FNU FIJI NATIONAL UNIVERSITY
College of Medicine, Nursing & Health Sciences

COLLEGE HUMAN HEALTH RESEARCH ETHICS COMMITTEE STAKEHOLDERS' MEETING

7-9 APRIL 2021 | HOLIDAY INN, SUVA, FIJI AND VIRTUALLY FOR THE REGION

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BACKGROUND: COLLEGE HUMAN HEALTH RESEARCH ETHICS COMMITTEE

The College Human Health Research Ethics Committee (CHHREC) is the research bioethics and oversight committee of the **College of Medicine Nursing and Health Sciences (**CMNHS) and is embedded within the structure of the Fiji Institute of Pacific Health Research (FIPHR)[1]. It was established in 2011 in response to the requirement of the Fiji National University that every College must set up a research ethics committee. The CHHREC also complies with the requirements of international ethical guidelines on the conduct of research involving humans. The CHHREC was accredited by the Fiji National Human Research Ethics Review Committee (FNHHREC) of the Ministry of Health and Medical Services in 2019, authorizing it to issue full approvals for research proposals that have met the ethics review requirements of CHHREC, as per its Standard Operating Procedures (SOP). Previously, all CMNHS proposals were required to be submitted to the Fiji National Human Health Research Ethics Committee (FNHHREC) after the CHHREC has issued a full approval.

Research is a mandatory course in all of the Masters programmes of CMNHS and is gradually becoming a requirement in the graduating year of most of undergraduate programmes. There has also been more research capacity building for our staff over the years, and corresponding increase in staff research activities in the College. An essential component of teaching research to the staff and students of CMNHS is the strong emphasis on understanding the role of ethical considerations in research. It is important that all involved in the research projects maintain a high level of research ethics awareness as this will influence how the research project is designed, implemented, monitored and results disseminated.

A prime role of any ethics committee, like the CHHREC, is to provide expert guidance to research projects primarily to protect the lives of research participants from prospective harm or risk, that are physical, psychological, socio-cultural, economic and financial in nature. Ethics committees work to ensure that researchers uphold the research participants' dignity, rights and health and more so, to achieve improved health and benefits as they participate in research. CHHREC also work to enforce methods to protect institutions such as CMNHS from institutional risks posed by the conduct of research. CHHREC also works in partnership with other organizations who may need to establish an ethics committee, or general assistance with research bioethics issues that arise from time to time.

CHHREC members and external professional reviewers review the research being proposed to be conducted by staff and students of the CMNHS and their affiliates, locally, regionally and internationally. The research project is not allowed to begin unless it has gone through CHHREC review processes. These processes comply with international research practices which also extends to requirements of publishers. The CHHREC governs the appointment of members as well as defines specific terms of appointment and roles for members and reviewers.

[1] FIPHR is an integrated virtual research institute of the CMNHS at the Fiji National University. FIPHR has an overall vision of supporting Pacific Island countries in developing healthier communities by focusing on knowledge creation, exchange, integration and application through research as well as innovation and research capacity needed to address their communicable disease, obesity and NCD crisis, address sexual health issues, promote, restore and/or maintain population health and well-being and reduce their inequalities in health (FIPHR Strategic plan 2020-2025).

Research Context

The context in which CMNHS students and staff conduct their research vary in study site or facility - from hospitals and health centers, clinics, to villages, communities, schools, shops, municipal markets, supermarkets, use of data available and not available in the public domain, archives, museums, and others in Fiji and in the Pacific Island Countries (PICs). Some research project target multi-sites within the country and other countries. Upon the granting of an ethics approval from CHHREC, the researcher applies for research governance permit from the research setting or facility in which the research will take place. The research setting or facility is tasked with the assessment of the suitability of the study to take place within their facility and if the facility grants a permit then the researcher provides this permit to CHHREC to complete the review process before CHHREC grants a full approval. This first endorsement from CHHREC is therefore a "conditional" approval. Many of these facilities are outside of FNU, so a research governance permit issued by the research setting or facility is required by the CHHREC for a full ethics approval and the research can begin.

Several recent negative experiences of our college students and staff submitting research proposals through the CHHREC process have highlighted several challenges:

- a lack of awareness of the research governance and research setting/facility approval processes across many Ministry of Health facilities (mostly in Fiji) and other research settings.
- a general lack of a supportive attitude towards the conduct of research
- absence of clear ethics approval processes when research needs to be conducted among specific populations, such as villages, settlements, workplaces, schools, etc.
- a lack of inter-agency (government & non-government) linkages as supportive structures for effective research ethics processes
- an absence of research ethics and governance structures and processes in some Pacific Island countries where our student/staff research is conducted

Aim

Given the perceived challenges, the main aim of this CHHREC Stakeholders' Meeting is to encourage collaboration among research industry partners, to achieve a harmonized, transparent and friendly, cross-sectoral research ethics processes which facilitate and support health research that address national health priority areas in Fiji and the Pacific Region, while complying with international standards and practices of research ethics.

Objectives

i. To bring together researchers, research organizations and custodians of research facilities in Fiji and Pacific Island Countries (PICs) to meet, discuss and share information, create awareness of research ethic and research governance mechanisms and strengthen partnerships between the CMNHS – Fiji Institute of Pacific Health Research (FIPHR), research facilities and research ethics committees in Fiji and other PICs.

ii. To determine the status quo of health research ethics processes in all stakeholder agencies in Fiji, as well as several select Pacific Island countries.
iii. To identify gaps and challenges in the current systems and develop possible solutions to streamline the implementation processes of human health research ethics and governance mechanisms.
iv. To identify sources of reliable and available data sets and application processes in government and non-government organizations.
v. Training of stakeholders in ethical and technical review of research proposals.

Anticipated Outcomes

i. A meeting of human health research stakeholders in Fiji and selected Pacific Island countries.
ii. Strengthened partnership among human health research stakeholders in Fiji and selected Pacific Island countries.
iii. Identified status of human health research ethics committees, their structures, standard operating procedures which includes their research ethics review processes, strengths, opportunities, gaps and challenges.
iv. A detailed list of recommendations to strengthen and improve human research ethics review process and 'facility approval' processes for Fiji and the participating PICs.
v. Identified list of data sources and data application processes for human research.
vi. Participants/Stakeholders basic knowledge of:
(a) human research bioethics principles
(b) international guidelines on the ethical conduct of research involving humans
(c) ethical/technical review of human health research proposal.

Spiritual Uplifting

Conducted by Mr Raymond Keshwan, Head of School, School of Health Sciences,

College of Medicine Nursing and Health Sciences.

…We talk about the greatness of God.
The fact that nothing in all creation compares to Him
many of us would be thinking of God as humble and loving
and because of the experiences that we have had
with our Lord Jesus Christ through the Bible,
Jesus was the perfect example and demonstration of love and humility
but let us not in any way equate his love to
weakness and insignificance in the 21st century.
God is prominent, preeminent, majestic, powerful, magnificent, and
He is marvelous in all His purposes.
Quite refreshing for us to take back a step in the shadow of our significance
and give full attention to the greatness of our God
As it is all about Him anyway
Whatever we are doing here is all done for Him
We may take steps through majority in our lives,
when we finally realize that it is not about us and our significance but
all that we do is about God's greatness and his Holiness and Glory,
"His Way is in the whirlwind and storm and clouds are the dust beneath His feet, The Lord is good, a stronghold in the day of trouble, and
He knows those who take refuge in Him." Nahum 1:3 &7
I remind us all that our God is transcendent He is mighty, and He is awesome,
He is all around us, He is above us and the bible tells us that those who trust in Him, He is within them, and without Him, there is no Holiness for us
without Him, there is no promise of forgiveness,
without him there is no source, of absolute truth,
the Bible says that He is the truth and the life,
and there would be no reason for us to endure and there would be no hope,
for me there would be no hope beyond the grave
and nothing compares to Him
Verse of a Song
"*Oh God, Oh worship the King, all glorious above, and gratefully sing his wonderful love, our shield and defender, the ancient of days, valiant in splendor, and girded with praise*"

God's character is the same yesterday, today and forever.
Amen.

Introduction of the Guest of Honour

Dr William May, Dean of the College of Medicine Nursing and Health Sciences introduced the

Guest of Honour Dr Changgyo Yoon, WHO Technical Officer

Good morning. Happy **World Health Day 2021** to all of you– Theme "***Fairer and Healthy World for Everyone".*** Thank you so much for fronting up this invitation from the College of Medicine Nursing and Health Sciences, I know the body language, seem to be a bit shocking that I announced that today is the World Health Day. Thank you to all the stakeholders and partners from various sectors of work for responding to the call to be here today. This call as you might have read in your invitation letter stems from a problem and we hope that you be part of the solution to not only our problem but the problem of the community that we serve, which research aims to do. I would like to talk about '*being fair and enjoying a healthy world for everyone*' and how that might tie in with our workshop today, that whatever we do in research we hope that it will address a gap, it will be a solution rather than creating more problem and creating more harm for everybody, it will narrow the gap of inequalities that it will create a fair share of health for the disadvantaged and for everyone that look up to us to address their problems. Ladies and gentlemen, development partners, technical agencies, representatives of the Government Ministries, and representatives of institutions that are present here today, our regional partners who are still trying to connect via zoom, and some of them might connect with us later in the day and once again, I say, Ni Sa Bula Vinaka to you all. I extend a very warm welcome to you as the Dean of the College of Medicine Nursing and Health Sciences.

It gives me much pleasure to introduce our keynote speaker this morning, Dr. Changgyo Yoon, Technical Officer of the Integrated health services delivery, based in the division of the Technical Support at the WHO representative's office for the South Pacific. He has been in this position since 2016. He has undertaken projects on strengthening primary health care primarily in Fiji, Kiribati and Tuvalu. Dr Yoon is a medical doctor and attained his Master of Public Health from the Seoul National University in Korea. From 2009-2012, he was the resident at the Seoul National University School of Public Health. Between 2012 to 2015, Dr Yoon served as a Medical Officer to the 3rd Republic of Korea Army and the armed forces medical command respectively prior to completing a stint with the KOICA Paraguay office as a consultant. He has published numerous publications and reports and supported research projects primarily in infectious diseases.

I now invite Dr Changgyo Yoon of the World Health Organization to deliver this keynote address ladies and gentlemen.

Remarks by the Guest of Honour

Dr Changgyo Yoon,
WHO Technical Officer

Dr William May, Dean of College of Medicine Nursing and Health Science of FNU, Representatives from relevant Ministries and hospitals, Representatives and colleagues from Kiribati Nauru, Solomon Islands, Samoa, Vanuatu, Tonga, and Tuvalu connected online, Ladies and gentlemen.

It is a great honour for me to speak at the Human Health Research Ethics Stakeholders Meeting hosted by FNU and the Ministry and Health.

Let me begin by expressing my deepest condolence to the people who have lost their lives due to COVID-19 in the world. Our world has been facing this unprecedented crisis like no other since 2020.

I also wish to extend my sincere gratitude to health workers in the Pacific who have been working tirelessly to protect the population from the virus.

Today, we gathered here to talk about strengthening human health ethics. We all understand that adhering to ethical principles is critical to protecting the dignity, rights and welfare of research participants.

I believe we will be discussing based on the implications and key recommendations that have been made in the first stakeholder meeting for health research ethics in 2019.

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. At this stage, WHO and Fiji Ministry of Health are working together to develop the new health research portal.

Health ethics is an interdisciplinary field encompassing a broad range of domains and issues, where we need not only health professionals' perspective but also others perspective, e.g. education sector, religious leaders, community people, etc.

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 2019, WHO and UNESCO convened the second 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). The participants of the meeting had deliberation on how to reflect health ethics perspective in dealing with communicable diseases, prevention of NCDs, climate change etc.

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.

Since the COVID-19 pandemic has started, we have witnessed many and diverse ethical issues related with COVID-19 such as allocating ICU resources for COVID patients and prioritizing certain sub-group of population for drugs and vaccines. This would be where we wish to deliberate to ensure equitable, just, and fairer distribution of essential health services, using key principles of health ethics.

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 reminding about health ethics that is a practical key to protecting our people in doing health research.

I expect that the results of this meeting will contribute to improving health ethics review process 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.

I look forward to working together with all partners on health ethics.

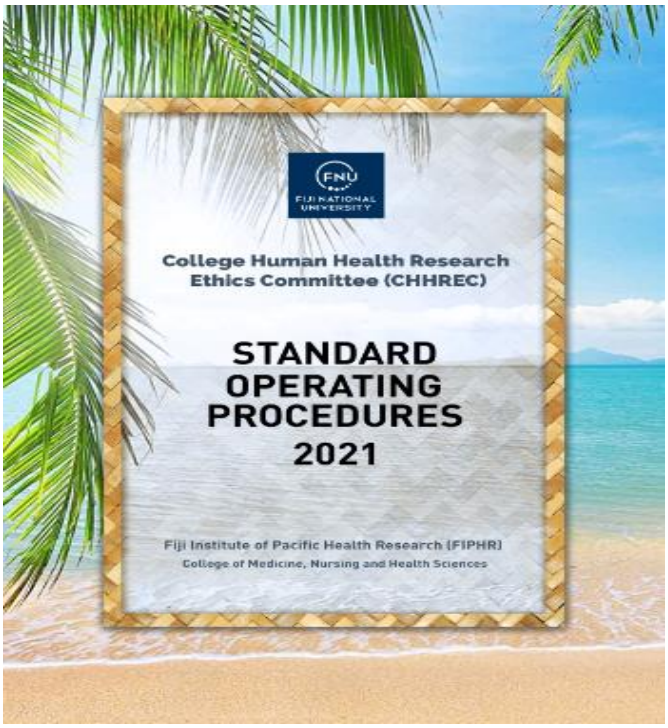
Let me conclude by sincerely wishing you a successful meeting.

Thank you.

A significant event of the day was the launch of the CHHREC Standard Operating Procedures, 2021. The Chief Guest, Dr Changgyo Yoon did the honour of launching the digital SOP 2021 which will later be printed in hard copies for distribution.

Launch of College Human Health Research Ethics Committee (CHHREC) Standard Operating Procedures (SOP) 2021

by Dr. Changgyo Yoon,
World Health Organization, Division of Pacific Technical Support



OVERVIEW OF THE CHHREC STAKEHOLDERS MEETING

Dr Donald Wilson,
Chair of CHHREC, Associate Dean of the CMNHS and
Director of the Fiji Institute of Pacific Health Research (FIPHR)

"Bula Vinaka, Talofa Lava, Malo e lelei, Mauri, Hello olgeta"

"Welcome to the College Human Health Research Ethics Stakeholders Meeting"

Good morning ladies and gentlemen and thank you once again for coming today. We are hoping that you have managed to say hullo to the person sitting next to you. We come from very different agencies, but I am hoping that at the end or after morning team you would have made new friends.

On behalf of the College, we welcome particularly our stakeholders to this meeting, we call you 'stakeholders' because you are very important because of the processes that are required for us to be able to ensure that the research that is conducted in Fiji complies with all requirements of research ethics. Today, we have a total of about 70 participants, and you represent a cross-sector of all the different stakeholders and that we are very happy about.

A Background - The reason why we are here today is because we, at the College of Medicine Nursing and Health Sciences have identified certain issues that have to do with processes related to research ethics. CHHREC is the College Human Health Research Ethics Committee and a few you here today are members of the CHHREC.

Last year (2020) we restructured the way we coordinate research within CMNHS. Under the structure of the Fiji Institute of Pacific Health Research (FIPHR) Strategic Plan 2020-2025, the FIPHR Organizational Structure which consist of the four arms, (i) The Research Centers (ii) Research Administration (iii) Research Training & Repository (iv) Research Ethics (that sits in the same structure but is an independent body and there is no external influence on the decision that are made in CHHREC). CHHREC membership are presented here today. They are the 2-3 representatives of each of the 5 Schools of CMNHS and we have three external members, and we are very happy to have two of them here with us today, one of whom is a retired judge, Mr. Sekove Naqiolevu and we are very happy that we have legal input in things that we discuss at CHHREC.

The purpose of today's meeting is, over the last year we have noticed that when students and staff submit research proposals to CHHREC for an ethics approval process, and that process sits with CHHREC, but research being proposed have different designs and protocols of data collection. For example, I might want to collect my data from the village, perhaps, looking at a community in the village or I am looking at a settlement in an informal settlement or I want to identify and conduct research on a fixed population, let's say may be teenage pregnancies in a given population and so

looking at pregnant women in a certain age group in a different population group, so where they are there is a different place, that the ethics approval needs to be sought from. If we want to conduct the research and want to find out the attitude or knowledge and attitude of nurses at St. Giles Hospital, then that is another different place that we need to go to for an approval. The CHHREC provides the researcher with a Conditional approval and then we ask the researcher to get an approval from the facility, so it covers where they want to conduct their research at. There is the grey area about conduct research in villages, conducting research in informal settlements, schools, there are places where the processes are clear, may be in the Ministry of Education and perhaps in the Ministry of iTaukei Affairs, so who do we go to get approval for the research that we want to do? It is straightforward if I just want to go to the hospital and collect data off patients that are admitted at the hospital, but all of you seated in this room, somehow, we are talking about Human Health Research and so all of us are related to Human Health, research, somehow or the other by virtue of the position that we hold and are present here today, the discussions that we were having recently was when we are not too clear about those processes, it hinders the process of actually conducting research. So, the researcher is caught in the middle because we do not have clear processes. So may be a certain Ministry is the Ministry that needs to approve or provide the facility approval, but they do not have the process in place. So, we would like to discuss today, for example, if we would like to go to a settlement in Nasinu and conduct research there because I know that there are children who are coming from that community who are always not provided with lunches so there must be something going on, so someone think we must try and find this out. But then when you start putting the paperwork together, then you say, who do we ask for the approval to conduct the study about this group of people? These are grey areas that we do not really know about, and we would like to use this opportunity, the CHHREC Stakeholder Consultation to clarify those issues. So, we really hope to have some very good discussion between the institutions that you represent and us an academic institution, we have the Fiji Higher Education Commission here and we hope we can get some input from there. We also have some participants joining us from at least four Pacific Regional countries, Tonga, Samoa, Solomon Is, Vanuatu and Kiribati. This is because we have students and staff conducting research in these countries. We also have our students from these countries, and we also have out staff conducting research and want to collaborate with people in those countries.

Research is important because we collect data to generate the evidence that we need locally and then to inform the policies that we have locally. So, it is important that we support research because it supports the growth of Government by informing policies with locally generated evidence. So, we are hoping again that your being here today, from your expertise, and you representing your respective organizations will contribute very much to that purpose. We want to support the research of our students and staff by providing the research training, you need a different skill sets to conduct research, but your contribution today is to help us identify and understand those processes. What we will hear from our regional participants what their approval processes are like, which will be educational for us as well. Fiji is in a better position because we have had this structured, and we have a very comprehensive standard operating procedure for our ethics

approval processes and we are happy that the Ministry of Health is also here, and they have just had their first meeting a few days ago and we are looking forward to the discussions. I have provided you with a background to the meeting today.

We hope from the discussion and expected outcomes at the end of the three days, we want to learn from various stakeholders, how their respective agencies view research ethics and what are the processes like in their agencies. We have researchers who come from abroad, NZ, Australia, America – when they come to Fiji to do research, there are different processes they need to go through. We need all the processes embedded in our SOP so that we advise our counterparts correctly such as ethics fees, research permit fees from Department of Immigration and others here today. At the end of the 3 days, we come up with clear resolutions and pathways and foster new relationships and new ways to collaborate in terms of research. There are opportunities for collaborations in this workshop today. That in a nutshell is the background to this meeting.

Thank you and welcome to morning tea.

Day 1: SESSION 1

OVERVIEW OF THE NEWLY LAUNCHED COLLEGE HUMAN HEALTH RESEARCH ETHICS COMMITTEE (CHHREC) STANDARD OPERATING PROCEDURES (SOP), 2021

Delivered by Etivina Lovo

Research Fellow, Bioethics and Professionalism

Member of CHHREC and Fiji Institute of Pacific Health Research

Overview of the SOP 2021

Sections 1 and 2 of the SOP include the Introduction of the CMNHS, FIPHR and CHHREC.

Section 3 presents an overview of the CHHREC. Main points.

The CHHREC was instituted in 2011 and named College Health Research Ethics Committee. CHHREC is the research bioethics and oversight committee of the CMNH. **CHHREC was accredited** in 2019 by the Fiji Government's National Human Research Ethics Review Committee (FNHRERC) for successfully meeting the international requirements of a Human Health Research Ethics Committee. The accreditation of CHHREC means that CHHREC has the authority to issue FULL APPROVAL for research proposals submitted for ethics review without sending to FHHREC as per the pre-accreditation process.

Some members of CHHREC, 2020-2021

From Left to Right: Avelina Rokoduru, Vinau Savu, Susana Lolohea, Dr Donald Wilson (Associate Dean Research, CMNHS and Chair of CHHREC), Kaminieli Tawake, Etivina Lovo, Dr Gade Waqa.

The Accreditation of the CHHREC, 2019

The CHHREC Accreditation Certificate

There under our hand in this day
March 26th 2019

Certificate Number 001/2019
Date of Expiration: 25th March 2022

MINISTRY OF HEALTH & MEDICAL SERVICES

This is to Certify that

College Human Research Ethics Committee

(College of Medicine, Nursing & Health Sciences, Fiji National University)

Has successfully met the conditions and requirements of the

Fiji National Human Research Ethic Review Committee (FNHRERC)

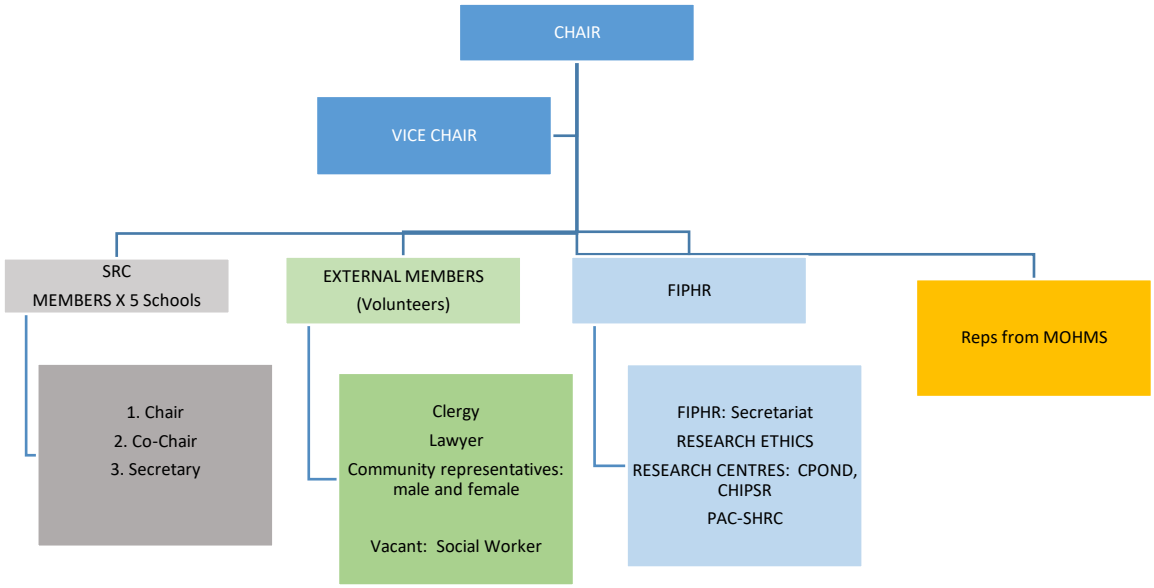
Awarded on March 26th 2019

Chair — FNHREC

Acting Permanent Secretary —
Ministry of Health & Medical Services

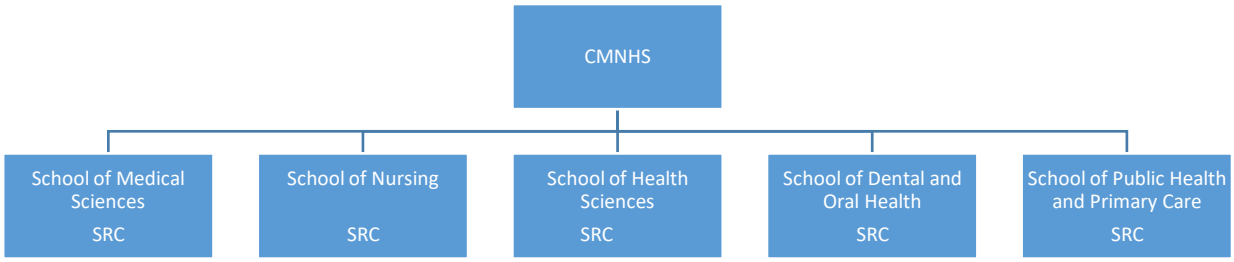
From Left-Right: Etivina Lovo (CHHREC Bioethicist), Professor Mohini Singh (Pro Vice Chancellor Research, FNU) and Dr Eric Rafai (Head of the Research and Innovation Division of the Ministry of Health and Medical Services, Fiji) with the CHHREC Accreditation Certificate.

Section 3.2: COMPOSITION OF MEMBERSHIP



Section 3.1 CMNHS Schools Research Committees (SRCs)

The SRCs are research committees located in the five schools of the CMNHS.
The functions of the SRCs focus on nurturing research within their schools for both staff and students and contribute towards the function and activities of the CHHREC.



Section 3.5 - Meetings, Frequencies, Quorum, Attendance, Confidentiality, Records

- Frequencies: CHHREC meets every month from February-November of every year. A special planning meeting is usually conducted in December.
- Quorum: 50%
- Attendance is taken, apologies, and members of SRCs who cannot come to the meetings can send a replacement.
- Discussions of issues regarding the review of research proposals are kept confidential.
- Secretariat – record the proceedings.

Sections 4 - CHHREC SOP, 4.1 Purpose of the SOP

To Guide the roles of CHHREC, describe the structure, roles, review processes that guide CHHREC functions. To map the Review process and to ensure that the Review Processes are applied. Serve as a Guide for researchers to assess their research for HIGH OR LOW RISK.

SOP includes a description of the following Processes

Section 5.0: Submission of new research proposals
Section 5.1: Staff and Students proposal submission guideline
Section 5.3: Requirements for facility approvals
Section 5.4: Special Conditions;

- Principal investigator as non-staff/student,
- Research in other Pacific Island countries,
- Staff as CHHREC member.

Section 6 - PROCESS FOR ETHICAL REVIEW OF RESEARCH PROPOSALS

6.1 Reviewers and their Roles, assess for level of risk, scientific rigor and make recommendations for improvements, approval or resubmit. 6.2 Review process, Figure 2 taken from page 25.

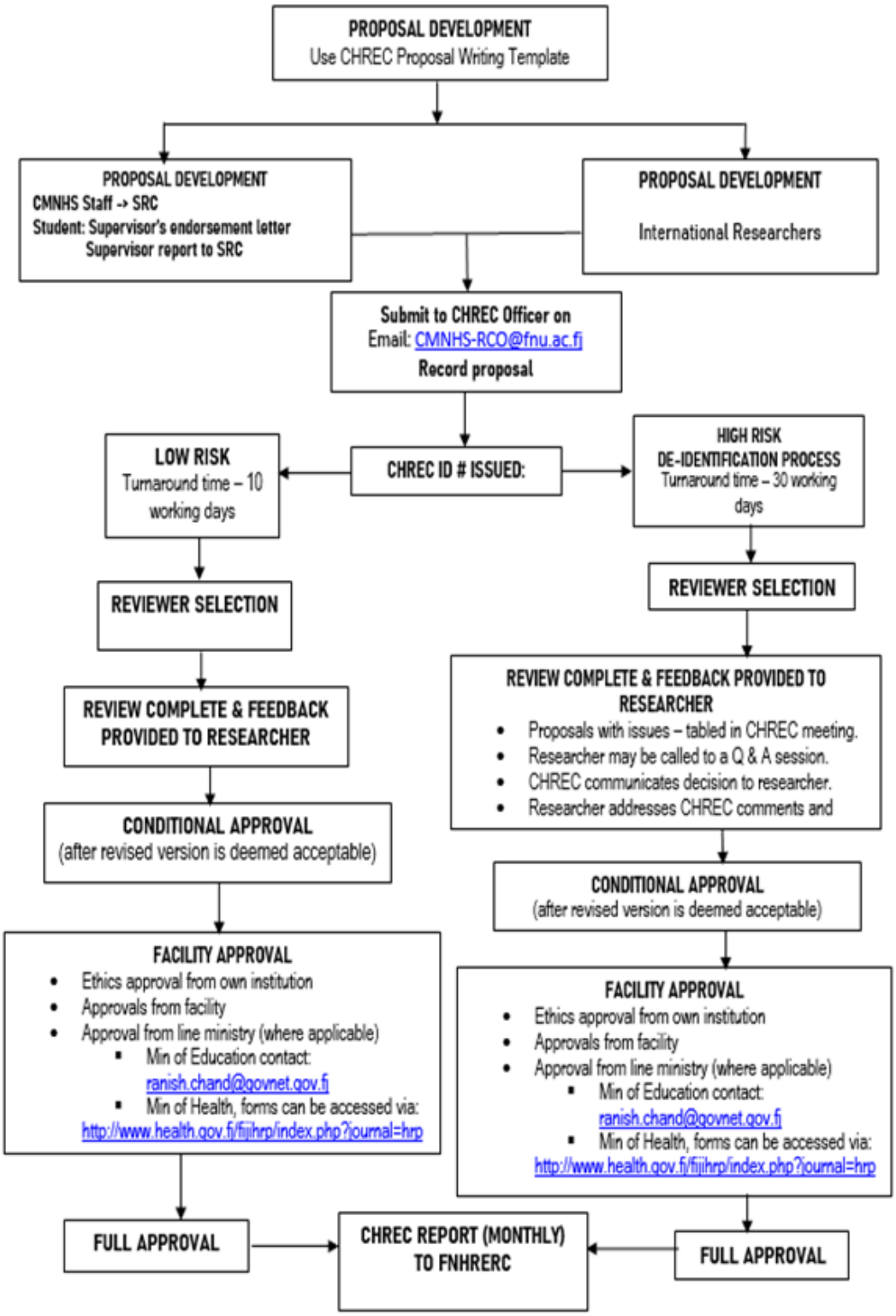
Section 6.11: FACILITY APPROVAL

Facilities or research settings are, Hospitals, divisional hospitals/Health centers and Dental clinics, Private hospitals, private clinics/Dental clinics, Schools, Government Ministries NGOs, CSOs, ITaukei Villages, Municipal Markets

List of Expertise: External Research Ethics Training

Experts may be called upon to conduct reviews and make recommendations but are not voting members or contribute to the quorum.

Figure 2: CHHREC Research Ethics Review Procedure



Research Ethics Training available on line.

Section 7: Monitoring Role of CHHREC

• Adverse Events Reporting • Random Spot-check on current research activities • Process for urgent safety related measure • Progress report – annual	• Auditing • Research Project Report Duration of CHHREC approval. • Final report to be submitted to CHHREC. • Changes in research project.

Other important sections in the SOP: Sections 8-18.

8. Urgent Safety related measures
9. Duration of CHHREC approval
10. Progress report and Annual report
11. Procedures on completion of research project
12. Authorship
13. Conflict of Interest
    13.1 CHHREC Members Declare Conflict of Interest
14. Suspension or Withdrawal of CHHREC approval
15. Complaints and Grievances
16. Adoption and amendments of the SOP
17. Periodic Review of CHHREC SOP
18. Special considerations of research involving vulnerable populations

(Appendix 13) and page 31-33

Appendices: Include Templates – Research tools

- Accreditation Process from MOHMS
- CHHREC Confidential Agreement
- Checklist for Low and High Risk Research
- CHHREC Templates:
- Students Research Projects Supervisors' Endorsement Letter
- CHHREC Research Proposal Submission Checklist
- CHHREC Guideline for the development of a full research proposal
- Sample Data Collection Forms, for Qualitative and Quantitative Research.
- Participants Information statement
- Voluntary Informed Consent Form
- Assent Form
- Secondary Data De-identification form – Sample Form
- Review form

- Progress Report template
- Definition of Vulnerable population

Higher Degree by Research (HDR) students and staff, Semester 2, 2020.

The presentation of the summary of the newly launched CHHREC SOP 2021 generated interest and a general discussion. The following section presents the points of discussion in Q and A format.

The SOP is a guide policy for CHHREC only and not any other ethics committee.

Question and Answer session.

Q: Do we have any relationship with institution (USP, UniFiji)?

A: CHHREC is independent from FNU Ethics Committee and other institutions, and we do not have any connection unless the National Research Council calls us for consultation on Human Health Research Ethics.

Q: Does the full accreditation approval include Facility Approval?

A: Yes, once reviewers reviewed the proposal, a conditional approval is granted and researcher are asking to provide their facility approval before CHHREC grant a Full Approval to conduct their research.

COMMENTS:

Representative of the St Giles Hospital sharing experiences.

- Having the awareness of how the process works is important.
- Currently we have received one research proposal.

- In previous years, the approval of any research proposal would be sought from the Ministry of Health.
- Changes in the process is very important for everyone to know the changes so there is no hindrance of the research proposal being reviewed.
- A case: A former staff was a Principal Investigator in a proposal for research. When there is an expected risk like the participants may be traumatized through the recall of memories via the interview process, how will this risk be managed? Would there be someone to give supporting counselling to participants.
- Time is very important. The research time allocated needs to be clear and they support the researcher with the information whether its qualitative or quantitative.
- As for Facility Approval, we help researchers because approval has come from MOH.
- Research with international collaboration, we ask the questions - how and what are the benefits of this research to us and our organization?

Response from ADR: A High-risk study will have risk management procedures included in the study. If the research protocol does not include a risk management procedure, the study being proposed is considered unethical and cannot be approved from CHHREC.

Representative of the Secretariat of the Pacific Community

SPC considers the College as a regional institution. One thing to consider is to have some clauses that give us the ability to submit research proposal from other countries.

Q: **Why do they do that (submitting research proposals from other countries)?**

- On average, every month they are involved in some sort of regional survey in one form or the other. So what SPC usually do is, the partner institutions whether it's the college of surgeon, or college of internal medicine and they ask for them to get prior ethics approval from the University close to them. The country wants comfort to see that it has gone through a thorough ethics procedure. That is what the countries want to see.
- From SPC if they could consider a case-by-case basis that don't have ethics committee - could submit to CHHREC as the process where one ethics committee serve several regional countries. On the other side of the coin, some small countries they are submitting their research literally to each other. The countries are too small and they are saying that they are so small, an independent eye to review is better. WE have that was done by Fiji Medical Councils for many years, e.g. Registering doctors in Medical Councils, we have done registers of Tuvalu Doctors in the Fiji Medical Council. In Micronesia, they would ask us to do the screening somewhere. So somewhere in that vigorous methodology procedures that you presented that if there is a clause that allows other countries to submit to CHHREC for consideration.
- Chair of CHHREC Chair, added that one of the processes in reviewing research proposal is separating the Low Risk and High Risk proposals. A high Risk study will have a backup on how you can handle situations.

RECOMMENDATION:
CHHREC is happy to engage with SPC and the region to provide research capacity building for the region. CHHREC has begun work with Vanuatu, because they do not have an ethics committee, and this is the ways in which CHHREC contribute in the development of Research Bioethics and Ethics Committee in the Region.

Day 1 - SESSION 2

There was a need to present the roles of CHHERC and the review processes to indicate the significance of the various institutions/stakeholders in the mechanisms of the CHHREC review processes. Relevance, collaboration, and partnership with stakeholders were important to achieve in this session. The Bioethicist in CHHREC presented the various research designs that are reviewed by CHHREC.

DESIGNS AND METHODOLOGIES of RESEARCH PROPOSALS SUBMITTED TO CHHREC

Presented by Mrs. Etivina Lovo
Research Fellow (Bioethics and Professionalism)
Fiji Institute of Pacific Health Research, College of Medicine Nursing and Health Sciences

1. **Roles of CHHREC included**
   - Scientific Review of research proposals
   - Ethics and Scientific Review of research proposals
   - Provide skills development in Research Bioethics
   - Assist PICTS in strengthening of ethics committees

2. CHHREC Achievements in terms of research proposals being received, reviewed and approved over the last three years were as follows;

   - 2018: 188
   - 2019: 160
   - 2020: 181

3. CHHREC review process

Include a "FACILITY (research setting) APPROVAL" STAGE. This is after the research proposal is assessed and found to be ethically and scientifically sound. A Conditional Approval is granted. The condition is to apply and be granted an approval from the research facility.

FACILITY APPROVALS are sought from research sites or settings, such as, Hospitals, health centers, clinics, Labs, Town councils, Pharmacies (public and private), Schools including Pre-schools, Government ministries and NGOs, Religious organizations, Informal settlements, Supermarkets and retail stores, Municipal markets, Dental clinics (public and private)

Pacific Islands health care settings and other settings; Samoa, Tonga, Kiribati, Vanuatu, Solomon Islands, Federated States of Micronesia, Timor Leste, and others.

4. Designs and methodologies of research proposals submitted to CHHREC, presentation by CMNHS schools and research centers.

Table (1): Research Reviewed by CHHREC in 2018-2020

Schools	2018	2019	2020	Approx. Total
CPOND	1	2	7	10
SDOH	44	24	29	97
SHS	69	60	42	171
SMS	43	33	56	132
SON		1	2	3
SPHPC	26	39	28	93
Approx. Total	183	159	164	**506**

4.1 WHO Collaborative Centre for Obesity Prevention and Management (CPOND)

Some Titles of Research Projects submitted to CHHREC;

- Pacific "Move for More" Physical Activity Campaign
- Scaling up food policy interventions to reduce NCDs in the Pacific Islands (SUP Pacific) – Dietary Survey;
- An assessment on the types and reach of alcohol marketing in selected Pacific Island Countries.

A Case of the Design of a Research Project from CPOND for illustration only

Research Title: **Formative research to guide Pacific "Move for More" Physical Activity Campaign**

Study Design: Formative research using qualitative interviews and focus groups with key stakeholders, parents, and children.

Pacific Islands: Multi Country Study

Solomon Islands, Samoa, New Caledonia, Cook Islands, Wallis and Futuna, Kiribati and Fiji, Tuvalu, Vanuatu, PNG, Marshall Islands, French Polynesia

Research settings/facilities

- Government; Ministries of Health, Education - schools, Women and Children, Home Affairs, Public Health, Sports, Women and Social Welfare
- Churches, Sports Organizations, Cultural Affairs, iTaukei Affairs (Fiji), Local government
- Cultural organizations/leaders
- NGOs – Marie Stopes, Save the children

4.2 School of Medical Sciences (facility in red)

Total of 29 study proposals submitted from Jan-April 2021.

Study Designs employed;

- Epidemiological studies: A Research Project Title*: Incidence and prevention of postoperative nausea and vomiting in The National Hospital of Timor Leste*
- Retrospective/Prospective Audits:
  Title*: A Prospective Audit on neuraxial complications and interventional therapy amongst the post-caesarean section population at the Tupua Tamasese Meaole Hospital(TTMH) in Samoa*
- Epidemiological studies:
  Title*: Incidence and prevention of postoperative nausea and vomiting in The National Hospital of Timor Leste*
- Retrospective/Prospective Audits:
- Systematic Literature Review
- Evaluation of systems and processes studies

  A Title: *Analysis of time utilization of scheduled operations in the main operating theatre of Vaiola Hospital, Tonga: A Prospective Study.*

- Medical education evaluation study:

A Title*: A Study of the UO Canterbury-FNU GHCR – a Global Health Classroom (GCHR) between medical students at UOC New Zealand and FNU Fiji.*

A Case of the Design of a Research Project from School of Medical Sciences for illustration only

Title: **Baseline Prevalence Rate of Sight Threatening Diabetic Retinopathy at The Fiji Diabetes Eye Center**

Study Design: A retrospective descriptive study conducted at the Diabetes Eye Center, Suva

The study will include diabetics attending the doctors' DIAB clinic from January 26, 2018 to December 7, 2018. Data collection is to begin in November of 2019, pending ethics and research approval.

Data will be extracted from the VIP.net database and from individual patient folders. Prevalence for STDR will be determined from the total number of STDR cases identified in the doctors' DIAB clinic within the 1-year study period.

Cases are defined as individual patients seen and not eyes seen.

Grading of retinopathy, whether done in the photo clinic or in the DIAB clinic, is based on the Diabetes Retinal Screening, Grading and Management Guidelines for use in the Pacific Island Nations. These guidelines are a modification of the New Zealand National Diabetes Retinal Screening, Grading and Referral Guidelines (2006).

4.3 School of Dental and Oral Health

Final year Undergraduate Students Research Studies. Titles;

i. Qualitative study; pregnant women's perception of dental services at Navua hospital.

ii. KAP of oral health and dental caries among young adults in the Rewa province (3 iTaukei villages)

iii. Epidemiological study about the prevalence of tooth loss among patients presenting at the Teaching D&O clinic, CMNHS

iv. *iv. Knowledge about the management of Tooth Aversion among primary school teachers in* – Tonga

v. (The same study was conducted by another student in – v. Nausori Schools and by another student in – vi. Lami Schools in Fiji)

A Case of the Design of a Research Project from School of Dental and Oral Health for illustration only

Title: Assessment of the knowledge, practice and attitude of parents and caregivers about Early Childhood Caries in Nausori. (Undergraduate SDOH student)

Study Design: This is a descriptive cross-sectional study.
Method of data collection: House to house survey. Data collection tool – structured questionnaire.
Study Setting: Random location was chosen in Nausori to represent whole of Nausori. The location chosen is Koronivia road, Nausori. Koronivia was chosen by random sampling. In a bowl, pieces of paper of names of different areas in Nausori were written and mixed. A piece of paper was drawn from the bowl and the area written on the paper was Koronivia. Koronivia is small community located 5 minutes' drive from the Nausori town. It is a community with multi ethic background.

4.4 School of health Sciences: 21 studies submitted to CHHREC from January – April 2021

Designs:

- Epidemiological studies – about senior citizens' understanding of their medical labels – CWMH
- Diabetic patient's management – Nausori Health Centre
- KAP study among women and oral contraceptives – Suva/Nausori corridor
- Mixed Methods Study: Anti-Diabetic medication and patients compliance in Solomon Islands main hospital

4.4.1.1 Physiotherapy Final Year Students Studies - Observational studies

- NCD among media and telecommunication workers in Fiji.
- Physical activity and hypertension among Retail store workers in Fiji
- Secondary data analysis of Laboratory based data on breast cancer, CWMH Laboratory data.
- Prevalence of Neisseria Gonorrhea and Their Antimicrobial Sensitive Test Pattern Among Females of Age 15 To 30 Years Old In Solomon Island National Referral Hospital Microbiology Lab From 2013 To 2017

5. **School of Public Health and Primary Care; 13 studies submitted to CHHREC January-April, 2021**

Study Designs

- **Epidemiological studies**: Settings: Sigatoka hospital, 5 health centers in the Central Division, Mother and Child health clinic in Bua, Pacific Eye clinic Suva
- **Qualitative studies**: 1 Rotuma hospital, 1 among HCWs and Tobacco Control Unit, 1HCW and child immunization, MOHMS, 1 Informal settlements in Suva,
- **Mixed Method Studies**: looking at '*Sodium content in processed foods in Supermarkets in Fiji,*

Research Topics

- *Factors Affecting Diabetes Patients' Attendance in Diabetes Eye Clinic of Five Health Centres in Central/Eastern Division of Fiji: A Mixed Method Study*
- *Perceptions of Foot Complications Amongst Diabetic Patients Attending Clinics and Health Care Workers working, in Rotuma Hospital: A qualitative study*

6. School of Nursing

Research Title: *Psychiatric nurses' experiences of workplace violence at St. Giles psychiatric hospital in Fiji*

Study Design

A qualitative descriptive phenomenological approach will be used to explore and describe the experiences of psychiatric nurses caring for psychiatric inpatients at the mental hospital in Fiji.

Study Setting

This study will be conducted at the St Giles Psychiatric hospital, in Fiji. Registered nurses working in the hospital will be recruited for the study.

7. Facility Approval

All researchers are to sought approval from RESEARCH FACILITIES PRIOR to the commencement of human research projects by staff and students of CMNHS.

Clear and transparent application processes are needed to facilitate the successful implementation of research projects from CMNHS.

The Representatives of stakeholder institutions delivered their presentations of Research Governance Processes in their various institutions.

8. General Discussions and Q and A Session

Q: Findings of the research – are they given back to those who will benefit from the research? like that in the St Giles.

A: SOP has a clause – research need to submit a final report to the research facility.

Q: Do you have any follow up programme?

A: CHHREC Officer follow up with researchers on their progressive report in which includes updates and these reports are submitted to the HOD, FIPHR and their respective stakeholders.

Q: The question was whether the final report is given back to the stakeholders. Is CHHREC following up on that. This is one of the processes to clarify.

A: When we change to the facility approval. The head of the facility can as the researcher to make a presentation to them at the end of the research.

Processes to establish or strengthen

1. Process of facilities accessing or receiving the research report at the end of the research project.

Q. Who is responsible to ensure that the final research report is given back to the stakeholders?

(i) To be included in the CHHREC SOP monitoring processes.

(ii) Feedback is very important we want something to come back to us -present to us – the nursing staff and management. They need the data as well.

(iii) The facility also can ensure to facilitate a session where the researcher present the result of his or her study to them at the end of the research.

2. *Process for CMNHS researchers e.g. MMED to present their research findings to research facilities.*

MMED presentations – so you expect to present back to hospital – who do they want to present to?

- CWMH – different units – MMed present in their departments, give them opportunities to present in the various departments in CWMH
- IMOP.

3. *In terms of getting the report itself, it has been difficult. Where are all these reports going to? In CMWH, will be useful to inform policy and operation planning – but the reports are not coming.*

CWMH Process - Dr Luke and secretary to have a tracking system where the MS secretary can, at the end of the research they can call the researcher to give a report back.

Q: How can we make these researchers to be made available to us to make policy or other decisions, if it is published, then it is available. Can university have the reports stored and be accessible for us – local data accessible.

Dr Wilson – when to submit – before the graduation?

FIPHR strategic plan, - Research Training and Repository – we have managed to get fund to create that data repository. Unpublished work in sitting somewhere in the library. Researchers will not know if a research topic is already researched. We need to digitalized the research reports and this will allow people to search and find work done in this topic area, unpublished, included MMED. This space we are going in to. How we deal with the facility approvals, feedbacks to facilities.

Comments: what we do with the research results – suggest that each of us here coming from institutions, could consider as part of our process, joint analysis of research, preliminary results process, discuss preliminary results, interpretation of results before write up, recommendation workshops, after the report produced, we could jointly translate the recommendations into policy and programmes so that the research that we are doing answer – and make changes where needed.

4. ***Authorship of research projects involving SPC member countries.***

Q: SPC: Authorship or Academic, are you contributing academically, asking our countries to be co-authors, are we encouraging ownership and countries step up to be co-authors. We demand the countries to be co-author. Or it is something to think about from the university.

A: DR Wilson – an authorship policy developed.

RECOMMENDATIONS:

(i) Research facilities to receive a copy of the final research report including data collected. Research facilities to facilitate an oral presentation from researcher of the findings of the research.
(ii) MMED students to present to the relevant division in the relevant hospital.
(iii) Present in IMOP conference.
(iv) Health facilities management to create a tracking system where the MS secretary can, at the end of the research they can call the researcher to give a report back.
(v) FIPHR to store the reports in a data repository and facilitate the publication of these reports.
(vi) Authorship policy to be developed in consultation with SPC.

SESSION 3: STAKEHOLDERS PRESENTATIONS OF RESEARCH PROCESSES

Presentation 1:

MINISTRY OF HEALTH AND MEDICAL SERVICES

By Ms Anjana Deo, Research Officer
Fiji Health Research Update

Requirements and Processes from MOHMS

a. Achievements:

- (Ministry of Health and Medical Services, 2019)(SOP) being endorsed and circulated widely. https://drive.google.com/drive/folders/1h_SCJv5pKyBWSvjQjK1uyR-323Kc0StS?usp=sharing
- Fiji Human Health Research Ethics Review Committee – consists of Bioethicist, Church leader, lawyer, iTaukei Affairs, other health systems background from MOHMS such as NCD, Communicable Diseases, Environmental Health, Internal Medicine and Surgery.

  First meeting was yesterday with the workshop.

b. Currently: Development of new online health research portal with the support from WHO.

- Phase 1 development in 2019.
- Phase 2 development in 2020 – 2021. To be finished in June-July 2021.
- The previous health research portal was developed in 2012 and based on consultation meeting the recommendations were made to review the system.
- The previous health research portal was developed in 2012 and based on consultation meeting the recommendations were made to review the system.

New online health research Portal

Features:

- Users – Admin, Coordinator (Research officer), researchers (upload proposals), Internal/ External reviewers (review online and fill in the review template), Chair.
- All to have login page – only communication with the coordinator.
- Researchers to submit final report.
- Universities able to upload the quarterly update.
- Data request section to be online, including approvals and submission.

c. Accreditation of the CHHREC at CMNHS

As of 26th of March 2019, the College Human Health Research Ethics Committee was accredited by the MOHMS to review all health/ human related research proposals submitted by students and staffs of CMNHS.

Accreditation does not include approval for access to the facilities or patients/staff under the MHMS, nor does it provide approval for direct access to the data at these facilities.

The researcher must seek approval from the head of the facility. Researchers are to complete the data request process.

c. Number of Research Proposal Received by FHHREC 2014-2021 April

2014 = 76, 2015= 73, 2016=70, 2017= 135, 2018=161, 2019=90, 2020=42, 2021 (up to April) =12

d. Requirement for Research Ethics Application

- A full proposal protocol (detailed)
- Data collection instruments – tools, survey, instruments, questionnaires
- Consent forms/Assent forms
- Participants' information sheets
- Local collaborators
- CVs of principal investigators
- Other ethics approval (if any)

- Evidence of obtaining research permit

Address for Enquiries: Phone: 3306177 ext 340170| Email: fijihealthresearch@gmail.com

e. Research Proposal Template:

Title Page (including the Primary Investigator & Co-Investigator Name, & Local Collaborator and the Institution Name of each Investigator)

1: Introduction

- 1.1 Background information
- 1.2 Statement of the problem
- 1.3 Literature Review

2: Aims and Objectives

3: Methodology

- 3.1 Study type
- 3.2 Variables of the study
- 3.3 Plan for data collection
- 3.4 Plan for data processing and analysis
- 3.5 Ethical consideration

4: Work plan

5: Budget

6: Plan for Administration, monitoring and utilization of results

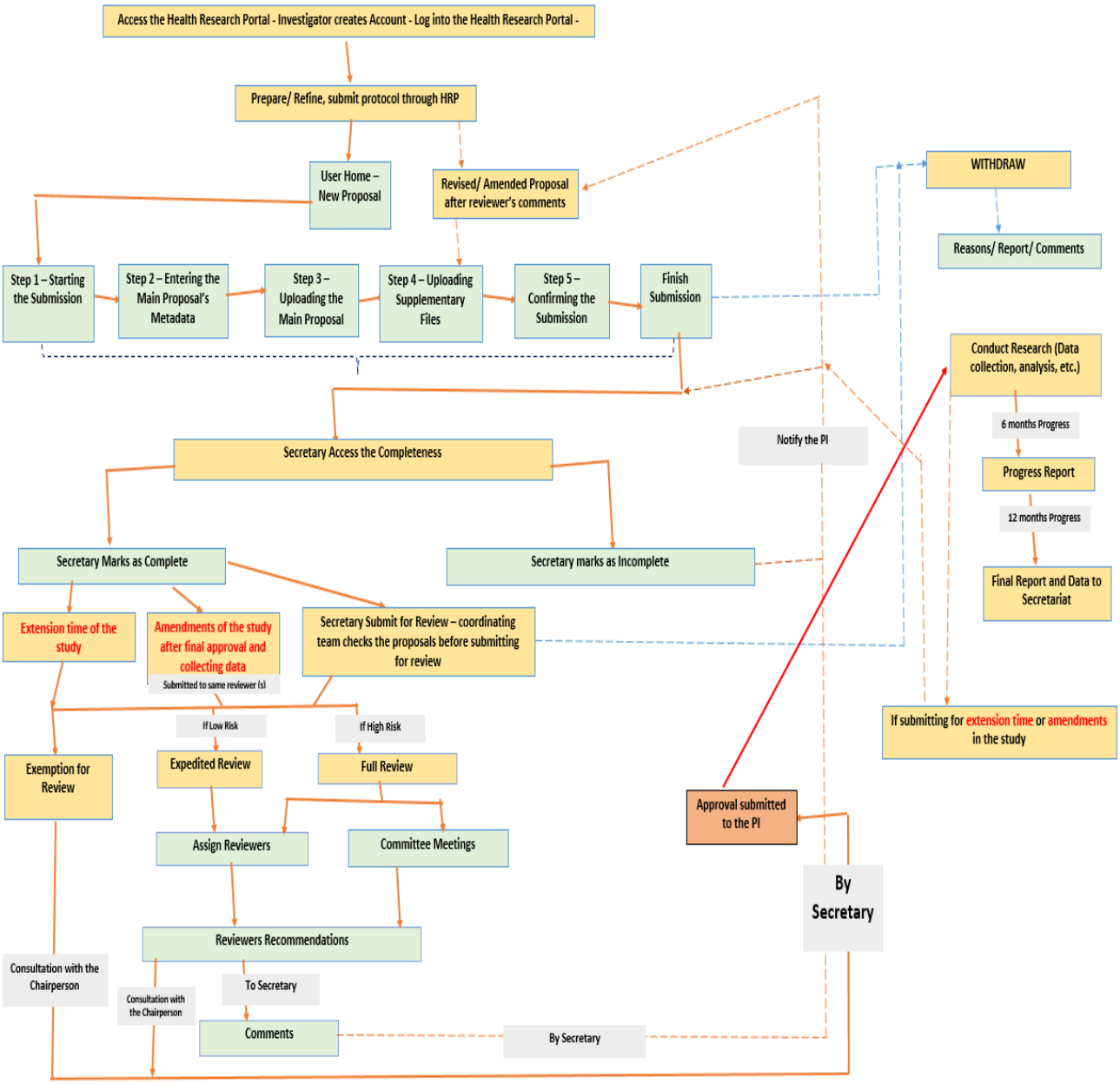
Annex 1: References

Annex 2: Log Sheet

Annex 3: Data Collection sheet

Annex 4: Consent Letter

Health Research Workflow



e. Other Approvals (Research Facility/ Data Requests)

To access any health facility, staff and patients in order to conduct human health research activities shall require Human Health Research Ethics approval either partial or an accredited institute of FHHREC.

An accredited institute is College of Human Health Research Ethics Committee (CHHREC) therefore, they give full approvals to their students and staff.

To access any health facilities by local researchers (students/ lecturers) need to seek approval from the head of the facility with the prior provision of the necessary information on the research project.

Any international researchers intending to conduct activities within health facilities or collate information from employees of the MoHMS should seek formal approvals from the PSHMS.

Human Health Research conducted outside Health facilities e.g. schools and village communities must go through the FHHREC.

Data Requests – need to request through filling the data request form and procedures follows.

f. Challenges

Lack of manpower for the Secretariat

Timeliness of review

Timelines of responses by the researchers to enquire on their research

Limited **number and capacity of reviews from specialized fields.**

g. <u>RECOMMENDATIONS</u>

- To help maintain the health research committee, need support on providing refresher trainings for ethics reviewers.
- The health research portal to be developed, so that the final reports, and research data is fully received from the researchers.

Presentation 2:

Access to Health Facilities for Research activities

presented by Dr Eric Rafai
Head of the Research and Innovation Division of the
Ministry of Health and Medical Services

a. Access to Health Facilities for Research activities presented by Dr Eric Rafai, Head of the Research and Innovation Division of the Ministry of Health and Medical Services

- Previous process – 'approval' by PSHMS or Minister
- New Process – Ethics approval is separate from access to facility. Head of facility/institution provides approval to access facility
- MOHMS Research Policy
- Hospital and Dispensaries Act

b. Rationale

- Health facility management is aware of research activities – accountability & responsibility – head of institution is responsible.
- Ensures better communication between researcher and head of facility. Need the investigator to communicate with the facility. Research unit of the Ministry can help facilitate research cases that are problem.
- Institutional rules are shared with the researcher
- Sharing of researcher's findings with participants for institutional improvements. Researchers presentation on how to use results is valuable.

c. Suggested SOP

Researcher/student

- Obtain Research ethics approval – complete/partial
- Make appointment or communicate with head of facility/institution – copied to research & innovation unit to help.
- Comply with conditions of institutions, time suitable is less busy time for clinics, dress code need to be respected in the institutions.
- Head of facility/institution – to understand the policy and guidelines. Under research policy & guidelines
- Acknowledge researchers request – via an email send to the facility.
- Identify conditions for research activities e.g. allocated time, etc. and expectations e.g. presentation to staff on research findings
- Exceptions e.g. International researchers, Quarantine facilities, etc. certain facilities only PS can give approval. Permissions of this kind is required from MOHMS.

d. **Way Forward:** Develop SOP with colleagues. Advise heads of facilities via a formal communique. All to create awareness. Research Portal will be up by June or July.

Question and Answer for Presentations from MOHMS

Those who are members of the committee. No reference from our University – comments we receive from your organization was poor. In terms of the quality and quantity and these have many linked with time, received one or two minor comments in 2-3 months. Who are the members and what is the link to the university?

(This comment indicates the need to train reviewers)

Q: Is maternal health represented on FHHREC?

Q: How do you avoid duplication of research in different facilities? Who keeps a check of this duplication in the same facility?

A: Data repository project.

Other points of discussion:

- Research have to target National priority areas for health research in Fiji.
- Strengthen communication between researchers and facility prior to research and after.
- Publish research projects.

Q: Local Journals? Fiji Journal of Public Health, Fiji Medical Journal

- Recommendation- gold standards is to publish – to avoid duplication. To be searchable online.
- Ethical approvals does not allow for data access.

Q: Fiji National Research Council Act 2017, any update?

Answer by Naqiolevu: We have had meetings with MEHA, and we MOHMS don't have any answer. Plans are still in the pipeline. The law is in force; it is a matter of setting up the body that will administer the Act itself. I don't know if funding is the issue. Mechanism should be in place so that people can apply to it. The law is in effect, an Act, it should really be – I was referred to the PS education, so I asked when the council is up – the body – membership – statutory authority. If I have an answer I will get back to you.

FHEC: We have a vested interested in the act – we worked together with MEHA to set up – to advertise for members – budget reduction etc. this has been put on hold.

ADR: Go back to Dr Rafai's SOP. We can have a look at that we agree to go forward. In the Suggested SOP – to include everything that will help with the process. We work on this in this meeting so that all the stakeholders are informed about what should happen at what stage and researcher and facility.

RECOMMENDATIONS:

- Develop SOP with colleagues. Ssuggestion from Dr Rafai for the group to compile an SOP to be actioned.
- Ethics Review of research proposals training be conducted for reviewers at FHHREC.
- Need a data repository.
- Need to facilitate publication of research project reports to ensure no duplication of research topics and accessible.
- Explore local journals to publish work in.

Presentation 3:

MINISTRY OF ITAUKEI AFFAIRS

presented by Waisale Ramoce

Chair- Policy & Research Unit, Development Services Division

a. Overview of Presentation: Divided into two main sections.

A. The iTaukei Research Protocol

B. MTA Research Approval Processes

When you apply to do research, the protocol itself in iTaukei emphasize.

"Research among indigenous peoples of the Pacific in the 21st century face a number of challenges. One of the most powerful of these is the unchecked and careless use of frames that do not take into account languages and Indigenous knowledge protocols, philosophies and principles, especially where and when their own knowledge's and tribal issues are researched." (Nabobo Baba, 2008)

Why do we do research protocol.

A. We begin with epistemology.

Epistemology

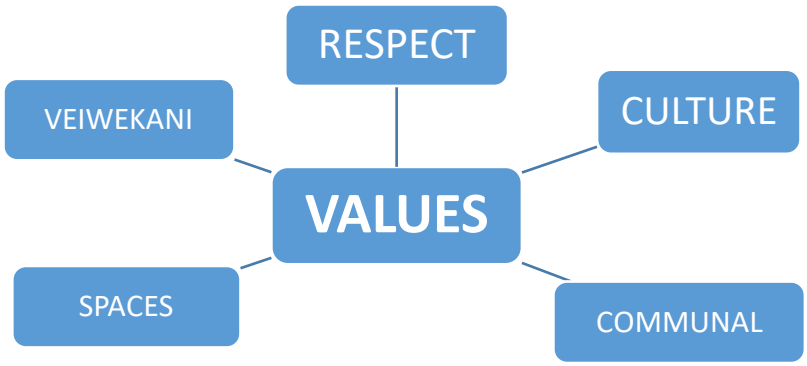
Whose knowledge? Are they after, or are we talking about – so it is about iTaukei knowledge.
Why do we need to know?
How do we acknowledge this way of learning?
What are the sources of this knowledge? Oral traditions, book, songs, written ones. A way of learning, when you extract that knowledge, how do you acknowledge the community.

Research Protocols

Vanua → People + Resources + Physical and Spiritual World

When we talk about the Vanua we talk about the people and the resources and (Nabobo-Baba) talks about the physical and spiritual world. These are all the aspects that need to be factored into the research.

Values



Space – representation of the Vanua, communal setting, culture which defines these values.

How do we analyze the processes of research?

Processes of Research Protocols

a. Na Vakatadumata- Entry Processes-Protocols

- Know the Culture, the greetings, the Location, the information – background information, to be factored into the proposal. Know the language.
- Know that Itaukei Structure within the Provincial level – dynamics of the culture, provincial level, yasana, koro
- Know the Processes of Submission
- Orientation programme with partners and stakeholders

b. Na Solesolevaki – Engagement protocol – research on the field, talking to people, extract information, work with turaga ni koro, interrelate with people.

- Present your Sevusevu
- Familiarise yourselves with your guides
- Interaction with your communities- dressing, languages, approach
- Traditional Obligations - Village Meetings
- Spaces – engage with the community.

c. <u>Nai Vakatale- Exiting-M&E – moving out of the community after the research process of exiting</u>

- Acknowledgement of your stay
- iTatau
- The 'Gifting" of Knowledge – show appreciation that you have taken things from the communication
- Communications with the Provincial Council and MTA
- Report of the Completion of you Research (this is an area is working hard on, most researchers have not given us a copy of their research, how do the community benefit? The report after the completion of research to be submitted.
- Exit form the Communities
- M& E and Report of the Outcome (iTaukei Affairs will follow up with this protocol.)

B. Research Application and approval processes for research requests in Itaukei Communities

Requirements for Research Support

- Letter of request for support to be addressed to the Permanent Secretary, Ministry of iTaukei Affairs
- Project summary
- Research team's bio data & contact information
- Project work plan to include the names of villages/province, length of the project, dates/year
- Consent Form – English /iTaukei – there is a unit that does translation.

Processing of Research applications

- Request received and assessed by desk officer (1day)
- Assess request with supporting documents and submit for approval to the Permanent Secretary iTaukei (will depend on the complete submission of requirements from researcher)
- Completed application process by Desk Officer (1-3weeks) if approved or turned down. If turn down, we will liaise with research as to what to be done.
- Endorsed support letter and supporting documents are communicated (email) to iTaukei Affairs Board & Provincial Council Office (Roko Tui) for their immediate action in assisting the Researcher.

14. Provincial Council Offices

- Researcher to contact the Provincial Council Office and provide Support Letter from the Ministry of iTaukei Affairs
- Provincial Office will assist in facilitating logistics (accommodation /traditional protocols)
- Consent Form is understood and signed by the community members - Provincial Council will facilitate researcher(s) introduction into the community and ensure that Free Prior Informed Consent principle is applied before any fieldwork is conducted.

- Completed research report is submitted to Ministry of iTaukei Affairs within three months of project completion (we are still working on this.

Support granted with the following conditions to be undertaken

- Provincial Office (Roko Tui) be informed of the research objectives and the communities that will be impacted in the process
- Free Prior Informed Consent (FPIC) guideline Principle is obtained by researcher and evidence of this provided with a copy of final report
- Individuals/communities that participate in the research are appropriately informed of the objectives and duration of the research
- Cultural sensitivity and traditional protocols are observed
- All fieldwork and research activity is to be put on hold on Sunday; that Sundays' be respected as a day of rest
- Status update(s) of the ongoing fieldwork be submitted at regular intervals to the Provincial Council office and the designated Ministry iTaukei Affairs desk officer
- the respective village communities are acknowledged in the research report;
- A copy of the finalized research findings report is submitted back to the community

Discussion points

- Acknowledge well structure your ministry.
- Entry involve Sevusevu. 2 levels – Provincial council – entry framework is done in the community level or the koro. The reps from the Provincial Council will accompany you to the koro (village).
- iTaukei language translation: iTaukei Affairs offer the iTaukei translation services to researchers for a fee.
- Free for other Government Ministries. FNU and other NGOs have to pay fees. Email to inform – to build the fees into the SOP
- A high risk proposal for example, genetic resources, that is, genetic material, and invasive nature of the research. iTaukei Affairs do not have the manpower to deal with genetics research. ITaukei Affairs will only deal with physical and social research,
- FPIC – Free Prior and Informed Consent FPIC is a guide that we use in the Ministry. FPIC to go into the new SOP.
- Translation to iTaukei in research proposals – only the FPIC is to be translated.
- To avoid causing harm in the villages – researchers are to work with the Provincial council Roko Tui and assistant Roko Tui – those who do not come via our process will be left alone.
- Research results to inform policy – the iTaukei affairs to facilitate the process of delivering an oral presentation to the people concerned. Provincial Council will also be involved with the logistics.

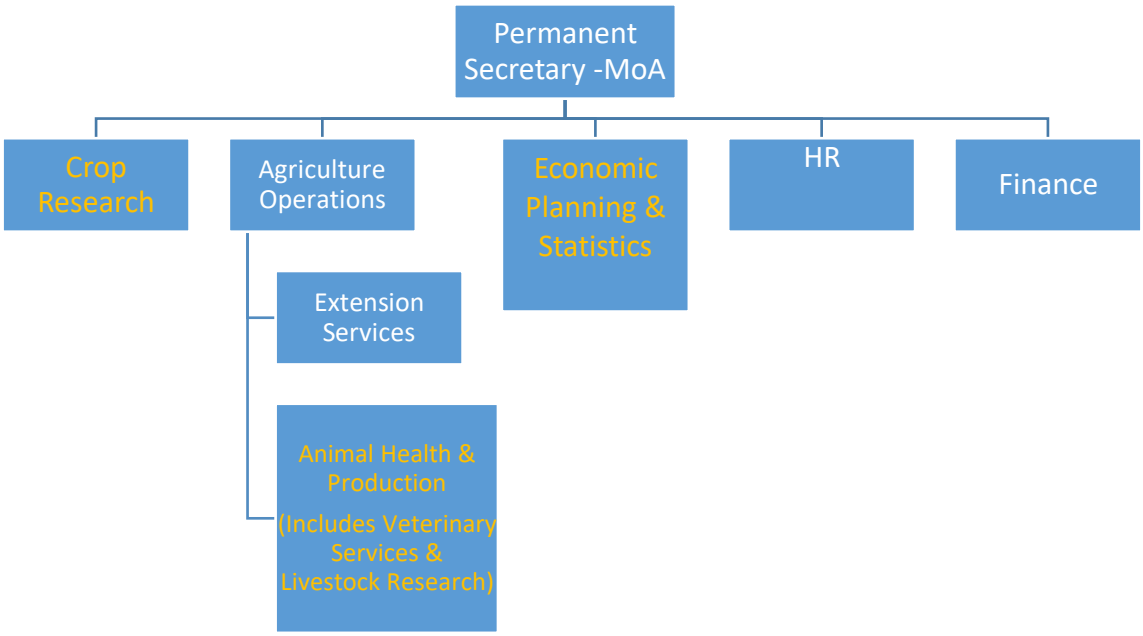
RECOMMENDATIONS:

- iTaukei fees structure to be made available to be included in this SOP.
- FPIC guidelines from iTaukei Affairs to be made available to go into the SOP.

Presentation 4:

Ministry of Agriculture (MOA)

By Dr Mereia Fong,
Koronivia Research Station, Nausori



- Research studies - MoA coordinates with MOH and the local university involved for ethics approval for any research that are expected to be published and that involve farmer interview/survey and specimen collection.
- Most of these research that require ethics approval are those related to public health/safety and involving live animals (due to animal welfare).
- Veterinary ethics - although there is a huge grey area in Fiji, veterinarians aims to practice diligent use of veterinary drugs and treatments particularly when using/dispensing antibiotics and other restricted medications. This is related to safeguarding against antimicrobial resistance, antimicrobial contamination in the environment and animal welfare.
- There is a legislation for the control of experiments on animals; "Animals (Control of Experiments) Act Cap 161 which to my understanding is under the Ministry of Health & Medical Services.
- Academic institutions have their own animal welfare ethics committee, mainly, USP and FNU (MoA is a member of the FNU Animal Research Ethics Committee)

Crop Research

- Work with Plants
- Interviews – there is no ethics approval required (MoA) – but if we go to community to do interview – we may need ethics approval. The MOA can look into. Research of students who work with us – we need an ethics approval from the university.
- USP/FNU – clearance is needed
- There are SOPs for all research/trial work within the Ministry

Statistical Operation for collecting processing and disseminating Agriculture Data

"A Census of Agriculture is a statistical operation for collecting, processing and disseminating data on the structure of Agriculture, covering the whole or a significant part of a country."

Typical Structural Data collected in a Census of Agriculture are Size of Holding, Land Tenure, Land Use, Crop Area, Irrigation, Livestock numbers, Labour, use of Machinery and other Agricultural Inputs.

However, data collection on Fisheries including Aquaculture, Forestry and Environment etc. have received special emphasis in the Agriculture Census in recent years.
Fiji has conducted four Agriculture Censuses whereby, the first was conducted in 1968 and 1978, 1991 and 2009. The 2020 Fiji Agriculture Census will be the fifth in this Census series. All other four earlier Censuses were conducted on Sample basis.

The 2020 FAC will be the first, whereby Census is conducted on complete Enumeration of all four Sub -Sectors of Agriculture: Crop (including Sugarcane), Livestock, Fisheries (including Aquaculture) & Forestry. Data collection will cover all localities within the rural and part of Peri-Urban area where agricultural activities are commonly practiced.

TERMS AND CONDITIONS OF SERVICE

Your terms of engagement as a Field Supervisor for the 2020 FAC will be clearly defined in your appointment letter.

Prior to this engagement, you will undergo training to provide you background information about 2020 FAC and all its requirements from you as a Field supervisor.

All assets and resources that will be assigned to your Field Team will be signed off by you and you must ensure proper inventory and safe keeping of these items.

During the three weeks enumeration period, all field operations will be expected to be carried out on FLEXI HOURS. Therefore, it is necessary that all field work are clearly planned and coordinated to ensure that each farming households/institution is visited according to their availability.

Ensure that the Public Service Code of Conduct is strictly adhered to.

Summary and conclusion

1. Importance of Ethics approvals for MoA and for animal ethics. Do we really need ethics approval for crop research? there are journals that require approval in crop research.
   a) Is there is a need?

b) Human research ethics - responsible for ensuring that research involving humans is conducted ethically and that the welfare and rights of participants in research are protected.

c) Animal ethics- responsible for ensuring that all activities relating to the care and use of animals are conducted in compliance with Fiji's legislations.

    - All members of a research team have to share responsibility for the ethical conduct of research, teaching and animal facility management &
    - must be aware of and satisfied with the degree to which the conduct of the research meets national and state requirements and Gov./Ministry policy.

d) MoA's link to villages & communities – protocols to go into the villages – MOA Extension officers, field officers, e.g. Tailevu, verata, we go through the extension. Sevusevu and iTatau are all included.

e) Aware of Fj. Gov. National Human Res Ethics Review Committee (FNHRERC) & not sure about Animal Ethic Group – maybe there is a need.

Discussion Points

- FNU has the animal ethics committee and MOA is a member.
- Pests – research – I think you would need an ethics approval – e.g. iguana killing in Taveuni needed ethics clearance.
- Develop your own ethics protocols and guidelines. We share our environment with animals and crop – genetic engineering of crops affects human lives. To develop for Fiji. Very important for Fiji.
- FNU constitution of FNU animal ethics committee – not too many people applying for animal ethics clearance. E.g. RISE project – trapped rats – what to do with the rats. Policy has to specify. Disposal of animals. Animals to return to consciousness after surgery. iTaukei Affairs – research on plants to engage the community – need ethics. Plants only – no ethics clearance.
- Research with farmers – where to apply for ethics approval. University ethics committee. Community research – field officers in farms – we usually use this avenue – because they know the farmers.
- An acknowledgement all the interface between animals and human – one health expert – interface – animal human interface – Covid.
- Repository for research done in Fiji – food unit regulations, do you have a repository for the research on plants and crops and animals. Available for research purposes.
- Fiji Agriculture journals – research here are published in this journal.
- iTaukei Affairs board – have village development plans, number of households, businesses in villages. Apply to PS of iTaukei Affairs Ministry

ROUND TABLE DISCUSSION SESSION

GROUP WORK: DISCUSSION

1. Researchers' Roles

2. Health Facility Roles – hospitals, St Giles, CWMH, Labasa Hospital,

RECOMMENDATION:
To include in the SOP. If a research proposal has received conditional approval from CHHREC, but the research setting made some comments for change, the researcher is to make the changes in the proposal and submit to the facility and to CHHREC for recording before an approval is granted from the facility and lastly a full approval from CHHREC.

3. Research Sites or settings – Suva City council, iTaukei, Agriculture, Regional Setting – IP to be part of the processes in the Ministry – or which sector. IP in the policy e.g. iTaukei processes. In a facility approval IP should also be included. A copy of your final report to be submitted to iTaukei Affairs. Research in the villages – Provincial office will solve these issues.

4. Group: **Statement** from stakeholders meeting for the National Research Council – and Act 2017, no mechanism. Need to formalize.

Points raised for the round table group discussions

- ITaukei Affairs Translation fees. MEHA has fees.
- To work with stakeholders to do collaborative research together. How do we get an ethics approval?
- Question to iTaukei Affairs – post disaster studies – after hurricane Winston – any special consideration on these kinds of research. Answer – process is the same. Post Covid because of the human contact – was happening in the internet. We had to stop all the research – to be done virtually. ADR: post
- Some government policy in place – disaster response – humanitarian approach – not a research approach. It is recommended to seek advice from the relevant ministry.
- Reporting after research – strengthen into the SOP – partnering with other partners, other ministries, from CHHREC – reports X 2, one to CHHREC and one to iTaukei. Reporting to community or knowledge owners is obligatory – in the SOP. For the CHHREC SOP too.

RECOMMENDATION:

- Form a NETWORK of Health Research Ethics. Strengthening the relationships of facilities to support research.

Group 1: Report

Points of Discussion

Should the SOP capture that researcher should do some groundwork in obtaining facility approvals.

Researcher to receive CHHREC Conditional Approval,

- Send it to the Facility (for facility approval before CHHREC Full Approval).
- The groundwork needs to be well captured and every researcher to begin the discussion at the facility level so that some form of understanding of the viability of the research is understood.
- Compliance: The researcher needs to know and understand the requirements that needs to be compliant with ethically important. For this purpose, a checklist to be generated as different facilities have different settings and processes.
- Report: Researcher to report back to the facility and the departments that come under it. For e.g. for those doing research in villages, information should be translated to easy understanding by the community.
- Mandatory or obligatory reporting for researcher for the purpose of alerting the members of the community and those in authority during research.
- Groundwork is done in preparation during groundwork. Relevance. Partners in country. Design. Clear understanding and communications done. Groundwork done prior to the finalization of the proposal. CPOND experience - Work closely with MOHMS – we engage with partners to the research.
- to capture in our policies and processes – student's/supervisor issues, staff members research team issues. How to resolve these issues? Internal FNU problem. Grievance processes.

MOHMS – SOP – international health researchers – need to find a local collaborator. Capacity building too. We recommend a person suitable.

Questions: Novice or experienced researcher? Which document should it appear?

The proposal template itself – in the vetting process.

Information to be ticked, compiled, CHHREC also has those requirements for villages research. to avoid delays.

Harm done – risks – to be captured in the SOP. → Reviewer templates to be included.

PhD students external to FNU – we advise them to have a coinvestigator in the MOHMS to facilitate the research.

Establish a small group of local advisors during proposal development stage.

Timeframe for applications – students research have strict timeframe that processes do not take too long.

For the student, the supervisors should guide the processes. But researchers from overseas, cannot wait till facility approval that their research cannot be done.

There should have been some groundwork already done prior to the submission of ethics application.

Group 2: Report

Health Facility Group: Dr Rafai, Sr Mili from St Giles, Dr Kama from Twomey Hospital, Representative from the Fiji Medical Council, Lautoka, Labasa, Dr. Shrish Archarya from CWMH

For inclusion in Governance Processes for the hospitals

The MOHMS supports the conduct of research. This is reflected in the annual plan.

Description of points	Details
SOP to guide	Institution, hospitals need a guideline. Terms of Reference. A Committee. Abide by the policies of the government. Is there a system that is not people dependent? Guide on application processes to be submitted to CHHREC or FHHREC. Research/facility to know about each other's expectations. (E.g. Receive the communications and applications from medical superintends and we communicate to researchers. Topic – risk? – I assign – MS DON – workplace violence – work together with risk officer. We ask the researcher for us to work together. Email communication. Verbal. We need to develop processes, TOR and committee. St Giles – committee to develop. MOH – to standardize.) Planning – need to be transparent

	Turnaround time for facility approval.
Communication between facility and researcher	Encouraged prior to the conduct of the research. Student researchers are encouraged to contact the facility first. Instead of contacting the department, for local students. During planning for research stage. For international students – Auckland, FNU – send it to us and we assess and we agree to participate. We look through – we have a focal person, training person. School of nursing, we go through the training coordinator and she or he liaise with the researcher.
Competency of researchers	Template – for researcher to apply for facility approval something in writing. Should something go wrong. You have given evidence. CV to be provided from researchers and supervisors. Dr Wilson – if the supervisor is a Professor then it is obvious.
Methodology	Get it right. CHHREC responsibility.
Authorships	Clear Guide on authorship. Co-investigator. Collaborator – do they also become co-authors. Supervisors, co-supervisors. Co-authors – to submit to publication – only those who work on the manuscript. Transparent and accountable way in the beginning – who would be authorship. E.g. Student – collecting secondary data – student submit a proposal – I collect the data – and result. Manuscript. No one necessary assisted me in the data collection – went through the MOHMS – collected data – who becomes the co-investigator when I did the work on my own. Who becomes co-investigator need to be clear. Co-investigator. What is the expectation from the facility? A point of discussion: Publication – concerns from our (MOHMS) facilities – their experience – when they attend international conference – data was presented with acknowledgment. How come we are not an author?
Documents to include in application for facility approval	Conditional Approval to be emailed to facility Summary of proposal - Researcher need to provide a summary, name, course, supervisor, institutional supervisor, facilitator representation.
Benefits	What benefit e.g. for St Giles.
For monitoring purpose	Work plan, time line in Gantt chart. We monitor, work together.
Ethics	Confidentiality forms – from the institution
Budget	Researchers to conduct their research using their own stationaries – budget to cover, not the facility.

Intellectual Property (IP) Data	Process for IP and materials transfer between the researcher and the school, the facility. Facility – Mataika house – PhD students – we would require them – screening – they collect samples; one set remain with us. Is this outlined in the proposal. Dr Rafai: IP – we have a process – that goes through Govt system, agreement. Indicate in the proposal - How do we engage with the facilities?
Reporting to Facility	Researchers' presentation – what we talked about, we need to go back to the divisional – and research committee – or SOP or guideline to guide us. Res – to be good for facilities, communication and any challenges – if process is not clear, Presentation of findings – preliminary or after the study is conducted, e.g. name is coming and he or she will come and present to us. Even before finishing from the university. We are always mindful that the information come back to us.
Safety – in all facilities (research in infectious diseases facilities)	Safety training provided to researchers and evidence is provided. Seed the safety reassurance from supervisors in student's research. Safety officer in schools. The safety and security of the researcher in the facility.
Research ethics training	To be conducted
Conduct of the researcher	facility be given the responsibility – of misconduct
Approval letter	To include: how do the institution access information, data, biological samples, data sets, that they require from the research.
Publication	The publication of a paper, the ethics approval, this work will be in the public domain, if the MOHMS says no publicity – researchers want scientific evidence – related to problems in Fiji – e.g. data repository – how can we move forward if we don't putting up in public domain.

Group 3: Fiji National Research Council.

Group Leader: Mr Sekove Naqiolevu

Tasked: How do we make progress with the Fiji National Research Council Act, 2017?

Actions taken: Mr Naqiolevu phoned the PS MEHA.
She asked me: "what is your interest in the research legislation". "I am an external member of CHHREC".
Answer from PS: "This has not been set up" – when it is set up – she will let us know.
We have established that with her and hope we can get a response from her in this relationship.
Sekove – council is under Education Ministry. PS education is a member of that committee.

We had a positive response from PS education

Recommendation:

Meeting with the PS to be organized. Face to face to get a response – to send a delegate – chairman and appointment to meet PS – officer of higher education to facilitate that.

Presentation 5:

Ministry of Health and Medical Services

By Ms Varanisese Smith
Data Analysis Management Unit

A. Overview of Data Request Process

The MHMS collects health related information at the Data Analysis Management Unit *(formerly known as Health Information Unit)*

The data collected is used by MHMS, Local Government Units, Non-government Organization, Researchers, Students and Private Sectors. E.g. MOU with Fiji Bureau of Statistics.

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 was reviewed in 2019 to be aligned to the Information Act 2018: A public agency must make the information available in the form preferred by the person who made the request unless to do so would impair the efficient administration of the public agency. Be detrimental to the preservation of the information or having regard to the physical nature of the information, would otherwise not be appropriate.

MOHMS Research Policy

- 20 days turn-around time for facilitation of request for information.
- Copyright Law – matters concerning

B. **Data Sources**

PATIS Plus:

- Admission; Pathology; Radiology; Birth data; Mortality; Oral Health.

Consolidated Monthly Return Information System (CMRIS)

Facility – Utilization data

Public Health Information System; Hospital Maternal Child Health; Hospital Monthly Return; Nutrition; School summary; Community Births and Deaths.

Registries (Standalone Database) Case – disease based

Cancer – DAMU; TB – TB Unit; Diabetes – DAMU; HIV – FHU; Notifiable – Fiji CDC; Data Repository.

C. Requirements to Access Data. Types of Application

Organizations

Within MHMS, Govt Dept./ Public sector, Private sector, NGO/ CSO, Education Institution, Media, Donor Agencies, Other

Individuals

Student, Health Worker, Researcher, Lobbyist/ Activist, Journalist, Other

D. Data Request form: Requirements

Types of data, information, statistics requested

- Detail description of time periods, database or data source, relevant disaggregation, geographical area by facility level, division or sub divisional level, ICD codes, etc.
- Provide clear indication of data elements, fields required

Purpose of the request

- Description of what the data/ statistics/ information will be used for
- Indicate if data is for research, publication, or any other purpose

Supporting documents

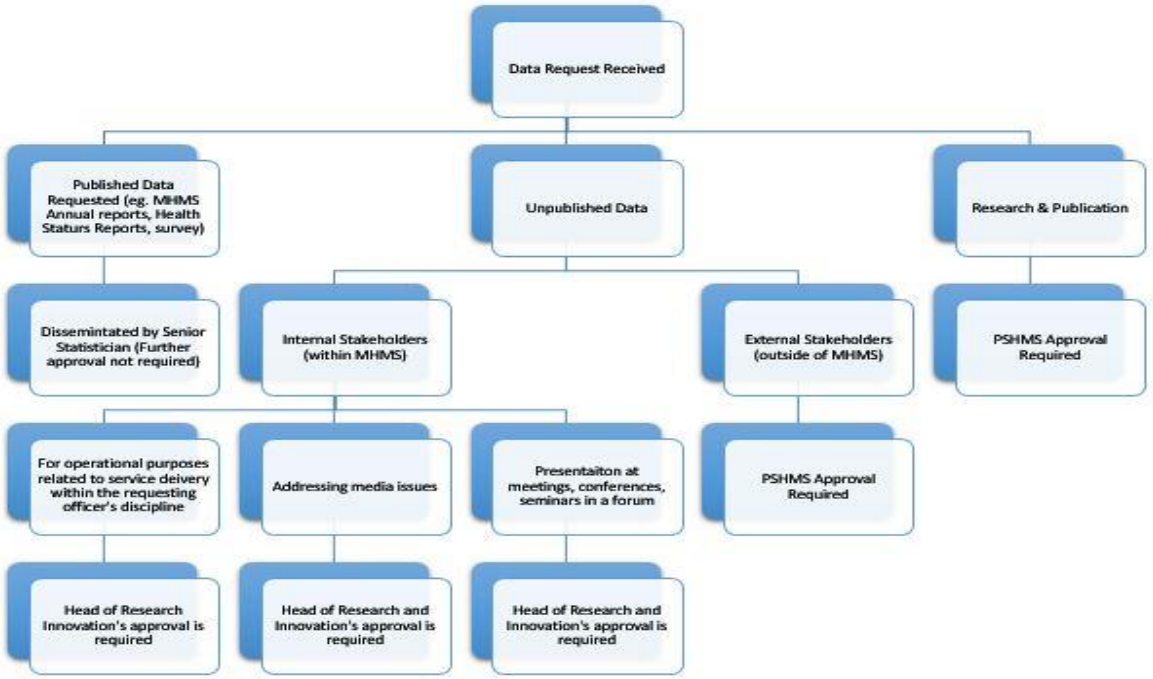
- Research/ Publication – ethics approval to be attached
- School activity – Letter from Supervisor or School
- Organization or institution – Copy of MOU or Letter with official letterhead
- Media – Email approval from Media Liaison Officer of MHMS

E. Data Request Approval Process

Types of Data request	Referring to	Approved by
Published data	Readily available on the website, annual reports, bulletins, journals	Senior Statistician

Unpublished Data	Includes raw data, information that is publicly shared though media, presentation at meetings, conference in a forum and external stakeholders Research and publication (high risk & sensitive data & to attach ethics approval	PSHMS
	operational purposes directly related to service delivery within the requesting officers discipline e.g. students	HoRIDAMIT
Research and Publication (low risk)	Needs to have ethics approval attached	HoRIDAMIT

F: Data Request Approval Process



Data Request Summary: 2017-2021(Jan-Mar)

Types of organizations	2017	2018	2019	2020	2021(Jan-Mar)
MHMS	51	55	45	17	6
Local Government	17	24	22	9	2
Education	31	10	18	16	9
Private Organization	22	48	21	19	10
Media	4	3	0	0	0
Total Request received	125	140	106	61	27

G. Challenges

- Delays in obtaining data from other sources within the Ministry E.g. Obstetricians have to review & by consensus agree to classification of Maternal death, Data sharing process governed by policy/regulation e.g. HIV
- Data extraction (backend) on mortality data and coding is highly technical. Backlog in coding through ICD 10 and ICD 10 AM
- Variables for some indicators are not entered into the PATISplus but recorded & remain registers at local level e.g. nurse's facility register.
- Data Quality Issues - Data entry errors by frontline staff, Incomplete data request forms, Unclear requests, etc.
- Health service operational issues

H. Strengthening data management

- Training (online training on Tuesdays on PATISplus & Friday on Digital Health Literacy)
- Digital Health Strategy 2021-2025
- Creation of new cadres of clinical coders position to improve coding
- Conduct regular data audits and verification in the field
- Expansion and enhancement of technology and infrastructure e.g. WB, ICD coding upgrading
- Regular feedback to supervisors/ managers on outstanding reports
- Standardization of registers
- Partnership with FBoS, UN Agencies and other Govt departments on national and international reporting
- Support from WHO, PHINET, SPC, FBOS, DFAT-Fiji Health Facility Programme

I. Improving the Data Management Process

Fiji HIS-CIS Strategy 2016-2020 Mid-Term

Digital Health Strategy 2021-2025

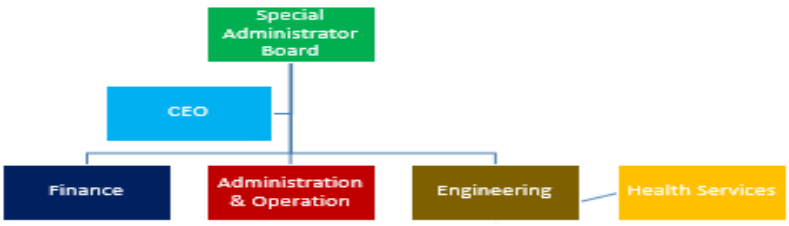
J. Global Strategy on Digital Health 2020-2024

- eHealth to Digital Health – incl. data is accessed from smart devices, internet of things, artificial intelligence, big data and analytics.
- Surge of new digital technologies and services -> new ways of interactions with individuals, citizens, families, communities, patients and health care workers. This requires new ways to protect populations against increasingly sophisticated collection and misuse of personal data.
- Encouraging the development and adoption of models and technologies for cross border data sharing and surveillance and ensuring data privacy and cyber-security.
- Key areas for action include the digital divide, digital health literacy, data privacy and security; data ownership rights and access; methods to support innovation that is effective, affordable, safe, scalable, and sustainable.

Presentation 6: SUVA CITY COUNCIL: FACILITY

By Mr Tomasi Bati
Health and Environment Inspector

A. Suva City Council Structure



B. Suva City Council- Facility Research Protocol

- Suva City Council protocol on research require all application to the CEO.
- Researcher presents a draft of the research paper.
- Approvals are granted based on vetting by CEO.
- Considerations are upon the type of data gathered, benefits,
- Research documentation presented to SA Board prior to release.
- Repository available on line (council website)

C. Research Protocol Procedure

D. Type of Research for Facility

(i) Solid Waste Management (ii) Food Safety issues (iii) Rate payer profiling (iv) Garbage surveys

E. Challenges

- Developing an SOP for council on research protocols.
- Ethics consideration on research application needs consideration
- Repository requirements for documented research emphasized.

F. Discussion points after Suva City Council Presentation

- Current Problems: CHHREC has received proposals to be conducted in Suva and need Suva City Council's contribution. If we are creating this network. We need to ensure that our processes are in place. All proposals after receiving CHHREC Conditional Approval need to go to CEO Suva City Council and if he is busy, it will sit on his desk until he is free. From CEO to board of directors. We need to have a timeline and approval turnaround time stated in the SOP for the facilities. There is no SOP in place right now.
- A Case portraying challenges: Valelevu project (Valelevu and Korovou) asking the health inspector's approval has taken 3 weeks for one application to get a response. Another application was sent to a council and researcher received the response in 2 days.

RECOMMENDATION:

ADR to write to the CEO of Suva City Council: Include the following points;

- to thank the CEO – Suva City council to thank for their participation
- Request going forward – discuss with team, also apply to Nasinu and Nausori Town Councils.
- Get an idea of the process at Suva city council.
- 3 months' turnaround time at council is not supportive of the researchers.

An SOP to be developed for Suva City Council Research Facility approval processes.

Presentation 7: THE FIJI POLICE FORCE

By Inspector Peceli Heritage

a. Introduction:

The Fiji Police Force always will act to protect lives and property in the interest of Justice. We keep matters confidentially, unless our performance of duty or needs of Justice dictates otherwise.

Our Strategic Planning Unit based at the Fiji Police Headquarters collects, collates and analyses data received from the Policing Divisions and compiles the Organization's Annual Crimes Statistics Report.

Data reflected in this report are utilized by our respective Units within the organization for Administration and Operational purposes.

b. Scope of Information

- Complaints received from members of the public
- Registered
- Investigated
- Classified

c. **Classification of Data – Crime Statistics**

- Offences Against Lawful Authority
- Offences Against Public Morality
- Offences Against the Person
- Offences Against the Property
- Other Offences Against Crime Act
- Offences Against Other Acts

d. Risks

- Strategic, Compliance to Legislations
- Confidentiality
- Public Interest:
  - Breach of Constitutional Rights

    - Vulnerable victims
    - Juvenile Offenders
    - Operational
- MOUs
- Conflict of Interest
- Compliance – FSO, Internal Directive, Policies and Guidelines

e. Anticipated Benefit of Research

- Feedback - Establish root course of why people commit an offence
- Contribute to Proactive measures to mitigate the reduction in Crime rate
- Assist in our reactive approach when dealing with offenders and victims of crimes
- To contribute towards building and strengthening relationship and networking with internal and external stakeholders

f. Data Access

- Personal representation/writing to the Office of the Commissioner of Police
  Email: fjcompol@gmail.com ; fpfstats@gmail.com

Discussions after the Police Department Presentation

Formal approval or ethics approval process from Police, e.g. homicide, any process for publication, data for high risk research.

Commissioner of Police has the last say. To be specified in the letter to the police commissioner. E.g. if cases are still in court, if publishing of those report will obstruct investigation. So you need to highlight to the commissioner and we will discuss the case before we give an answer.

In applications – put a timeline.

The quality of the data, for example, vulnerable communities, children, LGBT, sex workers, if the data you have can be further disaggregated, from just being male and female. Will you be able to disaggregate further?

Processes are not in place, as it should ideally be to assist the researcher. The researcher should not be victimized. Lack of information to the Policy, if we had a meeting with Commissioner Police and we can design a process going forward.

Items to be discussed with Commissioner Police. When research application comes to the Police department, who looks at it, who vets it, what is the process for the researcher?

RECOMMENDATION:

To have the meeting with Commissioner of Police regarding a way forward with facilitating research and design and process going forward with the Police department.

Presentation 8:

PIANGO (Pacific Islands Association of NGOs)

Research Model "Drua/Vaka"- By Mr Josaia Osborne

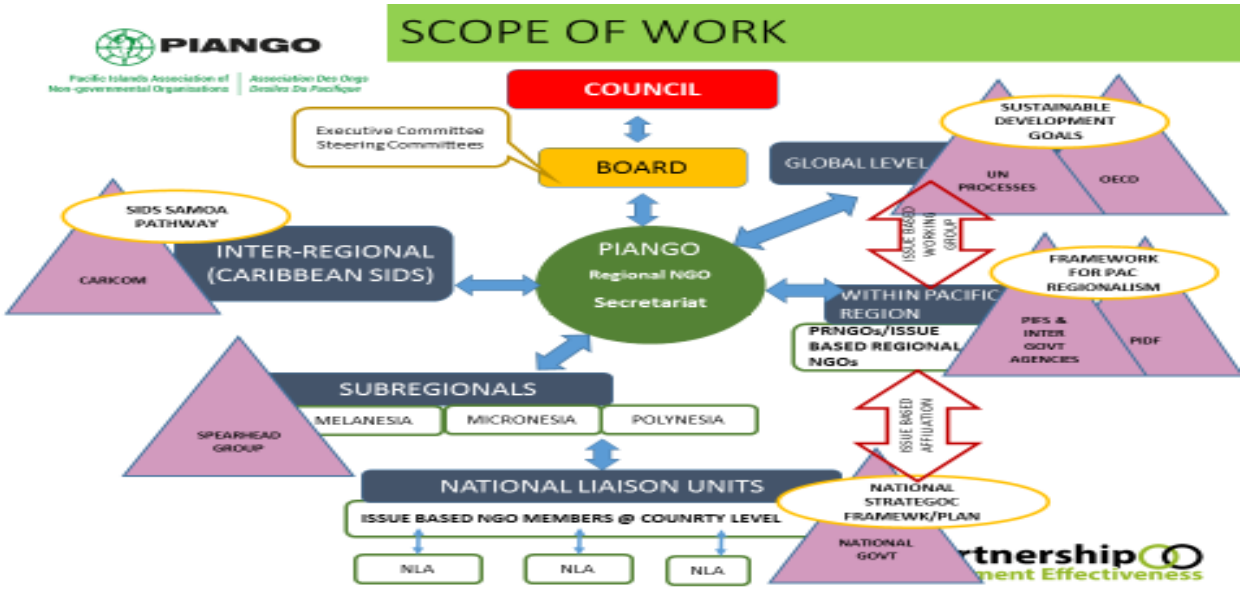
A. Who is PIANGO, what do we do?

- Initiated in the late 1970s; formally set up in Port Vila in the late 1980s; 1st Council meeting in 1991 (25 yrs. ago) in Pago Pago, American Samoa, to strengthen networking between Pacific NGOs & represent the authentic voices of Pacific Island NGOs; moved to Suva in 2004
- A regional network of national umbrella NGOs and national focal points or coordinating bodies known as National Liaison Units (NLUs) in 24 Pacific Island countries and territories.
- A regional umbrella platform of national umbrella NGOs
- Providing a common voice of Pacific National NGOs at regional and international fora
- Taking collective action of Pacific Umbrella NGOs to respond to priority regional and global concerns
- Advocacy on climate justice and incorporating traditional knowledge in our work

B. PIANGO Network

1. ASUNGO – American Samoa
2. ACFID - Australia
3. CIANGO/CICSO – Cook Is
4. CID – New Zealand
5. CSFT – Tonga
6. DSE – Solomon Islands
7. FANGO – FSM
8. FCOSS – Fiji
9. KANGO – Kiribati
10. NIANGO – Nauru
11. NIUANGO – Niue
12. MICNGOs – Marshall Is
13. Payuta – Guam
14. PNGCSF – PNG (*Interim*)
15. SUNGO – Samoa
16. TANGO – Tuvalu
17. UTLN – Kanaky
18. VANGO – Vanuatu
19. HITI TAU – French Polynesia
20. BANGO – Palau
21. FONGTIL – Timor Leste
22. Wallis & Futuna
23. Tokelau
24. West Papua – Coalition/ Fokir LSM?

C. Scope of Work



D. Core Work

- **Strategic Focus Area 1: Governance/Leadership -** to strengthen its NLUs as an institution and platform to serve their constituents and support the sector at the local level.
- **Strategic Focus Area 2: Voice** - actively include, promote, facilitate and amplify the voice of communities, vulnerable groups, and civil society organizations at the local level.
- **Strategic Focus Area 3: Approaches -** promote localized, responsive, relevant, and forward-thinking approaches to development in the region. The approaches will be aligned to the Agenda 2030 whist at the same time grounded on Pacific practices and values.
- **Strategic Focus Area 4: Partnership -** facilitate and support an enabling environment for strong, genuine, and sustained partnerships at the national, regional, and global level amongst CSOs, government, and development partners

E. PIANGO Research ethics

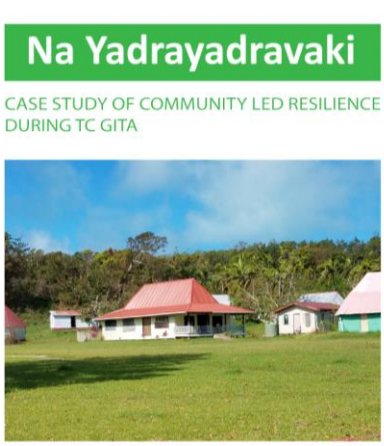
- Couched in our PIANGO values and principles on development effectiveness
- Embedded in the Pacific approaches and values
- Aligned to the requirements of national research policies
- Ensuring ownership by partners is vital: co-creating and co-designing
- Research for evidence based policy advocacy

F. PIANGO Research Work and Publication

- 2018 – two publications on localization

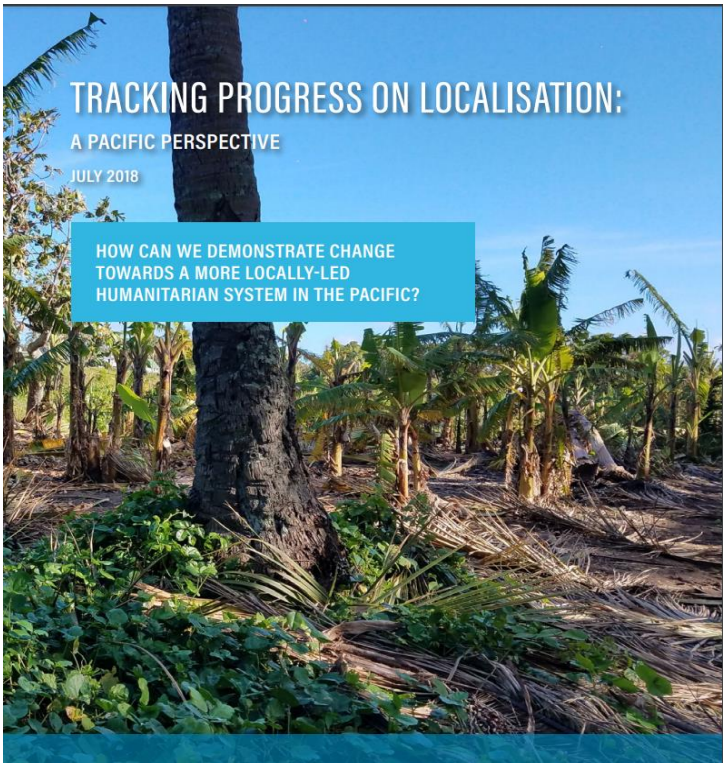
- 2019 – four publications on localization
- 2020 – three publication on localization of humanitarian response and COVID 19
- 2021 – five Citizen Budget Guide

G. Humanitarian Work



Na Yadrayadravaki Research (Conducted in 2018 in partnership with FCOSS and the Ono-i-Lau Development Committee)

PIANGO adopts a 'yadrayadravaki' concept to frame the community based approach to disaster risk reduction and how the people of Ono-i-Lau build their resilience prior, during and after a disaster.



- In June 2018, the Pacific Islands Association of Non-Government Organizations (PIANGO) and Humanitarian Advisory Group brought together Pacific humanitarian actors from Fiji, Tonga and Vanuatu to discuss progress on localization and to explore priorities for measuring change.
- This outcomes paper provides an overview of the consultation discussions and highlights Pacific priorities for measuring change. It will inform the development of a framework for measuring localization in Pacific case study countries across the next three years.
- Baseline reports for Fiji, Tonga, Vanuatu and Solomon Islands published in 2019.

This paper explores our successes, our challenges and our learning about partnership and research impact with the aim of promoting more equitable knowledge production and exchange in the humanitarian sector. As we move into the final phase of the project, this paper reflects on how we developed our partnership and what this has meant for the project's impact to date.

Civil Society and Public Finance Management

The **"Strengthening of public Finance Management and Governance in the Pacific Project (PFM)"** – how it came about.

Aims: to strengthen oversight over public financial management in the Pacific Region through improving budget scrutiny, public financial oversight and accountability capacities of parliaments, supreme audit institutions and civil society, aligning with international public financial oversight and accountability standards and fostering citizen engagement and oversight. Project is funded by the EU and implemented by UNDP. The project was implemented in Fiji, Tonga, Solomon Islands, Tuvalu and Vanuatu.

Public Finance is managed within legislative and regulation frameworks, according to precise processes and through various institutions who plan, execute (spend) and report on Public monies.

Parliaments and audits have an important role as guarantor and representatives of the public interest, in ensuring that public finances are used in a way which delivers the best services for citizens.

Citizens, media, civil society have themselves a role to play, by monitoring, checking and voicing their priorities and concerns on Public Finances. This role is the focus of this small grant scheme.

H. **The Contributions of Civil Societies**

5. CONTRIBUTIONS OF CIVIL SOCIETY (some of the Findings from the mapping in Tonga)

Ownership of Priorities – (A) Whose priorities?

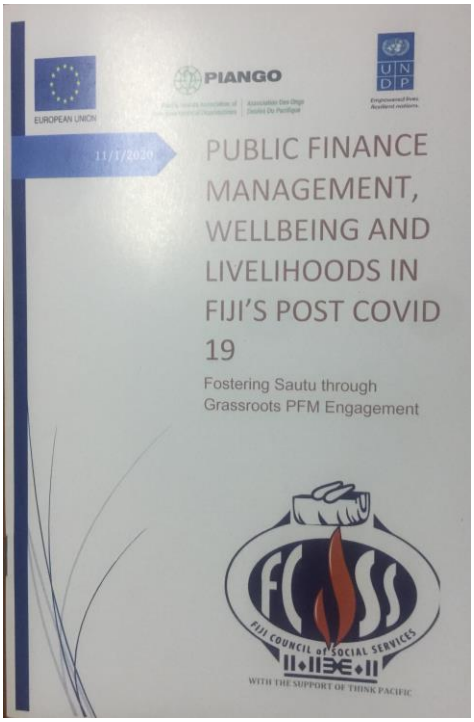
HOW CIVIL SOCIETY WORK IS CONTRIBUTING TO THE PRIORITIES OF THE COUNTRY REFLECTED IN THE NATIONAL BUDGET PRIORITIES.

Solomon Islands

Solomon Islands in 2013 enacted thePublic Finance Management Act (2013). According to s5 of the Act its purpose is to '**promote sound public financial management,** including **through the administration of the consolidated fund and other public resources,** according **to budgeted priorities, monitoring and reporting and to ensure** Government's **accountability** to **parliament in respect thereof'.** And the role of the Parliament Accounts Committee

Tuvalu

CSOs and Citizens PFM Perception Survey with focus on - PFM, National Budget and Covid 19



SAUTU: WELL BEING

RESEARCH HIGHLIGHTS

FIJI

Decentralizing Labour market support and livelihood incentives to district levels and supporting civil society efforts to connect vulnerable and near poverty population cohorts to the opportunities available from such an incentive.

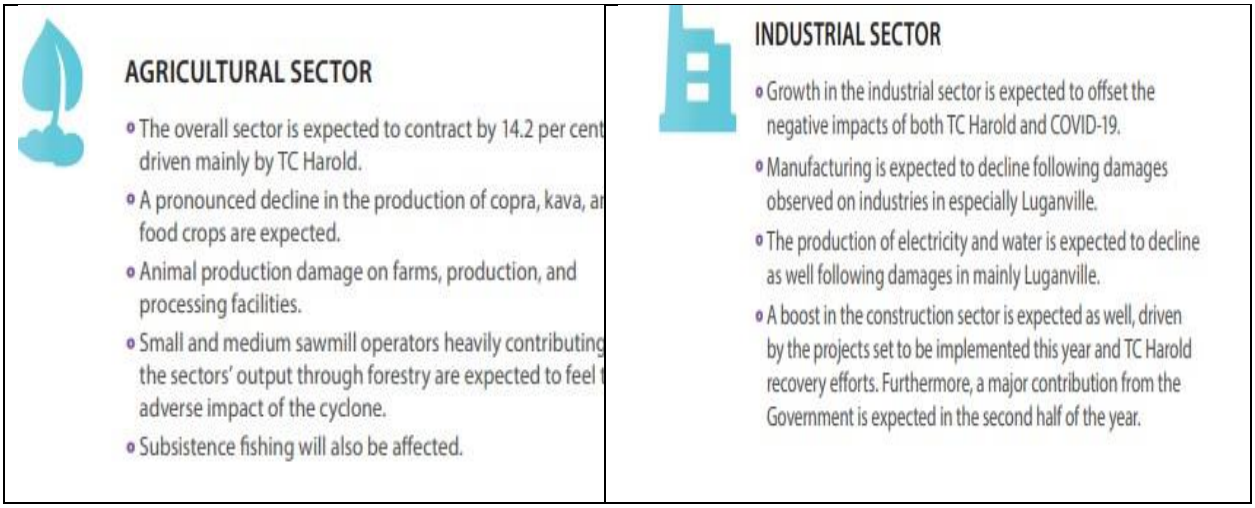
Strengthening participation of communities through the Integrated Village Development Plan which is an ideal entry point for engaging communities meaningfully in the Public Financial Management system. Recognizing too that community profiling is important for impetus for planning at these levels and allowing all voices to engage ensures sustainability of the outcomes of such a collaboration.

Cross sectoral collaboration to strengthen the capacity of advisory councilors, Turaga Ni Koro, Mata ni Tikina, Community Nurses and Zone nurses is key if the administrative and consultative structure built by successive governments is going to serve its original purpose and provide the entry point for citizens particularly in informal settlements and in rural areas to engage in governmental development planning and finance management.

The need for government to clearly demonstrate how inclusion and leaving no one behind has been mainstreamed and embedded into its approaches through its annual workplans and strategies.

Giving due respect to traditional and cultural governance that exists in Fijian communities but recognizing the need to add value to these structures by strengthening accountability mechanisms. This ensures that public resources invested into these structures are utilized for the benefit of communities.

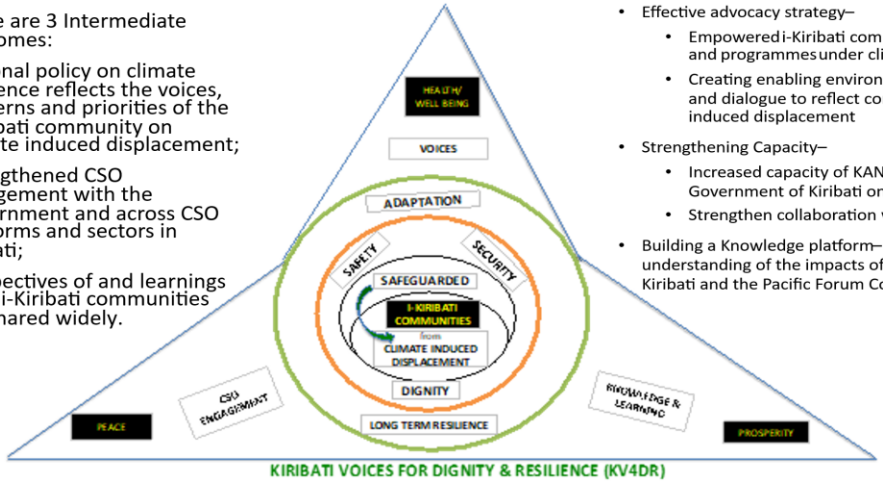
VANUATU



I. Kiribati Voices for Dignity & Resilience

- The ***Ultimate Outcome*** of the Project is to ensure that i-Kiribati communities are **safeguarded from climate induced displacement**, their **safety, security and dignity** in **adaptation and long-term resilience** (Kiribati Voices for Dignity and Resilience – KV4DR).

- There are 3 Intermediate Outcomes:
- National policy on climate resilience reflects the voices, concerns and priorities of the i-Kiribati community on climate induced displacement;
- Strengthened CSO engagement with the Government and across CSO platforms and sectors in Kiribati;
- Perspectives of and learnings from i-Kiribati communities are shared widely.



KIRIBATI VOICES FOR DIGNITY & RESILIENCE (KV4DR)

- The Short-term Outcomes of the project are in 3 areas with sub sections:
- Effective advocacy strategy–
  - Empowered i-Kiribati communities advocating for policies and programmes under climate induced displacement
  - Creating enabling environment for community engagement and dialogue to reflect concerns and priorities on climate induced displacement
- Strengthening Capacity–
  - Increased capacity of KANGO to strengthen engagement with Government of Kiribati on climate induced displacement
  - Strengthen collaboration with CSOs and other partners
- Building a Knowledge platform– Deepening knowledge and understanding of the impacts of climate induced displacement in Kiribati and the Pacific Forum Countries.

J. DRUA Model of Creating and Affirming Knowledge

Cycle 1: Action Research

Cycle 2: Advocacy

Constructing the Drua as a Research Process

- Conception – navunavuci, a ikerei, cici kete (research design)
- Research process and analysis – 'tukidreke' 'ulaula' and 'caru', 'vakata' (putting all the parts together)
- Final results and publication – 'Vonoti; and 'rovati' (accountability; reporting back)
- Advocacy – how do we use the research findings to inform our work

Values associated with Drua: Accompaniment, Cooperation, Commitment, Consciousness

Points of Discussion:

To strengthen partnership and collaboration) in research in Fiji.

Publication. How to disseminate results. Engage people from the beginning.

Research is funded by projects and timelines are strict, we pay for permit, while being processed, we do research and later do the application for ethics review because our CSO work with government to process our application. The relationship with civil societies.

PIANGO does humanitarian research, workshops, meetings to inform policy level and health is engaged while in COVID-19 e.g. sexual violence in humanitarian research to consider including in research.

PIANGO members - psychosocial team and research team. They are in the community, which makes it easy for us to enter - door way – health issues and there are avenues we can explore.

FCOSS worked with the MOHMS of Fiji. We do Networking with our partners in the Pacific.

Design and ethics of research. Concern, co-design and some of the newer designs that are favored by Pacific researchers, community based participatory research – problems of confidentiality – in terms of co-design – participatory research – does PIANGO have an M&E that ensures that data is authentic and consider confidentiality of participants. Focus group interviews and talanoa which has a lot of challenges in academia.

Design of the research process is done at organization level. Ethics of research – confidentiality and do no harm approach of informers is observed. We are reviewing the M&E framework. We have published our work on Partnership framework. The humanitarian work– is based on CSO level from Australia.

PIANGO project in Ono I Lau – they apply for ethics review from iTaukei Affairs and Ono I Lau Provincial council.

The Fiji National Research Council Act – need to standardized research in Fiji.

Regional work, not including health, PIANGO is considering health by CSOs working in PICT.

PIANGO – will consider working in partnership with others to access PICTS in research.

Presentation 9:

Fiji Medical Association

Dr Ronal Kumar, representing the Fiji Medical Association

Few points that the President of the FMA highlighted.

FMA we are not involved in the process of ethics approval; we hold an association of 600 doctors in the country and we associate a lot with the other doctors' association.

We have about 100 interns coming in, with the revised internship programme, it has become FMA's roles to look after the internship programme. With the internship programme coming in, we will expect somewhere between 50-100 more new researchers to come about. It is a 2-year project for the interns. Now our role is to support CHHREC, we want to be the users of valuable research on the other end so that we can make the differences, with research published in our country.

The issue is that FMA members know how to conduct research, but to convert to publication is the issue we face. There are about 1,500 doctors in the country and majority work in the public sector. They are mandated to produce a research paper, but we are struggling with publication.

Suggestions from FMA to CHHREC to reduce time for ethics approval processes and simplify and expedited to facilitate more publications.

FMA looks after the Fiji Medical Journal. Publication has been an ongoing issue. We tried to link FMJ to an online basis and it has not been easy.

FMA members are doing Masters degrees in the college and we do not have many research papers published.

2020 FMA published paper edition and they are still trying to get that edition online.

Discussion Points (FMA)

FMA to consider giving an edition of the FMJ to the PIHRS so that research presented in PIHRS can be published in FMJ. FMJ will be very happy to oblige.

Doctors have the capacity to do research, but need to make the link to the College academics to get the skills to do their research and then publish.

RECOMMENDATIONS:

To organize a meeting with the FMA and to discuss the following points.

- FIPHR to conduct Capacity building for FMA members in writing manuscript for publication.
- Special edition of FMJ for the PIHRS research papers – 48 abstracts.
- FMA to be requested to give the FMJ to FIPHR to manage.

Presentation 10:

Ministry of Health, Samoa

Dr Belladonna Portoi
Executive Member of the Samoa Medical Association,
Secretary for the Samoa Medical Council

Samoa Health & Research Ethics Committee and the process of what happens when you want to do research in Samoa.

Overview:

Three years ago the National Health System merged with the Ministry of Health. All hospital and district health clinic all comes under one Ministry. The Ministry of Health have 2 main islands Upolu & Savaii. Upolu has the main Referral Hospital, Tupua Tamasese Meaole Hospital at Motootua, Apia, which has 6 district hospitals; and Savaii with less resource has 1 referral hospital and 4 district hospitals. Majority of the doctors are in Ministry of Health, 30 practitioners in the Private Sector and a private cardiology.

Framework – Director General, Deputy Director of Public Health, Director General Deputy of Clinical Health Services

Research: To do research, you should have a proposal, and you must fill out a form. Form can be obtained from the Assistant CEO of Policy and Research Division (Ms Sina Faiuga) and the person changes every 3 years. The form and the proposal are mailed to her and then documents are circulated to a Health and Research Ethic Committee (HREC) and members will meet to discuss the proposal.

One of the requirement is that a Samoan should be a Co-investigator.

The committee has a legal representative for Ministry of Health, and they help out in sourcing intellectual property (IP).

Authorship – There should be a Samoan counterpart, and to publish in a Samoan Medical Journal all the guideline and policy need to be met.

Samoa have two (2) **Medical School**: School of Medicine – National University of Samoa (NUS); the Oceania University of Medicine (OUM).

Challenges: Protected time to do research – short of staff and moving forward to have a more attractive package career pathway for research. There is no funding for Research from the Ministry of Health but have a lot of interested stakeholders

The Samoa Medical Association is going through a process of formulating all the Primary Health Care guidelines and using that specialist that are in the Samoan medical associations. This is another avenue to push forward research.

Lack of Mentorship in terms of research within the medical schools, ministry of health and the GP sector. Having a zoom meeting for mentorship will be pretty exciting.

Q & A

1. Dr Masoud stated the process of getting research in Samoa is very good and emphasize more on the quality of research done by students. We have 2 Masters student last year who had delay in ethics processes. Overall Samoa is doing pretty good with their ethics approval and processes.

2. Dr Donald stated if a student or staff of CMNHS would like to do a research related to health but is on a population of who live in a village related to their health such as demographic information, taking their weights, blood etc., the ethical soundness of the research proposal is done by CHHREC, but the consent of the individual in the village and the process for us is to go through the Ministry of ITaukei Affairs; and for those living in peri-urban settlement we go through the Suva City Council, the Fiji Police if we would like to access their data, the MOHMS for facility approvals for research done in the hospitals (CWMH, Lautoka, Labasa) if we interview nurses, doctors or use their data for research. We trying to synchronize the processes so we don't disadvantage the researchers because we would like to promote research.

   Does Samoa have the same setup as in Fiji? For instance, those who want to do research in the villagers, who gives the ethics approvals for the researcher to conduct research amongst their population in the villagers.

   Dr Portoi mentioned that the process is similar as ours such as: -
   - For research related to health will have to go through the Health Research Ethic Committee.
   - They have village councils to approval research in the villagers' settlements

   Dr Portoi asked – **Is it part of a career pathway if you're not in the formal setting of the Master's Program, can you still do research as part of being a working doctor role as is expected of you?**

   Dr Donald response is for MOHMS, Dr Rafai role as Head of Research and Innovation Unit and his not necessarily conducting research but helps facilitate research processes. In the CMNHS, we have few staff who are researchers, and as we get more research opportunities in terms of funding we will help develop that space in research infrastructure, resources etc.

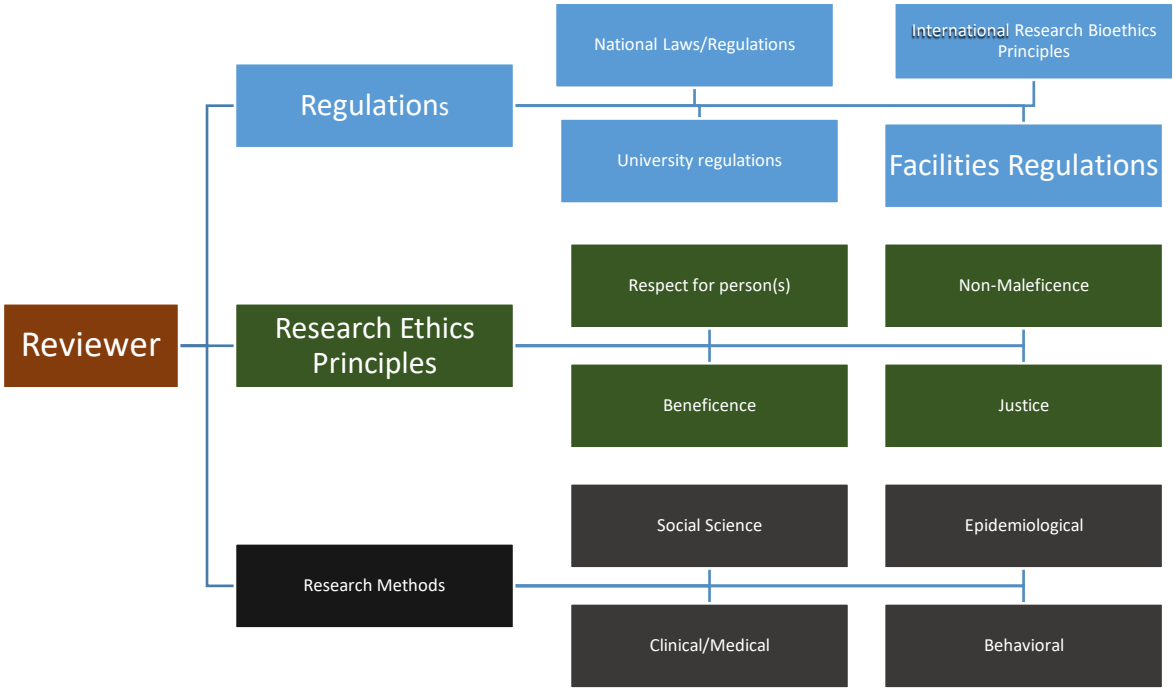
Research Ethics Proposal Review Training

by Etivina Lovo

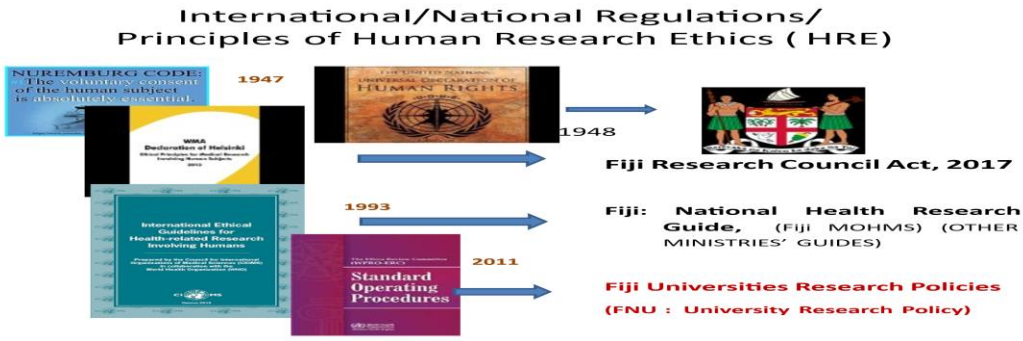
College Human Health Research Ethics Committee

Review of Human Research Protocols

A: Framework for Ethics Review (Source: Etivina Lovo, 2019)



B. International/National Regulations/Principles of Human Research Ethics (HRE)



C. Reviews of Research Proposals by a Human Research Ethics Committees (HREC)

Purpose:

i. Protect research participants - Maintaining the ethical standards for research conduct.

ii. Reviewer(s) observations communicated to the investigators to modify the research proposal to meet the required ethical standards
iii. Decision to approve or reject the research proposal
iv. Monitor the conduct of approved research proposals

Regulations:

- International - National Regulations - University policies

Principles Approach to Review

Fundamental principles set out the Guidelines to ethical review of research proposal

(i) Respect for the Autonomy of Persons and Community

- Protect the Autonomy of all people, self-determination
- Capacity or competence to make an informed decision
- The dignity of the individual or groups of people, treating them with courtesy and respect
- Respect for the community and local culture
- Researchers must be truthful in communication with prospective participants and participants
- conduct no deception

The informed consent process in a research study should be designed to empower a person to decide whether to participate in the study.

Special consideration must be given to persons who may have a diminished capacity to make their own choices due to physical, mental, social, or economic reasons

(ii) **Beneficence.** Research should beneficial society and that this benefit cannot be obtainable by other means

Beauchamp, T. L., & Childress, J. F. (2013). Principles of biomedical ethics (7th ed.). New York: Oxford University Press

- Doing good and maximizing benefits minimizing risks to the research subjects
- Physical, mental and social well-being
- Risks reduced to a minimum
- Protection of the participant is the primary responsibility of the researcher
- Benefits for communities where the research is conducted

(iii) **Non-Maleficence:** Research conducted must avoid all harm to participants and their families as well.

- "Do no harm “
- The researcher is duty bound – Ethical theory of Deontology -

- Harm/risks: physical, psychological, other
- Researcher have to anticipate risks involved in the research and confirm plans of how to Manage risks (harm)

(iv) **Justice:** fair distribution of scarce resources (distributive justice – equality), respect for people's rights (rights based justice) and respect for morally acceptable laws (legal justice)

- Equality
- Legal considerations
- Equal distribution of burdens of research and benefits
- Equitable recruitment of research participants
- Special protection of vulnerable groups

Low-resource communities should not be used for the benefit of more privileged communities, and possible benefits to the community where the research would be conducted should be addressed in the study protocol and its review by an Research ethics committee.

D. Application of principles

- Equitable recruitment of research participants
- Non-discrimination, non-judgmental, no exploitation
- Privacy of participants is protected
- Confidentiality of identity of participants
- Researchers must be truthful in communication with prospective participants

"Declaration of Helsinki"

- The well-being of research participants should take precedence over the interests of science and society
- Consent should be in writing
- Use caution if participants is in a dependent relationship with researcher – teacher/student, doctor/patient,
- Greater access to benefits

E. CHHREC Review Form: some examples

Benefits – benefits of the study is stated clearly

Study protocol – clearly stated

Statement of the problem: Is the topic a significant problem that requires research involving human participants? Reviewer to make an ethical judgment.

Rationale of the study: Why conduct the study? Reviewers are state the benefits of the study to participants, or general population.

Selection of the study population: no discrimination

Who are the participants?

Any existing relationship to the researcher? Treating doctor/patient? Teacher/students

Method for the recruiting of participants: Is the method promoting **voluntariness** of prospective participants – no coercion

Research Methods

Research Protocol – ethical or are there ethical issues?

F. FNU: College of Medicine Nursing and Health Science: Review Process

CHREC Research Ethics Review Procedure

CHREC reviewers and their roles

- CHREC members and CMNHS staff recommended by CHREC as reviewers are tasked with the review of research proposals.
- assess proposals for the level of risk.
- determine whether they should be granted ethical approval, declined, or exempted from ethical review.
- Where proposals are declined, CHREC can recommend experts to support the researchers or refer them to SCHOOL RESEARCH COMMITTEE for appropriate guidance for the improvement of the proposal and for re-submission.

Review Process

- All submissions will be initially vetted for completeness and appropriateness by the CHREC Secretariat.
- conduct a preliminary review to determine the level of risk of the proposal. If the preliminary review identifies the proposal to be of **"Low Risk" or "High Risk"**

G. High and Low Risk Projects

- High Risk: Full review: by an Ethics Adviser and 2 independent reviewers. Can request a external reviewer if content expert is unavailable internally. (30 days turnaround time).

  Final discussion in CHREC meeting.

- If projects proposed are large, multi-centered, multi phased the principal researcher may be called to present the project to CHREC and clarify aspects not understood by committee.

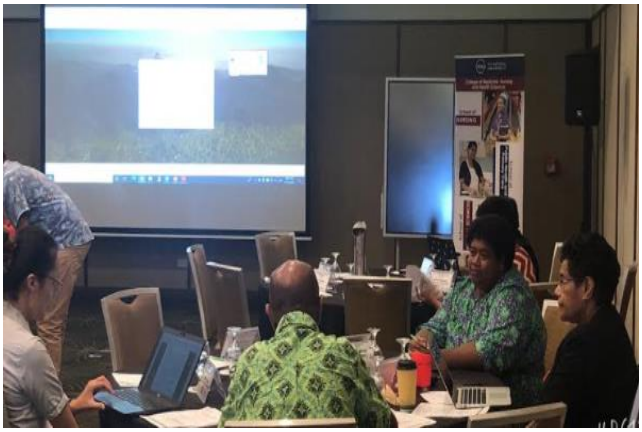
- **Animal Ethics review process:** research proposal(s) that involve animals will be send to the FNU College of Agriculture, Fisheries and Forests (CAFF) experts in animal health to review.

Low risk projects

- Low risk projects → Expedited review (10 working days)

A practical exercise of "conducting an ethics review of a de-identified research project" was implemented. The participants were given this exercise to do at home as a homework and to bring the finished exercise to the meeting on the 3rd day.






Participants in the workshop fully engaged in the programme.

Presentation 11:

FIJI HIGHER EDUCATION COMMISSION

INFORMATION SECURITY AND PROTECTION OF DATA POLICY

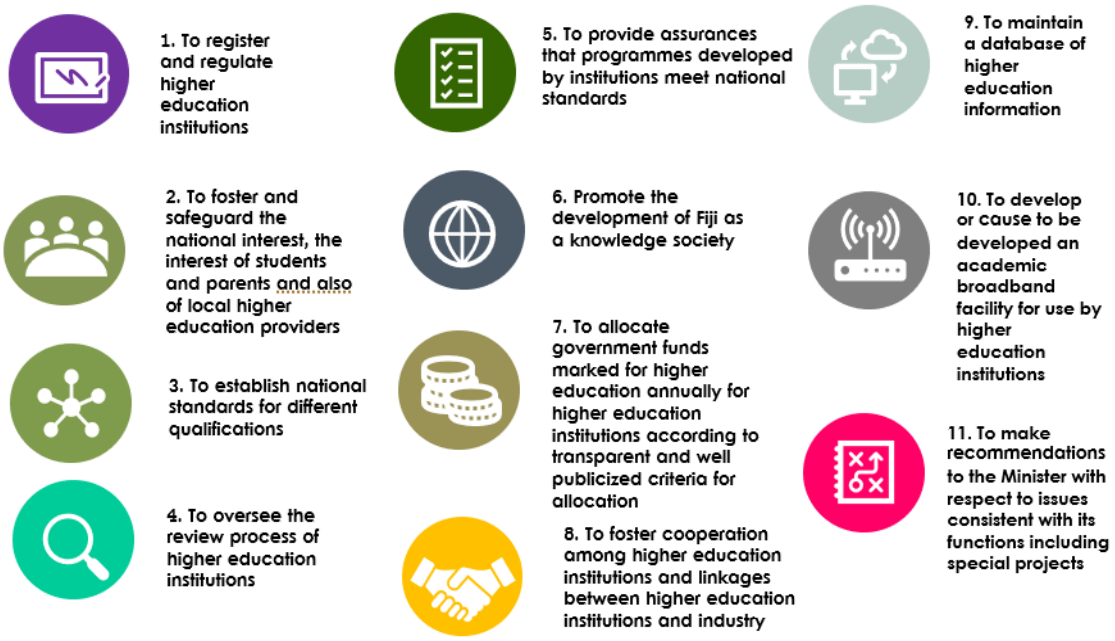
Background

Higher Education Act 2008; Higher Education Regulations 2009

Vision - Building together an educated and globally competitive Fiji.

Mission - To quality assure the delivery of higher education that meets the needs of our stakeholders.

Mandated functions



Data Collection/Sources and Usage by FHEC

Types of data FHEC currently collects:

- Learner management records
- Educational data: enrolments, completions, graduates
- Students' demographic data and data on their destinations and outcomes
- Financial data of Higher Education Institutions (HEIs)
- HEIs staffing information
- Programme related data: costing, learning outcomes, career pathways.

Data Sources:

Higher Education Institutions, Government Ministries and agencies.

Data Usage:

Higher Education Institutions (HEI) overall monitoring and performance
Funding advice to the Government
Programme accreditation and recording
National qualifications development

Information Security and Protection of Data Policy
HEIs need to provide written authority to disclose any data on the institution's operations to a third party.

All data requests must adhere to and provide the following:

- The purpose of the data request;
- List of the end-users of the data
- How the requestee will use the data
- Steps to avoid misrepresentation of data
- How the requestee will maintain the confidentiality of the data
- All requests for data will be approved for release by the Director.
- Requestee is required to provide the final output(s) in which the data from the Commission is used.
- Policy available on FHEC website: www.fhec.org.fj

Discussion Points

What Research Arm at FHEC, Research Officer, Research is new in FHEC 2 years now.

Research Conducted: (i) Graduate Outcome Survey, (ii) Investigation and Access and Equity in Higher Education. Yet to disseminate results.

The link between National Research Council and FHEC – using data to developing funding advice to government. **Research Value** (yet to be developed) is dependent on the establishment of the National Research Council – **this will determine the priority areas**. (in 2 years' time)

Strategic Research Framework depend on the NRC.

FNU/CMNHS wish to align work with the National Priority Areas identified by the National Research Council and FHEC, so that our work is relevant and not only academic.

National Research Council discussion is needed quickly, what does the government want us to do in Research?

Oversight of Academic institutions – medical institutions – is there a requirement for them to produce research?

FNU Programmers: Levels 8,9 (Masters level),10 is PHD, have to do research. Yes, we are required to do research. Undergraduate doing research depend on the institution because of the self-accreditation standard of universities.

Policy for institutions that are not doing research in higher level education – Universities are self-accredited. Fiji qualification network FHED monitors. FHEC will not know until there is a complaint.

Fiji qualification council – do the monitoring of qualification.

Presentation 12:

Accreditation Process by the National Health Research Committee

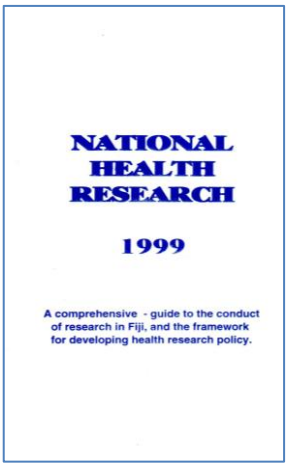
Historical Context

Fiji School Medicine & Ministry of Health & Medical Services – National Health Research Committee

The Heath Research ethics committee accredits and advises Divisional and institutional issues in their research – **National Health Research 1999**.

Fiji National University - CHHREC

MOHMS Human Health Research 2020 Policy **statement** *2.4. govern the accreditation of human health research for relevant stakeholders that includes academia, govt. departments, NGOs and international entities*



A. Chronology of the advances of Human Research Ethics in Fiji

1990's	Research Ethics Committee at FSM conducted the Research ethics reviews and approvals.
Before 1999	Research Ethics Committee moved to the Ministry of Health. It was known as Fiji National Research Committee (FNRC).
2007	The NHRC Guideline was revised which was developed in 1999.
2012	With the support of WHO the 1st review for the Fiji Human/ Health Research Ethics system, to improve the efficiency and effectiveness of the system.
2013	Development and implementation of the online health research portal (Fiji Health Research Portal, www.health.gov.fj/fijihrp).
2015	Development of Fiji National Health Research Guide 2015 and the Standard Operating Procedures (SOP)
2017	After that the FNHR system was reviewed via WHO assistance. Recommendations – revision of the templates, guidelines and SOPs.

2019: (March) FNHRERC conducted another review with the support from WHO

B. National Research Council Act 2017

- GOF Gazette, 26th May 2017 – Commencement notice by Minister for Education, Heritage & Arts, dated 23rd May, 2017.
- Objective 4(b) encourage or promote consideration of ethical issues relating to research and development
- Powers of the Council 8(d) set up committees for the purpose of conducting any scientific research
- Functions of the Council, 9. The functions of the council are to – (e) ensure that research is conducted in accordance with the highest ethical human welfare and environmental protection standards

C. National Consultation on Ethics and Governance of Human Research, Tanoa 26-27th March, 2019

Major change in the FNHREC revised SOP procedures is the accreditation policy and process. Application process & verification process

Accreditation guideline and form was drafted with WHO support and endorsed by A/PSHMS Accreditation of CCHREC on the 26th March,2019.

D. Guidelines for Accreditation of Ethics Committees in Fiji include the following sections;

Accreditation of Human Health Research Ethics Committees. Rationale.
Roles by FNHREC. Accreditation Quality Standards. How to obtain HHREC accreditation
Criteria for eligibility for HREC accreditation. HRECS Membership.
Duration and dates for annual reporting. Failure to Renew accreditation


MINISTRY OF HEALTH & MEDICAL SERVICES

This is to Certify that

College of Human Research Ethics Committee

(College of Medicine, Nursing & Health Sciences, Fiji National University)

Has successfully met the conditions and requirements of the

Fiji National Human Research Ethic Review Committee (FNHRERC)

Awarded on March 26th 2019

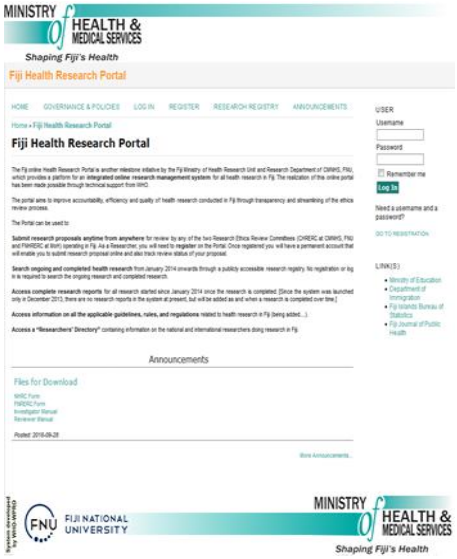
Presentation 13:

Technical support on health ethics committee in Fiji

Changgyo Yoon
Technical officer for health service delivery
WHO, Fiji

The Ministry of Health and Medical Services has been operating a National Health Research Ethics Review Committee to ensure ethically sound health research in the country.

Based on the recommendations made by the 1st review for the Fiji Human / Health Research Ethics system was done in 2012, MHMS and WPRO cooperated for the development of the health research portal to assist health researchers and committee reviewers in managing review process for health ethics since 2013: www.health.gov.fj/fijihrp



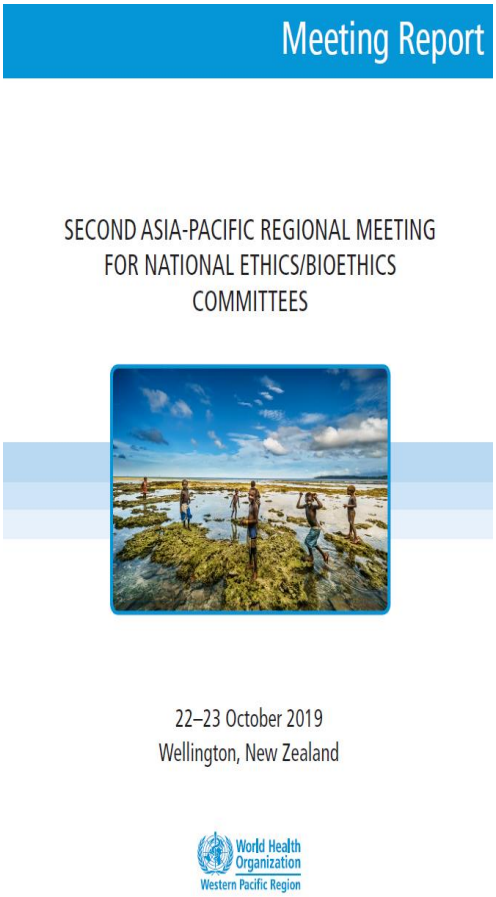
Also the development of the Fiji National Health Research Guide 2015 and the Standard Operating Procedures (SOP).

There is a National Research Council Act 2017 and the NRC is currently under its establishment stage.

Progress on health research ethics

- 2nd review jointly conducted by WHO and MOHMS in 2017 suggests:
  - Revision of SOP and templates for optimized ethics review process with consideration of minorities
  - Revision of Health Research Portal which is out dated and has gaps in assisting the secretariat of health research ethics committees
  - Enhance the cooperation between MHMS and educational institutions on health research ethics
- With support of WHO, MOHMS Fiji convened the 1st national consultation meeting with universities (March 2019).
  - MOHMS made a MOU with the Fiji national university to recognize it ability to endorse research proposal.
  - MOHMS revised SOP / template for review process (to be endorsed).
- Phase 1 development of Fiji MOHMS Health Research Portal (in 2019)
- 2nd AP-NEC meeting with Member States (Oct 2019)
- Phase 2 development of the Health Research Portal (in 2020-21)

The 1st National Consultation Meeting on Ethics and Governance of Human Research in Fiji, March, 2019



Recommendations for member states

(1) to continue to work towards the establishment of national ethics/bioethics committees or other oversight bodies, as appropriate, where these do not exist;

(2) to continue to revise/update guidelines and frameworks and create SOPs, as appropriate;

(3) to strengthen national ethics/bioethics committees through improved policy, administrative support, financing and better integration with challenges and opportunities in priority areas, including climate change, emerging technologies and the health of indigenous populations, such as through:

(4) to strengthen accountability over IRBs and other research oversight bodies;

(5) to develop ethics training and, if not already in place, introduce ethics into the curricula for health professionals and researchers, linking such training and guidance with WHO and UNESCO frameworks, and integrating cultural competencies into such training and guidance, as appropriate; and

(6) to strengthen national and regional networking and sharing for ethics/bioethics.

Recommendations for WHO

1. To provide assistance to Member States in advancing actions for health ethics, such as through:

    1.1. the establishment of national ethics/bioethics committees;

    1.2. support for specialist training on technical areas and ethics processes, e.g. writing guidelines or reviewing existing guidance and policies;

    1.3. the facilitation of country-to-country learning; and

    1.4. the development of international guidelines and standards on specialist topics, e.g. use of artificial intelligence in health, treatment of human biological data, data- and benefit-sharing, and climate change–related ethical guidance;

2. To support the organization of the Third Asia-Pacific Regional Meeting for National Ethics/Bioethics Committees in 2021.

Conclusion

- WHO has been supporting Fiji MOHMS in establishing the health research portal since 2011.
- Based on a review study on the health research committee in Fiji (2017), the development of HRE SOP, health research portal has started.
- Current efforts demonstrate that recommendations from the 2nd AP-NEC meeting are implemented
- In order to help maintain the committee, WHO further provides support on refresher trainings for ethics reviewers, the health research portal, making a regional network for health / bioethics committee, and liaises with other UN agencies such as UNESCO.

Discussion Points

How is WHO placed in the push for the establishment of Fiji National Research Council to progress at a faster rate.

The FNRC is the body that should moderate and control the research activities in Fiji. WHO is part of the United Nations and UN can make a recommendation to the Republic of Fiji and I have shared a very clear recommendation that we need to identify.

We need to know;

(i) The focal point in the National Research council.
(ii) What can the National Research Council provide for committees like Fiji MOHMS so making recommendations and feedback on the way.

(iii) We can identify and continue with the team at MOHMS to identify the focal point in the National Research Council for further work. Also to recognize FNRC.

Create a Pacific Network in Research to – WHO roles. (E.g. PIMNET)

No general platform to support all kinds of science – who has specific working groups, e.g. mental health, climate change, CDC, there is a **specific pacific platform, personal networks** linking ministries and units that can be used as a research oriented platform. AP-NEC –Regional platform to raise issues and sharing countries experience about health ethics in research. Secretariat of AP-NEC secretariat is in MOH NZ – how to link health research ethics and diseases and general bioethics. Another platform is HINARI – purely scientific library systems – encourage exchange between countries to better use of evidence and ongoing projects between countries. South to South Project at WHO – Regional bodies that we can use.

WHO will allow that the stakeholders of this network to join the AP-NEC group.

Check with Regional Office. But can request goes to Government of Fiji. If this meeting is virtual, then others from APNEC can zoom in to join the meeting to hear the stakeholder's views on different issues.

UNESCO can be requested to include.

RECOMMENDATION:

Dr Yoon to take it further – To organize a workshop like this one where the Ministry focal point can sit on behalf of the Ministry and be viewed, Ministries be invited, and we have contributions from the stakeholders. Ask WHO's support.

Benefit for this Network, the new sorts of studies and venturing into new areas of study, e.g. climate change and human health, how do ethics committees approve.

What are the MOHMS stance in clinical trials? What levels of RCTs MOHMS is able to approve to be conducted in Fiji?

MOHMS will seek expertise internationally and internally for any clinical trial. There will be a sub-committee that has the expertise, and they will meet and discuss the clinical trials. We have had RCTs in past few years but it was reviewed by international independent reviewers who provided expert advice to the MOHMS depending on the subject, for example, COVID-19 – a country wanted to conduct RCT on COVID-19 treatment drug, before we set up the committee, there was a blanket "no" from the MOHMS. Because we did not have enough information about COVID-19 and potential very high risk of conducting this trial in Fiji.

Oversight of ethics committees – in the absence of Fiji National Research Council and MOHMS is providing the accreditation of ethics committees, is WHO providing the oversight of ethics committees?

WHO provides an advisory and assist with the technical support, which is the expertise that we do not have. For 20 years MOHMS have had the role of oversight of ethics committees in the absence of a legislated body, now we have a legislated body, in reality FNRC should be tasked with the role of oversight and MOHMS should act according to the guidelines that FNRC sets, but none exist so MOHMS is doing this work as custodians of the population health as we are

looking after the welfare and health of the people. It becomes our responsibility. But when the FNRC is set up to take that role.
WHO does not provide the oversight but provide technical expertise and guidance, in terms of ethics or bioethics, many aspects of bioethics are culturally relevant, so WHO need to recognize the cultural and ethnic considerations of bioethics, so WHO is providing the pure technical expertise in networking with bioethicists and researchers.
Infrastructure for Research. There needs to be close cooperation with academic in the Region and Ministries of Health who are also publishers like the Fiji Journal of Public Health, Pacific Health Dialogue, need to build personal relationships between academic and researchers and academic institutions and WHO. So WHO encourages all these stakeholders to produce scientific evidence.
In nursing and medicine, professional bodies, we have the oversight of the international conventions, for nurses, we look to ICN international council of nurses, we have code of ethics for research is enough to provide the oversight.

Presentation 14:

Pacific Islands Health Research Symposium (PIHRS)

Presented by Avelina Rokoduru

Themes: Infectious Diseases, Non-Communicable Diseases, Health Systems strengthening, RMNCAH, One Health.

10th PIHRS this year virtually, Free Registration, 270 people have registered as of 19/4/21.

48 Abstracts for oral presentations.

Panel discussion sessions.

- Covid 19 and the learning in academic institutions in Pacific and CMNHS, National University of Samoa, University of Otago.
- Vaccinations COVID-19 COUNTRIES EXPERIENCES.
- Universal access to health while experiencing a pandemic, WHO, SPC, academics, leading experts in COVID 19.

Final session – Permanent Secretaries of Ministries of Health in Pacific Island Countries will share experiences in Covid-19.

Presentation 15:

Ministry of Fisheries

Presented by Ms Pritika Kumar

Application for Research Process in the MOF is simple, the approval for research is given by the Permanent Secretary for Fisheries. Researchers are to write an application letter and submit. Once approved, an approval letter is issued from the PS. A Terms of Reference is created and then the research takes place.

Request for data. Letter of application is sent to the PS. Director's office endorses the data sharing form. The letter should be in detail to specify the type of data request, timeframe urgency and we consider the confidentiality issues. PS is the only person who can approval this request for data.

Discussion points

There is a template for requesting data from the Ministry.

There is no template for application to conduct research. Researchers are required to write and submit a letter to the PS Fisheries.

Protection of endangered and protected fish – we work with biosecurity and agriculture with regards to research in these areas.

Latest research the Ministry has done in the last 5 years. Research in marine life, biological, socio economic assessment. Fish poisoning research with FNU.

Any guideline for quality of fish from the sea to market?

SOP, guideline and a checklist is provided to fishermen for storage of fish for quality. We also provide training for fishermen. Extension officers they monitor.

Fish poisoning is quite common in hospitals. The research project currently on with School of environment has a health component in which we are working with the turaga ni koro and health nurses in the villages to identify fish poisoning in their communities.

Presentation 16:

Processes for the Development of a Memorandum of Agreement Among Stakeholders

by Ms Avelina Rokoduru, Director of PacSRHRC

Context of the Stakeholders meeting

- To convene researchers, research organizations and custodians of research facilities in Fiji and some regional countries to meet, discuss and share information, create awareness of research ethics and research governance mechanisms to strengthen partnerships and the custodians of research in Fiji;
- To identify sources of liable and available data sets and data management processes among CHHREC, government and NGO that facilitate research;
- To develop regional, national and local research partnerships between government and NGOs partners and CMNHS.

Some Notes

- FNU – As national institution - responsibility to provide timely, impactful and sustainable solutions for the Fijian government and other PICs;
- FIPHR Strategic Plan 2020 – 2025:
    - Strategic Area 1: High Quality Research Environment
    - Strategic Area 2: Research Dissemination & Translation
    - Strategic Area 3: Research Capacity Development
    - Strategic Area 4: Governance & Resourcing of FIPHR
- **NOTE:** We note variability amongst stakeholders in their research capacity and structures and processes.
- Consultations – with who and why?
- Priorities? Way Forward?

Discussion Points

Dr Wilson, ask iTaukei Affairs or our team, when researcher get ethics approval – and gets approved, then the researcher apply for facility approval, at CHHREC what are we doing at this

time. Mechanism of proactive follow up? If there is no response from facility. If researcher does not get a response, we can follow up with an email. Are there timelines?

iTaukei affairs: 1-3 weeks' turnaround time. CHHREC need to see what the mechanisms for following up and pro-active. (To add to the CHHREC SOP.)

There is a paper submitted (in Government with fees for the iTaukei Affairs, at senior management team now, to charge researchers).

What is the fee for? How much will the fees for? Build in the research budget in internationally collaboration research.

Research fees at Itaukei Affairs – should go back to the community that is the research setting.

MOU with Ministries: Are there standard procedures in Ministries for MOU?

Signed MOUs – process – goes through Solicitor General's SGs office. We have done a few and if they give the greenlight, then good.

What is the benefit of MOU?

- Capacity building for staff and (women in fisheries).
- Benefit provincial council
- Vetting processes goes through the SG's office – processes in Ministries.

We had an MOU MOHMS since Fiji School of Medicine years.

Need the National Research council to direct us on the fees for application for research ethics and iTaukei Affairs fees.

This MOU with MOHMS will be built into the existing MOU that we have.

PIANGO, we focus on our members, a partnership agreement with national NGO. Now we have learnt that health cuts across all the work that we do in all our countries of membership. Agreement of Partnership with our communities. FCOSS is the member in Fiji.

FHEC: FNU we already have that relationship; we can partner with FNU and support FNU. We can partner to inform higher education.

Political level support of this network is needed.

MOUs take long processes. Ministries will channel via SG's office and will take a long time. We should just look at the operational level of research.

National Agenda in Fiji will require all these issues.

Gap of the National Human Research Ethics Committee in Fiji is missing in our structure. Comparing to Australia, the NHMRC, they are like the deciding body on guidelines and regulations

on ethics committee. The FHEC can possibly absorbed in research so that we can continue the work for National Guideline for Research ethics in Fiji.

The Act does not allow FHEC to take up anything to do with this research. Can take to Senate or Council of FNU. Dean will ask in the FNU Council meeting where PS Education will be attending.

NATIONAL RESEARCH AGENDA – to be formed. It does not stand alone, it links to Human Rights and Indigenous rights.

Fiji Medical Association – we are happy to work with CHHREC to ensure that our agendas are linked. Journals to FIPHR. We do not have a student's representative in this meeting. Dr Ronald. Ownership and Publication in research gaps.

Research to link to the MOHMS plans. Develop manuscripts from student's research – supervisors of student's research role.

Fiji Nursing Association: Difficult to have an MOA with MOHMS. Signed an MOA with the Chinese Nursing Association. Professional education, research, shipment paid for PPEs from China. We are working on guidelines for research. We are going to offer master and PhD scholarships from FNA. Capacity building for nurses in research is needed. Relationship with iTaukei Affairs, proposals that come from nurses that do studies in obesity, quality of life in youths and aged population in villages. Develop courses on lifestyle changes management in villages.

FIPHR an MOA with FNA for research – can be discussed to identify the details. To be prioritized.

Access to disaggregated data. We were instructed that we cannot access data by ethnic lines. Race is a biological determinant of health. Important information for research - an objective of the Network is trying to leverage our ability to access data without many obstructions.

The formation of National Research Council – stakeholders meeting – analysis, what people can contribute, an agreement as an outcome.

What has worked at FNU:

- Knowledge translations – policy development, curriculum.
- Research – to inform decisions and policy. Need the council to work to get budget for research.
- Ensure that the processes we create works – to see that it works. At MOHMS, Divisional level can work to drive research if National level is not working.
- Choice of research topic. Now they have moved it back and students can create their topic from their clinical experience, keep to timeline to finish, adequate supervision and forming partnership and also outside partnership. **Partnership and mentorship.**
- Keeping a good relationship with research partners for a successful BMLS research.
- Fijian ways enable the successful completion of research.

Successful programmes from the Pacific Islands that change policies, case from the Northern Pacific. The HDR programme. MMED programme with its research component. Amend CMNHS structure to include FIPHR. This change in structure is a leverage to attract research fund. We have had offers for research funding in FIPHR. Professional network that have been build up adds to the success of research in FIPHR and in upcoming years.

Discussions of Resolutions

PACIFIC HEALTH RESEARCH ETHICS NETWORK (PHREN)

Research ethics only.

Purpose and objectives

Benefits of membership in PHREN

- Research Ethics training
- Capacity building in research designs and research ethics.

COMBINED LIST OF RECOMMENDATIONS

1. Need a data repository.
2. FIPHR to store the reports in a data repository and facilitate the publication of these reports.
3. Training: Ethics Review of research proposals training be conducted for reviewers at FHHREC.
4. Need to facilitate publication of research project reports to ensure no duplication of research topics and accessible.
5. Explore local journals to publish research reports.
6. The suggestion from Dr Rafai for the group to compile an SOP to be actioned.
7. iTaukei fees structure to be made available to be included in this SOP.
8. FPIC guidelines from iTaukei Affairs to be made available to go into the SOP.
9. To include in the SOP. If a research proposal has received conditional approval from CHHREC, but the research setting made some comments for change, the researcher is to make the changes in the proposal and submit to the facility and to CHHREC for recording before an approval is granted from the facility and lastly a full approval from CHHREC.
10. Form a NETWORK for this group. Pacific Health Research Ethics Network. Strengthening the relationships of facilities to support research.
11. Recommendation: Meeting with the PS MEHA to be organized. Face to face in order to get a response – to send a delegate – chairman and appointment to meet PS – officer of higher education to facilitate that.
12. Suva City Council. ADR to write a letter;
    - to thank the CEO – Suva City council to thank for Tomasi's participation.
    - Request going forward – discuss with team, also apply to Nasinu and Nausori Town Councils.
    - Get an idea of the process at Suva city council.

- 3 months' turnaround time at council is not supportive of the researchers.
- An SOP to be developed for Suva City Council Research Facility approval processes.

13. Police Department. To have the meeting with Commissioner of Police regarding a way forward with facilitating research and design and process going forward with the Police department.
14. MOHMS: Research facilities to receive a copy of the final research report including data collected.

Research facilities to facilitate an oral presentation from researcher of the findings of the research.

MMED students to present to the relevant division in the relevant hospital. Present in IMOP conference.

Health facilities management to create a tracking system where the MS secretary can, at the end of the research they can call the researcher to give a report back.

15. **Recommendations for WHO**

- to provide assistance to Member States in advancing actions for health ethics, through:
  - the establishment of national ethics/bioethics committees;
  - support for specialist training on technical areas and ethics processes, e.g. writing guidelines or reviewing existing guidance and policies;
  - the facilitation of country-to-country learning; and
  - the development of international guidelines and standards on specialist topics, e.g. use of artificial intelligence in health, treatment of human biological data, data- and benefit-sharing, and climate change–related ethical guidance;
- to support the organization of the Third Asia-Pacific Regional Meeting for National Ethics/Bioethics Committees in 2021.
- Facilitate PHREN meeting virtually and AP Network of Ethics/Bioethics can join in.

CHHREC Stakeholders Meeting - Resolution

1. Form a research ethics network - networking of multi-sectoral partners including region
   a. **PACIFIC HEALTH RESEARCH ETHICS NETWORK** (PHREN)
      i. **Keep to research ethics only**
   b. **Terms of Reference**
      i. PURPOSE & OBJECTIVES
      ii. BENEFITS of membership – e.g.
      - ❖ Access to data (government ministries, FiBOS, etc.)
      - ❖ Capacity Building
        - Ethics training
        - Research training
        - Statistical Analyses
        - Proposal/Manuscript writing/reviewing
      - ❖ Further networking
        - Across local and regional government ministries, NGO's, academia, etc.
        - Funding opportunities

2. **Study Setting Approvals:**
   - Inclusion of mandatory or obligatory reporting for researcher to alert the members of the community and those in authority of their research – capture in research proposal or SOP or approval letter.
   - Researcher needs to engage the study site prior to conduct of research – capture in SOP

3. **Research engagement with health facilities**
   - All student proposals must go through SRC and have supervisor endorsement form signed. Any necessary training for the purpose of the research needs to have been conducted by the supervisor
   - Non-student researchers must submit CV's that inform CHHREC of the relevant qualifications to conduct the proposed research
   - Facility/Study Settings – ensuring that structures and processes are in place, including timelines of response to researcher

4. **National Research Council**
   - A few members of the PHREN to meet with the PS MEHA
     - Decide meeting agenda
     - Enquire on status of the National Research Council and other related matters (e.g., research funding)

5. **Suva City Council:**
   - Request the CEO SCC for a meeting to discuss outcomes of this meeting and how SCC could assist research that need to be conducted in the SCC jurisdiction
   - The same request would apply to the other local government municipalities

6. **Fiji Police**
   - Request the Commissioner of Police for a meeting to discuss outcomes of this meeting and how FPF could assist in processes related to access of data from FPF

7. **PIANGO**
   - Connecting FIPHR to their National Liaison Units
   - Mainstream "health" as a cross-cutting area of research for all NLUs
   - Request to FIPHR for research capacity building for its NLU's

8. **Fiji Medical Association**
   - To convene a meeting with FMA and FIPHR regarding FIPHR to administer the Fiji Medical Journal
   - FIPHR will also plan research capacity building programme with FMA

9. **Ministry of I-Taukei Affairs**
   - Open to collaboration
   - Translation of research tools into vernacular - to provide a fee breakdown –
   - Consider fees for ethics review process
   - Requirement on researchers to report back to communities on findings of research – CHHREC to identify where to capture this requirement

10. **Ministry of Agriculture**
    - MOA to develop their Animal Ethics Committee (need to rephrase)
    - Need to develop processes for ethics approval
    - Consultation between MoA, MoHMS and CHHREC in regards One Health research

11. **World Health Organization**
    - WHO to request UNESCO to extend invitation for this network to join APINET
    - WHO to spearhead the formalization of PHREN
    - WHO to support the annual meeting of PHREN

12. **Secretariat of the Pacific Community (SPC)**

CHHREC is happy to engage with SPC and the region to provide research capacity building for the region. CHHREC has begun work in Vanuatu because they do not have an ethics committee and this is the ways in which CHHREC can contribute in the development of research Bioethics and development of Ethics Committees in the Region. Authorship policy to be developed in consultation with SPC.

13. **Overall conclusions**
    - Concerns about inaccessibility of data from FiBOS
    - Need to Form the Fiji National Research Agenda
    - Need to capture compliance to IP Regulations.

CLOSING REMARKS

This is the end of the three days meeting. Thank you very much everyone. We have enjoyed the consultation. I hope you have made some new professional friends, and networking. Next year we ca make the program richer. Hope we can have more participation from the Region. Thank you once again.

Appendices

Appendix 1: Agenda

College Human Health Research Ethics Committee (CHHREC) Stakeholders Meeting Agenda, 7th – 9th April, 2021, Holiday Inn, Suva, Fiji & Virtually for the Region

Objectives

1. To convene researchers, research organizations and custodians of research facilities in Fiji and some regional countries to meet, discuss and share information, create awareness of research ethics and research governance mechanisms to strengthen partnerships and the custodians of research facilities in Fiji.
2. To determine the status quo of health research ethics processes in all stakeholder agencies in Fiji, as well as several select Pacific Island countries.
3. To identify gaps and challenges in the current systems and develop possible solutions to streamline the implementation processes of research governance mechanisms.
4. To identify sources of reliable and available data sets and data management processes among CHHREC, Government and Non-Governmental Organizations that facilitate research; and
5. Training of stakeholders in ethical and technical review of research proposals

Time	**DAY 1: Session (7th April 2021)**
8:00a.m.	Registration
	MCs: CHHREC Members
8:30a.m.	Spiritual Uplifting by Mr. Raymond Keshwan, Head of School, School of Health Sciences, College of Medicine Nursing and Health Sciences, (CMNHS)
8:45a.m.	Welcome & Introduction of the Chief Guest by the Dean, CMNHS, ***Dr. William May***
9:00a.m.	Keynote Address by Chief Guest***, Dr. Changgyo Yoon***, World Health Organization, Division of Pacific Technical Support
9:30a.m.	***Launch of College Human Health Research Ethics Committee (CHHREC), Standard Operating Procedures (SOP) 2021, by Dr. Changgyo Yoon, World Health Organization, Division of Pacific Technical Support***
10:00a.m.	***Morning Tea and Group Photo Shoot***
10:15a.m.	Meeting Overview and Expected Outcomes, ***Dr. Donald Wilson***, Associate Dean Research and Director of the Fiji Institute of Pacific Health Research (FIPHR), CMNHS
11.00a.m.	***Overview of CHHREC SOP, Mrs. Etivina Lovo,*** Research Fellow (Bioethics and Professionalism), FIPHR, CMNHS
11.30a.m.	Research Designs and Methodologies of proposals submitted to CHHREC, Mrs. Etivina Lovo, Research Fellow (Bioethics and Professionalism), FIPHR, CMNHS

Organization/Stakeholders presentations focusing on their research application processes and requirements for facility approvals. (half hour each: 20 mins presentation and 10 mins Q & A)

12:00a.m.	***Ministry of Health and Medical Services, Fiji Representatives***
	Dr. Eric Rafai, Head of Research, Innovation and Data Analysis Management
	Ms. Anjana Deo, Research Officer
12:30p.m.	***Lunch***
1:30p.m.	***Ministry of Education, Heritage and Arts, Fiji Representative***,
	Mr Saula Baleisuva
1:50p.m.	***Ministry of iTaukei Affairs, Fiji. Representative,***
	Mr Waisale Ramoce
2:10p.m.	Ministry of Women, Social Welfare and Poverty Alleviation, Fiji
2:30p.m	***Tonga National Health Research Ethics Committee (TNHREC) Representatives,***
	Dr. Lisiate 'Ulufonua, Chair, National Health Ethics Research Committee Tonga, Mr. Sioape Kupu, Acting Principal Health Planning Officer
3:00p.m.	***Afternoon Tea***
3.15p.m.	***Ministry of Agriculture, Fiji Representatives***
	Dr. Mereia Fong and Mr. Amena Banuve
3:35p.m.	Department of Immigration, Fiji
3:55p.m	***Vanuatu National Health Research Ethics Committee Representative***
	Ms. Wendy Williams
4;15p.m.	***Day 1 ENDS***

Time	**DAY 2: Session (8th April 2021)**
8:00a.m.	Registration
	MCs: CHHREC Members
8:30a.m.	Ministry of Regional Development and Local Governments, Fiji
	Suva City Council Rep
	Nasinu Town Council Rep
9:00a.m.	***Pacific Islands Association of NGOs (PIANGO), Representative,***
	Ms. Emeline Siale Ilolahia, Executive Director
9:30a.m.	***Representative from the National University of Samoa & Samoa Medical Association:*** *Oversight and Governance of Research in Samoa*
	Dr. Belladonna Potoi, Dr. Robert Thomsen
10:00a.m.	***Morning Tea***
10:30a.m.	Fiji Medical Association
11:00a.m.	***Fiji Police Force Representative,***
	Inspector Peceli Heritage
11:30a.m.	***National Food Nutrition Centre (NFNC),***
	Ms Ateca Kama, Director NFNC
12:00a.m.	***Representative from Kiribati Health Research Ethics Committee,***
	OIC Tiinia Raj and Team

1:00p.m. ***Lunch***

2:00p.m. ***Ministry of Health and Medical Services, Fiji Representative,***
Ms Varanisese Smith, Senior Statistician
Data Sources for Health Research. (Requirements for an application to access data)

2.30p.m. Round Table Discussion about Research Data Sources and Access
Interdisciplinary General Discussions on Data Sets
Moderators: Ms. Avelina Rokoduru and Ms. Etivina Lovo

3.00p.m. **Training Session:** Ethics Review Skills Development
Ms. Etivina Lovo, Research Fellow (Bioethics and Professionalism), FIPHR, CMNHS

3:30p.m. ***Afternoon Tea***

3:40p.m. Research Ethics Review Skills. Group work and Group presentations.

5:00p.m. **Day 2 ENDS**

Time	**DAY 3: Session (9th April, 2021)**
8:00a.m.	Registration **MCs: CHHREC Members**
8:30a.m.	***Human Health Ethics Committees- The Accreditation Process*** ***By:*** Dr. Eric Rafai, Ministry of Health and Medical Services Fiji; & Dr. Changgyo Yoon, WHO, Division of Pacific Technical Support
9.00a.m.	Pacific Islands Health Research Symposium, FIPHR, CMNHS
10:30a.m.	***Morning Tea***
11:00a.m.	Processes for Development of Memorandum of Agreement among Stakeholders. Moderator Avelina Rokoduru.
1:00p.m.	***Lunch***
2.00p.m.	***Group work:*** Round Table discussion on Way Forward and Recommendations.
3:30p.m.	***Afternoon Tea***
4.00p.m.	**Group Report and Summary**

Closing Remarks, Dr. Donald Wilson, Associate Dean Research and Director of the Fiji Institute of Pacific Health Research

Appendix 2: Participants List

FIPHR – COLLEGE HUMAN HEALTH RESEARCH ETHICS STAKEHOLDER'S MEETING, 7-9 April, 2021 @ Suva Holiday Inn

#	Name	Designation & Address	Organization	Phone	Email Address
1	Dr Changgyo Yoon	WHO Technical Officer	WHO		
2	Dr. William May	College Dean	CMHS, FNU		william.may@fnu.ac.fj
3	Dr. Donald Wilson	CHHREC Chair	FIPHR, CMNHS	8053931 or ext. 3128	donald.wilson@fnu.ac.fj adr-cmnhs@fnu.ac.fj
4	Dr. Gade Waqa	Head of C-POND	C-POND, FIPHR, CMNHS	9439888 or ext. 3842	gade.waqa@fnu.ac.fj
5	Ms. Avelina Rokoduru	Director	PaCS-RHRC, FIPHR, CMNHS	9321284 ext. 3855	avelina.rokoduru@fnu.ac.fj
6	Mrs. Etivina Lovo	Research Fellow	FIPHR, CMNHS	744724 or ext. 3020	etivina.lovo@fnu.ac.fj
7	Ms. Susana Lolohea	Administrative Assistant	C-POND, FIPHR, CMNHS	8606068 or ext. 3837	susana.lolohea@fnu.ac.fj
8	Mr. Kaminieli Tawake	Research Assistant - CHIPSR	CHIPSR, FIPHR, CMNHS	2821180/ 7101038 or ext. 3018	kaminieli.tawake@fnu.ac.fj
9	Ms. Nirma Lakhan	Research Fellow	FIPHR, CMNHS	8387161 or ext. 3024	nirma.lakhan@fnu.ac.fj
10	Ms. Vinau Savu	CHHREC Officer	FIPHR, CMNHS	9266972 or ext. 3024	vinau.savu@fnu.ac.fj
11	Ms. Losevati Mataitini	Administrative Officer	FIPHR, CMNHS	7694741 or 3018	Losevati.mataitini@fnu.ac.fj
12	Ratu Luke Mudreilagi	Chair, SRC	SON, CMNHS	8308305 or ext. 3639	ratu.mudreilagi@fnu.ac.fj
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