THE OPERATIONAL FUNCTIONALITY OF THE FIJI NATIONAL HEALTH RESEARCH ETHICS REVIEW COMMITTEE

REPORT ON CONSULTATIONS

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31 October 2017

Contents

Acknowledgements

The consultant wishes to acknowledge the assistance offered by those listed in Annex 1 during his visit to Suva. He is most grateful for the willingness of stakeholders in the ethics review process to express their ideas candidly and to make suggestions for strengthening this process in Fiji.

List of Acronyms

CHRERC	College Human Research Ethics Review Committee of the Fiji National University
CMNHS	College of Medicine, Nursing and Health Sciences of the Fiji National University
DRC	Divisional Research Committee
FNU	Fiji National University
FNHRERC	Fiji National Health Research Ethics Review Committee
IT	Information technology
MOHMS	Ministry of Health and Medical Services
NRC	National Research Council
PS	Permanent Secretary for the Ministry of Health and Medical Services
SOP	Standard Operating Procedures
USP	University of the South Pacific
WHO	World Health Organization
WPRO	Western Pacific Regional Office of the World Health Organization

Consultations

Consultations on the health research ethics review process in Fiji were conducted between 18 and 22 September 2017 in Suva. A list of persons consulted is to be found in Annexe 1. The information and suggestions provided by those consulted have been reported according to a number of themes.

The University of Fiji and the Tisi Sangam College of Nursing and Health Care Education were contacted by e-mail to seek their input, but no replies were received.

At the conclusion of the reporting of each theme a number of recommendations is made.

It should be noted that the present Fiji National Health Research Ethics Review Committee is an interim body. The previous ethics committee in the Ministry of Health and Medical Services was dissolved early in 2016.

Major findings

The Desk Audit and Consultations resulted in the following major findings:

1. A health research ethics review committee is a vital element in the work of the Ministry of Health and Medical Services, which must be assured that research associated with its facilities, staff, patients and data is of an acceptable ethical standard
2. The present interim Fiji National Health Research Ethics Review Committee (FNHRERC) process is not functioning at an acceptable standard and will need to be carefully reformed if it is to be confirmed as permanent. The various problems with the process, and suggested ways of improving it, are presented throughout this report
3. The role of the FNHRERC in the wider governance of health research ethics in Fiji needs to be re-examined to see if it should restrict its reviews to researchers not affiliated with Fiji's tertiary institutions and to negotiate the accreditation of the ethics committees of these institutions to deal independently with their own affiliated researchers
4. Consideration should be given to placing the FNHRERC under the authority of the newly-established National Research Council.

1. Potential models of governance for health research ethics in Fiji

Officers of the MOHMS stressed that their Ministry was ultimately responsible for the ethical oversight of most health research in Fiji since such research mostly occurred in Ministry facilities, used official data, and involved staff and patients in public health facilities. It was therefore vital for the Ministry to be aware of all health research conducted in the country and that there had been adequate ethical oversight had been provided.

The various consultations produced two significant suggestions for health ethics governance in Fiji:

1) Oversight by the National Health Research Council

   Exploring the possibility of placing the Fiji National Health Research Ethics Review Committee under the authority of The National Research Council. This would be in keeping with the model adopted in several countries, where oversight of health research ethics is separated from ministries of health. The FNHRERC would report to the NRC.

2) Accreditation of tertiary ethics committees by the Ministry of Health and Medical services

   Developing a system whereby health research ethics committees at tertiary institutions in Fiji are accredited by the MOHMS to deal with certain types of applications according to a set of guidelines. The FNHRERC would still retain the right to scrutinise all applications but would only actively review particular categories of research, including MOHMS projects and international applications not affiliated with a local tertiary institution. The system used in New Zealand could be adapted to Fijian needs. In New Zealand, a national body requires a checklist to be completed and assesses each committee for accreditation for a fixed period, after which re-accreditation is required. In the absence of legislation giving the MOHMS control over ethics committees in other institutions, such an accreditation process would need to be negotiated with the tertiary institutions.

   The tertiary institutions which would be considered for accreditation are:

   - The Fiji National University
   - The University of the South Pacific
   - The University of Fiji
   - The Tisi Sangam College of Nursing and Health Care Education

Recommendation

1.1 Consideration be given to these suggestions relating to the governance of health research ethics reviews in Fiji.

2. Leadership for strengthening the ethics review process in Fiji

It was generally felt that it will be vital to gain the strong support and endorsement from a high level in both the Ministry and the universities if the ethics review process is to be strengthened.

Recommendation

2.1 The Chair, Secretary of the FNHRERC, and another staff member of MOHMS who has substantial health research and ethics review experience, should be appointed as the leadership team to coordinate the process of reforming the administration and role of the Committee and engaging with stakeholders in health research ethics review in Fiji.

3. The need to ensure that health research ethics governance overseen by the Ministry of Health and Medical Services complies with recent legislation establishing the National Research Council

The National Research Council Act 2017, which came into law in April, poses some uncertainties for health research ethics governance in Fiji. The Act includes health as one of the concerns of the Council and states that the national body will "encourage or promote consideration of ethical issues relating to research and development" (Section 4 b). Section 15 requires researchers to protect the safety of persons and animals. Part 5 of the Act is concerned with misconduct or unethical behaviour and requires the Council to conduct a formal enquiry into any allegation of unethical behaviour and empowers it to "terminate the research or any approval of the research upon receiving evidence of misconduct or unethical behaviour". The detailed wording of these legislative provisions are to be found in Annexe 2.

The Act does not make any provision for ethical review committees, nor does it establish the relationship of the National Research Council to existing ethics review committees. The Ministry of Health and Medical Services was not consulted in the drafting of this legislation.

Recommendation

3.1 The Chair of the interim FNHRERC approach officers responsible for administering the National Research Council Act in the Ministry of Education, Heritage and Arts to seek clarification of the ramifications of the legislation for health research ethics governance in Fiji in general and for the FNHRERC in particular.

4. Referral of applications to the Solicitor-General

The Solicitor-General is responsible for overseeing the legal aspects of health research projects involving MOHMS conducted in Fiji, including research agreements and memoranda of understanding. If the FNHRERC considers it necessary, certain applications are forwarded to the Solicitor-General for action. In extreme cases these might take between 6 and 12 months to deal with.

Recommendation

4.1 The Chair and Secretary of FNHRERC seek to meet directly with the Solicitor-General to clarify the requirements for referring ethics review applications and to develop an agreement for timely responses.

5. Plans for re-organizing the MOHMS governance of research ethics

Although not made public and not yet documented, there has been planning for a new model of health research ethics review by the MOHMS.

It has been proposed that the FNHRERC would primarily play an overarching governance role with a secondary role as a reviewer of applications deemed to be high risk from a biomedical, regulatory or cultural perspective, those involving the staff, patients or premises of the MOHMS and applications from foreign researchers. The FNHRERC would also review applications referred to it from other Fijian ethics committees. There would be devolution of health research ethics to sub-national committees.

A divisional research committee (DRC) of ten members has been established in the Central, Eastern, Western and Northern divisions. Common terms of reference have been developed for these committees. It is proposed that each DRC will also include a sub-committee of 6 members to review ethics applications. This sub-committee is to include someone from a non-health sector background. The chair of each DRC will be an affiliate of FNHRERC. A member of the FNHRERC will, in turn, serve on each DRC. The members of each of these committees is, or will shortly be, receiving research training provided by the Monitoring and Evaluation Unit of the MOHMS. The specific ethics review functions of the DRC functions and training on research ethics are yet to be finalised. Nor have guidelines for ethical health research been developed. Until the DRCs are fully functional and generating research projects, it will not be possible to take the issue of ethics sub-committees further. This is unlikely to be realised in the near future.

In course of consultations, some non-MOHMS members of the FNHRERC expressed reservations about the creation of what is, in effect, four sub-national ethics committees under the auspices of the MOHMS. The new structure might complicate the review process and there might be difficulties in recruiting members in some of the regions.

Recommendation

5.1 The proposal to create sub-national ethics review committees within the MOHMS be set out in a formal document and be subject to a feasibility study which takes into account the problems identified in the interim FNHRERC process and the concerns expressed by some members of the FNHRERC.

6. The need to develop Standard Operating Procedures appropriate to the FNHRERC

It became clear after consulting with the Secretary and members of the FNHRERC that the Standard Operating Procedures were not being followed and the document was not being referred to in the actual running of the Committee. It was also evident that the SOP were unrealistic in terms of the required number of members and the period of notice given of meetings.

Recommendations

6.1 The Standard Operating Procedures should be revised as soon as possible to correct errors, remove conflicting instructions, improve comprehensibility and ensure that they are up-to-date. Section 7 of the Desk Audit identified a number of concerns. Particular consideration should be given to:

- Providing for an increased number of committee members in order to reduce the workload of individuals and ensure that meetings are quorate
- Requiring the appointment of at least one member from a non-health background (eg religious or community leaders).
- Stipulating that notice of at least four weeks be given to Committee members of the intended dates of meetings

6.2 In undertaking the revision of the SOP it is recommended that the guidelines developed by the New Zealand Health Research Council be consulted (see http://www.hrc.govt.nz/sites/default/files/Approval%20guidelines%20-%20November%202012_2.pdf) as they provide a number of practical suggestions for the composition and running of health research ethics committees. A selection of these guidelines is to be found in Annexe 3.

6.3 Consideration be given to contracting a person outside of the MOHMS to develop a draft revised SOP for consideration and further amendment by the FNHRERC.

7. Separating Ministry of Health and Medical Services access permission from the ethics review process

The point was made by several people that applicants whose projects were referred to the FNHRERC because they involved access to MOHMS facilities, staff, patient or data were obliged to undergo a second ethics review despite having their project already approved by their own institutional ethics committee. It was suggested that the process of seeking permission to gain access to MOHMS facilities, staff, patients and data be separated from the ethics review process. This can be achieved by a policy of tertiary institutions' ethics committees only granting ethics approval in cases where researchers have been granted the necessary access approvals by the MOHMS. Such an approach to access permission would solve the problem of duplication in ethics applications and reduce the workload of the FNHRERC. An access application form template would need to be developed for seeking such permission.

Recommendation

7.1 Consideration be given to developing a MOHMS access approval process which stipulates that such approval is conditional upon ethics review clearance by an accredited Fijian committee.

8. The need for standardised guidelines and documentation

It was generally agreed that there is a need to develop health research guidelines which reflect legal, cultural and religious dimensions relevant to the Fijian context. There was strong support for common guidelines for use by all health researchers and health research review committees in Fiji

There was a consensus that the adaption and revision of existing guidelines from Fiji, as well as other countries would allow for a more rapid and cost-effective development of guidelines for use in Fiji.

Support was also expressed for the development of standard documentation content for all ethics applications in Fiji. This would enable a degree of quality control and also avoid duplication.

The documents, which could be used by all ethics committees, are listed and described in Figure One

Table 1: List and description of standardised documents for ethics committees in Fiji

Title	Description
Application form	This document summarises the essential information required by reviewers as well as requiring researchers to acknowledge their legal and ethical obligations in a formal manner
Application form for clinical trials	This document is designed to provide the special information proper to clinical trials, as well as requiring researchers to formally acknowledge their legal and ethical obligations
Low-risk assessment check list	The applicant answers a series of questions about the research to determine if it is low-risk
Participant information statement	Research participants are told in plain language what the research is about, who is conducting it, who might benefit or not benefit from the findings, if they are to compensated in any way for their time, how their consent is to be obtained and that they may withdraw from the research, subject to any time limitations. They are also invited to ask questions about the research and are provided with details for enquiring about the ethics approval process and raising concerns or making complaints.
Informed consent form	Participants who have been given the Participant Information Statement and/or an oral explanation of what is being asked of them in the research, are asked give their consent in writing. The form should be countersigned by the person administering it. The form should also provide for a "tick box" to allow for audio and/or video recording, as well as the taking of written notes.
Withdrawal of consent form	Participants who no longer wish to be involved in the research may choose to indicate this in written form.
Discontinuation of research notification	Researchers use this form formally to notify the ethics committee that their project has been terminated and are required to report any ethical issues.
Ethics progress report	Researchers keep the ethics committee informed of any ethical issues during the research
Ethics final report	A final report on ethical dimensions of the research is made at its conclusion.
Ethics incident report	Adverse events and incidents relating to ethical matters, and the ways these were handled by the researchers, are reported to the ethics committee.
Application for MOHMS permission to conduct research	This form would be used to seek permission to access MOHMS premises, data, patients and staff

Recommendations

8.1 Existing guidelines and documents used in Fiji and by research agencies in other countries be adapted for use in the Fijian context.

8.2 A local person with expertise in ethical review issues and cultural sensitivities be contracted to develop a set of draft guidelines for both researchers and reviewers, as well as the associated documents.

8.3 That this person also works closely with the proposed facilitator of the Workshop proposed in Item 9 to present draft guidelines and documents for the scrutiny of the MOHMS prior to the Workshop being held.

8.4 The Pacific Health Strengthening Policy Unit of the WHO Fiji Country Office be approached by the MOHMS to provide technical assistance with the development of health ethics research guidelines and associated documents.

9. An intensive workshop to finalise research guidelines, a common application form and associated documents

It was agreed by all of these consulted that common guidelines and documentation would improve the conduct of ethical review in Fiji. It was felt that a process was needed to ensure that all revised or newly-developed documents in the Fiji research ethics review process were of an acceptable quality, covered the concerns of all stakeholders and were culturally appropriate. This could be done by holding a one-day intensive workshop at a venue outside of Suva. Stakeholders from the MOHMS, tertiary institutions, the WHO Country Office and other appropriate institutions would be invited to work through the documents. All participants would have been sent the documents well ahead of the meeting and be required to have carefully read them and to have made notes about any concerns. Their list of concerns would be sent to the workshop coordinator and would constitute the agenda for the workshop. The workshop would be facilitated by an independent person not connected to the stakeholders.

The workshop would provide a final check on the content and quality of documents and would also ensure their legitimacy since they would have been endorsed by all health research ethics committees in Fiji.

Practical considerations raised as part of this suggestion included the need to hold the workshop away from the normal environment of participants and to hold it on a Saturday since few of those involved in research ethics would be free on a working day.

Recommendations

9.1 That the FNHRERC develop clear aims for a guidelines and documentation workshop and invite appropriate stakeholders.

9.2 The Pacific Health Strengthening Policy Unit of the WHO Fiji Country Office be approached by the MOHMS to provide technical assistance for a workshop to finalise the development of health ethics research guidelines and associated documents.

10. The consequences of undue delays in reviewing applications and the need for more frequent meetings of the FNHRERC

A number of comments were made about problems caused by delayed decisions on applications. Increasing numbers of postgraduate medical students are required to complete a research project. Some students face reputational and financial harm when their projects are unduly delayed and they are unable to complete their degree in the required time. Some have to pay for a further period of enrolment. In some cases, the delays have led to students undertaking research without ethical approval in the expectation of ultimately obtaining it. One participant in the consultation considered that delays in reviews acted as a disincentive to both students and staff becoming involved in research. It was suggested that the FNHRERC benchmark its performance against examples of international best practice. Claims by some people consulted that delays in reviewing applications had consequences for international researchers seeking visas from the immigration authorities was not supported by the immigration Web site, which made no mention of ethics approval as part of the visa application process.

Several suggestions were made that the FNHRERC should meet more frequently and that a schedule for the meetings should be developed and made public.

Recommendations

10.1 The FNHRERC should meet at least once every two months.

10.2 A schedule of meetings be made publicly available on the Health Research Portal.

10.3 The FNHRERC set benchmarks for the time taken for reviews and make these public.

11. Inadequate human resources for the Secretariat

The Secretariat of the FNHRERC consists of a single officer who is the Secretary to the Committee. This officer currently works in an acting capacity and is also involved in other duties not connected to ethical reviews. Based on discussions with the Chair and Secretary of the FNHRERC, there is a need to strengthen human resources support for the Committee.

Recommendations

11.1 That the Permanent Secretary and Director of Human Resources of the MOHMS consider changing the status of the Secretary to the FNHRERC from “acting” to “confirmed”.

11.2 That a clerical officer be appointed to assist the Secretary.

12. Identifying appropriate reviewers for the full review of applications

Several comments were made about the need for the Secretariat to target the most appropriate reviewers for a particular application rather than requesting all members of the committee to deal with it. One member of the FNHRERC indicated that he was highly selective in responding to e-mails inviting a review and chose only those which he felt competent to deal with. Such comments were at variance with the practice reported by the Chair, who observed that “lead reviewers” are nominated but the application is also to given to all members of the Committee to provide them with the opportunity to comment.

Recommendation

12.1 Consideration be given to establishing a clearly articulated policy of identifying and appointing a pair of lead reviewers for each application. These committee members would lead the discussion of the application. Other members would be able to express their views if they so wished, thereby fulfilling the requirements for a full review of the committee

13. Provision of health ethics training and education

A number of those consulted expressed the view that health research ethics awareness and understanding was not strong in Fiji and that the consciousness of researchers about ethical uses needed to be raised. It was accepted that training and continuing education should be provided for existing and future members of ethics review committees. There is also a significant need for ethics committee members to be familiar with cultural and religious considerations in health research.

Staff with ethics expertise at the FNU and USP could be asked to contribute to health research ethics training and education. One such staff member with demonstrable expertise is Mrs Etivino Lovo, a research fellow at FNU who holds a master's degree in research ethics; she was recently a Visiting Scholar at James Cook University in Australia where she developed teaching modules on ethical health research. These are designed to recognise Pacific values and to relate universal ethical themes to the local contexts. She has developed a four-unit postgraduate certificate in research ethics for which endorsement is being sought at the FNU. These units could be presented in full, or in part, for the purpose of in-house training and continuing education.

It was also argued by some people consulted that health ethics training and education should be part of the syllabus of tertiary institutions or a requirement for all tertiary researchers both students and supervisors. Such training and education could be made part of formal degree programmes or offered as an ethics integrity module. It is noted that both the FNU and USP both have Moodle capacity to offer such a module on-line.

There are also free on-line courses in health research ethics which could be used, although their cultural context is not always appropriate to Fiji. Provision of ethics and training by universities could be made mandatory for their health research ethics committees to gain accreditation.

Recommendations

13.1 Health research ethics training and continuing education for FNHRERC members and support staff be strengthened.

13.2 The Pacific Health Strengthening Policy Unit of the WHO Fiji Country Office be approached to offer technical support for training and continuing education programmes for members and support staff of FNHRERC.

13.3 FNHRERC approach a suitably qualified person with local cultural knowledge to develop sessions to support the training and continuing education of members and support staff of health ethics committees in Fiji.

13.4 The Secretariat of the FNHRERC explore appropriate free on-line courses on health research ethics and present a description of these to the FNHRERC for its consideration as one of the means of training new members.

14. The Health Research Portal

The Health Research Portal is available on the Web sites of both the MOHMS and the Government of Fiji. It was generally felt that the Portal has a number of valuable functioning features (lists of topic, details of projects and register of researchers) but needed considerable further development to make it fully functional. There was also a general agreement that the Portal has the potential to make available to Fijian researchers a range of material on health research ethics from international sources.

As well as the problems reported in the Desk Audit, participants in the consultation identified a number of serious deficiencies in the Portal:

- Applicants who choose to submit their applications to CHRERC through the Portal have not successfully submitted them since the Secretariat of CHRERC is unable to access the submission site. Moreover, the Secretariat of FNHRERC is also unable to access applications submitted to CHRERC
- Revised applications cannot be downloaded by the Secretariat of FNHRERC.
- For almost two years the Secretariat of FNHRERC has been unable to upload reports on completed research
- The Portal does not display the current status of an application (approved, sent for revision or rejected)
- The availability of the Portal on the Fiji Government Website is variable due to problems with that site

A major issue to be resolved is the ownership of the Portal. Since its development in partnership with WPRO, all of the officers involved in its development have moved to other positions. There has been a loss of corporate memory. The present Acting Secretary to FNHRERC has raised a number of technical problems concerning the Portal with MOHMS IT staff but has been told that they did not have the code to gain access in order to alter its functions. The MOHMS apparently considers to Portal to still be under the control of WPRO. For its part, WPRO considers that it has assisted in the establishment of the Portal, handed control to MOHMS and left the access code with officers of the Ministry.

Recommendations

14.1 The question of the ownership of the Portal be settled by WPRO providing written confirmation that the Portal was handed over to MOHMS, as well as providing the necessary access codes.

14.2 The Pacific Health Strengthening Policy Unit of the WHO Fiji Country Office be approached to offer technical support for further developing the functionality of the health research portal with particular attention to the problems identified above.

14.3 The MOHMS ensures that the Portal has the documents and instructions necessary for the submission of applications for ethics reviews and also provides links to a range of health research ethics resources, including those identified and recommended in Section 9.1 of the Desk Audit.

14.4 In order to assist with the improvement of the Portal, the Secretary of FNHRERC prepares a short report listing the Portal's technical deficiencies and new functions which should be introduced.

15. Charging fees for ethics review

The possibility of charging fees for reviews when they involved commercial gain was raised during consultations but received little support. No commercial research had been submitted for approval by FNHRERC. There might be a rationale for allowing commercial entities to be charged for ethical research reviews, since to not do so would constitute a state subsidy for their development of new therapeutic products. It was noted that it is common practice of hospital ethics committees in the several countries to charge a commercial cost recovery rate to certain applicants. There is also a case for large foreign-funded projects to be charged an ethics review fee as this cost can be included in the project budget in much the same way as is done for the costs of open access publication of research findings.

It was noted that international researchers are charged a fee for registration by the Education Ministry for registration and approval of research projects, so the MOHMS was reluctant to impose a further financial burden on researchers.

Recommendation

15.1 Consideration be given to including provisions for a review fee for commercial projects and those funded by international agencies or research bodies in anticipation of such applications in the future.

16. Problems recruiting members to serve on the FNHRERC

It was noted that a number of non-MOHMS committee members had given generously of their time to review ethics applications and that this work is not remunerated. Moreover, such service is not accepted for professional development points for medical members, despite an approach by the FNHRERC to the local medical association to give a degree of recognition for such work. For staff of the MOHMS, committee service is usually an added duty at a time of staff shortages.

It was reported that attempts to recruit community members for the FNHRERC had not been successful. A low response rate to invitations was recorded and there was ultimately no community member appointed. It was suggested that potential volunteers be reminded that they would be eligible to a transport allowance to assist with attendance. Some form of ceremony, as well as the issuing of certificates of appreciation, was suggested as a way of ensuring that committee members felt acknowledged for their valuable contribution. It was also suggested that appropriate civil society umbrella organizations and religious training bodies might be approached with the request that they nominate people to serve on health research ethics committees

It was felt that the FNHRERC needed to consider various ways to attract new members.

The PS had written to Fiji's universities early in 2017 seeking cooperation in recruiting ethics committee members but had not received any replies.

There is potential for middle-level academics to be recruited and it is important for institutions of higher education to ensure that such service is adequately recognised for the career development of participating staff. Retired academic and civil service staff could also be approach. It was also suggested that some general practitioners might be interested in becoming reviewers. A short information piece on the work of FNHRERC and the role of volunteers could be sent to the

professional newsletters of the medical and allied health associations in Fiji in order to generate interest in volunteering for committee service.

Recommendations

16.1 The leadership team of the FNHRERC:

- identify and invite potential reviewers from among academic staff at tertiary institutions, retirees from academia and the civil service, community leaders, and general practitioners
- prepare a short description of the work of the FNHRERC and an expression of interest and request the editors of medical and allied health professional newsletters to assist with publication
- arrange for some form of annual recognition ceremony at which a certificate of appreciation is awarded to those who have served on the Committee
- ensure that the provisions for financial remuneration for travel costs are made known to committee members and that such remuneration is paid all non-MHMS committee members who request it.

17. The need for cooperation between the MOHMS and higher education institutions in Fiji.

Consultations were held with representatives of the ethics committees of the College of Medicine, Nursing and Health Sciences, Fiji National University and the University of the South Pacific.

University of the South Pacific

Professor Jito Vanualailai, Director of Research at the USP, explained that his university has a generic ethics review system which included consideration of health research. High risk applications were referred to the USP ethics committee which meets fortnightly. USP conducts some health research and has had collaborations with the College of Medicine, Nursing and Health Sciences FNU and international researchers. The Solomon Islands campus will offer courses in public health. Some students and staff of this campus may become involved in Fiji-based research.

Professor Vanualailai noted that health researchers were advised that they needed FNHRERC clearance after they had been reviewed by the USP committee.

Professor Vanualailai indicated that he was amenable to a meeting of chairs of Fijian ethics committees to explore how these committees could cooperate and develop shared standard documentation. He was also favourably disposed to the possibility of ethics committees at tertiary institutions being accredited by the FNHRERC

College of Medicine, Nursing and Health Sciences, Fiji National University

A meeting was held with Dr Wayne Irava, Chair of College Human Research Ethics Review Committee. He explained that the College of Medicine, Nursing and Health Sciences has recently revised its Standard Operating Procedure (SOP), which will operate in a pilot phase for a year in order to allow revisions. Comments and suggestions for improvement have been invited. The College Human Research Ethics Review Committee (CHRERC) has also set revised targets for the processing of applications at a maximum 7 days for low risk and 30 days for high risk. The committee is answerable to staff and students of the FNU for its performance according to these benchmarks. In

order to reduce the risk of bias in CHRERC, the revised SOP requires non-FNU members to be recruited from the community.

CHRERC is planning to recognise the work of its members by presenting them with a certificate of appreciation at a formal ceremony at the end of each year.

All ethics committee members are required to complete an on-line health research ethics course. It was noted that these courses were designed for a Western cultural context so did not provide cultural content relevant to Fiji.

When discussing CHRERC's relationship with the Ministry of Health and Medical Services and the Fiji National Health Research Ethics Review Committee concerns were expressed about securing the attendance of Ministry staff who were members of the FNHRERC, at meetings of the College ethics committee. The CHRERC meets ten times each year but since January 2016 only one FNHRERC representative has attended and this was for a single meeting.

On the question of providing training and support in ethical research it was pointed out that the College of Medicine, Nursing and Health Sciences could make a significant contribution since it already embeds ethics into its research capacity building workshops, as well as in its research course. CHRERC also includes ethics continuing education in its meetings, at the end of which, a committee member is invited to give a 10-15 minutes' presentation on a topic of relevance to ethics and this was followed by a general discussion.

The issue of duplication of functions was raised, since some FNU members of the interim FNHRERC are presented with applications that have already gone through CHRERC.

The Health Research Portal did not allow applicants to link directly to CHRERC. In order to better monitor and evaluate its activities, CHRERC was considering establishing its own Portal on the Web.

A number of suggestions were made for strengthening the ethics process in Fiji:

- There needs to be better and more frequent communications between CHRERC and FNHRERC, including meetings of the chairs of each committee
- The MOHMS should ensure that a MOHMS member of the FNHRERC attends each meeting of CHRERC
- FNHRERC needs to meet more regularly
- The Health Research Portal needs to be accessible to the administrators of CHRERC
- FNHRERC could accredit health research ethics committees in Fiji to carry out reviews, subject to:
    - clear guidelines about which sort of applications should be sent to FNHRERC and
    - the provision of details of all approved applications to FNHRERC so that they can be scrutinised if this is required
    - monitoring of the performance of accredited ethics committees by the FNHRERC
- The development of common pro forma documents (eg application for ethics review, participant information sheet, consent and withdrawal of consent forms) which could be used by all committees

Recommendation

17.1 A 'summit' meeting be held between the chairs of FNHRERC, CHRERC and the ethics committee of the University of the South Pacific to explore how the three committees can cooperate and benefit from the synergy thereby created. The agenda for the meeting might include:

- The possibility of the MOHMS accrediting university ethics committees to deal with most types of applications
- Clearly establishing which kinds of research project require FNHRERC consideration
- A common application form and associated pro forma documentation for all health research review applications
- Development of common national guidelines for ethical health research in Fiji for both researchers and reviewers
- Recruitment of ethics review committee members
- Ensuring that a representative from each university sits on the FNHRERC
- Developing a list of ad hoc consultants who can be called upon for expert advice by each of the three committees
- Co-operation on ethics training and continuing education for committee members

Annex 1. List of consultations

Ministry of Health and Medical Services members of the Interim Fiji National Health Research Ethics Review Committee

Mr Shivnay Naidu, Chair

Ms Rosimina Tubuitamana (Secretary)

Dr Devina Nand

Ms Silina Waqa

Dr Shrish Acharya

Mr Pranil Maharaj

Ministry of Health and Medical Services

Ms Mere Delai (Public Health Research Officer [Project] and Secretary of a previous FNHRERC)

College of Medicine, Nursing and Health Sciences, Fiji National University

Dr Wayne Irava, Chair of College Human Research Ethics Review Committee

Mrs Etivina Lovo, Research Fellow, Bioethics and Professionalism

The University of the South Pacific

Professor Jito Vanualailai, Director of Research

World Health Organization

Dr Kunhee Park, Technical Officer

Dr Changgyo Yoon, Technical Officer, Health Service Delivery

Dr Corinne Capuano, Director, Fiji Country Office

Annex 2. Sections of the national research council act 2017 relevant to the governance of research ethics

PART 2—NATIONAL RESEARCH COUNCIL
Establishment of the National Research Council

9 (e) ensure that research is conducted in accordance with the highest ethical, human welfare and environmental protection standards;

PART 5—MISCONDUCT OR UNETHICAL BEHAVIOUR
Misconduct or unethical behaviour

25

(1) Complaints alleging misconduct or unethical behaviour must be made in writing to the Council and the Council must conduct a formal inquiry into the allegation.
(2) Following a formal inquiry under subsection (1), the Council must make a decision to—
(a) not take any action against the alleged person and close the matter;
(b) terminate the research or any approval of the research upon receiving evidence of the misconduct or unethical behaviour; or
(c) remedy the situation as may be required by regulations.
(3) In this section—
(a) "misconduct" or "unethical behaviour" means a breach of a provision of this Act, including the following—
(i) fabrication, falsification or misrepresentation in reporting or of any finding or result;
(ii) plagiarism;
(iii) misleading ascription of authorship;
(iv) failure to declare and manage conflicts of interest without any reasonable excuse;
(v) falsification, misrepresentation or deception in a proposal to obtain funding;
(vi) compromising the safety of human participants, or the wellbeing of animals or the environment;
(vii) negligence of the obligations and duties under the Act; and
(viii) wilful concealment or facilitation of research misconduct by others;
and
(b) "research misconduct" does not include honest differences in judgment in management of the research project, and may not include honest errors that are minor or unintentional.

Annex 3. Selected Health Research Council of New Zealand Guidelines for Approval of Ethics Committees

4.2 Membership

a) Guiding principle

The primary guiding principle for appointing members to the ethics committee is to ensure that the committee has the appropriate expertise, skills, knowledge and perspectives to conduct ethical review of the best quality.

Membership should be capable of ensuring a review which is robust, expert, and includes an element of independence.

Members should possess an attitude that is accepting of the values of other professions and community perspectives, and it is important for committees to be comprised of people from a range of backgrounds, expertise and ethnicities.

Despite being drawn from groups identified with particular interests or responsibilities in connection with health and community issues, appointed members are not in any way the representatives of those groups. They are appointed in their own right to participate in the work of the committee as equal individuals of sound judgement, relevant experience and adequate training in ethical review.

b) Lay/non-lay membership

The ethics committee should have a lay Chairperson and a non-lay Deputy Chairperson. HRC Guidelines for Approval of Ethics Committees

4.3 Policies and procedures

The organisation that sets up the ethics committee has the responsibility to establish the necessary policies to govern the ethics committee. To ensure efficient operation, the policies and written procedures adopted by the ethics committee should be reviewed periodically as part of an ongoing assessment of performances and outcomes, to determine whether any revisions are needed.

Through the process of approval, the HRC EC will review the policies and procedures of the ethics committee and may suggest revisions if necessary for the ethics committee to be approved.

The policies and written procedures must include the following topics: HRC Guidelines for Approval of Ethics Committees

a) Terms and conditions of appointment

The HRC EC takes the view that a systematic turnover of members is important for the effective functioning of an ethics committee over time. The terms of office of members shall be staggered to ensure continuity of membership.

HRC EC recommends that members of an ethics committee be appointed for up to three years, with reappointment to a maximum of six years in total, and that three years should elapse before a further term of appointment. However, the HRC EC is aware that there may be practical difficulties in recruiting members in some categories, and of the value of experienced members of the committee, and so the HRC EC will consider an extension of an appointment beyond six years where the effectiveness of the committee would otherwise be compromised.

b) Training

The HRC EC expects an ethics committee to provide appropriate training for new members and on-going training for its existing members throughout the terms of office.

c) Chairperson

The committee should be chaired by a lay person with no primary background in health research or with no affiliation to the institution or organisation that is responsible for the committee. The chair needs to have established skills in consensus decision-making.

If it is not possible or feasible to appoint a lay person as the chairperson of an ethics committee, the situation should be managed appropriately with a comment in the annual report detailing the processes the committee adopts for dealing with perceived, potential or actual conflicts of interest.

d) Review processes

The HRC EC has a preference for ethics committees to meet face-to-face because it believes that such interaction best ensures robust and thorough review. However, other means of review will be considered for approval. The HRC EC recognises that ethics committees may adopt a range of review processes, such as:

i) all applications reviewed by committee members by email and only those with queries discussed at face-to-face committee meetings;

ii) some applications reviewed by subcommittees of the approved ethics committee, and

iii) low risk applications reviewed by departments/schools with a list sent to the approved ethics committee.

For approval, the HRC EC must be satisfied that the process ensures robust ethical review. The ethics committee will need to provide convincing evidence that this is the case.

e) Decision making process

The HRC EC prefers consensus decision-making wherever possible, because it believes it is more likely to reflect the full range of views on the committee. Consensus does not require that all members support the decision, but that all members consider the decision acceptable. In order for an ethics committee to be able to function with a consensus decision making approach members of committees must be free to participate fully in discussion and debate. It is particularly the role of the Chair to ensure this happens.

On occasion, individual members may wish to abstain from some or all of the decision making process because of strong personal, moral or religious reasons. Such abstentions shall not affect the approval process.

Other methods of decision making are possible (such as voting by a simple majority of members present with the chair having a casting vote) but these need to be justified and pre-defined for approval.

f) Consultation outside the committee

The HRC EC encourages committees to have members with a range of relevant expertise, experience and understanding, but recognises that on occasion a committee may feel the need to consult outside their regular membership. This consultation may be either on ethical or on more technical issues. For example, on ethical issues this may be with individuals, groups, iwi and hapu. The HRC EC supports and encourages such consultation. However, the confidentiality of the proposal and details of the issue under appraisal must be protected.

Where there is insufficient expertise on the committee to assess an application properly or address an issue raised, the ethics committee should seek additional expert advice. Such experts may be invited to attend a relevant meeting to provide advice, but they should not be present during committee deliberations.

g) Other processes

To be approved, an ethics committee will need to detail any variations to normal processes of review, for example, fast-track (expedited) review, variations for particular protocols (e.g. student research projects, key informant interviews), chair's action, and so on.

The HRC EC will need to be satisfied that a complaints procedure for the research participants, researchers and other interested parties is in place.

In relation to research involving Māori, it is important that Māori expertise be available to ensure that all issues are appropriately considered. Where it is not possible for Māori members to attend a meeting or for those members' views to be sought and represented at the meeting, the matter should be deferred.

h) Documents required

The HRC EC requires a complete set of policies and procedures outlining:

i) the functions of the committee;
ii) the Terms of Reference of the committee
iii) the decision making process;
iv) the process for ensuring there has been appropriate peer review of the research proposal;
v) the method of submitting and reviewing application;
vi) the kind of applications which require ethical approval;
vii) the details of research activities for which ethical approval would not be required;
viii) the descriptions of normal procedures for review;
ix) the descriptions of any variations to the normal procedures and the types of research protocols that can be reviewed under these variations (e.g. review under departmental level, by delegated or subcommittee; expedited review; low risk review);
x) the details of the complaints procedure;
xi) the details of the lines of reporting and responsibility to and from the ethics committee, in respect of its parent body and any sub-committees (inclusion of a structure diagram is encouraged).
A layperson is a person who:

- has no affiliation to the institution that sponsors, funds, or conducts research reviewed by that committee, and
- is not a registered health practitioner, and has not been a registered health practitioner at any time during the five years preceding in the date of their appointment, and
- is not involved in conducting health or disability research, or employed by an organisation whose primary purpose relates to health and disability research, and
- may not otherwise be construed by virtue of employment, profession, relationship or otherwise to have a potential conflict or bias with the work of the committee.

c) Composition of ethics committee

The membership requirements must be "fit for purpose" and set out in the Terms of Reference of the committee.
Membership must reflect the knowledge and expertise that an ethics committee requires to ensure (1) protection of research participants, and (2) the enhancement of public confidence in the system of ethics review.
An ethics committee should take the following factors into consideration when appointing members.
i) Committees must be large enough to ensure that a range of perspectives, experience and expertise are represented in the ethical review. Where relevant to the committee's scope of work, members should include individuals with experience and expertise in:

- a recognised awareness of te reo Māori and the understanding of tikanga Māori,
- ethical and moral reasoning,
- law,
- the perspectives of wider community (e.g. the perspectives of consumers of health and disability services, ethnic community)
- the design and conduct of intervention studies,
- the design and conduct of observational studies,
- the provision of health and disability services,
- reviewing either qualitative or quantitative research,
- the perspectives of student community.

It is important to note that a person could fall into more than one of the above categories.
ii) The quorum for any meeting must be at least half of the appointed members (including the chairperson or acting chairperson).

iii) An ethics committee that reviews health research must appoint sufficient members whose background is not in health research to ensure that they feel comfortable voicing their views.
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iv) For ethics committees that review low risk health research, the HRC EC requires two appropriately qualified health professionals, one clinically trained and one in active practice.

v) Gender balance of an ethics committee should be as close to half male and half female as practicable.

vi) In some situations a conflict may arise in terms of appointment of new or replacement members where it is not possible to comply exactly with the requirements of the *Approval Guidelines*. An example of such a situation would be where both a member with science expertise and a Māori member need to be appointed and the appointment of a lay member would unbalance committee membership. The HRC EC expects that as a general principle, the appointment of the Māori member will take precedence over other considerations of balance. The lay/non-lay and gender balance of the committee will be taken as secondary issues in this instance. The order of priority is - Māori, gender, lay versus non-lay, other cultural considerations.

d) Documents required
The HRC EC requires a list of members of the committee indicating:
i) the status of each member of the committee as lay or non-lay ;
ii) the areas of expertise or experience which each member brings to the committee (e.g. ethics, law, Tikanga Māori, qualitative research, quantitative research, community involvement (state wider, Māori or student community), medical practice, health research);
iii) the gender of each appointed member;
iv) the membership start and finish date of each appointee;
v) how the member was appointed (e.g. public nomination and interview by committee member(s), nomination by a professional body (state which), nomination by institution); and
vi) a short biography for each member

SOURCE: Health Research Council of New Zealand, HRC Guidelines for Approval of Ethics Committees (Approval Guidelines)
Available at: http://www.hrc.govt.nz/sites/default/files/Approval%20guidelines%20-%20November%202012_2.pdf)