

## Form EA 05/02

The application guidelines (**EA0502nt.doc**) are to be read before completing this form to ensure that the questions are answered appropriately.

The electronic version of this form is formatted the same way as the paper version so that, for example, where an answer needs 6 lines, 6 lines are formatted, but where it only needs 1 line, 1 line is formatted. Please note the number of lines allowed for a question before answering it, and make sure that no extra lines are used.

You may find it helpful to print out the application form before completing it to help you to keep to the page limits allowed. **No extra pages should be added**, except where specified, as appendices.

The “**Page Break**” and “**End of Section**”, breaks are not to be deleted as removing these breaks will seriously affect the formatting of the form.

# NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

## PART I : BASIC INFORMATION

Protocol number and date  
received (for office use only)

1. Full project title

2. Short project title (lay title)

3. Lead Principal Investigator's name and position

4. Address of lead Investigator

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

5. Lead investigator's qualifications and experience in past 5 years (relevant to proposed research)

6. Co-investigators' name(s) and position(s) or, if multicentre, Principal Investigator at each site

A	
B	
C	
D	

7. Address of co-investigator A

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

**8. Address of co-investigator B**

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

**9. Address of co-investigator C**

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

**10. Address of co-investigator D**

	Work phone No.	
	Emergency No.*	
	Fax	
	E-mail	

(\* option for Committee's information only)

**11. Where this is supervised work**

11.1 Supervisor's name

Position

Day time phone number


11.2 Signature of supervisor (where relevant)

Declaration: I take responsibility for all ethical aspects of the project

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**12. List any other New Zealand Ethics Committees to which this project has been submitted and attach their letters of approval where available**

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**13. I wish the protocol to be heard in a closed meeting**

If the answer is yes, provide reason why you wish it to be heard in a closed meeting

<input type="checkbox"/>	Yes	<input type="checkbox"/>	No

**14. Proposed starting date (dd/mm/yy)**

**15. Proposed finishing date (dd/mm/yy)**

**16. Duration of project (mm/yy)**

**17. Proposed final report date (mm/yy)**


## PART II : PROJECT SUMMARY

### 1. Multicentre proposals

*(Important: read the guidelines, Appendix 1)*

1.1 Is this a multicentre study? (if no, go to question 2)  Yes  No

1.2 If yes, name the primary ethics committee for New Zealand

1.3 Has the protocol been submitted to any other ethics committees in New Zealand? (If yes, attach copies of relevant correspondence)  Yes  No

1.4 Who is the lead investigator or institution in New Zealand?

1.5 List the other New Zealand sites involved

1.6 Have the Principal Investigators from secondary sites agreed to participate? (attach copies of signed Part V Declaration for each site)  Yes  No

1.7 If the study is based overseas, which countries are involved?

### 2. Gene Studies

Does this research involve any gene or genetic studies?  Yes  No  
If yes, complete section 16.

### 3. Scientific Assessment

Has this project been scientifically assessed by independent review?  Yes  No

If yes, by whom? (name and position)  
A copy of the report should also be attached  
If no, is it intended to have the project scientifically assessed, and by whom?

  

### 4. Data and Safety Monitoring Board (DSMB)

3.1 Is the trial being reviewed by a data and safety monitoring board?  Yes  No  
If yes, who is the funder of the DSMB?  Sponsor  HRC

### 5. Summary

Give a brief summary of the study (not more than 200 words, in lay language)



## PART III : PROJECT DETAILS

### SCIENTIFIC BASIS

#### 1. Aims of Project

1.1 What is the hypothesis/research question(s)? (state briefly)

1.2 What are the specific aims of the project?

#### 2. Scientific Background of the Research

Describe the scientific basis of the project (300 words maximum). Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

### 3. Participants

3.1 How many participants is it intended to recruit?

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3.2 How will potential participants be identified?

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3.3 How will participants be recruited?  
(e.g. advertisements, notices)

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3.3.1 Where will potential participants be approached? (e.g. outpatient clinic) If appropriate, describe by type (e.g. students)

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3.3.2 Who will make the initial approach to potential participants?

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3.3.3 Is there any special relationship between the participants and the researchers?  
e.g. doctor/patient, student/teacher

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3.4 Briefly describe the inclusion/ exclusion criteria and include the relevant page number(s) of the protocol or investigator's brochure

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3.5 If randomisation is used, explain how this will be done

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#### 4. Study Design

4.1 Describe the study design. Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

4.2 How many visits/admissions of participants will this project involve? Give also an estimate of total time involved for participants.

4.3 Describe any methods for obtaining information. Attach questionnaires and interview guidelines.

4.4 Who will carry out the research procedures?

4.5 Where will the research procedures take place?

4.6 If blood, tissue or body fluid samples are to be obtained, state type, use, access to, frequency, number of samples, total volume, means of storage and labelling, length of proposed storage and method of disposal.

4.7 Will data or other information be stored for later use in a future study?  Yes  No

If yes, explain how

4.8 Will any samples go out of New Zealand?  Yes  No

If so where, and for what purpose?

### 5. Research Methods and Procedures

5.1 Is the method of analysis :  quantitative  or qualitative?

If the method of analysis is qualitative, go to question 5.2.

If the method of analysis is **wholly or partly quantitative**, complete the following :

5.1.1 Describe the statistical method that will be used

5.1.2 Has specialist statistical advice been obtained?  Yes  No

If **yes**, from whom?

(A brief statistical report should be included if appropriate)

5.1.3 Give a justification for the number of research participants proposed, using appropriate power calculations.

5.1.4 What are the criteria for terminating the study?

5.2 If the method of analysis is **wholly or partly qualitative**, specify the method. Why is this method appropriate? If interviews are to be used include the general areas around which they will be based. Copies of any questionnaires that will be used should be appended.

**6. Risks and benefits**

6.1 What are the benefits to research participants of taking part?

6.2 How do the research procedures differ from standard treatment procedures?

6.3 What are the physical or psychological risks, or side effects to participants or third parties? Describe what action will be taken to minimise any such risks or side effects.

6.4 What arrangements will be made for monitoring and detecting adverse outcomes?

6.5 Will any potential toxins, mutagens or teratogens be used?  Yes  No

If **yes**, specify and outline the justification for their use

6.6 Will any radiation or radioactive substances be used?  Yes  No

**Note: If any form of radiation is being used please answer the following. If no, go to question 6.8**

6.6.1 Under whose license is the radiation being used?

6.6.2 Has the National Radiation Laboratory (NRL) risk assessment been completed?

Yes  No

If **yes**, please enclose a copy of the risk assessment, and the contact name and phone number

If **no**, please explain why

6.7 What facilities/procedures and personnel are there for dealing with emergencies?

6.8 Will any drugs be administered for the purposes of this study?  Yes  No

If **yes** is SCOTT approval required?  Yes  No

Has SCOTT approval been given? (please attach)  Yes  No

**7. Expected outcomes or impacts of research**

7.1 What is the potential significance of this project for improved health care?

7.2 What is the potential significance of this project for the advancement of knowledge?

7.3 What steps will be taken to disseminate the research results?

## PART IV: BUDGET AND USE OF RESOURCES

### 8. Budget

8.1 How will the project be funded?

8.2 Does the researcher, the host department or the host institution, have any financial interest in the outcome of this research? Please give details.

8.3 Will the researcher personally receive payment according to the number of participants recruited, or a lump sum payment, or any other benefit to conduct the study? If so, please specify:

8.4 What other research studies is the lead investigator currently involved with?

### 9. Resource Implications

9.1 Does the study involve the use of healthcare resources?

Yes

No

If **yes**, please specify:

9.2 What effect will this use of resources have on waiting list times for patients ie., for diagnostic tests or for standard treatments?

### 10. Financial Costs and Payments to Participants

10.1 Will there be any financial cost to the participant? Give examples including travel.

10.2 Will the study drug/treatment continue to be available to the participant after the study ends?  Yes  No  N/a  
 If yes, will there be a cost, and how will this be met?

10.3 Will any payments be made to participants or will they gain materially in other ways from participating in this project?  Yes  No  
 If yes, please supply details

**11. Compensation for Harm Suffered by Participants**

*(refer to Appendix 3 of the Guidelines)*

Is this a clinical trial under accident compensation legislation (see form guidelines)  Yes  No

If yes, please answer the following:

11.1 Is the trial being carried out principally for the benefit of a manufacturer or distributor of the drug or item in respect of which the trial is taking place?  Yes  No

- (a) If the answer to 11.1 is **yes**, please complete **Statutory Declaration Form B** and answer questions 11.2, 11.3 and 11.4
- (b) If the answer to 11.1 is **no** please complete **Statutory Declaration Form A**

11.2 What type of injury/adverse consequence resulting from participation in the trial has the manufacturer or distributor undertaken to cover? (please tick the appropriate box/es)

	Yes	No
a) any injury (mental or physical)	<input type="checkbox"/>	<input type="checkbox"/>
b) only serious or disabling injuries.	<input type="checkbox"/>	<input type="checkbox"/>
c) only physical injuries	<input type="checkbox"/>	<input type="checkbox"/>
d) only physical injuries resulting from the trial drug or item, but not from any other aspect of the trial	<input type="checkbox"/>	<input type="checkbox"/>
e) physical and mental injury resulting from the trial drug or item, but not from any other aspect of the trial.	<input type="checkbox"/>	<input type="checkbox"/>
f) any other qualification (explain) <input style="width: 400px;" type="text"/>		

11.3 What type of compensation has manufacturer or distributor agreed to pay?

	Yes	No
a) medical expenses	<input type="checkbox"/>	<input type="checkbox"/>
b) pain and suffering	<input type="checkbox"/>	<input type="checkbox"/>
c) loss of earnings	<input type="checkbox"/>	<input type="checkbox"/>
d) loss of earning capacity	<input type="checkbox"/>	<input type="checkbox"/>
e) loss of potential earnings	<input type="checkbox"/>	<input type="checkbox"/>
f) any other financial loss or expenses	<input type="checkbox"/>	<input type="checkbox"/>
g) funeral costs	<input type="checkbox"/>	<input type="checkbox"/>
h) dependants' allowances	<input type="checkbox"/>	<input type="checkbox"/>

11.4 Exclusion clauses:

- a) Has the manufacturer or distributor limited or excluded liability if the injury is attributable to the negligence of someone other than the manufacturer or distributor? (such as negligence by the investigator, research staff, the hospital or institution, or the participant).  Yes  No
- b) Has the manufacturer or distributor limited or excluded liability if the injury resulted from a deviation from the study protocol by someone other than the manufacturer or distributor?  Yes  No
- c) Is company liability limited in any other way?  Yes  No  
 If yes, please specify

**12. Information and Consent**

Consent should be obtained in writing, unless there are good reasons to the contrary. If consent is not to be obtained in writing the justification should be given and the circumstances under which consent is obtained should be recorded. Attach a copy of the information sheet and consent form.

- 12.1 By whom, and how, will the project be explained to potential participants?
- 12.2 When and where will the explanation be given?
- 12.3 Will a competent interpreter be available, if required?
- 12.4 How much time will be allowed for the potential participant to decide about taking part?
- 12.5 Will the participants be capable of giving consent themselves? - if not, complete Part VI
- 12.6 In what form (written, or oral) will consent be obtained? If oral consent only, state reasons.
- 12.7 Are participants in clinical trials to be provided with a card confirming their participation, medication and contact phone number of the principal investigator?


Yes  No

**13. Confidentiality and Use of Results**

- 13.1 How will data including audio and video tapes, be handled and stored to safeguard confidentiality (both during and after completion of the research project)?
- 13.2 What will be done with the raw data when the study is finished?
- 13.3 How long will the data from the study be kept and who will be responsible for its safe keeping?
- 13.4 Who will have access to the raw data and/or clinical records during, or after, the study?
- 13.5 Describe any arrangements to make results available to participants, including whether they will be offered their audio tapes or videos.
- 13.6 If recordings are made, will participants be offered the opportunity to edit the transcripts of the recordings?
- 13.7 Is it intended to inform the participant's GP of individual results of the investigations, and their participation, if the participant consents?


Yes  No

Yes  No

If **no**, outline the reasons

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- 13.8 Will any restriction be placed on publication of results?  Yes  No

If **yes**, please supply details

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**14. Treaty of Waitangi**

14.1 Have you read the HRC booklet, “Guidelines for Researchers on Health Research involving Maori”?

Yes  No

14.2 Does the proposed research project impact on Maori people in any way?

Yes  No

14.3 Explain how the intended research process is consistent with the provisions of the Treaty of Waitangi

14.4 Identify the group(s) with whom consultation has taken place, and attach evidence of their support

14.5 Describe the consultation process that has been undertaken **prior** to the project’s development

14.6 Describe any ongoing involvement the group consulted has in the project

14.7 Describe how information will be disseminated to participants and the group consulted at the end of the project

### 15. Other Issues

15.1 Are there any aspects of the research which might raise specific cultural issues?  Yes  No

If yes, please explain

15.1.1 What ethnic or cultural group(s) does your research involve?

Describe what consultation has taken place with the group prior to the project's development

15.1.2 Identify the group(s) with whom consultation has taken place and attach evidence of their support

15.1.3 Describe any ongoing involvement the group consulted has in the project

15.1.4 Describe how you intend to disseminate information to participants and the group consulted at the end of the project

**16. Genetics Check List**

16.1 Does the proposed research study involve use of products made by genetic modification, analyses of DNA or clinical genetics?  Yes  No  
If it does not, proceed to question 17.

16.2 Have you read, and does your research comply with, the Guidelines “Ethical considerations relating to Research in Human Genetics? *Applicant responses to these questions may initiate a request from the Ethics Committee for more detailed information.*  Yes  No

16.3 Will the study involve administration of any products produced by genetic modification, other than licensed medicines?  Yes  No  
If yes, has approval from GTAC been obtained?  Yes  No

If yes please describe.

16.4 Information on Samples :

16.4.1 Is tissue or body fluid samples for DNA analysis to be taken for :

- |  |                          |     |                          |    |
|--|--------------------------|-----|--------------------------|----|
| a) immediate analysis  | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| b) storage for future analyses   | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| c) analyses outside New Zealand  | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| d) analyses by individuals or organisations other than the study investigators | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

*(tick all boxes which apply)*

16.4.2 Describe processes for storage and disposal of samples taken for DNA analyses

16.4.3 Up to what point would withdrawal of the sample or the data at the request of the

participant be possible?

16.5 Is personal and health information from individuals and DNA analysis to be linked?

If yes, please describe how confidentiality will be assured.

Yes  No

16.6 Are samples to be obtained from Maori?

If yes, please describe any relevant issues additional to Section 16.4.1

Yes  No

16.7 Will the study involve participant contact with a clinical geneticist?

If yes, please provide :

- the name of the clinical geneticist, and
  
- describe the purpose

Yes  No

16.8 Will provision be made where appropriate for genetic counselling?

If yes, please describe the process.

Yes  No

## 17. Ethical Issues

17.1 Describe and discuss any ethical issues arising from this project, other than those already dealt with in your answers?

**Thank you for your assistance in helping us assess your project fully**

**Please now complete:**

- **the declarations (Part V)**
- **a drug administration form (if applicable)**
- **Form A or B relating to accident compensation**

## PART V: DECLARATIONS

**Full Project Title :** \_\_\_\_\_  
\_\_\_\_\_

**Short Project Title :** \_\_\_\_\_

### 1. Declaration by Principal Investigator

The information supplied in this application is, to the best of my knowledge and belief, accurate. I have considered the ethical issues involved in this research and believe that I have adequately addressed them in this application. I understand that if the protocol for this research changes in any way I must inform the Ethics Committee.

NAME OF PRINCIPAL INVESTIGATOR (PLEASE PRINT):

SIGNATURE OF PRINCIPAL INVESTIGATOR:

DATE:

*A separate declaration will be required for each multi-centre site, signed by the principal investigator for that site.*

### 2. Declaration by Head of Department in which the Principal Investigator is located or appropriate Dean or other Senior Manager

I have read the application and it is appropriate for this research to be conducted in this department I give my consent for the application to be forwarded to the Ethics Committee.

NAME AND DESIGNATION (PLEASE PRINT):

SIGNATURE:

INSTITUTION:

DATE:

DESIGNATION:

- *Where the head of department is also one of the investigators, the head of department declaration must be signed by the appropriate Dean, or other senior manager.*
- *If the application is for a student project, the supervisor should sign here.*

### 3. Declaration by the General Manager of the Health Service in which the research is being undertaken (if applicable)

I have reviewed the proposal for cost, resources, and administrative aspects and issues regarding patient participation and staff involvement. The proposal has my approval subject to the consent of the Ethics Committee.

NAME OF GENERAL MANAGER (PLEASE PRINT):

SIGNATURE:

INSTITUTION:

DATE:





**INFORMATION REQUIRED FOR TRIALS INVOLVING ADMINISTRATION OF DRUGS CURRENTLY REGISTERED IN NEW ZEALAND.**

Trade name of drug:

Chemical name of drug

Pharmacological class:

Brief details of any special features:

(E.g., long half life, receptor selectivity)

Recommended dose range:

Form of administration in the study:

Known or possible interactions with non-trial drugs the participants may be taking:

Side effects and adverse reactions:

## PART VI: WHEN A PARTICIPANT IS UNABLE TO MAKE AN INFORMED CHOICE

To be completed when one or more participants in a project will likely not be able to make an informed choice about whether to take part. ***Do not complete this section if all participants in the study will be competent to make an informed choice and give informed consent themselves.*** Refer to the Guidelines for information about children in research.

1. Will any of the participants have a person with them who is available and entitled to make an informed choice on their behalf if they themselves are unable to do so. yes   
no

**If yes**, that person can make a proxy informed choice for the potential participant. Include an appropriate consent form for that person legally entitled. (Note: Where possible the incompetent person should also orally consent to the level of his or her understanding.)

**If no**, complete section 1.1

- 1.1 Is there any person interested in the potential participant's welfare who knows the participant (eg family member/friend/whanau) and is willing and available to express a view as to what the potential participant would choose were he or she competent and fully informed about the study. yes   
no

**If yes**, include an information sheet for the family member/friend/whanau statement as per page 24.

Please note: if it is appropriate that there be wider consultation with family, then this should be encouraged

**If no**, complete section 1.2

- 1.2 Explain why it is not possible for a potential participant to make an informed choice and why it is not possible for a proxy choice to be made or for a person interested in the potential participant's welfare to state what the participant would choose if he or she was competent and fully informed.

2. What would be the risks to the participants of taking part in this study?

3. Could the research be carried out on people who are able to consent

yes	<input type="checkbox"/>
no	<input type="checkbox"/>

4. Explain why approval is being sought to use this participant/population/.patient group.

5. What is the potential health interest for the group of patients/population of which the participant would be a member?

(to be on letterhead)  
(include the Lay Title at the top of each page)

**STATEMENT BY RELATIVE/FRIEND/WHANAU**

Lay Title \_\_\_\_\_

Principal Investigator \_\_\_\_\_

Participant's Name \_\_\_\_\_

I have read and I understand the information sheet dated \_\_\_\_\_ for people taking part in the study designed to \_\_\_\_\_. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I believe that \_\_\_\_\_ (participant's name) would have chosen and consented to participate in this study if he/she had been able to understand the information that I have received and understood.

I understand that taking part in this study is voluntary and that my relative/friend may withdraw from the study at any time if he/she wishes. This will not affect his/her continuing health care.

I understand that his/her participation in this study is confidential and that no material which could identify him/her will be used in any reports on this study.

I understand that the treatment will be stopped if it should appear to be harmful. **(if applicable)**

I understand the compensation provisions for this study. **(if applicable)**

I know whom to contact if my relative/friend has any side effects to the study or if anything occurs which I think he/she would consider a reason to withdraw from the study.

I know whom to contact if I have any questions about the medication or the study.

This study has been given ethical approval by the \_\_\_\_\_ Ethics Committee. This means that the Committee may check at any time that the study is following appropriate ethical procedures.

I believe my relative/friend would agree to an auditor appointed by the sponsoring pharmaceutical company and approved by the \_\_\_\_\_ Ethics Committee reviewing my relative's/friend's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study. **(if applicable)**

I/my relative/friend would like a copy of the results of the study. **YES/NO**

I believe my relative/friend would agree to his/her GP being informed of his/her participation in this study **YES/NO**

Signed: \_\_\_\_\_ Date \_\_\_\_\_

Printed Name: \_\_\_\_\_

Relationship to Participant: \_\_\_\_\_

Address for results : \_\_\_\_\_

**STATEMENT BY PRINCIPAL INVESTIGATOR**

I (name of investigator) declare that this study is in the potential health interest of the group of patients of which (name of participant) is a member and that participation in this study is not adverse to (name of participant)'s interests.

**(if applicable)**

I confirm that if the participant becomes competent to make an informed choice and give an informed consent, full information will be given to him/her as soon as possible, and his/her participation will be explained. If the participant makes an informed choice to continue in the study, written consent will be requested and if the participant does not wish to continue in the study, he/she will be withdrawn.

Signed: \_\_\_\_\_  
Principal Investigator

Date \_\_\_\_\_

**(If applicable at a later stage)**

I \_\_\_\_\_ (participant) having been fully informed about this study agree to continue taking part in it.

Signed: \_\_\_\_\_  
Participant

Date \_\_\_\_\_

**STATEMENT BY INDEPENDENT CLINICIAN**

I confirm that participation in the study is not adverse to \_\_\_\_\_ (participant)'s interests.

Signed: \_\_\_\_\_  
Clinician

Date \_\_\_\_\_

Printed Name : \_\_\_\_\_