

## DRAFT 2

<p style="text-align: center;"><b>NATIONAL APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT</b></p>
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## NAF-2008-v1

The application guidelines (NAFG-2008-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.

Ministry of Health  
Health Research Council of New Zealand  
..... 2008

**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.**

Reference	Item	Yes or N/A
Observational Studies Guidelines 5.11	*Study protocol – must be supplied with all applications	
Page 17 of NAFG, QE on NAF	*Consent form	
Page 19 of NAFG, QE on NAF	*Information sheet	
QB11 on NAF	*Questionnaire/interview guidelines	
Page 7 of NAFG, QA2 of NAF	Scientific assessment	
QA3.2.2 of NAF	Statistical report	
QD2, NAFG Page 7	*Advertisement, letter of invitation	
Section F of NAFG	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 16	Registered Drug form (for each drug currently registered in NZ)	
Pages 16 and 27 (Appendix 1) of NAFG, QB19 on NAF	Standing Committee on Therapeutic Trials (SCOTT) approval attached if drug is unregistered in New Zealand	
Locality assessments form(s) NAFG Pages 14-16	Completed by ethics committee if required, or completed by locality organisation(s) if received at time of submission	
NAFG Pages 24-25	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	
Appendix 2 of NAFG	Part 8 of NAF If any participants are unable to consent themselves including children	
Parts 6 & 7, Appendix 2	GTAC approval if required	
QB18 of NAF, Appendix 4	National Radiation Laboratory risk assessment enclosed if	
<b>Company sponsored studies</b>	Investigator brochure (if product is unregistered in NZ)	
	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

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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

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Work phone no.

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Emergency no.\*

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Fax

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Email

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7.7 Address of G above

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Work phone no.

--

Emergency no.\*

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Fax

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Email

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(\* option for ethics committee's information only)

8. Where this is supervised work

8.1 Supervisor's name

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Position

--

Daytime phone number

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8.2 Signature of supervisor (where relevant)

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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-2008-v1))

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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 and append the decision of that committee)

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? If **yes**, complete Part 7.  Yes  No

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 (mm/yy)

21. Proposed final report date (mm/yy)

22. Has the study been registered?

Yes  No

If **yes**, name the register.

# 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)? (State briefly.)

A1.2 What are the specific aims of the project?

#### 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.*

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.

A3.2 Is the method of analysis:  quantitative  and/or qualitative?

If the method of analysis is **wholly qualitative**, go to question A3.3.

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

A3.2.1 Describe the statistical method that will be used.

A3.2.2 Has specialist statistical advice been obtained?

Yes

No

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

A3.3 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 must be included.

#### **A4. Participants**

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

A4.2 If randomisation is used, explain how this will be done.

#### **A5. Expected outcomes or impacts of research**

A5.1 What is the potential significance of this project for improved health outcomes?

A5.2 What is the potential significance of this project for the advancement of knowledge?

A5.3 What steps will be taken to disseminate the research results?

### A6. Publication of results

Will any restriction be placed on publication of results?

Yes  No

If **yes**, please supply details.

### A7. Funding

A7.1 How will the project be funded?

A7.2 Does the researcher, the host department, the host institution or the locality organisation have any financial interest in the outcome of this research?  
If **yes**, please give details.

Yes  No

### A8. Incentive payments

A8.1 Will the researcher, the host department, the host institution, the locality organisation or any individual/organisation who recruits participants into the project but who will not be involved in the research as investigators receive payment (in money or kind) or reward in connection with this project – including any payment (in money or kind) or reward for recruiting participants into the project?

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.**

A8.2 If **yes**, please provide details and include, in the information sheet, notice of the fact that an incentive is paid to researchers.

A8.3 Will the payment or reward be made directly to the researcher or to an audited research account or cost centre?

A8.4 Will the payment or reward be for early or complete recruitment of a specified number of participants?

A8.5 What will be the amount of the payment or reward (indicate whether this will be per participant or lump sum)?

**B. Minimisation of harm**

*(Operational Standard Paragraphs 60–68)*

B1. How many visits/admissions of participants will this project involve? 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. Give a justification for the number of research participants proposed, using appropriate power calculations.

B6. Are participants in clinical trials to be provided with a card confirming their participation, medication and the contact phone number of the principal investigator?

Yes

No

B7. Do you intend to inform the participant's GP of individual results of the investigations and their participation, if the participant consents?

Yes

No

If **no**, outline the reasons for not doing so.

B8. How do the research procedures differ from standard treatment procedures?

B9. What are the benefits to research participants of taking part in the project?

B10. Briefly describe the inclusion/exclusion criteria and include the relevant page number(s) of the protocol or investigator's brochure.

B11. Describe any methods for obtaining information. Attach questionnaires and interview guidelines. (If National Health Index (NHI) information is used, see the Guidelines (NAFG-2008-v1).)

B12. 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.

B13. What facilities/procedures and personnel are there for dealing with emergencies?

B14. What arrangements will be made for monitoring and detecting adverse outcomes?

B15. 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

B16. What are the criteria for terminating the study?

B17. Will any potential toxins, mutagens or teratogens be used?  Yes  No

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

B18. Will any radiation or radioactive substances be used?  Yes  No

**Note: If any form of radiation is being used, please answer B18.1–B18.2. If no, go to question B19.**

B18.1 Under whose licence is the radiation being used?

B18.2 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.

B19. Will any drugs be administered for the purposes of this study?  Yes  No

B19.1 If **yes**, is Standing Committee on Therapeutic Trials (SCOTT) approval required?  Yes  No

B19.2 Has SCOTT approval been given? (Please attach.)  Yes  No

B20. Does the study involve the use of health care resources?  Yes  No

If **yes**, please specify:

B21. 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-2008-v1).)*

C1. Will participants be treated by, or at the direction of, a registered health professional as part of the research? (Treatment includes diagnosis, for definitions see the Guidelines (NAFG-2008-v1) page 5(4).)  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.

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?

C5. 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

C5.1 If yes, please state what is excluded. 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 C6 below.

C6. Exclusion clauses:

C6.1 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

C6.2 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

If yes to either C6.1 or C6.2:

C6.3 Is evidence of the following indemnity insurance attached?

Sponsor

Yes  No

Hospital/institution

Yes  No

Investigator

Yes  No

C6.4 Is company liability limited in any other way?

Yes  No

If **yes**, please specify.

**D. Privacy and confidentiality**

*(Operational Standard Paragraphs 44–49)*

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?

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 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 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 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?

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-2008-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)*

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. Based on your sampling frame, what are the anticipated numbers of Māori participants?

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? If **yes**, please outline.

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.

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 What will happen to participants on a placebo arm?

**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
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before me

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



**Registered Drug Form**  
***(Refer Question B19)***

**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 (for example, 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

## Locality Assessment by Locality Organisation

Refer to pages 13–15 of Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAFG-2008-v1).

### Locality organisation sign off

Ethics committees review whether investigators have ensured their studies would meet established ethical standards if conducted at appropriate localities. Each locality organisation is asked to use the locality assessment form to check that the investigator has also made the appropriate local study arrangements.

Ethics approval for study conduct at each site is conditional on favourable locality assessment at that locality.

Please note that the locality organisation may have additional requirements to be met before a study may commence at that locality.

### Part One: General

To be completed by the principal investigator for this locality.

Full project title:

Short project title:

Locality to be assess:

Brief outline of study:

Principal investigator (for this locality):

Contact details:

Other local investigators (list all at this site):

Contact details:

### Part Two: Locality Issues

To be completed by the principal investigator for this locality and signed by the authorised locality representative. (See the Guidelines (NAFG-2008-v1) (pages 13–15) for more information and examples.) Identify any local issues and specify how these issues will be addressed.

1. **Suitability of local researcher**  Yes  No  
 For example, are all roles for the investigator(s) at the local site appropriate (for example, has any conflict the investigator might have between her or his local roles in research and in patient care been adequately resolved)?
  
2. **Suitability of the local research environment**  Yes  No
  - a) Are all the resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires appropriate and available (for example, is staffing adequate? is this site accessible for mobility-impaired people where necessary)?  Yes  No
  
  - b) Have all potentially affected managers of resources such as patient records or laboratory managers been notified?  Yes  No
  
3. **Have issues such as cultural issues specific to this locality or to people being recruited at this locality been addressed?**  Yes  No
  
4. **Have the local investigator contact details and other important contact details been provided to the locality organisation for checking?**  Yes  No

### Part Three: Declaration by locality organisation

I am authorised to complete locality approval on behalf of this locality organisation. I understand that I may withdraw locality approval if any significant local concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur. **(Questions 1–4 at Part Two above must be completed prior to signing.)**

Signature:  Date:

Name:  Position:

Contact details:

### Second signature (if required by your organisation)

Signature:  Date:

Name:  Position:

Contact details:

## Locality Assessment by Ethics Committee

To be completed when there is no independent locality to carry out a locality assessment and to be submitted with the ethics application. Refer to pages 13–15 of Guidelines for Completion of the National Application Form for Ethical Approval of a Research Project (NAFG-2008-v1).

Full project title:

Short project title:

Principal investigator:

Other local investigators:

Contact details (if not already provided on the application form):

Ethics approval for study conduct at each site is conditional on favourable locality assessment. For the ethics committee to carry out an assessment, the following questions need to be fully answered by the principal investigator at each locality if more than one is involved in the study.

### Locality issues

(See the Guidelines (NAFG-2008-v1) for more information and examples. Identify any local issues and specify how they will be addressed.

1. **Suitability of local researcher**

For example, are all roles for the investigator(s) at the local site appropriate (for example, has any conflict the investigator might have between her or his local roles in research and in patient care been adequately resolved)?

2. **Suitability of the local research environment**

a) Are all the resources (other than funding that is conditional on ethical approval) and/or facilities that the study requires appropriate and available (for example, is staffing adequate? is this site accessible for mobility-impaired people where necessary)?

- b) Have all potentially affected managers of resources such as patient records or laboratory managers been notified?

- c) What are the specific issues relating to the local community? Are there any issues such as cultural issues as specific to this locality or to people being recruited at this locality?