Form : R1

Ministry of Health
Health Ethics and Research Application Form

PART 1 : BASIC INFORMATION

1 Full Project Title:

2 Short Project Title (lay title):

3 Lead Principal Investigator's Name and Position:

4 Address of Lead Investigator

	Work ph	
	Home ph	
	Fax	
	E-Mail	

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

6 Co-Investigator's name(s) and position(s)

A	
B	
C	
D	

7 Address of co-investigator A

	Work ph	
	Home ph	
	Fax	
	E-Mail	

8 Address of co-investigator B

	Work ph	
	Home ph	
	Fax	
	E-Mail	

9 Address of co-investigator C

	Work ph	
	Home ph	
	Fax	
	E-Mail	

10 Address of co-investigator D

	Work ph	
	Home ph	
	Fax	
	E-Mail	

11 Where this is supervised work, list Supervisors

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

13 Proposed starting date (dd/mm/yy)	
14 Proposed finishing date (dd/mm/yy)	
15 Duration of Project (mm/yy)	
16 Proposed final report date (mm/yy)	

UNDERTAKINGS

1. In signing the application form, all applicants ***UNDERTAKE*** that they will:

Take all reasonable actions to ensure that the Ministry of Health (Tonga)'s contribution to the research is suitably acknowledged in all publications.
Ensure that all research papers (based wholly or partly upon the research will be forwarded to the Ministry of Health (Tonga) upon publication.
Not enter into any commercial enterprise that will, in any way, allow the commercial exploitation of any knowledge gained as a result of this research without first obtaining the Ministry of Health (Tonga)'s authority in writing.

I have read the conditions above and, if this application is successful, I agree to abide by them. I shall be actively engaged in the day-to-day control of the project.

Signature of Lead Investigator : ……. Date : …….

2. In signing the application form, the **Head of Department** ***UNDERTAKES*** that, in relation to any Research resulting from the application, he or she will:

Not benefit personally from any equity interests (substantive or by rights, options or otherwise) as a result of the commercial exploitation of this research to be funded without first obtaining the Ministry of Health (Tonga)'s consent in writing.

I have read the undertakings detailed above and, if this application is successful, I agree to abide by them. I confirm that I have read and support this application and I agree to this research being carried by members of my department, and that all necessary licenses and approvals from my Department/Institution have been obtained.

Signature of Head of Department : …… Date:……

PART II : PROJECT SUMMARY

1. **Multicentre Proposals**

	Yes	No
1.1 Is this a Multicentre study? (if no, go to question 2)	☐	☐
1.2 Has the protocol been submitted to any other Ethics Committees?	☐	☐

2. **Scientific Assessment**

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

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 reported upon prior commencement of the study and by whom?

3. **Lay Summary of Research (200 words maximum, in lay language)**

PART III : PROJECT DETAILS

SCIENTIFIC BASIS

1. **Aims of Project**

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

What are the specific research objectives?

2. Scientific Background of the Research (300 words maximum)

3. Participants

How many participants are it intended to recruit?

How will potential participants be identified?

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

Briefly describe the inclusion/exclusion criteria of participants.

4. Study Design

Describe the methodology, methods for obtaining information as well as methods of analysis. Attach all research instruments including questionnaires, interview guidelines and consent instruments.

Who will carry out the research procedures?

Where will the research procedure take place?

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 labeling, length of proposed storage and method of disposal.

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

If yes, explain how?

	Yes	No
Will any samples go out of Tonga?	☐	☐

If so where, and for what purpose?

5. Risks and Benefits

What are the benefits to research participants of taking part?

How do the research procedures differ from standard treatment procedures?

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

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

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

If yes, specify and outline the justification for their use

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

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

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

6. Expected Outcomes or Impacts of research

What is the potential significance of this project for improved health care for Tongans and non-Tongans/and for the advancement of knowledge?

What steps will be taken to disseminate the research results?

PART IV : BUDGET AND USE OF RESOURCES

7. Budget

How will the project be funded?

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

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, specify:

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

8. Financial Costs and Payments to Participants

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

	Yes	No	N/A
Will the study/drug/treatment continue to be available to the participant after the study ends?	☐	☐	☐

If yes, will there be a cost, and how will this be met?

	Yes	No
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. Compensation for Harm Suffered by Participants

What type of injury/adverse consequence resulting from participation in any trials has the manufacturer or distributor undertaken to cover.

10. Information and Consent

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

When and where will the explanation be given?

Will a competent interpreter be available, if required?

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

Will the participants be capable of giving consent themselves? If not, to whom will the project be explained and who will give consent?

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

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

11. Confidentiality and Use of Results

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

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

How long and where will the data from the study be kept and who will be responsible for its safekeeping?

Who will have access to the raw data and/or clinical records during, or after, the study?

12. Ethical Issues

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

(End)