

NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

NAF-2009-v1

The application guidelines (NAFG-2009-v1) 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 six lines, six lines are formatted, but where an answer only needs one line, one line is formatted. Please note the number of lines allowed for a question before answering it and make sure that you do not use extra lines.

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 relevant paragraphs of the Operational Standard for Ethics Committees (Ministry of Health document) have been included in subject headings for reference.

The page breaks are not to be deleted as this will affect the formatting of the form.

When collating your application, please ensure that the information sheet, consent form and any attachments are placed behind the application form before copying. Applications not correctly collated, ie not in complete sets ready to be sent to committee members will be returned.

Do not include this page with your application.

Checklist for Applicants – attach to front of application

Before sending your application form, please check to make sure that all relevant information has been attached. If not applicable to the application write N/A. Protocols, information sheets, consent forms, questionnaires, advertisements, letters of invitation, data collection or other study forms must have a version number and date (marked *).

Please note: Incomplete applications will not be considered. Pending is an option only for written confirmation of Maori consultation, SCOTT approval, and Locality assessment by organisation. For multi-region studies, the documentation for one site must be complete.

Reference	Item	Yes, pending or N/A
Observational Studies Guidelines 5.11	* Study protocol – must be supplied with all applications	
Page 21 of NAFG, QE on NAF	* Consent form	
Page 23 of NAFG, QE on NAF	*Information sheet	
QA5.4 on NAF	* Questionnaire/interview guidelines	
Page 8 of NAFG, QA2 of NAF	Scientific assessment	
QA5.3 of NAF	Statistical report	
QD2, NAFG page 8 Q A4	* Advertisement, letter of invitation	
Section F of NAFG, Page 15	Evidence of Māori consultation	
Part 4 of NAF	Declaration signed by principal investigator, Head of Department or Dean (for each site)	
Part 4, Form A or B of NAF	Accident compensation declaration correctly witnessed	
NAFG page 20, NAF page 28	Form/s for registered and unregistered medicines	
Pages 11 and 35 (Appendix 1) of NAFG, QB17 on NAF	Standing Committee on Therapeutic Trials (SCOTT) approval attached if drug is unregistered in New Zealand	
Locality assessments form(s) NAFG pages 18-20	Completed by ethics committee if required, or completed by locality organisation(s) if received at time of submission	
NAFG pages 30-32	Part 5: If there any use of tissue (includes blood, saliva, skin)	
Appendix 2 of NAFG	Part 6: If the research involves any gene or genetic studies	
Appendix 2 of NAFG	Part 7 if the study involves xenotransplantation	
NAFG pages 33-34	Part 8 if any participants are unable to consent themselves including children	
Parts 6 and 7, Appendix 2 of NAFG	GTAC approval if required	
QB17 of NAF, Appendix 4 of NAFG	National Radiation Laboratory risk assessment if required	
Company sponsored studies	Investigator brochure (if product is unregistered in New Zealand)	
	Signed indemnity agreement (sponsor/institution/investigator)	
	Current company insurance certificate	
If yes to C.6	Evidence of sponsor indemnity insurance to cover C.6	
If yes to C.6	Evidence of hospital/institution indemnity insurance to cover C.6	
If yes to C.6	Evidence of Investigator indemnity insurance to cover C.6	

NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT

Ethics reference number and date received
(for office use only)

Part 1: Basic Information

1. Full project title (include protocol number if applicable)

2. Short project title (lay title)

3. Principal investigator's name and position

4. Contact address of principal investigator

Work phone no.
Emergency no.*
Fax
Email

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

6. Co-investigator's name(s), qualifications and position(s) and, if more than one locality; principal investigator at **each** locality

A	
B	
C	
D	
E	
F	
G	

7.1 Address of A above

	Work phone no.	
	Emergency no.*	
	Fax	
	Email	

7.2 Address of B above

	Work phone no.	
	Emergency no.*	
	Fax	
	Email	

7.3 Address of C above

	Work phone no.	
	Emergency no.*	
	Fax	
	Email	

7.4 Address of D above

	Work phone no.	
	Emergency no.*	
	Fax	
	Email	

7.5 Address of E above

	Work phone no.	
	Emergency no.*	
	Fax	
	Email	

7.6 Address of F above

Work phone no.

Emergency no.*

Fax

Email

7.7 Address of G above

Work phone no.

Emergency no.*

Fax

Email

(* option for ethics committee's information only)

8. Where this is supervised work

8.1 Supervisor's name

Position

Daytime phone number

8.2 Signature of supervisor (where relevant)

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

9. List locality organisation/s involved, including contact address, and complete the locality assessment in Part 4: Declarations (refer to the Guidelines (NAFG-2009-v1))

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

Yes No

If the answer is yes, please provide a reason why you wish the protocol to be heard in a closed meeting in accordance with the Official Information Act 1982.

11. If the study is based, in part or in full, overseas, which countries are involved?

12. Has this application been reviewed by another ethics committee in New Zealand or overseas?

Yes No

(If yes, advise which country, the name of the committee/s and the decision/s of the committee/s)

Please note a copy of the report/s may be requested.

13. **Human tissue** – Does the project involve collection or use of human tissue? If **yes**, complete Part 5.

Yes No

14. **Gene studies** – Does this research involve any gene or genetic studies? If **yes**, complete Part 6.

Yes No

15. **Xenotransplantation** – Does this research involve the transplantation of living biological material from one species to another?

Yes No

If **yes**, complete Part 7.

16. **Consent** – Are all participants able to provide consent for themselves? If **no**, complete Part 8.

Yes No

17. **Lay summary** – give a brief **lay (non-technical)** summary of the study (not more than 200 words) such as you would give as an explanation to participants.

18. Proposed starting date (dd/mm/yy)

19. Proposed finishing date (dd/mm/yy)

20. Duration of project in New Zealand (mm/yy)

21. Proposed final report date (mm/yy)

22. Has the clinical trial been registered?

Yes No

If **yes**, name the register.

If **no**, has registration been applied for?

Yes No

Comment:

Part 2: Ethical Principles

A. Validity of research

(Operational standard paragraphs 53–59)

SCIENTIFIC BASIS

A1. Aims of the project

A1.1 What is the hypothesis/research question(s) and/or the specific aims of the project? (State briefly.)

Comment:

A2. Scientific background of the research

A2.1 Has this project been scientifically assessed by independent review? Yes No

If **yes**, describe the process, for example, HRC funding assessment process. *A copy of the report should also be attached. The researcher's response may also be included.*

If **no**, do you intend to have the project scientifically assessed and by whom?

A2.2 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.

A3. Study design

A3.1 Describe the study design. Where this space is inadequate, continue on a separate sheet of paper. *Do not* delete page breaks or renumber pages.

A4. Participants

A4.1 How many participants do you intend to recruit? (Include details for each locality organisation.)

A4.2 Give a justification for the number of research participants proposed, giving the details of power calculations when appropriate.

A4.3 If randomisation is used, explain how this will be done.

A5. Statistical method

A5.1 Is the method of analysis quantitative?

Yes

No

Or qualitative?

Yes

No

If the method of analysis is **wholly qualitative**, go to question A5.4.

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

A5.2 Describe the statistical method that will be used to analyse the data.

A5.3 Has specialist statistical advice been obtained about this study?

Yes

No

If **yes**, from whom? (A brief statistical report should be included if appropriate.)

A5.4 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 and a copy of the interview guide, if one is to be used. Copies of any questionnaires that will be used must be included.

A6. Expected outcomes or impacts of research

A6.1 What is the potential significance of this project for improved health outcomes?

A6.2 What is the potential significance of this project for the advancement of knowledge?

A6.3 What steps will be taken to disseminate the research results?

A7. Publication of results

Will any restriction be placed on publication of results?

Yes

No

If **yes**, please supply details.

A8. Funding

A8.1 How will the project be funded?

A8.2 Does the researcher, the host department, the host institution or the locality organisation have any conflict of interest, eg, financial interest, in the outcome of this research? If **yes**, please give details.

Yes

No

A9. Incentive payments

A9.1 Have you read and understood the description of incentive payments in the Guidelines?

Yes

No

Note: Details about any payment (in money or kind) or reward made to participants recruited into the project are to be provided in question E10.

A9.2 Does the funding available to the project depend upon the number of participants recruited, eg, is the funding on a per participant basis?. If **yes**, give details of the amount per participant. Where there is a significant difference between these, this incentive to recruit should be declared in the information sheet.

Yes

No

- A9.3 Does the funding available to the project include any form of incentive (in money or kind) for the early or complete recruitment of a specified number of participants, eg, bonus payments to the researcher, host department or host institution? If **yes**, give details. Yes No

- A9.4 Will **all** funding available to the project be passed through an audited research account or cost centre? If **yes**, give details. If **no**, specify why not. Yes No

B. Minimisation of harm

(Operational standard paragraphs 60–68)

- B1. How many visits/admissions of participants will this study involve? Clarify what is in addition to standard treatment. Give also an estimate of total time involved for participants.

- B2. Who will carry out the research procedures?

- B3. What other research studies is the lead investigator currently involved with?

B4. Where will the research procedures take place?

B5. How do the research procedures differ from standard treatment procedures?

B6. What are the benefits to research participants of taking part in the project?

B7. Describe any methods for obtaining information. Attach questionnaires and interview guidelines. (If National Health Index (NHI) information is used, see the Guidelines (NAFG-2009-v1).)

B8. Briefly describe the inclusion/exclusion criteria and include the relevant page number(s) of the protocol or investigator's brochure.

B9. 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.

B10. What facilities/procedures and personnel are there for dealing with emergencies?

B11. What arrangements will be made for monitoring and detecting adverse outcomes?

B12. If the study is a clinical trial, are participants to be provided with a card confirming their participation, medication and the contact phone number of the principal investigator? Yes No

B12.1 Do you intend to inform the participant's GP that their patient is a participant in this study? (If yes, consent from the participant is required.) Yes No

B12.2 Do you intend to inform the GP of all clinically significant abnormal results obtained during study conduct? Yes No

B13. Is the trial being reviewed by a data and safety monitoring board (DSMB)? Yes No

If **yes**, who is the funder of the DSMB? HRC Sponsor Other

If **'Other'**, please specify.

B14. What are the criteria for terminating the study?

B15. Will participants be exposed to any potential toxins, mutagens or teratogens? Yes No

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

B16. Will any radiation or radioactive substances be used? Yes No
Note: If any form of radiation is being used, please answer B16.1–B16.2. If no, go to question B17.

B16.1 How many x-rays or other procedures are planned for the purposes of this study, ie, that are not part of standard treatment?

B16.2 Under whose licence is the radiation being used?

B16.3 Has the National Radiation Laboratory (NRL) risk assessment been completed? Yes No

If **yes**, please enclose a copy of the risk assessment and a contact name and phone number.
 If **no**, please explain why not.

B17. Will any medicines be administered for the purposes of this study? Yes No

B17.1 If **yes**, is Standing Committee on Therapeutic Trials (SCOTT) approval required? Yes No

B17.2 Has SCOTT approval been given? (Please attach.) Yes No

B18. Does the study involve the use of health care resources? Yes No
 If **yes**, please specify:

B19. What effect will this use of resources have on waiting list times for patients, that is, for diagnostic tests or for standard treatments?

C. Compensation for harm suffered by participants

(Operational standard paragraphs 87–95)

(Refer also to Appendix 3 of the Guidelines (NAFG-2009-v1).)

C1. Will participants be treated by, or at the direction of, a registered health professional as part of the research? (Treatment includes screening, diagnosis, for definitions see the Guidelines (NAFG-2009-v1) pages 11-13.) Yes No

If **no**, go to section D. If **yes**, please answer questions C2–C6.4.

C2. Is the research being carried out principally for the benefit of a manufacturer or distributor of the drug or item in respect of which the research is taking place? Yes No

C2.1 If the answer to C2 is **yes**, please complete **Statutory Declaration Form B** and answer questions C3–C6.4.

C2.2 If the answer to C2 is **no**, please complete **Statutory Declaration Form A** and go to section D.

Depending on all the circumstances, the minimum cover that is likely to be acceptable to the ethics committee is that provided under ACC. In any case, all exclusions to compensation must be clearly and explicitly set out in the participant information sheet, including those that may be described in C5.

C3. Is the manufacturer/distributor’s agreement to provide compensation in accordance with the RMI attached? Yes No

C4. Has the manufacturer or distributor agreed to cover any injury/adverse consequence resulting from participation in this research? Yes No

C4.1 If no, what qualifications have been specified for cover?

C4.2 Limiting the type of compensation

C4.2.1 Has the manufacturer or distributor excluded any type of compensation, for example, pain and suffering, loss of earnings, loss of earning capacity, funeral costs, dependents’ allowances or any other financial loss or expenses? Yes No

C4.2.2 If yes, please state what is excluded. (Include in the compensation statement on the information sheet)

C5. Limiting liability – exclusion clauses

C5.1 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

C5.2 Has the manufacturer or distributor limited or excluded liability if the injury resulted from a significant deviation from the study protocol by someone other than the manufacturer or distributor? Yes No

C5.3 Is evidence of the following indemnity insurance attached?
Sponsor Yes No

If yes to either C5.1 or C5.2;
Hospital/institution Yes No

Investigator Yes No

C5.4 Is company liability limited in any other way? Yes No

If **yes**, please specify.

D. Privacy and confidentiality

(Operational standard paragraphs 48–56)

D1. How will potential participants be identified?

D2. How will participants be recruited (for example, advertisements, notices)?

D3. Where will potential participants be approached (for example, outpatient clinic)? If appropriate, describe by type (for example, students).

D4. Who will make the initial approach to potential participants?

NB: Do not include information on storage and use of tissue samples and related information in the following questions. That is covered separately under Part 5.

D5. How will data, including audio- and videotapes, be handled and stored to safeguard confidentiality (both during and after completion of the research project)?

D6. What will be done with the raw data when the study is finished?

D7. How long will the data from the study be kept, and who will be responsible for their safe keeping? (Health information relating to an identifiable individual must be retained for at least 10 years, or in the case of a child, 10 years from the age of 16.)

D8. Name those who will have access to the raw data, participant information and/or clinical records during, or after, the study?

D9. Describe any arrangements to make results available to participants, including whether they will be offered their audio- or videotapes.

E. Informed consent

(Operational standard paragraphs 28–43)

A participant’s informed consent should be obtained in writing, unless the procedures are not experimental and there are good reasons for not requiring written consent. 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 provided to participants.

E1. By whom, and how, will the project be explained to potential participants?

E2. When and where will the explanation be given?

E3. Will a competent interpreter be available, if required?

Yes No

If **no**, why not?

E4. How much time will be allowed for the potential participant to decide about taking part in the project?

E5. In what form (written, or oral) will consent be obtained? If oral consent only, state reasons.

E6. If recordings are made, will participants be offered the opportunity to edit the transcripts of the recordings?

Yes No

E7. Will data or other information be stored for use in a different study for which ethics committee approval would be required?

Yes No

E7.1 If **yes**, please explain how.

E8. Is there any special relationship between the participants and the researchers (for example, doctor/patient, student/teacher)?

E9. Will there be any financial cost to the participant, for example, travel and parking costs? If so, will such cost be reimbursed? (Refer to the Guidelines (NAFG-2009-v1).)

E10. Will any payments be made to participants, or will they gain materially in other ways from participating in this project?

Yes No

E10.1 If **yes**, please supply details.

F. Cultural and social responsibility (Operational standard paragraphs 73–82)

Section F enshrines two fundamental principles. They are:

- i. Culturally safe research practice: Research involving participants from specific ethnic or socially identified groups (even when small numbers from each group are involved) must involve those participant groups in the research process as full participants. Where a particular ethnic or socially identified group is the principal subject of the research, there must be engagement with appropriate parties, and this process must be outlined in the application.
- ii. If the research is in an area of health inequalities, then the researcher must demonstrate how the research will contribute to achieving equity of outcomes for those population groups most in need within the public good health system.

F1. Have you read the HRC booklet *Guidelines for Researchers on Health Research Involving Māori*?

Yes No

Relevance and responsiveness to Māori

F2. **All health research conducted in Aotearoa New Zealand is of relevance to Māori.** How relevant is a decision to be made by Māori. The researcher must be able to articulate the context and the relevance of the proposed research to Māori and the possible consequences for Māori health outcomes, and generally, the greater the degree of relevance to Māori, the greater the expectation of participation of Māori and hence consultation expectations.

F2.1 Given your approach to sampling, what are the anticipated numbers of Māori participants?

F2.2 What is the incidence among Māori of the health issue/disability relevant to the study?

F3. Please explain how this research will contribute to improving Māori health outcomes and reducing health inequalities for Māori.

F4. Describe the process by which Māori have been engaged in the conception and design of the proposed research. Please identify the group/s with which consultation has taken place and outline their stated view about the proposed research. Please attach their letter/s of support for this specific research project.

F4.1 Describe any ongoing involvement the group(s) consulted have in the project.

F4.2 Describe how information will be disseminated to participants and the group(s) consulted during and at the conclusion of the research project.

Responsiveness to ethnic peoples

F5. What other ethnic groups will be participating in this research based on your sampling frame (for example, Pacific peoples or Asian peoples)?

F5.1 Are there any aspects of the research based on participation or the relevance of the research to specific ethnic groups that might raise specific cultural issues?

Yes

No

If **yes**, please outline.
If **no**, go to F6.

F5.2 How can this research contribute to reducing inequalities for ethnic peoples in the New Zealand health system?

F5.3 Describe what consultation has taken place with specific ethnic group(s) prior to the project's development and attach evidence of their support.

F5.4 Describe any ongoing involvement the group(s) consulted have in the project.

F5.5 Describe how you intend to disseminate information to participants and the group(s) consulted at the end of the project.

Responsiveness to other peoples of interest

F6. Are there any aspects of the research based on participation or the relevance of the research to specific peoples of interest that might raise specific issues for such communities (for example, for prisoners, people with disabilities, people with diverse sexual identities)?

Yes

No

If **yes**, please outline.
If **no**, go to F7.

F6.1 How can this research contribute to reducing inequalities for other peoples of interest in the New Zealand health system?

F6.2 Describe what consultation has taken place with specific peoples of interest group(s) prior to the project's development and attach evidence of their support.

F6.3 Describe any ongoing involvement the group(s) consulted have in the project.

F6.4 Describe how you intend to disseminate information to participants and the group(s) consulted at the end of the project.

F7. Will the study drug/treatment continue to be available to the participant after the study ends?

Yes

No

F7.1 If **yes**, will there be a cost, and how will this be met?

F7.2 If **no**, why not?

F7.3 If there was a placebo arm, what will happen to these participants at the end of the study?

Note: This information needs to be included in the information sheet.

Part 3: General

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

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

Please now complete:

- the declarations (Part 4). If there is more than one site, include a declaration for each site.

If applicable complete:

- a Registered Drug Form
- Form A or B
- Part 5
- Part 6
- Part 7
- Part 8

Attach:

- Checklist to ensure all relevant documents are attached. Incomplete applications will not be reviewed.

Part 4: 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:

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 (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 the Head of Department declaration.
- Submit a declaration by the principal investigator for each site.

3. Locality organisation approval

Locality organisation approval is being sought/is attached from the following locations:

Form A: Declaration of Eligibility of a Clinical Trial for Consideration of Coverage under Accident Compensation Legislation

Instructions: This form is to be completed and the statutory declaration signed by the most senior registered health professional providing or directing the provision of treatment as part of the research. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that the proposed research is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

The provision of this information will enable the ethics committee to be satisfied that participants in the clinical trial will be considered for coverage under accident compensation legislation for injury caused as a result of their participation in the research.

Details of proposed research study

Title of research project:	<input style="width: 95%; height: 20px;" type="text"/>
Name of research director/investigator:	<input style="width: 95%; height: 20px;" type="text"/>
Location/s of proposed study:	<input style="width: 95%; height: 20px;" type="text"/>
Number of participants:	<input style="width: 95%; height: 20px;" type="text"/>
Organisations providing support (in money or kind) for the direct and indirect costs of the research (<i>please provide names of organisations and details of the type of support provided</i>):	<input style="width: 95%; height: 40px;" type="text"/>
Relationship of proposed research to the pharmaceutical industry or other company involved in health research (<i>please describe the involvement of industry in your proposed research and provide details of support to be received from them</i>):	<input style="width: 95%; height: 60px;" type="text"/>

Statutory declaration

I _____ (name) of _____ (town/city) solemnly and sincerely declare that as the most senior registered health professional providing or directing the provision of treatment as part of the research, the proposed study is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Name (<i>please print</i>)	Signature	this day of
------------------------------	-----------	-------------

before me

Name of witness (<i>please print</i>) a Justice of the Peace, or a Solicitor of the High Court or other person authorised to take a statutory declaration.	Signature of witness <input style="width: 40px; height: 15px; margin-bottom: 5px;" type="text"/> <input style="width: 40px; height: 15px; margin-bottom: 5px;" type="text"/> <input style="width: 40px; height: 15px;" type="text"/>
---	---

Warning: Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form B.

Form B: Declaration of Provision of Compensation for Injury for Participants in a Research Study for a Pharmaceutical Company or any Other Company Involved in Health Research

Instructions: This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate ethics committee together with the documents seeking ethical approval for the proposed study and appropriate assurance from the pharmaceutical company or any other company involved in health research. The information provided must be sufficiently detailed to enable the ethics committee to be satisfied that:

- the proposed research is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out
- participants in the proposed research project will receive an acceptable level of compensation from a pharmaceutical company or any other company involved in health research in the event of injury to participants resulting from their involvement in the proposed research project.
- researchers and institutions have indemnity cover to provide an acceptable level of compensation in the event of injury to participants resulting from any researcher or research staff deviating substantially from the trial protocol.

Details of proposed research project

Title of research project:

Name of research director/investigator:

Location of proposed study:

Number of participants:

Organisations providing support (in money or kind) for the direct and indirect costs of the research (*please provide names of organisations and details of the type of support provided*):

Relationship of proposed research to the pharmaceutical industry or other company involved in health research (*please describe the involvement of industry in your proposed research and provide details of support to be received from them*):

Details of compensation to be provided to participants in the event of injury (*documents signed by the sponsoring pharmaceutical company or other company involved in health research must be attached*):

Statutory declaration

I (name) of (town/city) solemnly and sincerely declare that as director of the proposed research, the proposed study is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out and that in the event of injury arising from their participation in the research, an appropriate level of compensation, in line with the *New Zealand Researched Medicines Industry Guidelines on Clinical Trials – Compensation for Injury Resulting from Participation in Industry Sponsored Clinical Trials*, will be provided by (name of pharmaceutical company or another company involved in the research project) as detailed in the attached documents, unless the injury is a result of a significant deviation from the study protocol. I confirm that I, my research staff and the host institution have indemnity insurance that covers injury as a result of significant deviation from the study protocol. I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Name (*please print*)

Signature

this day of

before me

Name of witness (*please print*)

a Justice of the Peace, or

a Solicitor of the High Court

or other person authorised to take a statutory declaration.

Signature of witness

Warning: Please note that it is an offence under part VI subsection 111 of the Crimes Act 1961 to make a false statutory declaration. **Note:** Applicants conducting a research study that is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form A.

Form for Registered and Unregistered Medicines
(Refer Question B19)

Information required for trials involving administration of medicines currently registered in New Zealand

This form is to be completed for all medicines including non-registered medicines except where the medicine will be given regardless of entry into the trial (eg, anaesthetic) and that medicine is not being studied in any way

Trade name of medicines

Generic name of medicines

Pharmacological class

Form of administration used in the study

Recommended dose range

Contraindications

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

Common side effects and serious adverse reactions

Additional information, eg, long half-life, immunosuppression