

# APPLICATION FORM FOR ETHICAL APPROVAL OF A RESEARCH PROJECT FROM THE FIJI NATIONAL RESEARCH ETHICS REVIEW COMMITTEE

## PART I : BASIC INFORMATION AND PROTOCOL

*It is proposed that data from this page will be made publicly available.*

1. Full Project Title
  
2. Short Project Title (lay title)  
*(Use a description readily understandable by laypersons. This title is also to be used on consent form and information sheet.)*
  
3. Principal Investigator Name and Position:  
*(If this is supervised work then the student should be listed as the principal investigator)*
  
4. Location of Principal Investigator
  
5. Co-investigators Name and Position:  
*(Include the names and qualifications of all persons who will be conducting the research)*
  
6. Supervisors Name and Position (where this is supervised work):
  
7. Proposed Starting Date:  
*(Note: this should not be prior to the notification of ethical approval)*  
  
\_\_\_\_\_
8. Proposed Finishing Date:  
  
\_\_\_\_\_
9. Duration of Project:  
*(Note: a final report will be required within 3 months of completion of the study)*

10. Proposed and/or Required Number of Participants:
  
11. Is this a multicentre project?  
*(If YES, please complete question 1. in Part II)*
  
12. Do you request a fast track procedure?  
*(This procedure will be used only for certain projects. See Guidelines/Explanatory Notes)*

## **PART II : PROJECT SUMMARY**

***Please reproduce all of the questions and provide answers in a different typeface. Those questions that do not apply to your project should be marked N/A (Not applicable)***

### **1. MULTICENTRE PROPOSALS**

1.1 Is this a multicentre study?

1.1.1 If yes, please provide name and address of the principal investigator in Fiji, if any, and local contact name and address

1.1.2 Please list all other centres involved in the study

*(Note: If there is a principal investigator in Fiji, protocols will be dealt with by the FSM Research Ethics Review Committee who will correspond with other Ethics Committees as necessary. Please see details of the multicentre process appended.)*

1.2 Has the protocol been reviewed by any other Ethics Committees?

*(If yes, please name and enclose copies of any relevant correspondence)*

### **2. FUNDING**

2.1 What is the proposed source of funding?

2.2 Give name of proposed funder and date when result of funding application will be known

### **3. SCIENTIFIC ASSESSMENT**

Has this project been scientifically assessed by independent review?

**If yes:**

By whom? (Name and Position)

*(A copy of the report should be enclosed.)*

**If no:**

Is it intended to have the project scientifically assessed and by whom?

### **4. SUMMARY**

Give a brief summary, not more than 200 words, of the study

*(Please write in language that will make the project comprehensible to lay persons)*

## **PART III : PROJECT DETAILS**

*Please reproduce all of the questions and provide answers in a different typeface. Those questions that do not apply to your project should be marked N/A (Not applicable)*

### A SCIENTIFIC BASIS

#### 1. AIMS OF PROJECT

*(Note: The description of the project should not use jargon. References accessible to the Committee should be given.)*

1.1 What does the project aim to investigate?

1.2 Is it based on specific hypotheses? (If so, state them briefly)

1.3 What is the potential significance of this project for improved health care for the community; for capacity strengthening at the local, national and/or regional level; and for the advancement of knowledge?

1.4 Is this project to be used to formulate policy?

#### 2. RESEARCHER QUALIFICATIONS

2.1 What experience do the researchers have in this type of research? (Please include a brief curriculum vitae, and details of recent publications.)

#### 3. RESEARCH METHODS

*(The following 2 sections should be described in lay terms)*

3.1 What is the method of analysis? If this is (wholly or partly) quantitative research, please give the following:

3.2 If the research methods are (wholly or partly) qualitative, give a brief description of their theoretical basis:

3.3 Describe the study design. Include diagrams and charts to illustrate if necessary.

#### 4. PROCEDURES

4.1 What procedures will be carried out? Include all tests to be carried out on samples.

- 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 interview methods involved and **attach copies** of any questionnaires being used.
- 4.4 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, length of proposed storage and method of disposal.
- 4.5 Will any drugs be administered? If so, then the attached Drug Administration Form for trials involving the administration of drugs MUST be completed.

## 5. RISKS AND SAFETY

- 5.1 Who will carry out the research procedures?
- 5.2 Where will the research procedures take place?
- 5.3 Is there scientific evidence of any physical or psychological risks?
- 5.4 What arrangements will be made for monitoring and detecting adverse outcomes?
- 5.5 Will any potential toxins, mutagens or teratogens be used? If so outline the justification for their use.
- 5.6 Will any radiation or radioactive substances be used?

*(Note: If any form of radiation is being used please answer the following):*

- 5.6.1 Under whose license is the radiation being used?
- 5.6.2 Has approval been sought to use radiation in this study?  
If **yes**, please enclose a copy of the approval, and contact name and phone number.  
If **no**, please explain why:
- 5.7 What facilities are there for dealing with emergencies?

B BUDGET AND USE OF RESOURCES

6. BUDGET

- 6.1 Please supply a budget for this study, including a description of all financial support to be received by the researchers, such as fees or expenses.
- 6.2 Does the researcher, the host department or the host institution, have any financial interest in the outcome of this research?
- 6.3 Will there be payments according to the number of participants recruited? If so, please specify.

*(Note: Investigators are entitled to adequate and reasonable reimbursement for their own time on the project. Funds arising additional to actual expenses for the Investigators own time, should be paid to a specified Trust Account.)*

7. RESOURCE IMPLICATIONS

- 7.1 Does the study involve the use of healthcare resources?
- 7.2 What effect will this use of resources have on waiting list times for patients i.e., for diagnostic tests or for standard treatments?
- 7.3 What are the likely benefits to participants?

C PARTICIPANTS

8. SAMPLE

- 8.1 How will potential participants be identified?
- 8.2 What relationship, (if any) will participants have to the researchers?
- 8.3 How many participants is it intended to recruit?
- 8.4 What are the inclusion/exclusion criteria?

- 8.5 How will participants be recruited, e.g. advertisements, notices?  
(Note: Copies of any advertisements/notices to be included with this application)

9. FINANCIAL COSTS AND PAYMENTS

- 9.1 Will there be any financial cost to the participant? Give examples.
- 9.2 Will the study drug/treatment continue to be available to the participant after the study ends?  
If yes, will there be a cost?
- 9.3 Will any payments be made to participants or will they gain materially in other ways from participating in this project?  
If yes, please supply details:
- 9.4 What are the additional benefits to the participants from participating in this project?

10. COMPENSATION OF PARTICIPANTS

Is this a clinical trial as defined in the ICH GCP guidelines?  
If yes, please answer the following:

- 10.1 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?
- 10.2 a) If the answer to 10.1 is NO please proceed to the questions in Section 11.  
b) If the answer to 10.2 is YES, please answer questions 10.3, 10.4 and 10.5.

(Note: This information is also to be included in the Patient Information Sheet)

- 10.3 What type of injury/adverse consequence resulting from participation in the trial has the manufacturer or distributor undertaken to cover?
- a) any injury (mental or physical)
  - b) only serious or disabling injuries
  - c) only physical injuries
  - d) only physical injuries resulting from the trial drug or item, but not from any other aspect of the trial
  - e) physical and mental injury resulting from the trial drug or item, but not from any other aspect of the trial
  - f) any other qualification
- 10.4 What type of compensation has the manufacturer or distributor agreed to pay?
- a) medical expenses
  - b) pain and suffering
  - c) loss of earnings
  - d) loss of earning capacity
  - e) loss of potential earnings
  - f) any other financial loss or expenses
  - g) funeral costs
  - h) dependants' allowances

- 10.5 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).
  - 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?
  - c) Is company liability limited in any other way?

## 11. INFORMATION AND CONSENT

*(Note: 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. A protocol should be attached, indicating the form of words to be used on the Consent Form and on any relevant Participant Information Sheet.)*

- 11.1 Who will explain the project to potential participants?
- 11.2 Is there any special relationship between the person explaining the project, or any of the investigators and the participants (e.g. teacher/student; doctor/patient)?
- 11.3 When and where will the explanation be given?
- 11.4 Will a competent interpreter be available, if required?
- 11.5 How much time will be allowed for the potential participant to decide about taking part?
- 11.6 Will the participants be capable of giving consent themselves?  
- If not, to whom will the project be explained and who will give consent?
- 11.7 In what form (written, or oral) will consent be obtained? If oral consent only, state reasons why.

## 12. CONFIDENTIALITY AND USE OF RESULTS

- 12.1 How will data be handled to safeguard confidentiality (both during and after completion of the research project)?
- 12.2 How long will the data from the study be kept and who will be responsible for its safekeeping?

- 12.3 Who will have access to the raw data and/or clinical records during, or after, the study?
- 12.4 If recordings are made, will participants be offered the opportunity to edit the transcripts of the recordings?  
Yes / No
- 12.5 What will be done with the raw data when the study is finished?

If audio or videotapes are used how will these be stored and disposed of?

- 12.6 Describe any arrangements to make results available to participants, including whether they will be offered their audiotapes or videos.
- 12.7 Is it intended to inform the participants' GP of the results of the investigations, if the participant consents? If NO, outline the reasons.  
*(NOTE: Specific consent to inform the GP should be included on the consent form. If it is regarded as essential to inform the GP, then refusal of a participant should constitute an exclusion criterion)*
- 12.8 Will any restriction be placed on publication of results? If yes, please supply details.

13. CULTURAL ISSUES

*It is important that issues regarding cultural safety are addressed when research involves participants from various ethnic groups. This issue should be addressed even when a minority of participants from other cultural groups are involved. Where a particular nationality is the principal subject of the research, consultations must be undertaken with appropriate parties and this process outlined in the application.*

- 13.1 Are there any aspects of the research that might raise specific cultural issues? If yes, please explain.
- 13.2 What ethnic or cultural group(s) does the research involve?
- 13.3 Describe what consultation has taken place with the group(s) prior to the project's development.
- 13.4 Describe any ongoing involvement the group consulted has in the project.

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

14. OTHER ETHICAL ISSUES

14.1 Do you see any other 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 declaration's page (Part IV) and then enclose a completed Drug Administration Form (if applicable), and appropriate Declarations (if applicable).

# **PART IV: DECLARATIONS**

## **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 FSM Research Ethics Review Committee.

NAME OF PRINCIPAL INVESTIGATOR (PLEASE PRINT):

SIGNATURE OF PRINCIPAL INVESTIGATOR:

DATE:

## **2. DECLARATION BY THE HEAD OF THE DEPARTMENT OR SERVICE MANAGER IN WHICH THE PRINCIPAL INVESTIGATOR IS LOCATED\*\***

I have read the application and believe it to be scientifically and ethically sound. I approve the Research Design. I give my consent for the application to be forwarded to the Ethics Committee.

NAME OF HEAD OF DEPARTMENT OR SERVICE MANAGER (PLEASE PRINT):

SIGNATURE OF HEAD OF DEPARTMENT OR SERVICE MANAGER:

DATE:

\*\* (NOTE: WHERE THE HEAD OF DEPARTMENT IS ALSO ONE OF THE INVESTIGATORS, THE HEAD OF DEPARTMENT DECLARATION MUST BE SIGNED BY THE APPROPRIATE DEAN, OR RELEVANT SENIOR OFFICER)