices, including comparators, are being tested in the trial? 1

9.1.1... Provide the following information for each device

9.1.1...Device 1

9.1.1... Approved name
test

9.1.1... Trade name
test

9.1.1... Is the device implantable? Yes

9.1.1... Known adverse effects
test

9.1.1... Known contra-indications/warnings
test

9.1.1... Length of time participants will be monitored for adverse reactions

test

9.1.1... Has the sponsor or manufacturer agreed to supply the device free of charge for the duration of the trial? Yes

9.1.1... Implantable Device

9.1.1... Describe procedures for tracking participants for the life time of the device on the completion of the trial.

test

9.1.1... Use of a somatic cell gene therapy

9.1.1... Has CTAC advice been sought? Yes

You have indicated that this study involves the use of human somatic cell gene therapy under the CTN/CTX scheme.

Guidelines for gene therapy

The following questions should be answered after reading the NHMRC *Guidelines for Ethical Review of Research Proposals for Human Somatic Cell Gene Therapy and Related Therapies* and the Gene and Related Therapies Research Advisory Panel's (GTRAP) *Guidelines for the Writing of Gene Therapy Proposals*. You may need to reconsider your answers to questions in section 3 in light of these guidelines.

9.1.1... Indicate the trial phase for the gene therapy

test

9.1.1... Describe the nucleic acid (DNA/RNA) to be introduced.

test

9.1.1... On what basis has it been decided to conduct the trial under CTN?

The product has already been evaluated and approved by the TGA (i.e. for a different indication)

The product has been approved by a National Control Authority

The product had been approved by another competent authority for a clinical trial for a different indication or route of administration

9.1.1... By what means will the nucleic acid (RNA/DNA) be introduced to the participant.

test

9.1.1... Describe how the risk of viral transmission will be managed including collection and disposal of human products/waste

test

9.1.1... In what setting (hospital in-patient, out-patient) will the course of gene therapy be administered?

test

9.1.1... Does the study need approval by the Gene Technology Regulator? Yes

If there is any likelihood that the gene therapy will be incorporated into the germline then the research cannot be approved.

9.1.1... Has this been obtained? Yes

9.1.1... Indicate the procedures for monitoring presence and/or expression of administered nucleic acid; please indicate method of assessment and its sensitivity.

test

9.1.1... How will it be determined whether the new gene sequences are limited to the target cell population?

test

9.1.1... Is there any likelihood of the therapeutic (or a non-therapeutic) gene being incorporated into the germ-line? Yes

9.1.1... Describe known adverse effects of the therapy and any related therapy

test

9.1.1... Indicate how long, after completion of the research, participants will be monitored for adverse effects and indicate why this period of time was chosen? Please ensure that you describe the method of monitoring including how patients will be contacted.

test

9.2. Clinical research

9.2.1. The study examines:

9.2.1... The administration of a drug / medicine (includes a complementary / alternative medicine) Yes

9.2.1... The use of a medical device Yes

9.2.1... Other	Yes
4.1.1... Describe briefly the type of study to be conducted *test*	
9.2.2. Provide the following details for the study protocol:	
Protocol title	*test*
Protocol version number	*test*
Protocol version date	22/08/2009
9.2.3. Provide a statement describing the following:	
9.2.3... Method of randomisation *test*	
9.2.3... Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment. *test*	
9.2.3... The justification for the use of placebo or non-treatment control group, including alternative effective treatments and any risk of harm in the absence of treatment. *test*	
9.2.3... How variations in response will be treated *test*	
9.2.3... Endpoints *test*	
9.2.3... Details of contingencies and management of these *test*	
9.2.3... Explain the arrangements in place to ensure there is adequate compensation for participants. *test*	
9.2.4 How many drugs will be used in this research project?	1
9.2.5. Provide the following information for each drug	
9.2.5. Drug 1	
9.2.5... Approved name *test*	
9.2.5... Trade name *test*	
9.2.5... Approved therapeutic indication, dose and duration in Australia *test*	
9.2.5... Dosage regimen *test*	
9.2.5... Known adverse effects *test*	
9.2.5... Known contra-indications/warnings *test*	
9.2.5... Concurrent drugs to be avoided *test*	
9.10. Research involving stem cells	
9.10.1 Will identifiers of individual participants be attached to stem cells? NS 3.6.3	Yes
9.10.1... Will identifiers be removed? NS 3.6.3	Yes
9.10.1... Will participant consent be obtained for the removal of identifiers? NS 3.6.3	Yes
9.10.2 Will stem cells be derived from a human embryo or foetus? NS 3.6.5	Yes
9.10.2... Will any of those conducting the research have an involvement in the clinical care of any woman from whom an ovum, embryo or foetus will be obtained for the research? NS 3.6.5	Yes
9.10.2... Describe the involvement. NS 3.6.5	

test

9.10.2... Describe the location at which the clinical care of the women from whom any ovum, embryo or fetus to be used in the research will be obtained. [NS 3.6.5](#)

test

9.10.3 Will any stem cells used in the research have been created in another country? Yes
[NS 3.6.8](#)

9.10.3... Please detail the source of these stem cells. [NS 3.4.4](#)

test

10. DECLARATIONS AND SIGNATURES

10.1 Project Title

DEMONSTRATION Clinical Trials

10.2 Human Research Ethics Committee to which this application is made

Barwon Health Research and Ethics Advisory Committee (EC00208)

Behavioural & Social Sciences Ethical Review Committee (EC00176)

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)

Ms *test* *test*
test

_____/_____/_____
Signature Date

Prof *test* *test*
test

_____/_____/_____
Signature Date

Dr *test* *test*
test

_____/_____/_____
Signature Date

Associate Researchers

Dr *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

Core Attachments	Attachments which may be required/appropriate.
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

Attachments specific to project or participant group	Attachments which may be required/appropriate.
Administration of a drug for research but is not clinical research	Technical information about the drug
Clinical trial under CTN/CTX scheme	Outcome of TGA evaluation under CTX scheme Compensation statement Indemnity agreement Insurance certificate Clinical trial agreement TGA forms for signature if study approved
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
State/territory privacy legislation applies	Copy of any relevant documents / correspondence
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

Core Elements	Issues to consider in participant information
	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.

Specific to project or participant group	Additional issues to consider in participant information
Administration of a drug for research but is not clinical research	Information about the drug, contra-indications etc
Clinical trial under CTN/CTX scheme	Explain that the trial therapy is experimental Describe the phase of the trial, where applicable Describe arms of trial, where applicable and explain what the trial therapy is being compared to eg. standard therapy or placebo Describe the meaning of placebo, randomisation, cross-over, wash-out period etc as applicable Compensation and indemnity arrangements as applicable / appropriate
Aboriginal and/or Torres Strait Islander peoples	describe consultation process to date and involvement of leaders whether ATSI status will be recorded