National Health Ethics and Research Committee (NHERC)

Terms of Reference

To improve the health of Tongans through supporting appropriate high quality health research which is consistent with Tongan People's values and processes.

1. Terms of Reference

1.2 NHERC Functions

a) To review and make recommendations to the Ministry of Health (MOH) on ethical issues in relation to all health research proposals engaging the Ministry of Health on human subjects and human tissues/parts

b) To provide and continually review Ethical Codes and Guidelines for personnel undertaking research with human subjects and human tissue/parts in the Kingdom of Tonga engaging the MOH

c) Development of a national research application form

d) To provide independent comment on ethical problems that may arise in any aspect of health research.

The NHERC in turn will be guided by the principles outlined in the *Universal Declaration of Human Rights (Article 1 to 30: General Assembly of the United Nations: 10 December 1948). Universal Declaration of the Human Genome and Human Rights (General Conference of UNESCO: 11 November 1997)* and relevant Legislation and Policies of the Government of Tonga. Other relevant Guidelines include:-

- *Declaration of Helsinki*, Adopted by the 18th World Medical Association. Helsinki, Finland (1964) and as revised in 1989 by the World Medical Association.
- *International Guidelines for Biomedical Research Involving Human Subjects,* Council for International Organisations of Medical Sciences (CIOMS), Geneva (1)
- *International Guidelines for Epidemiological Research. Council for International* Organisations of Medical Sciences (CIOMS) Geneva (1991)
- *Report on Ethics in Epidemiological Research*. National Health and Medical Research Council, Canberra (1985)
- *Research Involving Patients*. A report of the Royal College of Physicians (1990).
- *Unlinked Anonymous Screening for the Public Health Surveillance of HIV Infections: Proposed International Guideline*. World Health Organization Global Programme On AIDS. Geneva (1989)

e) Non-Tongan researchers must obtain an Ethical Clearance from their respective institution prior such a proposal is forwarded to the NHERC for review

f) Non-Tongan researchers not affiliated with an organization with a Health Ethics and Research Review Committee will apply to the NHERC for such a review

. advising the Minister on national health research policy:

. the fostering and recruitment, education, training, and retention of those engaged in health research in Tonga

. the initiation and support for health research

. the encouragement of initiatives into health research by soliciting research proposals and applications, particularly in areas considered by the Council to have a high priority

. the promotion and dissemination of results of health research and the utilization of these results to the health sciences, health policy, and health care delivery

1.3 Membership

The Interim membership of the NHERC was approved by the National Development Committee meeting of the 26 January, 2001 and consists of the following:-

Chairperson
Dr. Taniela Palu (Chairperson)

Secretary
Sunia Foliaki

Dr. Malakai ‘Ake (CMO PH)
Dr. Bernard Tu’inukuafe (TMA)
Nursing Division (One Representative)
School of Nursing (One Representative)
Dr. Viliami Sikalu (Dental)
Dr. Toakase Fakakovi (Paediatric and Medical Section)
Dr. Semisi Latu (Obstetrics and Surgical Section)
Dr. Siale ‘Akau’ola (Laboratory and Radiology Section)
Dr. Leiukamea Saafi (ENT and Ophthalmology)

Members representing 2 Sections such as Obs/Surgical can have a representative from either Section at any one time meeting (i.e. either an Obstetrics or Surgical representative).

1.4 Operations

Liaisons With Other Organisations

1. The Council shall develop close and supportive relationships with any charitable, private, or other organisations that fund health research.

2. The Council shall set up formal mechanisms of liaison to develop a national health research strategy for Tonga.

3. Liaison under this section may include joint ventures in support of specific research proposals.

4. The Council shall develop and maintain close links with the Ministry of Health and persons purchasing or providing health services to assist those bodies in meeting their research needs.

5. The Council may, by agreement with the Minister of Health or with any person purchasing or providing health services, –

   (a) Act as the agent of the Minister of Health or of the person purchasing or providing health services in letting contracts for health research; or
   (b) Perform the scientific assessment of in-house research carried out by or on behalf of the Ministry of Health or the person purchasing or providing health services."

Partnership Initiatives

The Tonga Health Research Council Partnership Initiatives aims to engage partners with common research priorities and creates a resource pool to focus on agreed research needs. Each initiative is also developed to maximize opportunities for building research competency and capability.

Examples of partnership research priorities are cancer, diabetes and other noncommunicable diseases, disability, health sector reforms.

International Partnerships

The Tonga Health Research Council is to actively engage in fostering and maintaining research collaboration and partnership with international agencies and research institutions in implementing health research activities of common interest. These include regional organizations such as the Pacific Health Research Council, the Fiji School of Medicine, the World Health Organization and other Australian and New Zealand institutions conduction health research .

1.4 Operations

a) The NHERC is to meet on a regular basis and at least once a quarter or as directed

b) The NHERC is to report directly to the National Health Development Committee

c) The NHERC is to monitor all ethical aspects of health research in order to provide timely and appropriate comment on ethical issues.

d) The NHERC submits an annual report by the end of March of each year to the Ministry of Health's Technical Sub-Committee

2 HEALTH RESEARCH POLICY

2.1 Responsible Research (Determining appropriate ethical and professional behavior)

2.1.1 General Principles

a) The Ministry of Health is committed to upholding and promoting the highest standards of research practice. All research undertaken within the Ministry of Health must therefore comply with the requirements of relevant legislation and ethical procedures specific to the area or field of research and to the principles of professional conduct and responsibility.

b) Research workers shall undertaken research only in fields in which they are competent or in which they are provided with appropriate and responsible supervision.

2.1.2 Retention of Data

a) Data generated by research workers be recorded in durable and appropriately referenced form. Any research or ethical protocols under which these data have been obtained may nevertheless condition such a practice. Where research is based on data held by the Ministry of Health, in libraries and archives, it is imperative that those data be accurately and fully referenced.

b) Because of the interest which may follow publication, research workers should ensure that the data on which the research is based are safely held for a period of at least five years from publication

c) Wherever research or ethical protocols under which the research was undertaken allow it, a copy of the original data shall be retained in such a manner that both the research worker and the Ministry of Health can access them in the event of an allegation of research misconduct or related dishonest practices. Data obtained from limited access databases or associated with a contracted project may not be able to retained. In such cases, a written indication of the location of the original data or key information regarding the limited access database from which they were extracted shall be similarly retained. It should be understood that retention solely by the individual research worker does not provide adequate protection to the research worker or the Ministry of Health in the event of an allegation of falsification of data (in which event data should be made available in their original form for review.)

d) Property Ownership

2.1.3 Publication and Authorship

a) Where it is intended to offer for publication a scholarly work that has been derived form a research project, care must be taken to ensure that attribution of authorship of this work is established according to the prevailing protocols for the discipline within which that research has been undertaken. It shall be the responsibility of the principal researcher research team leader, and research supervisor or in the case of uncertainty the Head of Division or Principle Investigator is to ensure that such appropriate authorship is attributed.

b) Contributions to a research project that leads to a publication which do not fit the criteria for inclusion in the authorship of that publication must nevertheless be appropriately acknowledged in the publication. Determination of the appropriateness of such acknowledgement should follow established practice within the research discipline.

c) No person may included as author who has not contributed in substantial way to the conception execution or interpretation of the research work or in the composition of the scholarly publication derived from it. The attribution of "honorary authorship" is completely unethical. This occurs when persons are

listed as authors but have not participated in any substantial way in the conception execution or interpretation of at least pat of the work described in the publication.

d) Wherever appropriate it is prudent for every manuscript to adequately communicate the findings and major conclusions of the research project

e) Offering for publication multiple papers based on the same set(s) or sub-set(s) of data is unethical unless there is complete cross-referencing (for example by reference to a preliminary publication at the time of publication of the complete work which grew form it) Simultaneous submission to more than one journal or publisher of material based on the same set(s) or sub-set(s) of data must be disclosed to the publishers at the time of submission

2.1.4 Management and Supervision

a) Only appropriately qualified and experienced research workers may be assigned to the task supervising the work of other academic staff general staff or students within the context of a research project. Responsibility for selecting the appropriate supervisor shall lie with the Head of Division or NHERC.

b) The number of supervised research workers assigned to any one supervisor at any one time should be limited by the need to ensure effectiveness personal interaction between each such research worker and the supervisor and by the need to maintain effective supervision of the various research projects undertaken

c) Where research is undertaken on a joint basis or as part of a team or co-operative project particularly where general staff or students are involved responsibility for ensuring that the research conforms to the required standards shall lie with the Head of Division

d) Supervisors should be the primary source of guidance to supervised research workers in all matters of sound research practice.

e) Supervisors must ensure that research workers under their supervision have the necessary skills. For example those using statistics should have competent statistical procedures are used.

f) Heads of Division or National Health Ethics and Research Committee (NHERC) in consultation with supervisors must ensure that adequate resources are available for the research to be satisfactorily carried out so as to avoid situations where research workers might engage in incorrect, compromised or unethical research practice. Where a lack of resources is such that the integrity of the research is threatened it shall be the responsibility of the Head of Division or National Health Ethics and Research Committee (NHERC) to ensure that all obligations to third parties and supervised research workers are met

g) It is the duty of supervisors to ensure that work submitted by any supervised research worker for examination publication or incorporation in a joint project is that of the supervised person and that all data provided as part of the work submitted have been validated.

h) Where possible the Head of Division or the National Health Ethics and Research Committee (NHERC) should be personally involved in active research supervision and observe the research activities of those for whom he or she is responsible while ensuring that the rights of research workers under the principles of academic freedom are maintained. Professional relationships should be engaged at all times. In particular there should be wide discussion of the work of all individuals by their peers.

2.1.5 Disclosure of Potential Conflict of Interest

Disclosure of any potential conflict of interest is essential for the responsible conduct of research. Such conflicts of interest are likely to arise when a research worker has an affiliation with family or other personal connection to or financial involvement in any organization or entity which has a direct interest in the subject matter or the provision of materials for the research or which stands to gain materially from the results of the research

3 Research Conduct to be Observed by Research Workers

3.1 General Obligations

a) All research workers conducting research at or for the Ministry of Health are required to observe the highest standards of professional and ethical conduct in relation to that research. They must therefore scrupulously avoid practices of dishonesty fraudulent conduct or misrepresentation of research findings

b) Research workers may participate only in work which complies with established ethical and professional standards and which they are competent to perform as judged by the prevailing standards of the discipline. Prior to embarking on a project research workers must acquaint themselves with relevant legal and ethical protocols relating to the research to be undertaken.

c) Research workers may participate only in work which complies with established ethical and professional standards and which they are engaged.

d) In relation to questions of confidentiality of research data or findings or other information to which they have access in the course of their research all research workers must observe relevant legislation relating to privacy and confidentiality and the provisions of existing Ministry of Health codes and committees.

e) During the course of research confidential information obtained or generated about individuals or groups of individuals must be respected. Research workers

must not use such information for their personal advantage or for any other purpose than that for which it was obtained. Such information may not be passed on to any third party.

f) When participating in joint research projects research workers must make every effort to work co-operatively and collegially with other researchers involved in the project and may not knowingly denigrate disparage or misrepresent the contributions of others. This structure does not preclude robust debate relating to research procedures or outcomes which is essential for the production of quality research.

g) All research workers and particularly those in positions of leadership or seniority within a research project must ensure that credit for work done is appropriately attributed only to the worker or workers responsible for generating it no person may knowingly claim credit for work done by others

h) All research workers shall as soon as practicable disclose to the Ministry of Health via the National Health Ethics and Research Committee (NHERC) any existing or perceived conflicts of interest in relation to the research project in which they may be engaged

4 Dealing with allegations of Misconduct in Research Misconduct in research includes:

a) The fabrication of data including claiming results where they have not been obtained

b) The falsification of data, including fraudulent or improper changing of records

c) Plagiarism including the direct copying of textual materials the use of other people's data without acknowledgement or the use of ideas from other people without proper attribution

d) Misleading ascription of authorship including listing authors without their permission attributing work to others who have not in fact contributed to the research and failing to properly acknowledge work primarily produced by a research student/trainee/associate.

e) Intentional infringements of the Ministry of Health's NHERC practice and codes of ethics and/or other relevant professional practices and codes of ethics.

f) Other practices which deviate in some inappropriate manner from those commonly acceptable within the research community for proposing conducting or reporting research.

g) Misconduct does not include honest errors or honest differences in the interpretation or judgments of data nor matters of personal grievance between individuals.

4.1 Allegations of misconduct in research will be referred to the NHERC.

4.1.1 Protection of Persons

When an allegation of misconduct in research is made all persons who may be affected shall have their rights assessed and properly protected

Persons who may need protection are

- The person making the allegation of misconduct ("the complainant")
- The research workers collaborating with the respondent
- Publishers by whom allegedly fraudulent manuscripts have been or are about to be published
- Funding bodies which have contributed to the research
- The Ministry of Health
- The public

4.1.2 Due Dispatch

A prompt investigation enhances the rights of all affected persons