National Consultation on Ethics and Governance of Human Research in Fiji

Organized by the Research and Innovation Unit, Ministry of Health and Medical Services, Fiji

In Partnership with the World Health Organization (WHO) Suva, Fiji

Venue: Tanoa International Hotel, Nadi
Date: 26th-27th March 2019

WORKSHOP REPORT

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WELCOME REMARK

Photo:

Welcoming remark was delivered by Dr Eric Rafai.

Dr Rafai began by quoting, "*Wherever the art of Medicine is loved, there is also a love of Humanity*." Hippocrates. He stated that the quote applies to the workshop, in regards to "*Love for humanities, love for people of Fiji, the people that we serve which is the pre-requisite to think of other people*".

He extended a warm welcome, to the Honourable Minister of Health and Medical Services who was also the Chief Guest. He acknowledged colleagues from WHO, Dr Changgyo Yoon who is representing Dr Corinne Capuano, Director of Pacific Technical Support and WHO Representative to the South Pacific Office. Dr Rafai further acknowledged members of other Government Ministries like the Ministry of Education Heritage and Arts, patrons, academics, media personnel, who were there for the concerns for Human Research Ethics and the welfare and protection of people from unsolicited research practices.

Dr Rafai, delivered a formal introduction of the Chief Guest the Honourable Minister of Health, Dr Ifereimi Waqainabete and read a short description of his credentials which included former senior member of staff of the College of Medicine, Nursing and Health Sciences, School of Medical Sciences, professional appointments include being a member of International Society of Surgery, President of the Pacific Islands Surgeon Association, Fiji Medical Association, a general surgeon with specific interest in gastrointestinal, breast and endocrine surgery, senior academic at FNU, former Honorary lecturer at the University of Otago and former Senior Medical superintend of Colonial War Memorial Hospital.

OPENING ADDRESS BY THE HONOURABLE MINISTER FOR HEALTH AND MEDICAL SERVICES

Minister for Health and Medical Services

Honorable Dr Ifereimi Waqainabete

National Consultation on Governance for the National Human Research Ethics in Fiji

Tanoa International Hotel, Nadi, 26th March 2019

Bula and a warm welcome to you all. It is an honour for me to be here to officiate in the opening of a discussion forum that will have as its final outcome the establishment of a proposed new Governance System for Human Research Ethics in Fiji. As a basic principle according to the World Health Organisation (WHO), research ethics governs the standards of conduct for scientific researchers. The intent is to enable researchers to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants, especially in communities around Fiji. In-light of the above, it is only proper that all research involving human beings should be reviewed by an independent Research. Ethics Committee (Bossert & Strech), to ensure that the appropriate ethical standards are being upheld.

It is equally important that the Research Ethics Committee exists under a national policy or legislative framework that has an appropriate and sustainable system to monitor the quality and effectiveness of research ethics review with prescribed guidelines and standards. These guidelines should help promote the ethical conduct of research and protect the rights and well-being of research participants and communities. A key component of research ethics guideline is that research should be subject to the outcome of an independent ethical review by a competent REC, and not after the research began or has been completed. Furthermore, research should not be reviewed or approved by any other authority or through any other means, and certainly not through a request to my office which used to happen in the past, and it's something that I will never accommodate moving forward. The intention of the review by the Review Ethics Committee is to ensure that the ethical principles and practice put forward in the guidelines are complied with in the proposed research.

I have to admit that I have experienced first-hand the cumbersome process and procedures that is frequently encountered in connection with the National health research ethics in the recent past in my previous capacity as a professor at the College of Medicine, Nursing & Health Sciences of the Fiji National University.
Therefore, earlier into my tenure as the Minister for Health & Medical Services, I visited a few of the academic institutions and conversed with its senior members to discuss their issues and work out possible solutions. It seems that the problem remain the same, primarily the unnecessary long process it took for approval by the Ministry of Health & Medical services and with no resolution in-sight for many years, which was highlighted through the office of the Permanent Secretary as a crucial problem that eventually led to this two-days event.

In this workshop, I challenge you to work with our team from the Health Research & Innovation unit, the WHO technical advisor Dr Yoon and consultants to come up with a new system of Human Research Ethics Review that is adaptable, efficient, effective but robust enough to protect our Fijian population from any harmful research. I urge you to consider in your deliberations the greater good and the final outcomes this Human research ethics will achieve for all Fijians, and in saying that, requesting you all to briefly put aside your individual and institutional interests and let's focus on building this in the next two days.

Having said that, ladies and gentlemen, it gives me great pleasure to officially open this workshop on the '*Proposed New Governance System and Processes for the Ethical Review of Human Research in Fiji'*.

VINAKA VAKALEVU AND I WISH YOU ALL THE BEST

REMARKS BY DR CORINNE CAPUANO, WHO REPRESENTATIVE FOR THE SOUTH PACIFIC

The message from Dr Capuano was delivered by Dr Changgyo Yoon from WHO South Pacific Office. Dr Yoon conveyed an apology from Dr Corinne Capuano, WHO Representative for the South Pacific and said that he is privileged to be representing Dr Capuano in this meeting. Dr Yoon respectfully acknowledged the Honourable Dr Ifereimi Waqainabete, Minister for Health and Medical Services, Representatives from the Ministry of Education, Higher Education Commission and Immigration Department, Representatives from Fiji National University, University of South Pacific, and University of Fiji, Ladies and gentlemen.

Bula vinaka and very good morning to you all. It is a great privilege to be here alongside the Honourable health minister, Dr Ifereimi Waqainabete, and representatives from other ministries and educational institutions, on behalf of Dr Corinne Capuano, WHO Representative for the South Pacific.

Today, we gathered here to talk about how to strengthen health research ethics in Fiji. We all understand that adhering to ethical principles is critical to protecting the dignity, rights and welfare of research participants. Since 1964, when the World Medical Association adopted the Declaration of Helsinki to set ethical principles for medical research involving human subjects, the World Health Organization has been supporting Member States to comply with these standards, and to develop national capacities to mainstream the principles of health ethics in health education and research. In Fiji, WHO and the Ministry have worked together to establish the Fiji Health Research Portal to help operate health research ethics committees since 2014 and conducted a study to review the national health research ethics committee in 2017.

Health ethics is an interdisciplinary field encompassing a broad range of domains and issues. In health research, key questions also include: what value does the research have for communities, who benefits, how are the participants chosen, and how are the rights and well-being of participants protected? In 2017, WHO and UNESCO convened the Asia Pacific regional meeting for national ethics/bioethics committees. During the meeting, Member States recognized that health ethics is integral to the attainment of the Sustainable Development Goals (SDGs), as ethical consideration must include a focus on the shape of health policy and practice that are keys to achieving health related SDGs. Ethics underpins SDG 3 in that, ensuring "no one is left behind" as we work to attain the goal of universal health coverage means that we need to invest more in health research, especially research that helps to understand the disparities in health outcomes – generating disaggregated quantitative data, as well as qualitative data that help to explain the quantitative findings.

From a public health perspective, research ethics considers risks and benefits to society in addition to the individual research participants. Health research aimed at protecting the population as a whole needs to consider how the benefits and burdens of research can be shared fairly across society. We have witnessed evolutions in bioscience that have made it possible to treat some diseases that were considered untreatable in the past. However, this evolution also challenges us to tackle new bioethics issues difficult to address within existing ethics frameworks. These challenges include questions as to: how personal genetic or health information should be collected and managed, how newly emerging medical resources should be distributed, and so forth. Ladies and gentlemen, though we anticipate challenges upcoming on health ethics, I want to commend all participants here for this gathering and strong interest on improving health ethics review process that is a practical key to protecting our people in doing health research. I expect that the results of this workshop may contribute to improving health ethics review process of other countries in the region. It is very crucial to have a regional context in improving health ethics as it relates ethnical, cultural consideration in review process.

We look forward to continue working together with all partners on health ethics. Let me conclude by sincerely wishing you a successful workshop.

Thank you.

1. INTRODUCTION

The workshop was implemented based on activities recommended by the Asia Pacific Regional Meeting for National Ethics/Bioethics Committees (AP-NEC) convened by the WHO Regional Office for the West Pacific in Seoul, Republic of Korea in 2017. The meeting participants discussed the capacities of health ethics of the countries and agreed that there are significant variations in institutional structures and capacities. They stated that "*emerging technologies, resourcing of ethics systems and health inequalities both within and between countries are common issues across the region*". Member States were encouraged to do the following;

i. Strengthen national ethics/bioethics committees through improved policy, more administrative support and better integration with trends in health care
ii. integrate ethics training in curricula for public health, clinical care, and research
iii. to support research that has a focus on reducing health inequality, and continue to recognize, refine and incorporate into their structures and processes the way they deal with cultural dimensions in the health and health ethics space; for advanced countries, to support and mentor countries (e.g. Pacific island countries) in developing their national health ethics frameworks; and to strengthen national and regional networking and sharing.

WHO was requested to provide technical assistance to Member states in mainstreaming health ethics into national health policies and adapt ethics training materials for implementation in countries to conduct mapping of processes in countries and across countries; to develop an assessment tool for protocols and provide technical assistance to countries in revising/updating guidelines and creating standard operating procedures (SOPs) for research ethics committees (WHO Regional Office for the Western Pacific, 2017). WHO conducted a baseline study to review available resources of health research ethics. The review exercise looked at Research Ethics Committees at Fiji national government level and Fiji universities. This work generated an evaluation report suggesting recommendations to optimize the health ethics review process in the country. It includes revising templates and guidelines, standard operating procedures, reorganizing governance, and providing practical models for the Research Ethics Committees.

The Fiji Ministry of Health and Medical Services, held a technical consultation workshop at the Tanoa International Hotel, Nadi on 26th-27th March 2019, engaging various stakeholders who are involved in human research in Fiji, to inform and discuss processes and new directions of strengthening the Fiji Human Research Ethics governance mechanisms.

2. OBJECTIVES

i. To conduct a consultation meeting about the Fiji Human Research Ethics Governance and Review mechanisms.
ii. To implement the accreditation of the Human Research Ethics Committee in Fiji that met national and international standards.
iii. To build capacity and awareness on Human Research Ethics Guidelines and Review Processes in Fiji.

3. PARTICIPANTS

Thirty participants attended the Consultation Workshop (Refer to the 'List of Participants' attached as Appendix 1). They were representing the following organizations;

- Fiji Government: Ministry of Civil Services, Ministry of Education, Heritage and Arts, Fiji Immigration and the Fiji Higher Education Commission.
- Fiji based Universities; the Fiji National University, University of Fiji and the University of the South Pacific.
- Kirby Institute of the University of New South Wales
- Methodist Church
- Secretariat of the Pacific Community
- WHO staff and consultants

4. PROGRAM

4.1 Strengthening Health Research Ethics Reviewing in Fiji.

A presentation of the key findings of the Situational Analysis 2017, by Dr Simon Barraclough

The key recommendations of Dr Barraclough's situation analysis of the human research ethics reviews in Fiji, 2017 are as follows;

- Reducing the overlapping functions of committees in Fiji in order to saving time and money
- Facilitating sound governance of the ethics review process, including anticipating the role of the National Research Council

- Clarifying the role of the Solicitor-General, the Ministry of Education and Ministry of Immigration in the ethics approval process
- Standardizing documentation to ensure quality and reduce costs
- Providing culturally appropriate training and continuing education for committee members
- Ensuring the recruitment of adequate numbers of reviewers with appropriate expertise
- Re-developing the Fiji Health Research Portal to more fully realise its potential in a digital age

It was also recommended that an accreditation of tertiary ethics committees be conducted. This recommendation will involve the development of 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 agreed guidelines. The FNHRERC would 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.

The review also stated that there is a need for national ethics research guideline to be used by all applicants and reviewers. The guidelines can adapt the existing documents in Fiji, for example, application for ethics review, participants information sheet, consent and withdrawal forms and from other countries. This would enable a degree of quality control and avoid duplication.

There was an expressed need to provide continuing education for members of ethics committees. Staff of the universities with ethics expertise could be asked to contribute to training. Furthermore, a more formal qualification in health and research ethics be offered in universities. There are existing online courses in health ethics that committee members can access. These online courses are not relevant for Fiji's cultural context. Ethics committee members can still complete it.

The health research portal available on the MOHMS website was reported to have some valuable features, but need further development to make it fully functional.

It was also recommended that there is a need to recruit more members for the ethics committees. Each university ethics committee needs to have a regularly attending member from the MOHMS and university committees nominating a member to serve on the FNHRERC.

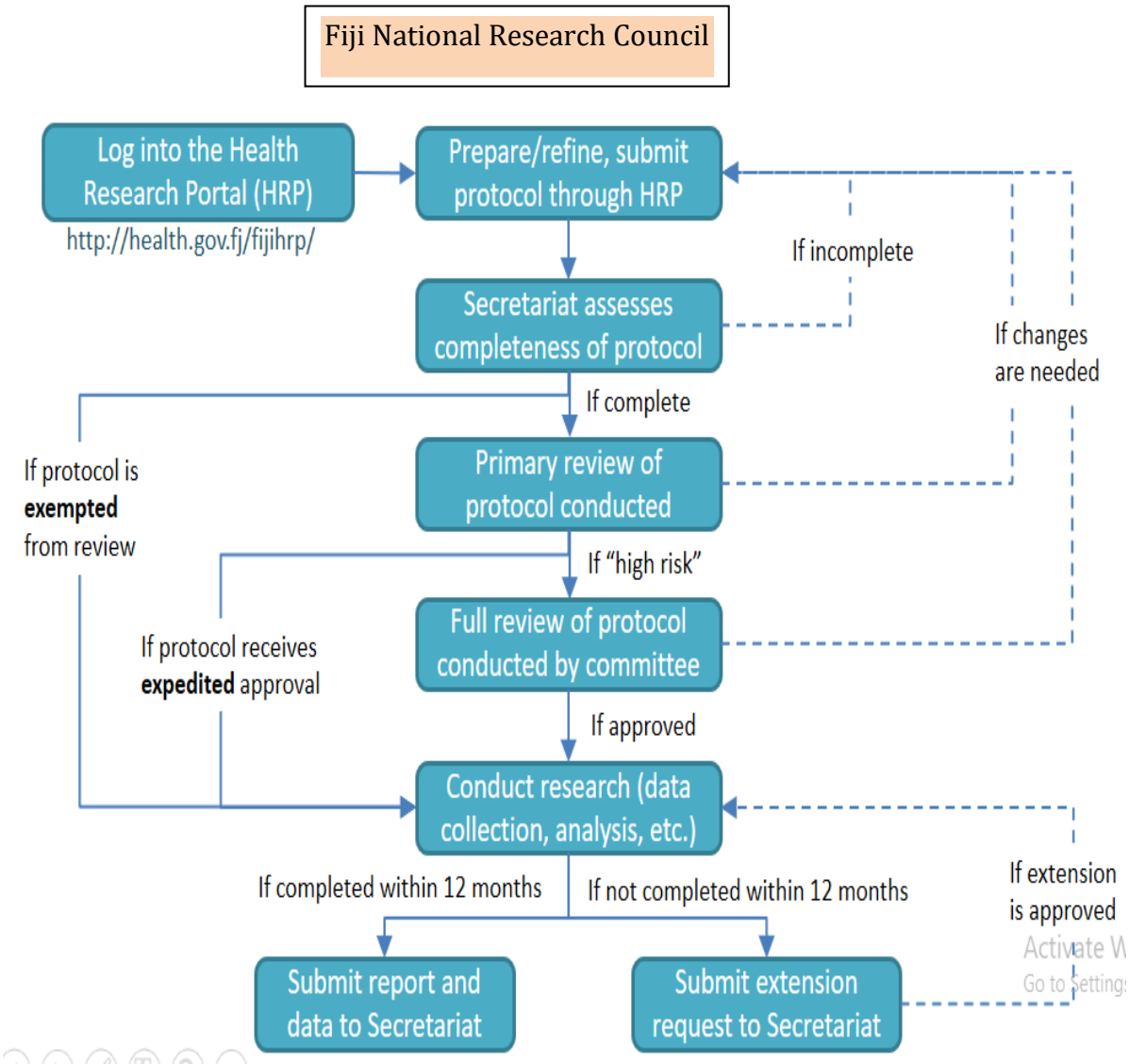
A list of ad hoc consultants who can be called upon for expert advice by university and MOHMS committees be developed. Recruitment of community members, to serve on the various ethics committees be conducted. Providing official public recognition and appreciation for those who have served on ethics committees was also recommended.

4.2 Overview of the current health research ethics review process at the MOHMS

Analysis of the data from the Research Portal

The Fiji National Health Research Ethics Review Committee (FNHRERC) at the Ministry of Health and Medical Services (MOHMS) is authorized by the Fiji National Research Council (NRC). The flow diagram below (Figure 1) was presented as the current review process of the FNHRERC.

Figure 1: Review process of the FNHRERC prior to March 2019.



The research portal is an online system which has been in operation since 2012. The establishment of the portal was assisted by the WHO and now, 2019, WHO is assisting the MHMS again to revise the system. The first step is the researcher register in order to get a username and password. After that the researcher logs in and submits the application for ethics review. The arrows indicate the process of review. The secretariat receives the application and vets for completeness of the submission. After that, then the secretariat conducts a preliminary assessment to determine low or high risk. If it is low

risk, then the application will be submitted to be reviewed through the low risk process which is the expedited review process. If it is high risk, then it be reviewed through the high risk review process. The broken line indicates the communication between secretariat and the researcher regarding incomplete application, or if there are changes or revisions that need to be done. The review result will be communicated to the researcher in due course.

The FNHRERC is guided by international standards and guidelines such as the Declaration of Helsinki (WMS, 2008), International Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 2002) and the International Guidelines for Ethical Review of Epidemiological Studies (CIOMS, 2008). Relevant guiding documents are the National Health Research Guide (1999), The Fiji National Health Research Guide, 2015, Ministry of Health and Medical Servcies: Health Information Policy (2011).

The FNHRERC reviewed and cleared a total of 540 research proposals from 2014-February 2019. Turn-around time for review of low risk studies were between 7 days – 2 months. Turn-around time for full review of high risk research was reported as taking up to seven months.

The Challenges that the FNHREC faced were lack of manpower for the Secretariat, timeliness of review by the Committee, timeliness of re-submission by the principal investigator, multiple levels of institutions reviews, capacity of reviewers from specialized fields and also the composition of the committee.

5. HUMAN RESEARCH ETHICS COMMITTEES IN UNIVERSITIES

5.1 Fiji National University, College of Medicine Nursing and Health Sciences (CMNHS)

College Human Research Ethics Committee, by Mrs Etivina Lovo

College Human Research Ethics Committee (CHREC) is the research bioethics and oversight committee of CMNHS with authority stated in the Fiji National University Research Policy.

The CHREC follows the same guidelines as the Fiji National Human Research Ethics Committee. There are 21 members of CHREC. The CHREC membership composition include the Chair who is the Associate Dean of research, Vice Chair is an elected member of CHREC. The head of the schools in CMNHS nominate three representatives from their various schools' research committees. CHREC also have external members; a clergy, a lawyer and two lay

persons – a man and a woman. Staffs of the Research Unit form the Secretariat. Members go through an internal research ethics training conducted by other CHREC members. Additional training is available online. Members are encouraged to attend and complete ethics trainings that are available. Term of membership is one academic year.

CHREC meeting proceedings are confidential. CHREC meets once a month for eleven months in a year. The secretariat keeps all the minutes of meeting and other records. 50% of full membership in any meeting can make quorum. CHREC reported receiving and reviewing more low risk proposals than high risk proposal in 2018. Low risk proposal may be reviewed in 10 days. High risk research proposal take about 30 days to review. The secretariat keeps an Excel database of CHREC reviews. In the case of complaints procedures, CHREC follows the FNU policies that exist for handling complains and grievances from both staff and students. The CHREC experience challenges related to reviews. There are expressed difficulties in identifying discipline reviewers. Repetition of reviews at CHREC and the FNHREC is very time consuming.

Recommendation

It is proposed that ethics reviews be incentivized in order to motivate staff and external reviewers to conduct timely and thorough reviews of proposals.

5.2 University of the South Pacific (USP), Research Ethics Review Process

by Dr Jito Vanualailai

a) Priority areas of research:

- Economic growth, regional cooperation and integration for Sustainable Pacific Economies
- Environment, Sustainable Development and Climate Change
- Government, Public Policy and Social Cohesion
- Human Capacity Building and Leadership
- ICT and Knowledge Economy
- Pacific Cultures and Societies
- Pacific Ocean and Natural Resources

b) Research outputs

Records of publications at USP steadily increased from about 100 in 2010 to 236 in 2018 (Elsevier Scopus, March 2019). In 2018, there were 127 published articles, 35 conference papers, 26 articles in press, 19 book chapters, 9 reviews, 2 books and 1 short survey.

c) Ethics approval process

Applications for ethics review begins at the Faculty Research committee. Screening of questionnaires is guided by the UNESCO's Universal declaration on Bioethics and Human Rights. If the first screening indicates further consideration then the researcher is required to complete and application and submit to the University Research Committee (URC). The Human 'Ethics Handbook' which consist of the code of ethical conduct and the 'Animal Research Ethics Handbook' must be read by all researchers. The USP Research Ethics Committee is a sub-committee of the URC, chaired by the Deputy Vice-Chancellor. It takes up to 2 weeks to arrive at a decision.

d) Procedure for Unethical Conduct

A process to address unethical conduct in research is in place where one of the possible decision is to cancel the ethics approval that was granted. The Deputy Vice Chancellor has the power to discipline researchers guided by the USP regulations.

e) **Research data** can be sensitive. What should be done about it? The ANDS Guide: Publishing and Sharing Sensitive Data was recommended to guide issues of research data. Available at: https://www.ands.org.au/guides/sensitivedata

f) Intellectual Property and Copyright Policy

g) **IP generated by Staff and students of the USP:** As a general rule, the USP will assert ownership of IP created, invented or discovered by USP staff in the course of their employment (excluding copyright in scholarly works), including but not limited to teaching and research materials. Generally the USP will not assert ownership of IP rights developed by students.

Recommendation: Dr Vanualailai recommended the *Massey University Code of Ethical Conduct for Research, Teaching and Evaluations Involving Human Participants as* a good sample as framework for the for the establishment of the Fiji Research Council.

5.3 University of Fiji Human Research Ethics Review Process

by Dr Elic Narayan

The Human Research Ethics Policy of University of Fiji is well established and was recently reviewed in February 2019. It encompasses the following:

1. Responsibility for Ethical Conduct of research
2. Value of research and the Public Interest
3. Informed consent
4. Archiving Data, privacy, storage and use of information
5. Minimization of Harm
6. Declaration of potential conflicts of interest
7. Researcher appeals and addressing concerns

a) **Membership**: The University of Fiji has a Human Research and Ethics Committee which comprises of The Vice Chancellor who is the Chair of the committee, Deans of all schools, two elected members from the academic staff, one of which must be from UPSMHS, Director of the Center for I-Taukei Studies, Research and Technical Officer of the University and the Secretary is the Registrar or his/her nominee.

The purpose of the UoF Human Research Policy is to provide details and conditions under which the University shall approve research involving human participants, and to facilitate ethical conduct which respects the rights of people, communities, companies, and other organizations, involved in research. Policy applies to all University staff, including adjunct staff appointments, and all students and volunteers engaged in research, whether at the University or working in collaboration with staff/students from any other institution locally or internationally.

b) Application Procedures

All research involving humans shall be subject to formal ethics review and receive approval by the Human Research Ethics Committee before data collection commences;
Where applications are made to an external ethics committee, an application shall also be submitted to, and approved by, the Human Research Ethics Committee before data collection commences. If an ethical issue relating to the research was not envisaged at the beginning, however arises during its course, the researcher(s) shall discontinue the research, consult the Chair of the Human Research Ethics Committee, and if necessary apply for further approval. The researcher(s) shall not commence the research again until the necessary approval has been obtained.

An application is to be completed by the researcher(s) and submit to the office of the Registrar, 5 days before a scheduled meeting of the HREC for review. A decision will be communicated to the researcher within 10 working days. International collaborators must comply with MOHMS, Immigrations and any other such regulations that may be required.

The supervisor and Vice-Chancellor are jointly responsible for monitoring compliance with the Human Research Ethics Policy, with administrative services provided by the Office of the Registrar. Frequency of meetings of the HREC is every 2 months and at least 6 members must be present. Time taken for review of high risk research is 10 working day and 5 working days for low risk research.

Challenges were expressed to include inadequate expertise for medical research, inadequate research expertise, lack of manpower to do appropriate high risk reviews.

6. INTRODUCE FNHREC REVISED STANDARD OPERATING PROCEDURES

By Ms Mere Delai

The major change to the SOP is the accreditation policy and process. The major revision of the FNHREC is the accreditation policy and process. Guideline and application form for the accreditation is attached as Appendix 2.

The SOP needs to be revised and participants' comments are welcome. It is important for everyone to comment while the process of reform is taking place. The experts will have some ideas of processes and systems that we want to develop.

6.1 Adoption of the Accreditation Process

Accreditation will be part of the FNHREC guideline. There is also an application form for accreditation. The form will be given to all the ethics committees HRECs. If the HRECs wish to be accredited by the FNHREC – they must complete the application form and submit to the FNHREC with all the necessary supporting documents. The FNHREC will consider the application and conduct a verification process before an accreditation is granted. The accreditation is recognition by FNHREC that HRECs have achieved local and international ethical operating standards required of a HREC.

The discussion referred to the relevant documents for the accreditation process. The accreditation guideline and the accreditation application form are first drafts developed by the WHO consultants. First page of the form is the introduction of the accreditation process, rationale and the roles of the FNHREC as the national accreditation body. Page 2, presents the accreditation quality standards and the criteria for eligibility to apply for HREC accreditation. Page 3 presents a guideline on how an HREC can obtain accreditation. Page 4 covers the duration of accreditation and dates for annual reporting as well as the re-accreditations process. The accreditation guideline is attached as Appendix 2.

The Permanent Secretary of Health approved the guiding documents thus the process of accreditation is the certification of one of the HRECs which will be conducted in an evening programme. FNHREC will award one HREC with an accreditation certificate in the evening programme.

There was a general discussion of the accreditation process guideline and the application and participants felt that the documents need to be revised.

6.2 **Recommendations for revisions of the accreditation guideline** and application form for accreditation.

Theme	**Points of recommendations**
Terminology	Suggested the terms "Human health research". CHREC is health only while FNHREC is inclusive of all human research.
Criteria for HREC accreditation	HRECs are to review all research proposal involving human beings.
	Minimum number of proposals that will enable the formation of a HREC – the current guideline states 20 proposals. The participants suggested that 20 may be too high, but perhaps to say "20 proposals unless otherwise suggested". There was a suggestion that a "per-capita" calculation be conducted by institutions to determine the minimum number. Therefore, if members of the institution are too small then they cannot meet the criteria to form a HREC. Another suggestion was to say "*20 unless otherwise suggested*".
Fee	HRECs can **charge a fee** for review of proposals
Need to review the templates to include human/health research in order to include USP research designs.	The accreditation guideline focus on health research only and not on other research involving human beings. HRECS are to include all research proposals involving humans. To include USP research – social science, ethnographic, phenomenological research, grounded theory, interview based research, case studies. Quantitative and qualitative research. Where are these

	research placed? These are not specifically health research but they are also involving humans. Revise the current templates to include 2 sections. One section about health research only and the other one to include other human research not related to health in order for the USP research designs to fit in – which includes qualitative research.
	Risks and vulnerability are two research ethics issues that need to be considered in the review of the templates.
Health and Human and Animal Research clarification	Animal ethics are to be considered for review.
Example of a HREC membership that is not accepted.	Include in an Annex document some description of an ethics committee that will not be approved for accreditation, for example, an all males HREC, or all females HRECs.
Accreditation forms, items to be clearly defined.	Revise the re-accreditation criteria to be clearer. Elaborate on committee membership ethnicity and cultural sensitivity Roles of the Chairperson Include in an Annex document some description of an ethics committee that will not be approved for accreditation, for example, an all males HREC, or all females HRECs.

8. REVISED TEMPLATES FOR FNHREC APPLICATION FOR ETHICS REVIEW

By Mrs Etivina Lovo

8.1 Participants' discussions

a) USP types of research (Social Science) be included in the application templates.
b) Research to be described in terms of the RISKS OR THE VULNERABILITY of research participants.
c) Questioned the involvement of Animal Ethics? CHREC does not review research proposals involving animals, but CHREC seeks the help of overseas animal ethics committees to review the proposal.
d) Application form – to separate items for local and overseas applications. Overseas applications be approved from their own university or country ethics committee first. This policy to be mandatory. International researcher need to involve a Fijian researcher first, prior to get the ethics approval from a local HREC.

e) If staff of universities are conducting the research in the university and must get the ethics approval from the institution ethics committee. In the case of FNU, if staff needs to get CHREC approval regardless of where the research is being done. If the principle researcher is Fijian then other things, the requirements that to get the ethics approval from their own institutions.

f) Funding sources in relevant and if the principle investigator is from Fiji, and need an expert in the area that is being researched on and that person is from abroad is the only expert and Fiji person is the Principal investigator, so it not relevant to get any ethical approval as it is difficult from the overseas universities.

g) What is the role of other Government ministries?
    - The Immigration Department or the Education Department.
      Ministry of Education Heritage and Arts (MEHA). All researchers who wish to interact with students and schools will need to register with the Fiji Teachers Registration Authority. Provide necessary SUPPORT LETTER for international researchers to obtain a RESEARCH PERMIT from Fiji's Department of Immigration – to allow them to conduct research in Fiji [There is no communication between MEHA and Immigration Department]
    - **Fiji Research Council** is not functioning yet.
    - **Biosecurity Department**: If research requires biological samples taken and send

the generic samples abroad, the biosecurity department is responsible and ethics review need to cover this aspect of sample transportation.

- Ministry of Environment and the Ministry of I-Taukei to be consulted in research related to their areas of work.

8.2 Recommendations for the revision of the FNHREC review Processes to be reflected in the application form.

Comments in categories	
Definitions	Definition of 'local researcher' (is the one who works in Fiji or a Fijian who has a Fijian passport. To confirm.) Vulnerable
Research Design	Clinical research Public Health interventions. Medical interventions. Mass drug trial, health education trial in the community using the snap tool – Australian tool not trailed in Fiji.
High Risk research	Definition of the high risk need to be cleared. Review of high risk research. If the high risk research reviewed by CHREC is submitted again to the FNHREC. What is the next process? FNHREC will accept the recommendation made by CHREC and conduct a fast track review. Any high risk proposal approved by the university ethics committee – do not need to be submitted to the FNRHEC.
Government Ministries	Dr Rafai – Other sectors – eg. Legal sectors – it needs to come to MOH at some stage to decide the things to be consulted as government do have only MOH but other sectors as well.
Review process	Fast track procedure – removes or defines and elaborates – Timely review.
Review Exemption	Literature review for a publication – will the publication require an ethics approval, if yes, this would be considered a very low risk issue and would get approval without any formal process similarly where the research pulls out the information from already published. facts about research – being responsible researchers – ethics to review and it is the data for Ministry of health then could consider as Operational work but not for research, rather than publish it.
Secondary data research	Use of personal data obtained from any government department – identified and de identified data – High risk / low risk.
Dissemination of research result	Important about research – contributing to information and understanding and if causing harm to the community then it needs to be shared.

	Issue of confidentiality and also issue of sharing information for protection.
Supporting documents	Principle Investigator – why need the CV – specify one page limit – undergraduate student will need supervisors' approval – Dr Rajat - police clearance?? Immigration need it for researchers from overseas.
timeline	Research project – finishing date – timeline is important – flexibility – if delay in approval then the staring date will be delayed.
Monitoring	Why to get the monthly update – CHREC is monitoring the progress. Dr Donald – Monitoring and Evaluation of Research Work – increase your Human Resource.
Funding support	Funding Source – if there is no funding support – the people who are assessing the research should support.

9. REMARK IN CLOSING OF THE FIRST DAY'S PROGRAMME

Dr Eric Rafai, welcomed Professor Mohini Singh, the ProVice Chancellor Research of the Fiji National University. He also welcomed and congratulated the new Associate Dean Research for College of Medicine Nursing and Health Sciences, Dr Donald Wilson. He thanked everyone who has contributed to the fruitful discussions of the first day of the workshop and invited all the participants to the evening programme which is the award of the accreditation certificate to CHREC.

11. EVENING PROGRAMME: AWARD OF THE ACCREDITATION CERTIFICATE TO FNU, COLLEGE HEALTH RESEARCH ETHICS COMMITTEE

Dr Eric Rafai awarded the accreditation certificate to the chair of the College Health Research Ethics Committee on behalf of the Honourable Minister of Health. CHREC was the only HREC that applied for accreditation. FNHREC appraised the application and found that CHREC met the set criteria for accreditation. The certification is for 3 years. During the years of accreditation, CHREC is required to submit monthly reports of proposals reviewed. An annual report is also required by FNHREC from CHREC and any other accredited HREC.

From left to right: Etivina Lovo (Bioethicist, College of Medicine Nursing and Health Sciences, Professor Mohini Singh (FNU Pro Vice Chancellor Research), Dr Donald Wilson (Associate Dean Research and Head of School of School of Public Health, College of Medicine Nursing and Health Sciences), Dr Eric Rafai (Director of the ……)

DAY 2

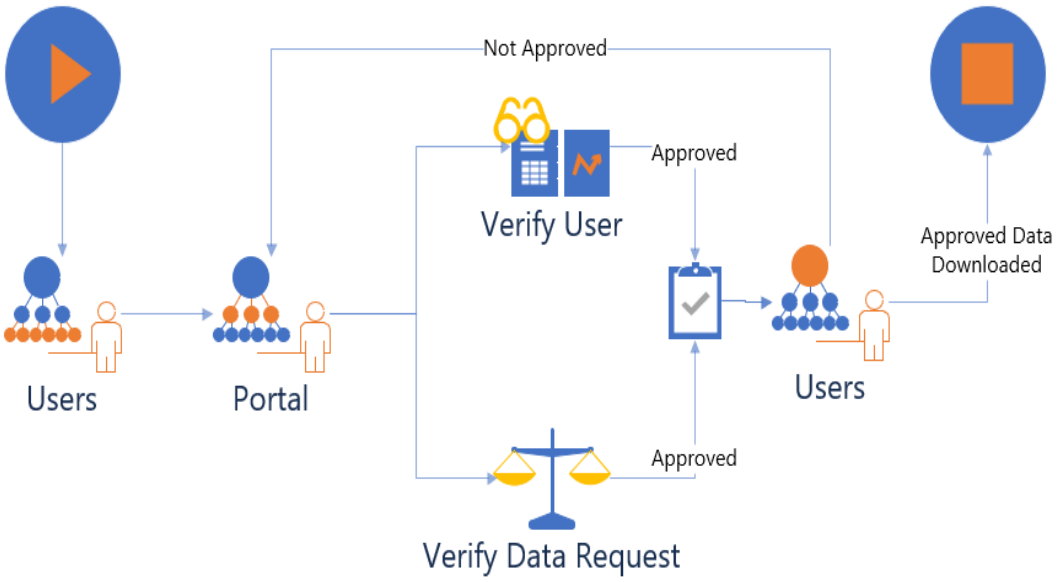
12. THE NATIONAL DATA REPOSITORY

11.1 An overview of the National Data Repository, by Rajneshwar Prasad

The National Data Repository is a system where the data is made available on request in various formats digitally. Issue before the portal was installed was that data request is submitted and we issue the data in CSD or other formats, then the researcher need to convert it to other format, like SPSS or other then use it. This system provides the data and user can convert it to a format of their choice to enable analysis.

An overview of the data request process was presented. Process of accessing data from National Data Repository is illustrated in Figure 2.

Figure 2: Process of accessing data from the Fiji National Data Repository



The overall process begins with the published data being identified, then the data template is created – which is a data dictionary and then it is uploaded on the portal and made accessible to the user. It is not a portal where the user can download automatically. It is a portal where the user makes a request and the request goes through a verification process, then the data is made available. This process takes only a few minutes then the data is made available and the user can download the data.

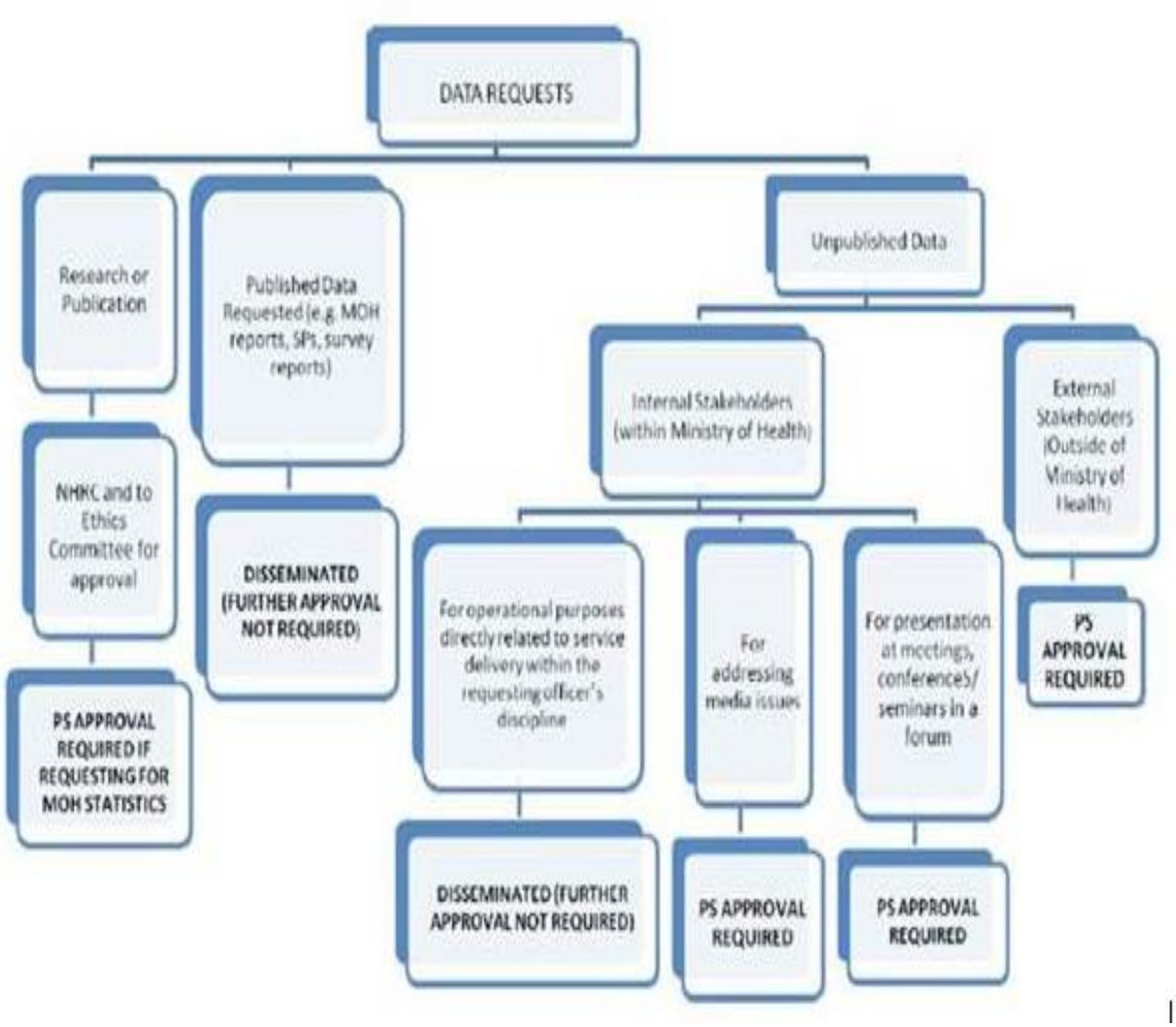
11.2 Brief Overview of Data Request Process presented by Ms Anjana Deo

The Data Analysis and Management Unit was formerly known as Health Information Unit. The information collected is used by MoHMS, Local Government Units, Non-government Organization, Researchers, School Students and Private Sectors.

The data request form was developed in 2013 by the Health Information Research Analysis (HIRA) team and approved by the PSHMS. The data request form is currently under-review and intended to align to the Information Act 2018. The Information Act 2018 sets out the processes to be followed by the members of the public of requesting data from the MoHMS. Turn-around time for facilitation of data request is 20 days. Copyright law is also enforced. The MOHMS or any public agency is required under the Information Act to make the information available in the form preferred by the person who made the request unless to do so would (i) impair the efficient administration of the public agency or (Suaalii-Sauni & Fulu-Aiolupotea) be detrimental to the preservation of the information or (iii) having regard to the physical nature of the information, would otherwise not be appropriate (iv) involve infringement of copyright law. If information cannot be available in the form preferred by the person who made the request, the public agency (i) may provide the information in another form as determined by the public agency; and (Suaalii - Sauni & Fulu - Aiolupotea) must give the person a written statement of the reason for not making the information available in the form preferred by the person who made the request.

The process for data request was presented and is illustrated in Figure 3.

Figure 3: Schematic for proposed information dissemination and release protocol for data request



a) **Data that do not need approval from the Permanent Secretary of Health are as follows;**
   - Published data such as annual reports, bulletins, journals are readily available on the website.
   - Unpublished data - operational purposes directly related to service delivery within the requesting officers discipline

b) **Unpublished data that requires Permanent Secretary of Health approval includes**;
   - raw data
   - information that is publicly shared though media, research and publication
   - presentation at meetings conference in a forum and external stakeholders.

- Data requested for research and publication purposes, need to have FNHREC approval.

c) Data Requested by Organizations from 2016-2019

Type of Organization	2016	2017	2018	2019 (Jan – March)
MoHMS	82	51	55	11
Local Government	15	17	24	7
Education	26	31	10	3
Private Organization	39	22	48	10
Media	4	4	3	0
Total	166	125	140	31

d) Challenges experienced by the unit were;

- incomplete data request forms
- unclear requests
- turn-around time to close the request

e) **Improvements:** Data Management Framework – ANDs, Streamline approval process, Link on the research portal and Ministry Webpage

https://docs.google.com/forms/d/17YMS8YBnNcdJYYgpQMRRQR1x8QvRGcqdi_BPQvHwhJE/prefill

11.3 Rrecommendations

Theme	Points of recommendations
Systems and processes: Streamline the processes to be more efficient.	Data available in National Data Repository. If researchers need these data they do not have to get the ethics approval again as it is already approved and de-identified data.
Reports of completed research Archives	Aim is to benefit the people of Fiji. The report should go back to the people who decide how it going to benefit the people of Fiji. No update Low reporting for researchers – after they completed they supposed to submit the report.

	Processes to include the following; • Send the reminders to the researchers • FIRCA have the authority to stop the researcher to leave the country. • Fiji research council – is that something to look forward to the council? Establishment of the Research Council Case at the University of the South Pacific • There is a repository at USP and a copy of the publication goes to the archives. Reports must be made available. This policy is applicable to all research at USP.
Archives	Policies: Need to formulate policies that require the researchers to deposit the data and the reports on annual basis and share the outcomes. Policy that requires the tertiary inclusions to deposit the data and other requirements. Policy/Guideline on data sharing, Example: At USP has a research repository and requires all researchers to deposit their research and data. Suggestion for the representative from the MEHA to inform the national archives and create directives for archiving research materials.
Data Request to Data Analysis and Management Unit	To change the name of Health Information Unit. Now Reporting to Dr Rafai. Clarifications on subscription to NDAMU. • Data Request – one time registration and form will be reviewed. Once registration is digitalized, there is no need to repeat registration. • Currently, every request has to reach PS Health for approval. However, there are also organizational approvals. • No data sharing.

13. Ministry of Education Heritage and Arts (MEHA)

by Mr Isoa Wainiqolo

The presentation from the MEHA aims to inform the workshop participants about MEHA Research and Ethics Committee, its functions and processes for processing application for research in Fiji from International Researchers.

The composition of membership includes the following positions;

- Director Corporate Services
- Director TVET
- Director Primary [including ECCE and Special Education]
- Director Curriculum Advisory Services
- Any other Director of relevant Section affected by the Research Area
- Senior Education Officer Research is Secretariat

13.1 The functions of the Ministry of Education Heritage and Arts Research and Ethics Committee

a) The **MEHA Research and Ethics Committee** ensure students are protected from physical, psychological and other forms of harm and abuse during research. The privacy and confidentiality of participants during and after research is to be maintained. The committee ensures that research does not have negative effects on the learning and teaching environment. Research at schools brings maximum educational benefits to schools and stakeholders involved. The committee assesses the research methodologies to ensure that it is appropriately designed to produce good results. The research results are to be made accessible to policy makers and educationalists.

b) Who are the researchers that must submit an application for permit from MEHA research and ethics committee?

- Researchers who wish to conduct research in **Schools** and in the **MEHA**
- **International Researchers**. For those applying for research in MoHMS or Health Issues they need to have an approval from an ethics committee. They also need to produce evidence of support from relevant Government Ministries or local Fiji Universities and the organization/institution approving the research.

13.2 The Application process

When an application is received, the processing time is 10 working days.

All researchers who wish to interact with students and schools will need to register with the Fiji Teachers Registration Authority.

The research and ethics committee provides the necessary support letter for international researchers to obtain a research permit from Fiji's Department of Immigration – to allow them to conduct research in Fiji.

Any MEHA information and data are released only after PSEHA Approval

13.3 Fees

All researchers shall pay a prescribed nominal research fee as per Table …..

	Local Applicant	**Overseas Applicant**
Undergraduate	No Fees	No Fees
Post Graduate Units	FJD $20.00	FJD $50.00
Masters	FJD $50.00	FJD $ 100.00
PhD	FJD $100.00	FJD $500.00
Organizations/tertiary Institutions	FJD $200.00	FJD $500.00
Ministries/Government Departments	No Fees	FJD $500.00
Research Extension Fee (over 3 months)	FJD $50.00	FJD $200.00

Supporting documents to submit with the application to MEHA

- A request letter to the Permanent Secretary for Education
- Applicant's Curriculum Vitae
- Birth Certificate/Copy of the bio-data page of the valid passport
- A support letter from the Institution/Organization approving the research
- A letter from relevant Ministry supporting the research
- Ethics approval from the University (where applicable)
- A copy of the research proposal.

13.4 Monitoring of Research Projects

At the end of research tenure, reminders are sent to researchers for submission of their findings or research reports or publications to the Ministry for filing and may be used as references for policy makings.

13.5 Process for application for extension of timeframe of research

The researcher must apply for an extension of the timeframe of the research if necessary. An application is sent to the PSEHA with a support letter from the supervisor or institution. No fees if extension requested for is less than three months. Refer to the fees table for the fee of an extension of more than three months.

13.6 Challenges/Achievements of MEHA Research and Ethics Committee

It was reported that the challenges experiences include the following issues;

- Submission of incomplete documentations [Support Letter/ collaboration with local institutions and organizations…]
- Late submission of application – and requesting for quick processing.
- Submission of Completed/Published Research and findings

12.7 Achievements

- 2018 – 63 Research Applications received and processed
- 3 research conducted
- 2019 – 11 research approved/ 6 pending

14. Research Permit from the Department of Immigration

Research presented by Mr Deepak Karan[1]

The Authority that governs research permit is under Section 9(2)(e) of the Immigration Act, 2003. Research Permit is defined in the Immigration Act as a permit granted to a person to undertake research for the benefit of local universities/institutions or as a part of his/her professional or educational requirement.

The policies for research permit require the researcher to apply and obtain a research permit prior to entering the country. Applications are assessed on a case by case basis.
Documents required for the application for research permit

- Completed application form
- Applicant's passport bio-data page
- Letter of consent and endorsement from supporting organization
- Ministry of education support letter
- Medical report
- Police reports
- Sponsorship letter and or financial standing of the applicant
- Copy of a return airline ticket and
- The required fees – FJD $632.00 (application for research permit)

Research permit will be granted to research sponsored by
The research permit is granted for a total of 18 months. 6 months is awarded first and the researcher is required to submit a report after every six months in order for the balance of the duration of the permit (6 months X 2) is granted.

There is a refundable bond fee to be paid if the application for research permit is for the duration of 12 months. If the time frame requested is less than 12 months, then there is no bond fee required, only the copy of a valid return air ticket to be submitted.

Permit for a researcher with family who will all come to Fiji for the research requires one application to cover all the family members.

[1] Deepak Karan, Acting Immigration Manager – West, Department of Immigration, Fiji, Nadi International Airport, Ph: 9906836, Email: Deepak.karan@immi.gov.fj. Website: www.immigration.gov.fj

13.1 Fee for research permit is FJD $632.00 (exclude bond).

The validity of the research permit as per the research act and policies, initial approval for 18 months,

Business permit of 14 days can be granted upon arrival of researcher at the airport with supporting documents. This permit can be extended for another 3 months providing the researcher submit the application for extension supported with a letter from MEHA or a local Fiji institution that is supporting the research. The fee for this business permit for research is $180.00.

The turn-around time for the Department of Immigration to process the application for research is 14 days and the extension of a research permit is 5 days.

13.2 Recommendations

The research permit systems in Fiji are independent of each other, MEHA, Immigration, Environmental. Culture, MOHMS it is very difficult to do research in Fiji. There has also been minimal reporting from researchers when their research project is finished. Enable research through systems that support research such as immigration policies to enable the issue of research permits and management of research reports at Fiji National level.

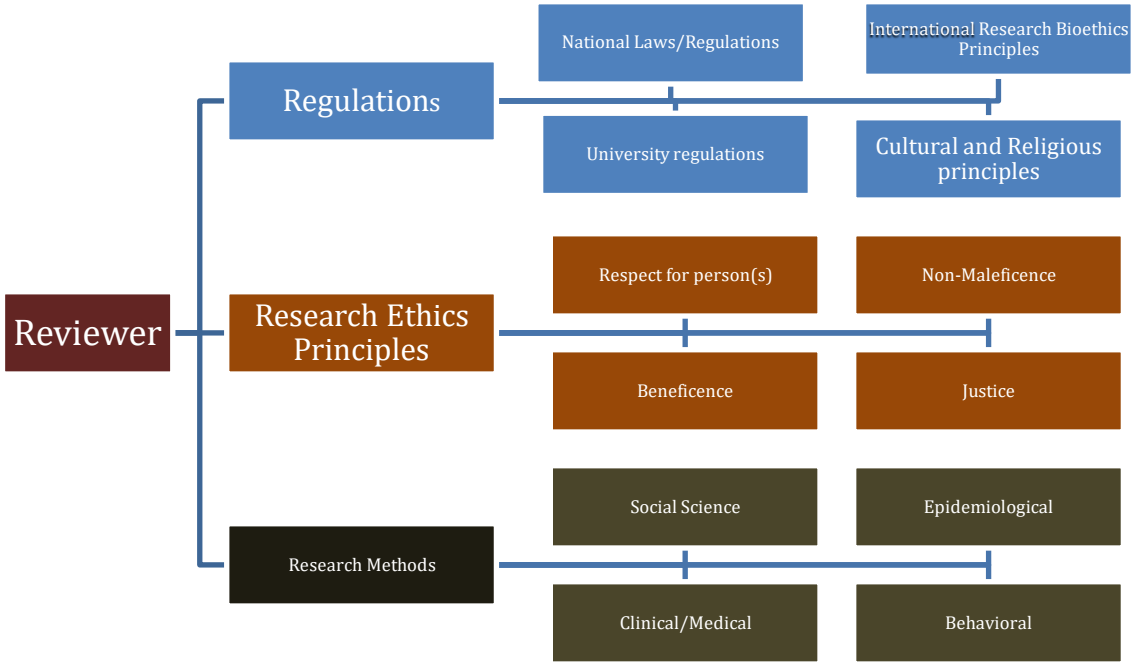
Fiji to establish the **Fiji National Research Council** so that they can streamline the processes of application for research permits.

Policies to be developed and implemented

- Mandatory for researchers to deposit research data in the national data repository.
- Develop and implement policies to enforce the deposits of research data in national data repository. Researchers must submit a final report of their research along with research data to be deposited in the data repository.
- Develop policies on data sharing.

15. Background of Ethics Review by Mrs Etivina Lovo

A Framework for ethics Review was presented.



The framework presents the reviewer's approach to review of research proposals of research involving human beings. This framework consists of three major components.

(i) Regulations (Suaalii - Sauni & Fulu - Aiolupotea) Research Ethics Principles and (iii) Research methods.

i. **Regulations** involve the consideration of the International Research Bioethics principles adopted by international agencies like WHO, UNESCO, WMA and others. The laws and regulations of the nation of the research setting as well as the cultural and religions principles and regulations. University policies are also considered in review of research proposal from staff or students of a university.

i. **Research Ethics principles or the principlism approach** is also employed in research proposal ethical reviews. Fundamental principles set out the Guidelines to ethical review of research proposal. The fundamental principles are; beneficence, non-maleficence,

respect for autonomy and justice.

ii. Research methods are also considered while reviewing. Research methods relevant to research in Social Science, Behavioural Science, Epidemiological research designs, Clinical and Medical research designs.

The purpose of reviews is to protect human participants in research and to maintain the ethical standards for research conduct. Through this process, the reviewer(s) can communicate their observations to the investigators in order for the investigators to modify the research proposal to meet the required ethical standards. Through the review process, a decision can be made to approve or reject the research proposal and in the longer term, monitor the conduct of the approved research proposals. The review process is based on aspects of the applications of the Principles of Research Ethics. The applications are conducted in order to create systems to protect human participants in research. For example, based on the principle of respect for autonomy of human participants in research, it is necessary to create systems and processes in order to observe the principle. Therefore, the voluntary informed consent process was designed to empower the potential participant to make a voluntary informed decision, free of coercion, on whether to participate or not in a research study. This voluntary informed consent process begins with the design of a communication process. The appropriate language is to be employed. The reading level is to be appropriate to the level of reading comprehension of the participant. The voluntary informed process is to be completed before the research is begins and continue throughout the duration of the study ensuring that participants have received the necessary information, has adequately understood the information and after considering the information, has arrived at a decision (without having been subjected to coercion, undue influence or inducement, or intimidation) to participate.

A review form is designed and provided to reviewers as a tool for the reviewers to use to guide review and to write review comments in the relevant sections. A review form is attached for information as Appendix 3.

14.1 Reviewers and their Roles, a case study

Reviewers and their Roles, the case of College Health Research and Ethics (CHREC) Committee Reviewers

CHREC members and CMNHS staff recommended by CHREC as reviewers are tasked with the review of research proposals. The review process begins with the initial check for completeness and appropriateness by the CHREC Secretariat. Then the next step is to conduct a preliminary assessment to determine the level of risk of the proposal. If the preliminary review identifies the proposal to be of **"Low Risk" or "High Risk"** then

the proposal is submitted for review through the relevant review process of either low risk review or high risk review processes. The reviewers will make a decision whether the proposal should be endorsed and granted ethical approval, declined, or exempted from ethical review. Where proposals are declined, CHREC can recommend experts (within or external to the college) to support the researchers or refer them to SCHOOL RESEARCH COMMITTEE for appropriate guidance for the improvement of the proposal and for re-submission. A low risk research proposal review can be done within 10 work days' timeframe.

High Risk research proposals require a full review by an ethics adviser and 2 independent reviewers. It is also necessary, in cases where internal expertise is unavailable, that external reviewer(s) with content expertise be asked to conduct the review. The final decision of approval will be made by the Chair after discussion in a CHREC meeting. If projects proposed are large, multicenter, multi phased the principal researcher may be called to present the project to CHREC and clarify aspects not understood by committee.

Animal Ethics review process: research proposal(s) that involve animals will be send to the FNU College of Agriculture, Fisheries and Forests (McFall-McCaffery) experts in animal health to review. This process will cease upon the establishment of an animal ethics committee at the CAFF or in Fiji.

16. CAPACITY DEVELOPMENT ACTIVITY IN RESEARCH PROPOSAL REVIEW

15.1 Group Exercise: Health Ethics Review Committee Exercise

by Dr C. Yoon, Mrs Etivina Lovo and Ms Mere Delai

Dr Yoon delivered the outline of the group exercise and provided the instructions. The arrangement will be in the order of, firstly, group exercise for one hour and followed by a panel discussion of half hour.

a) Objectives:

- To simulate a review meeting with sample study proposals
- To capture reflections and challenges that usually arise during the review process
- To test templates and SOPs proposed by the ministry

b) Preparation (will be given by facilitators)

- Reviewer's form / pens
- Sample study proposals (high / low risk studies)

c) Process

- Ms Lovo and Delai will give a presentation on review of high risk study as an example. Everyone is invited to join as review member at each group. Facilitators will guide participants to be grouped into three (A/B/C). The three groups will have a chair, note taker and review members. Each group will be given one hour to review high / low risk studies. A seating arrangement is proposed to resemble an general arrangement of a review committee. In the last half hour of the time, Prof. Simon will invite chairs to have a panel discussion on what they have identified and addressed during the exercise.

d) Seating arrangement (proposed)

- The arrangement is proposed to have an optimum composition of a review committee in consideration of participants. Three groups were formed with membership composition as follows, Groups A, B and C memberships consisting of the following person roles;

- Chair and 1 note taker, 2 health professionals, 2 expert with law or other background, 1 representative from the church and 1 representative from the community.

The three groups were given Reviewers' form with instructions, pens and cases of research proposal that were low to medium risk for the review exercise.

15.5 Outcome of the review exercise

Groups were able to conduct the review exercise well especially on the scientific research method, referencing, language of questionnaire, data and the consent of the consent form, confidentiality and privacy, questionnaire, sampling. Reviewers paid less attention to ethical principles such as "persons with no capacity to provide informed consent", ethical recruitment process of research participants.

They mentioned a few areas in the proposals that were problematic as follows;

- Technical language is to be explained in the proposal. Need to use plain language or lay persons language
- A way of detecting plagiarism
- Risk of research – insufficient information

15.6 Recommendation about the Review Form

- The current form is sufficient for review of low risk research.
- Review form need to say at relevant sections, like data collection tool, or Participants Information statement: "Use plain (lay persons) language".

Recommendation to develop and use an application form

- Application form to be developed for use in applying for ethics review. Researchers are not to submit the full proposal, but submit an application form with summarized information for the ethics review. This way the reviewers will not have to read through the whole proposal document.

17. FIJI'S WIDER ROLE

In Developing Ethics Governance and practice in Other Pacific Nations, By Simon Barraclough, WHO Consultant

WHO (Office of the Western Pacific Region) is seeking to support regional nations to further develop the governance and practice of their ethics committees. A desk audit was conducted in 2018 of health ethics governance in **Papua New Guinea, Solomon Islands, Samoa and Vanuatu**

The major problems faced by most national authorities in terms of governance, administration and information technology were:

- Limited availability of national health research ethics information on the Web
- The absence of a clearly identified central information officer to provide guidance to applicants
- Confusion over whether states have a central ethics review committee from which clearance must be obtained or the reviews of other committees are accepted
- The need to develop improved standard operating procedures
- Variations in the quality and comprehensiveness of documentation

Fiji has advanced ethics review capacity in comparison with the other Pacific nations surveyed. Fiji's universities and MOHMS have the potential to offer assistance through sharing documents, experience, training and education.

Participants in the workshop are invited to suggest ways in which cooperation can progress further.

18. CONCLUDING DISCUSSIONS

Way Forward: Moderated by Dr Eric Rafai and Ms Mere Delai

Dr Eric revisited the workshop objectives to see if they have been achieved;

a) To conduct a consultation meeting about the Fiji Human Research Ethics Governance and Review mechanisms.
b) To implement the accreditation of the Human Research Ethics Committee in Fiji that met national and international standards.
c) To build capacity and awareness on Human Research Ethics Guidelines and Review Processes in Fiji.

Objectives a, b and c have been achieved. The consultation workshop is now concluding. The FNU, CHREC was awarded an accreditation certification. The capacity building awareness exercise about HRE guidelines and review process in Fiji was conducted in the afternoon of the last day of workshop.

17.1 The Way Forward

The working committee welcomes comments and ideas to improve governance processes of Human Research Ethics in Fiji. A two weeks timeframe is given to participants to make more comments on the documents in the google drive and any other comments to be communicated back to the secretariat.

We are looking at formulating 2 working groups. One group will work on redesigning of the data repository in the support of WHO. Members interested and come forward to join this working group which is more Information Technology oriented.

Another working group will be looking at the general policy within the MOHMS which will combine the Human Research Ethics Standard Operating Procedures and Guidelines. These documents are to be submitted to Cabinet for approval. This Cabinet approval will be the formal government authority for the FNHREC to operate as the national governing mechanism of HRE in the absence of the National Research Council.

Trainings of the research ethics committee. We have contacts from UNESCO to conduct training on Ethics Committees.

Asia Pacific Bioethics Network. A meeting of this network is being organized by WHO to be held in October. Participants will share experiences of ethics committees.

Fiji Health Research Ethics Network is a discussion group to be led by the Universities; Fiji National University and University of the South Pacific. Participants expressed their support of the FHREN, but wanted to know the source of fund. Dr Eric explained that it is a communications network and can be conducted on online platforms which does not cost anything.

The representative from the USP re-iterated that the FHREN is include all human research and not concentrate only on health research. USP is happy to help with the formation of the FHREN. Through the USP and FNU, the FHREN membership can be extended to the Pacific Region.

Dr Eric re-emphasized the commitment of the Honourable Minister of Health to the development of Human Research Ethics governance mechanisms in government.

Dr Neil Sharma extended the participants' "thank you" note.

19. Closing

The workshop was closed with a prayer.

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Appendix 1: Participants' List

National Consultation on Ethics and Governance of Human Research in Fiji
Tanoa International Hotel, Nadi
26th – 27th March 2019

Attendance List

No.	Name	Email address	Designation :	Employer/Institution
	Dr. Ifereimi Waqainabete	waqainabete@govnet.gov.fj	Hon Minister for Health Medical Services	Chief Guest (Day 1)
1	Dr. Eric rafai	eric.rafai@govnet.gov.fj	Dr	Ministry of Health & Medical Services
2	Dr Jito Vanualailai	jito.vanualailai@usp.ac.fj	Prof	USP
3	Nilesh Narayan	narayan.nilesh.anish@gmail.com	Mr	Fiji Higher Education Commission
4	Isoa Wainiqolo (26th-27th)	isoa.wainiqolo@govnet.gov.fj	Mr	MINISTRY OF EDUCATION, HERITAGE AND ARTS
5	Dr. Jojo Merilles (26th – 27th)	JojoM@spc.int	Mr	Pacific Community (SPC)
6	Dr. Brian Guevara	brian.guevara@gmail.com	Dr	Ministry of Civil Service
7	Dr.Bridget Haire	b.haire@unsw.edu.au	Dr	Kirby Institute, UNSW
8	Dr. Anaseini Moala	anna.seinim@gmail.com	Dr	MOHMS/ Wellness Centre
9	Dr Shrish Acharya	shrish.acharya@health.gov.fj	Dr	CWM Hospital
10	Dr.Elick Narayan	elickn@unifiji.ac.fj	Dr	UPSMHS/UNIVERSITY OF FIJI
11	Ranjana Prabhu	ranjanapra25@gmail.com	Ms	MOHMS
12	Dr.Neil Sharma	nsharma2@connect.com.fj	Dr	Private Medical Clinic-Baksih St
13	Dr Josaia Tiko	josaia.tiko@health.gov.fj	Dr	Ministry of Health and Medical Services
14	Dr.Mike Kama	mnkama02@gmail.com	Dr	Ministry of Health and Medical Services
15	Dr. Bijend P Ram	drbijendpram@yahoo.com	Dr	University of Fiji
16	Rev Immanuel Reuben	revreuben2010@yahoo.com	Rev.	Lay representative – Methodist Church of Fiji

17	Lucricia Ana Lewaqai	lucricia.lewaqai@health.gov.fj	Ms	Ministry of Health Medical Services
18	Ben Chand	ben.chand@immi.gov.fj	Mr	Immigration Department
19	Mohini Singh	pvc-r@fnu.ac.fj	Prof.	Fiji National University
20	Simon Barraclough	simonbarraclogh1066@gmail.com	Prof	WHO Consultant
21	Dr. Donald Wilson	donald.wilson@fnu.ac.fj	Prof	Fiji National University - CMNHS
22	Dr. Rajat Gyaneshwar	rajat.gyaneshwar@gmail.com	Prof	Fiji National University - CMNHS
23	Deepak Karan	deepak.karan@immi.gov.fj	Mr	Immigration Department
24	Etivina Lovo	etivina.lovo@fnu.ac.fj	Ms	Fiji National University
25	Mere Y Delai	delai.merey@gmail.com	Ms	MOHMS
26	Rajneshwar Prasad	rajneshwar@gmail.com	Mr	Ministry of Health and Medical Services
27	Varanisese Saumaka	varanisese.saumaka@ag.gov.fj	Ms	MoHMS
28	Anjana Deo	anjideo@gmail.com	Ms	Ministry of Health and Medical Services
29	Kalisiana Ravai	Kalisiana Ravai	Ms	Ministry of Health and Medical Services
30	Rosimina Tubuitamana	rtubuitamana@gmail.com	Ms	Ministry of Health & Medical Services

Appendix 2: Fiji National Human Research Ethics Committee, Guidelines for Accreditation of Ethics Committees in Fiji, (DRAFT A_06 03 2019)

Accreditation of Human Research Ethics Committees

The FNHREC aims to conduct an accreditation exercise for HREC in Fiji. The FNHREC provides these guideline for HRECs and their governing bodies to guide the application for accreditation. This section will present the process of accreditation of Ethics Committees in Fiji by the FNHREC.

Rationale for HREC accreditation

The accreditation process seeks to establish HRECs are doing their best to fulfill international and national standards of human research ethics and are accountable to the Government of the Republic of Fiji. The accreditation process provides feedback to HREC governing bodies on compliance to standards and identifies weaknesses for improvement. Each HREC in Fiji must prove institutional effectiveness as assessed by the accrediting process and verification team.

Human research projects that have received ethics approval by an accredited HRECs can access Health Information databases, for example, Non-Communicable Diseases data from the MHMS, in accordance with its Data Request process in compliance with principles of the INFORMATION ACT 2018, (ACT NO. 9 OF 2018). Researchers may access Health information for research purposes with ethical approval of the particular research method.

Roles to be performed by FNHREC as the national accreditation body

The FNHREC will

- Facilitate and monitor the accreditation process.
- Establish an application process
- Prepare criteria for eligibility and other standards for accreditation of a HREC.
- Develop and implement a monitoring system for accredited HRECs on an annual basis.
- Provide feedback on the yearly evaluation of HRECs.
- Provide advice to HRECs on standards and ethical requirements for human research.

Accreditation quality standards

1. Research proposals submitted to HREC for ethical review will justify the involvement of humans in the research.
2. HREC is based on sound internationally and locally accepted ethical principles.
3. Compliance with national and institutional policies and regulations.

4. A diverse range of research study designs is entertained, (for example, clinical trials, surveys, student projects, and behavioral studies.)
5. Research participants and applications are considered with respect and privacy. HRECS put safety and voluntary participation first. Respect for privacy and confidentiality extends to the identity of researchers.
6. The review of research proposals will be conducted by an independent committee of reviewers. The reviewers should have content or ethical expertise andbe familiar with international standards for the protection of human participants in research.
7. Any conflict of interest amongst researchers and their institutions; including membership in the HREC in the review of proposals must be identified early and addressed.
8. The review processes involve a risk and benefit analysis and make recommendations to researchers to minimize risks.
9. A monitoring role and process for research projects needs to be implemented that enables yearly reporting to the FNHREC.
10. Reviews of research projects must establish a process for obtaining the voluntary informed consent of participants.

The accreditation process is a continuous process and FNHREC welcomes feedback from any of the HRECs.

Criteria for eligibility to apply for HREC accreditation

To award an accreditation certificate to a HREC the FNHREC needs to be assured that the HREC has the capacity to offer protection to human participants in research.
HRECS operate under a governing legitimate institution registered and located in the Republic of Fiji. The governing institution's staff or students or affiliates conduct research.

HRECS has a Standard Operating Procedure (SOP) that may be submitted together with the application for evaluation. If SOPs are not documented then the FNHREC and HREC agree on a site visit for evaluation to be conducted.

HRECS Membership

HREC membership must be identified clearly in the SOP. HREC membership needs persons with appropriate expertise in research design and skills to conduct thorough reviews of research proposals and provide constructive feedback to researchers. Members or reviewers will need to address ethical issues and risks identified through the review process. The HREC will require a Chairperson, Vice Chairperson and a small number of committee membership that is balanced in gender and representative of the diverse cultures and ethnicity in Fiji. An example of a HREC that does not have a balanced membership is a HREC with only academics or clinicians as members. The membership for HREC will need to be consistent with international standards for HREC memberships that include members from the governing institution and external members who maybe lay persons; a clergy, a lawyer

and a social worker who have fair judgment and relevant experience. External members are independent members who volunteer to participate in the work of the HREC but are not officially a representative of any group(s) to the HREC.
Fiji is a multi-ethnic society and therefore the composition of members in the HREC should include members who are well versed with socio-cultural expectations of various ethnic individuals or groups that are prospective subjects in research.
The quorum for meetings will be 50% of membership and including the Chairperson or Vice Chairperson.

The HRECs should receive and review a minimum of 20 proposals per year.
An accreditation of a HREC should be for a period of 3 years. Before the end of the 3rd year, the HREC should apply for another review process. However, **if HRECs fail to maintain appropriate standards** at any point of operations; the FNHREC may request HREC to cease/suspend operations with sufficient reason and notice.
Approval for accreditation cannot be granted retrospectively.

How to obtain HREC Accreditation

The steps are as follows:

1. Read and understand the FNREC Research guideline and SOP. The principles of research stated or referred to in the FNREC Research Guideline apply to all research involving human beings.
2. Applications for accreditation are sent to the FNREC by the governing institution of the respective HREC. An application cover sheet is provided as attached in Appendix A.
3. Attach the SOP of the HREC to the application for accreditation. The SOP should have a description of the following
    - HREC functions
    - Terms of Reference of the HREC
    - Process for decision making
    - Review process
    - Process of submitting an application for ethics review, expedited review or exemption of an ethics review
    - Responsibilities of the ethics committee to the governing institution and other national regulations
    - Complaint procedure
    - Ethical standards that the HREC has accepted for the conduct of research. The ethical standards section of the SOP will include sections on processes of voluntary informed consent, minimization and management of risks, protection of privacy and confidentiality of participants in research
    - Policy on cultural sensitivity.

Duration of Accreditation and Dates for Annual Reporting

Accreditation is for a maximum term of 3 years from the date of notification by FNHREC subject to satisfactory review by its secretariat or independent persons.

Reaccreditation Procedures

Applications for re-accreditation should be made 3 months ahead of the anniversary of the end of the accreditation term of 3 years. The reaccreditation process may not be too cumbersome if the HREC has been consistent with the submission of reports.

- Reports are to be completed and email to FNHREC secretariat by the end of each month.
- How many meeting convened per month ?
- Detail of the Chairperson's delegation.
- Numbers of proposals received, reviewed, approved, and rejected, low or high risk.
- Any changes to membership?
- Review process, changes and/or challenges to structure of review.
- Any other items that HREC require guidance or assistant from FNHREC?
- Capacity building activities relevant to HREC
- Ethnicity and cultural sensitivity
- Any complaints and how was it resolved.
- Other information that the HREC wish to include in the report

Failure to renew accreditation

Failure to seek a renewal of the accreditation status of a HREC mean that the HREC's accredited status has lapsed at the end of the accredited period.
The HREC will not be able to review applications for ethical and scientific review of research proposals involving humans. Other privileges will also lapse like the access to health data and other data required for research.

For further Information, please contact the Secretariat of the FNHRERC, Research Unit, Ministry of Health Medical Services

Fiji National Human Research Ethics Committee

Application for the Accreditation of Human Research Ethics Committee

New application [ ] **Renewal of Accreditation [ ]**

(Please tick (√) the appropriate description.)

1. Name of HREC…….....
2. Name of Governing Institution……..
3. Name of Chairperson of HREC …….
4. Year of establishment of HREC……
5. Contact address

   Physical address……...

   Postal address……..……

   Telephone…….

   E-mail: ……......

   Webpage address: ……
6. Authority to the formation of HREC

   a. ……..
7. Guiding Principles and Standards for HREC.
   …….. (Add more space if needed)
8. HREC Self-Assessment report. Please attach.

Ethics committee composition

9.1 Membership Profile

Name	**Qualifications**	**Area of Expertise/Skills/**	**Telephone/Email**

9.2 How often does your HREC meet? (Please, tick)
1. Weekly [ ] 2. Monthly [ ] 3. Bi - monthly [ ] 4. Quarterly [ ]
Others (specify)…….

10. Does the HREC governing Institution offer any support to the REC?
Yes [ ] No [ ]
If yes, please specify the nature of support the institution provides to the REC
……..
……
……

11. Does the governing institution offer administrative support?
Yes [ ] No [ ]
If yes, please specify the nature of support the institution provides to the REC
……..
……
……

12. Attach a document to describe the HREC Review process.

13. How does the HREC protect the rights, safety and wellbeing of research participants? Attach a document.
14. Does the HREC have a Standard Operating Procedure document? If yes, please attach.
15. Does your HREC charge any fees for review of protocols?
Yes [ ] No [ ]
If yes, please specify the charges/fees charged by the REC
16. Do you have a database of research protocols reviewed, record keeping and archives of HREC activities? Briefly describe it.

17. Do you have a complaint policy? Please attach.

Submitted by…… Date……

Signature……

Date: ……..

Appendix 3: Review Form

Logo

Fiji Nat

NOTE TO REVIEWERS

Please provide constructive review comments with helpful suggestions/alternatives. Please refrain from negative and personalized remarks or vague recommendations.

Fiji National Human Research Ethics Review (FNHRER); Reference Number. ……..

	COMMENTS
Title	
Relevance	Is the proposed research relevant to Fiji Context? Yes. No. Not Sure. Unclear. Comments to investigator(s)
Contribution to new generalizable knowledge	Will the research contribute to new generalizable knowledge to improve health of Fiji people? Yes. No. Not Sure. Unclear. Comments to investigator(s)
Introduction & Background	
Statement of the Problem	
Rationale of the study	
Benefits of Study	
Research Question, Aim, Hypothesis/ese	
Objectives	
Review of Literature	
Study Methods	
Study design	
Study Setting	
Study Population or Sample.	
Selection of participants	
Sampling, sample size & Power of Study	
Method for Recruitment of Participants (where appropriate not in secondary data analysis type of research)	
Data Collection Techniques & Instruments	

[2] Adopted from the Fiji National Health Research Ethics Review Committee review form and the College Health Research Ethics Committee review form.

Cultural Sensitivity (where appropriate)	
Reliability & Validity of Methods & Tools	
Data Management	
Data Storage	
Data Analysis Plan	
Pretest or Pilot Study where appropriate	
4.0 ETHICAL CONSIDERATIONS	
Confidentiality	
Privacy	
Voluntary Informed Consent	
Provision of debriefing, counselling, referral for treatment and processes to enhance duty of care for participants	
Anticipated Risks of research & planned methods of management of risks	
Work Plan	
Timelines/ Gant Chart	
Budget	
Activities, Equipment, Personnel etc	
Source of Funds	
Plan for Administration, Monitoring and Utilization of Results	
Administration Monitoring Utilization(including Publication)	
References	
References included	
Appendices	
Data Collection Form, Tools, Surveys, Questionnaires, FGD & Interview Guides	
Secondary Data De-identification/ Coding Forms	
Information Statement(s) (Written in a language that will be understood by prospective participants.)	
Consent Form(s)	
Third Party Consent	
Assent Forms	
Translated versions of above if applicable	
Facility Approvals	
Other Country Research & Ethics Approvals	
General Comments:	
Recommendation:	
Please tick (√) as appropriate. Fully Endorsed: No Changes Required: ……	

Endorsed pending Minor Changes: ……. Resubmit (Major Changes Required):……..
Acknowledgement The information used in this review form was sourced from the FNU College of Medicine Nursing and Health Sciences, College Health Research Ethics Committee Review form, 2017 and Fiji National Human Research Ethics Reviewer Feedback Form.