MINISTRY OF HEALTH AND MEDICAL SERVICES

Fiji Human Research Ethics Committee (FHHREC)

Standard Operating Procedures

A collaborative initiative of the Republic of Fiji Ministry of Health Medical Services, Fiji National University's College of Medicine, Nursing, Health Sciences (CMNHS), and technically supported by the World Health Organization, Western Pacific Regional Office (WHO-WPRO)

Ministry of Health Medical Services

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The SOP was cleared by the MOHMS's National Health Information Committee (NHIC) on ……..and approved by the National Health Executive Committee on (date ……..).

The SOP was developed and reviewed by …….

A consultation workshop was initiated by the ……..

We would like to acknowledge the contributions of participants of the …….. Consultation workshop, conducted in…….;

…….comments and inputs, which has culminated in the finalization of this SOP.

A special acknowledgement to …….

A copy of this publication with any further update and additional information will also be provided through the electronic Fiji health research registry portal (http://www.health.gov.fj/fijihrp).

Your comments and feedback are welcome and can be submitted to info@health.gov.fj

FORWARD

The Fiji Human Research Ethics Committee (FHHREC) Standard Operating Procedure (SOP) is a guide developed to facilitate the systematic implementation of the roles of the FHHREC. The SOP aims to streamline the ethical review processes of FHHREC for reviewers and researchers in Fiji, delineating the review structure, process and functions of the committee. The SOP serves as a tool to inform and assist the FHHREC and external reviewers to carry out responsible ethical review of health related research submitted to the FHHREC for ethical review.

One of the major objectives of MOHMS is to strengthen human research activities to ensure the ethical conduct of human research in Fiji. It is hoped that users of this SOP will maximize its use, ensuring and promoting responsible research practices. Researchers alike are to abide and comply with Fiji Human research regulations in order to conduct responsible and ethics health research in the Republic of Fiji to maximize benefits for our peoples.

..... (Name)

Permanent Secretary for Health Medical Services
Ministry of Health Medical Services, Fiji

CONTENTS

LIST OF ACRONYMS

CMNHS	College of Medicine, Nursing Health Sciences
CHREC	College Health Research Ethics Committee
CIMOS	Council for International Organization of Medical Services
HRIU	Head of Research Innovation Unit
DMO	Divisional Medical Officer
DSMB	Data Safety and Monitoring Board
ERC	Ethics Review Committee
FNHREC	Fiji National Health Research Ethics Committee
FNU	Fiji National University
HIRA	Health Information Research Analysis
HRO	Health Research Officer
ID	Identifier
IRB	International Review Board
MOHMS	Ministry of Health Medical Services
MS	Medical Superintendent
NHRO	National Health Research Office
PI	Principal Investigator
PSHMS	Permanent Secretary for Health Medical Services
PSC	Public Service Commission
SOP	Standard Operating Procedure
UNESCO	United National Educational Scientific and Cultural Organization
WHO	World Health Organization
WHO-ERB	World Health Organization Ethics Review Board
WMA	World Medical Assembly
WPRO	WHO Western Pacific Regional Office Worlds Health Organization

PREAMBLE

Fiji Human Research Ethics Committee (FHHREC) is the human research ethics accreditation body of the Republic of Fiji.

The FHHREC's roles to be performed as the national accreditation body include the following;

i. Facilitate and monitor the accreditation process.
ii. Establish an application process.
iii. Prepare criteria for eligibility and other standards for accreditation of a Human Research Ethics Committee.
iv. Develop and implement a monitoring system for accredited Human Research Ethics Committees on an annual basis.
v. Provide feedback on the yearly evaluation of HRECs.
vi. Provide advice to HRECs on standards and ethical requirements for human research.

In March 2019, Human Research Ethics Committees in Universities in Fiji were invited by the FHHREC to apply for accreditation.

An application was received by the FHHREC from the Fiji National University's College of Medicine Nursing and Health Sciences, "College Health Research Ethics Committee" (CHREC). The FNHREC awarded CHREC with an accreditation certificate on the 26 March, 2019 for successfully meeting the conditions and requirements of a Human Research Ethics Committee. The accreditation of CHREC means that it has proven institutional effectiveness as assessed by the accrediting process and verification team from the FHHREC. The assessment recognized that CHREC fulfilled international and national standards of governance of human research ethics. The FHHREC, under the Fiji Government regulations that govern human health research, has granted full authority to CHREC to conduct independent review of research conducted by students enrolled in College of Medicine, Nursing and Health Sciences (CMNHS), Fiji National University, (FNU) as part of their academic requirements and human research where faculty of CMNHS, FNU is the principal investigator, member of the research team and/or responsible for overall management of the research.

In cases of reviews of research such as clinical trials, drug trials and genetic related research projects will be conducted by the FHHREC. Guidelines and Application form for Accreditation of Ethics Committees in Fiji is attached as Appendix 1.

1. Overview of the Standard Operating Procedures (SOP)

This SOP delineates the structure, functions, and process to be followed by the FHHREC. The SOP will override any other administrative rules or procedures previously specified.

2. The Purpose of the Fiji Human Health Research Ethics Committee (FHHREC)

1. The purpose of FHHREC is to ensure that all human research proposed to be conducted in the Republic of Fiji is appropriately designed to address the needs of the people of the Republic of Fiji. The FHHREC will ensure that the research project(s) proposed meet the ethical standards of research in accordance with the fundamental ethical principles of respect for persons, beneficence, non-maleficence and justice as stated in international guidelines such as the *International Ethical Guidelines For Health-Related Research Involving Humans, 2016*, issued by the Council for International Organizations of Medical Sciences (CIOMS) and others. [1,2] The FHHREC will also ensure that research is scientifically sound and justifies the involvement of human participants in research and ensures their protection from harm.

2. The FHHREC requires all research that uses human participants, tissues and specimens from humans, data and records from human participants, or surveys of human participants and is proposed to be conducted in the Republic of Fiji will require prior review and approval from one of the accredited Human Research Ethics Committee located in Universities or review to be conducted by the FHHREC. Descriptions of research that must be submitted to a Republic of Fiji Human Research Ethics Committee for review include but not limited to the following types of research;

- Research of physiological, biochemical, pathological or social process types involving Fiji peoples.
- Intervention type research including diagnostic, preventive or therapeutic measures, or studies designed to determine the consequences for individuals and communities of implementing preventive or therapeutic measures.
- Research concerning human health related behavior in a variety of circumstances and environments.
- Research that involves social science methods including but not limited to interviews, focus group discussions, ethnographic observation and surveys.
- Research involving quasi-experimental or experimental intervention, drugs and devices.
- Research involving invasive procedures and research involving deception.
- Research involving sensitive questions or information that can result in stigmatization, discrimination, persecution, prosecution or indictment or unnecessary stressful situations

[1] International Ethical Guidelines for Health-related Research Involving Humans https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

[2] Beauchamp, T. L., & Childress, J. F. (2001). *Principles of biomedical ethics*. Oxford University Press, USA.

to participants.

3. Jurisdiction of FHHREC and other Ethics Review Committee

Note: Upon completion of the accreditation of Fiji Universities' Human Research Ethics Committees, the FHHREC will **not** review research proposals of students or staff or affiliates of Fiji Universities. Researchers who are not affiliated with one of the Fiji universities must apply for review by the FHHREC. For further information about accredited HRECs in Fiji, please contact the FHHREC. The contact details are stated on the last page of this SOP.

As of 26th of March 2019, the Human Research Ethics Committee at the College of Medicine, Nursing & Health Sciences of the FNU was accredited by the Ministry of Health Medical Services to review all health/human related research proposals submitted by students and staffs of CMNHS.

However, 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. A data request form is available at the Ministry of Health & Medical Services website for researchers/students to complete and submit;

FHHREC will review the following research;

- Clinical trials, Drug Trials and Genetics research
- All overseas multi-donor/sponsored research to be conducted in the Republic of Fiji either by individuals (e.g. foreign students) or by external research institutions including bilateral or multilateral donors with or without collaboration with MHMS staff must be submitted to FHHREC for review.
- All health research funded by MHMS or its affiliated institutions.
- All health research initiated by MHMS staff as principal investigators or where MHMS staff is primarily responsible for overall management of the research.

4. FHHREC Membership

4.1 Composition of Membership

The Committee shall consist of at least 15 members the Secretariat.

Membership shall have an appropriate gender balance, and at least member(s) (a single member may have multiple expertise) must have the following expertise or background in each of the following areas:

- Biostatistics, Epidemiology and Research Methodologies;
- Social or behavioral research;
- Health systems, preferably also with health economics background;

- Communicable diseases;
- Non-communicable diseases; and
- Clergy
- Community lay persons
- Human rights and law
- Social worker
- I-Taukei Affairs

Members who are MHMS staff shall serve in an individual capacity and as official representatives of any unit or programme of the MHMS. They may not be able to delegate their responsibilities as member of the Committee to any other technical staff in their unit or program.

There shall be at least five Committee members (to maximum of 7) not employed by the MHMS. These members shall be known as "nonaffiliated members". These members will also serve in an individual capacity and not as an official representative of their organization.

Affiliated nor nonaffiliated members will not receive any remuneration for specifically serving on the Committee or attending its meetings. However, if they have to incur travel expenses to attend the meeting, then travel allowance will be paid to members travelling in for the meeting.

4.2 Appointment of Members

Members shall be appointed by the Permanent Secretary for Health Medical Services (PSHMS) on the recommendation of the Head of Research and Innovation Unit for a three-year term, renewable once for a maximum of two consecutive terms.

Members shall be appointed based on (but not limited to) the following descriptions;

- Their willingness to commit the time required for the implementation of their duties for the Committee.

- Their expert knowledge in medicine, science, or another field, as appropriate.

- Their willingness to acquire knowledge of research methods and research ethics through appropriate training and education. These training and education exercises will be conducted within two months of the beginning of their membership.

- Notwithstanding their term of appointment, the service of MHMS staff on the Committee shall end when their employment with MHMS terminates.

4.3 Redundancy of Membership

For members to maintain membership, they must attend 40% of meetings in a year and participate in review of at least 30% of the proposals received by FHHREC.

To ensure the independence of the Committee and the ability of its members to exercise their judgment concerning matters coming before the Committee, the members may be removed from the Committee only by the PSHMS in the event(s) of:

a) Failure to attend three consecutive meetings for which they had previously committed, without informing the Secretariat in advance of the meetings.

b) Failure to attend at least 40% of the Committee meetings in any given year.

c) Failure to perform the functions expected of Committee members, including serving as a primary reviewer of assigned research proposals.

d) Flagrant departure from Committee SOP, except in the case of removal for cause, members shall serve until their successors are appointed.

e) Members who are unable to fulfill their responsibilities may submit a letter of resignation to the Head of Research and Innovation Unit, copying the Secretariat).

4.4 Chair and Vice Chair

4.4.1 Appointment

(a) The PSHMS shall appoint a Chairperson and a Vice-Chairperson of the Committee among its 15 members based on the recommendations from Head of Research and Innovation Unit.

(b) Appointment as Chair and Vice-Chair shall be for a maximum of two renewable terms of three years each or for the duration of the membership, whichever is shorter.

4.4.2 Roles of the Chair

a) Chair FHHREC meetings.

b) Sign FHHREC documents intended for approval or communicating review outcomes and recommendations about ethics review of research proposals submitted to FHHREC on behalf of the Committee.

c) Convey to Head of Research and Innovation Unit the Committee's advice on matters related to the ethics of research involving human participants or to the activities and responsibilities of the Committee.

d) Work with and provide general direction to the Secretary regarding the operation of the Committee and the Secretariat.

e) Recommend to Head of Research and Innovation Unit possible new members, endeavoring to ensure appropriate balance of expertise, gender, and cross-division involvement.

4.4.3 Roles of the Vice Chair

The role of the Vice Chair is to perform the duties of the Chair in the absence of the Chair or if the Chair is unable to carry out the responsibilities of the office, the Vice-Chairperson, shall, in addition to such other functions provided for in these Rules:

4.4.4 Maintaining Independence of ethics reviews

To maintain the independence of the FHHREC, the Chairperson will hand over the responsibility of the office to the Vice-Chairperson whenever research proposals from the Chair's department in MHMS are being reviewed or discussed. If the discussion is in FHHREC meeting, the chair will leave the room until this discussion is over.

Similarly, the Vice-Chair shall not act as the Chair if proposals his or her department within MHMS is being reviewed or discussed. If the discussion is in the FHHREC meeting, the Vice-Chair will leave the room until this discussion is over. The same rule will apply to other members of the committee in the case of reviewing research proposals in which they are members of the research team.

In the event that neither the Chairperson nor the Vice-Chairperson is available, the Chairperson will delegate authority to a Committee member in writing to act on behalf of the Chairperson.

5. The Secretariat of FHHREC

The Secretariat of FHHREC comprise of the Research and Innovation Unit (RIU) of the MHMS. The RIU has the mandate of overall governance and management of health research in the Republic of Fiji.

The Secretariat will provide the support services for FHHREC. The Secretariat will not count towards a quorum for full review of research proposals.

5.1 Roles of the Secretariat

i. Serve ex-officio members of the Committee.

ii. Certify, on behalf of MHMS, which research proposals have been duly

iii. Approved by the Committee in accordance with these procedures.

iv. Make available to the Head of Research and Innovation Unit, MHMS staff and new Committee members the information and educational materials and training on ethical issues relating to research with human participants.

v. Disseminate ethics review guideline or standard information to Committee members and reviewers.

vi. Ensure that the Secretariat operates in an efficient, accountable and transparent manner.

vii. Undertaking a preliminary review of all submitted proposals to assess whether they are

complete. If the application is incomplete, the Secretariat is to inform the investigators accordingly.

viii. Scheduling, coordinating and organizing Committee meetings at such intervals and in such a manner as specified in these rules or as otherwise directed by the Committee to ensure prompt reviews of new and pending research proposals.

viii. Provision of administrative assistant duties to assist the Chairperson and members in carrying out the Committee's functions.

x. Informing the investigators in a timely manner of the Committee's decision for each research proposal reviewed.

xi. Recording and timely drafting of meeting minutes, the annual report and other reports as may be required regarding the work of the Secretariat and of the Committee.

xii. Maintaining and archiving the following documentation:

- A copy of the SOP and any amendments;
- An up-dated list of all Committee members, with their terms of service, titles, and curriculum vitae or other biographical information sufficient to describe their qualifications (e.g., educational background, current employer and relevant area(s) of expertise);
- A full set of minutes of Committee meetings and decisions and such additional detailed records as the Committee may require;
- Data documenting the status of all research proposals submitted to the Committee (e.g. whether exempt from review, approved, awaiting changes before action, or not approved);
- Copies of all research proposals submitted to the Committee, including comments from any scientific or technical bodies and any other research ethics committees that reviewed any such proposal.
- All project-related documentation shall be retained for three years after the closure of the project and all Secretariat-related documentation (meeting agenda, minutes of meetings, annual reports, reports etc.) shall be retained for five years, unless otherwise advised by the Records and Archive Department of MHMS/PSC.

6. Committee Meetings

6.1 Frequency of Meetings

Committee meetings shall be convened and organized by the Secretariat on a quarterly basis depending upon the number and timing of research proposals received by the Secretariat in any particular month for review.

The secretariat will organize Committee meetings in such a way so as to respond to the research team within 3 weeks for low risk and 2 months for high risks of receiving

the proposal by the Secretariat.

The Secretariat shall provide the Committee members with at least one week's notice of all meetings, together with a copy of the proposed agenda and required meeting materials.

6.2 Attendance

Committee meetings may only be attended by members, the Secretariat and ad hoc members permitted by the Chair to attend for a particular meeting or a portion thereof. Committee members are responsible for attending all meetings. If member(s) are unable to do so, they should notify the Secretariat four days ahead of the meeting date. If the secretariat receives a number of apologies from members and anticipate that there will be no quorum, then the Secretariat must arrange for alternate dates to hold the meeting. The responsibility of attending and participating in Committee meetings shall be borne equitably by all members. The Secretariat shall keep records of the service of each member and distribute assignments accordingly.

6.2.1 Attendance of Principal Investigator in Committee Meetings

At the invitation of the Chairperson, the principal or co-investigators responsible for a submitted proposal may attend meetings at which the proposal will be reviewed for the purposes of offering additional information and clarifications requested by the Committee.

6.2.2 Attendance of External experts in Committee Meetings

The Chairperson may invite external experts to provide advice on special issues when the Chairperson considers that their expertise is needed for the review of a research proposal or for other matters before the Committee. When consulted on a research proposal, experts may attend those portions of the meeting at which the proposal is being reviewed and participate in the discussion.

6.2.3 Attendance of Observers in Committee Meetings

In the interest of transparency and improving the wider understanding of the work of the Committee, the Chairperson may also, discretely invite a limited number of individuals as observers during Committee meetings. Observers may attend the entire meeting to which they have been invited, but may not take part in discussions unless explicitly invited by the Chairperson to do so. The Chairperson at his or her discretion may decide to request the invited observers to leave the meeting room during specific portions of the discussions.

6.3 Confidentiality

Research project proposal documents and the Committee meeting proceedings are confidential and all Committee members are to uphold the principle of confidentiality. All experts and observers invited to any Committee meeting must commit to maintain confidentiality regarding the Committee's work for each meeting that they are invited to attend. In order to ensure that the Committee is able to engage in a robust review

of research proposals, the minutes of its meetings and all other Committee records shall be kept in such a manner that the points discussed are recorded without ascribing the views or conclusions to particular members of the Committee. In all communications from the Committee and Secretariat, reasonable steps will be taken not to reveal confidential or proprietary information concerning any research proposal or investigator. Such measures, however, shall not interfere with the ability of the Committee to fully perform its function.

All members of the Committee are to sign a Confidentiality Agreement form (attached as Appendix 2).

6.4 Quorum

Five members, including the Chairperson, must be present to constitute a quorum. A meeting can only commence once a quorum is obtained. If at any time during the meeting the quorum is lost, the meeting must be concluded. Members of the Secretariat and other experts or observers do not count towards the quorum.

6.5 Meeting Records

Minutes shall be recorded by the Secretariat following the template provided for all meetings and shall be submitted to the Chairperson, and subsequently to the Committee for approval.

7. Conflict of Interest

Definition of Conflict of Interest
The Australian National Statement on Ethical Conduct in Human Research (2015) defines conflict of interest in the context of research as;

(i) Person's individual interests or responsibilities that have the potential to influence the carrying out of his or her institutional role or professional obligation in research; or

(ii) An institution's interests or responsibilities have the potential to influence the carrying out of its research obligations.

Conflict of interest can relate to financial interest, private or institutional benefits or advantages that depend significantly on the research outcome.

A conflict of interest may compromise the research processes itself, and/or the institutional processes governing research, and may lead researchers or institutions to base decisions about the research on factors outside the research requirements.

A perception that a conflict of interest exists can be as serious as an actual conflict, raising concerns about an individual's integrity or an institution's management practices[3].

The guidance on avoidance of conflicts of interest is discussed in details in the WHO

[3] *The Australian National Statement on Ethical Conduct in Human Research, 2015*

WPRO-ERC Standard Operating Procedures pp. 29-31.

"*The avoidance of conflicts of interest or the appearance thereof is important to ensure both the quality and credibility of research review. The Committee will therefore take necessary steps to avoid conflicts of interest and the appearance of conflicts of interest for investigators, the Committee members and the Secretariat. 1. It is important that all people participating in the submission and review of proposals involving human research avoid situations that could affect their ability to provide objective guidance for, or review of, research proposals regarding particular drugs, devices, vaccines, or other interventions. 2. The Committee shall ensure that its resolution of any situation involving a potential conflict of interest avoids not only the occurrence of unacceptable interests but also the appearance of such conflicts of interest. 3. In all cases in which a conflict of interest is revealed, but is not so material as to warrant not approving the project, the Committee shall determine the type of description of such interest that needs to be included in the information provided to prospective participants in the research and shall ensure that the consent documentation also includes an appropriate disclosure*."[4]

7.1 Investigator's Conflict of Interest

The Principal Investigator who will conduct the research should not have any material conflict of interest or any other interests that may damage the scientific objectivity of the research.

All Principal Investigators involved in the proposed research proposal have to clearly mention at the time of submission that they do not have any conflict of interest with the proposed research.

The Committee shall approve a research proposal only if it concludes that the Principal Investigator does not have any material conflict of interest or that such interests are not sufficient to damage the scientific objectivity of the research.

7.2 Committee members' Financial Conflict

In the event a committee member has a vested interest in an entity having a commercial interest or common area of activity involving a research proposal submitted to the Committee, the committee member shall inform the Secretariat and sign a COI form. 2. Non-MHMS members shall agree to be bound by the same obligation of disclosure to the Secretariat with respect to interests in an entity having a commercial interest or common area of activity involving a project submitted to the Committee.

7.3 Committee members: Role Conflicts

A Committee member who is also connected to the proposal under review or is connected closely to a proposal (such as being on the same team as the researcher submitting the proposal or being in a supervisory position with the submitting

[4] World Health Organization. (2011). The Ethics Review Committee (WPRO-ERC) standard operating procedures.

researcher) would have a conflict of interest if one is to participate in the ethics review of the proposal.

7.4 Resolution of Conflict

When asked to perform an expedited review or to be a primary reviewer, a Committee member that has a financial or role conflict shall disclose such a conflict and decline to undertake the review.

Committee members having reported a financial or role conflict may, unless the Chairperson determines otherwise, comment on the matter before the Committee but may not participate in the Committee's decision on the matter, and the Chairperson (subject to being overruled by the Committee) may impose additional restrictions (such as requesting the member to leave the meeting while the matter is discussed) as he or she believes are warranted under the circumstances. The conflict of interest shall be announced during the meeting and the minutes of the meeting shall record the declared conflict of interest and the steps taken to deal with the situation with regard to the Committee's deliberations and decisions.

Similarly, the Chairperson will hand over his or her responsibility to the Vice-Chairperson whenever he or she has a role conflict and the minutes of the meeting shall record the declared conflict of interest and the steps taken to deal with the situation with regard to the Committee's deliberations and decisions.

8. Application for ethical review

The detailed operational process of ethics review is illustrated in the diagram labeled "Figure 1: FHHREC Current Ethical Review Process".

All proposals must be submitted by either proposed principal investigator or one of the co- investigators of the research project. The person submitting the research will become the contact person for the Committee regarding the proposal.

8.1 Submission via Research Portal

All the research (whether to be reviewed by FHHREC is required to be submitted via Fiji Health Research Portal (http://www.health.gov.fj/fijihrp). Follow the step by step instructions below for the online submission.

Step 1: Acknowledgement by the researchers on having read the guidelines for conducting health research in Fiji, and agreement to provide the final research report within 12 months of planned end-date, and research data (if considered of long-term and wider-value) within 24 months of planned end-date.

Step 2*:* Enter proposal Metadata: The researchers is required to enter the names and designation of principal investigator and up to two co-investigators. Other information to upload into the portal;

a) An abstract (less than 250 words). To comprise of a succinct summary of the background, research question, the population and interventions involved, anticipated outcomes, methods, potential risk for human research participants.
b) Names of participating institutions.
c) Potential benefits of the research for public health.
d) Budget and source(s) of funding.
e) Sponsors; primary and secondary.
f) Research design.
g) Research setting in Fiji.

Step 3*:* Uploading the research proposal document. The research proposal should include

a) Background, Problem Statement and Rationale.
b) Literature Review and gap statement.
c) Research Questions or objectives of the study.
d) Methodology (including sampling methodology and sample size), clinical/lab procedures and data analysis plan.
e) Limitation, if any
f) Ethical consideration in the study with a careful assessment of predictable risks and burdens to individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by condition under investigation. It should clearly state what measures has been taken in the research design to maximize the benefits and minimize the harms. It should also describe potential risk to individual by disclosure of information collected in the study and what measures have been taken to protect the privacy and confidentiality of the population.
g) Plans for dissemination of research results to the relevant stakeholders.
h) Estimated budget and study timelines.
i) In-text referencing and a list of references are required.

Step 4: Upload supplementary files such as questionnaires, informed consent, and information statement, curriculum vitae of principal investigator and co-investigator, approvals from other Ethics Review Committee - as described in section C below.

Step 5: This step will show all the information provided by the researcher in step 2 and all the files uploaded in step 3 and 4 for the researcher to confirm accuracy. The researcher will be required to review all the information submitted and confirm that the information submitted is correct to the best of his/her knowledge. A unique identifier (ID) will automatically be assigned to the proposal on electronic submission and an automated confirmation for successful submission along with the unique ID will be sent to the researcher submitting the proposal. Once the required documentation (as described in subsection C below) is verified by the Secretariat, the proposal submission will be recorded as 'complete' and then record whether the proposal is subject to 'expedited review' or 'full review' in the electronic processing system.

8.2 Documentation Required for Submission

Each research proposal should be accompanied by the following supplementary documentation to be considered for review by FHHREC.

a) Two pages Curriculum vitae of the principal investigator and the co- investigator.
b) Voluntary Informed consent documentation.
c) Participant Information Statement.
d) Data collection tools such as the questionnaires and/or other tools.
e) Memorandum of Agreement (MOA), if the study is a national study or MOA with relevant authority who are major stakeholders of the research project.
f) Other relevant documents.

9. Ethics Review of Research Proposals

9.1 Reviewers

FHHREC members' roles are to review research proposals submitted to FHHREC. The Chair of FHHREC can recommend non-committee members and experts within the MHMS or external as external expert reviewers or ad hoc reviewers to conduct reviews.

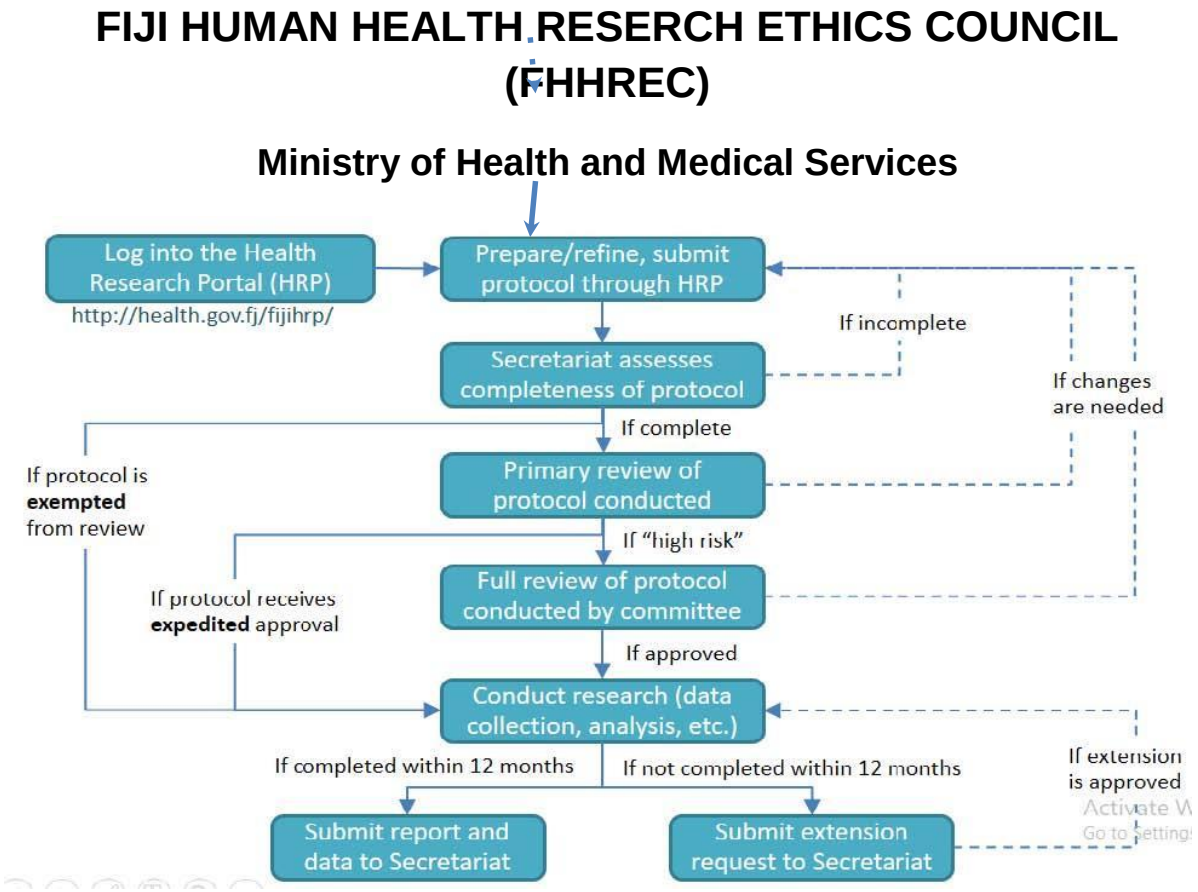
9.2 Ad Hoc Reviewers

The Secretariat shall maintain a roster of ad hoc reviewers with expertise on specific health issues and their expertise shall be called upon by the Committee depending on the need and the topic of the research proposal in review. When called upon by the Committee, ad hoc reviewers are expected to participate in the review process and make recommendations but not to vote on research proposals. Their attendance will be recorded but will not contribute towards the quorum of the meeting.

9.3 The review process

The ethics review process of all proposals at FHHREC is illustrated in Figure 1.

Figure 1: FHHREC Current Ethical Review Process:



Research proposals submitted to FHHREC via the Research Portal will be assessed by the Secretariat for completeness (Please see section 13 and the Checklist (Appendix 6).

The Committees does **not** conduct retrospective review of research that has begun data collection or have completed.

Any pending reports from the previous research submitted by the same researcher or co-investigators will be examined in the electronic system, and the review process for the research proposal will not start until the Principal Investigator (PI) or co- investigators has submitted all pending reports for any earlier research approved by the Committee.

If submission is incomplete, the Secretariat will communicate with researchers to inform of the incomplete submissions and the documents required. If the Secretariat's assessment finds that the submission is complete then the proposal is sent to reviewer(s) for a Primary Review to determine if the research proposal is of Low Risk or High Risk. When the proposal is classified "low risk" then it will be send to reviewers for a low risk review. The low risk review process takes a turn-around time of 3 weeks.

If the research proposal is of High Risk it will require a full review by the committee. Full

reviews' turn-around time is up to 2 months or more.

Low risk and High Risk research proposal description is attached as Appendix 3

9.4 Review training

The following international human research ethics guidelines are recommended to reviewers to study and be familiar with in order to conduct an ethical review of human research proposals.

It is further recommended that all FHHREC members and reviewers complete online research bioethics training available online from the Office of International Research Ethics FHI360, available at: https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/.

The ethical evaluation of research proposals shall be guided by the best practice indicated by internationally accepted guidelines for the conduct of research involving humans.

Here is a list of some of these guidelines;

World Medical Association, Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects, Amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013. Available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) CIOMS Geneva 2002; Available at: https://cioms.ch/wp-content/uploads/2016/08/ International_ Ethical_Guidelines_for_ Biomedical_Research_Involving_Human_Subjects.pdf
3.

International Ethical Guidelines for Epidemiological Studies, 2009; Available at: https://cioms.ch/shop/product/international-ethical-guidelines-for-epidemiological-studies/

International Ethical Guidelines for Health-related Research Involving Humans, 2016, Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO); Available at: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

9.5 Reviewers assessment

The reviewers will assess the proposals to ensure that the following points (as per the international best practice and guidelines) are considered;

a) **Research design** is scientifically sound and justifies the involvement of human beings as research participants.
b) That the research protocol expresses the **respect** for participants' human rights and human dignity as individuals and collectively as members of a community or group(s).

c) **Risk** to human participants. If there is risk, that there is plan to managed and

minimized risk as appropriate. A sound research design is implemented without exposing participants to risks.

d) The **benefits** of the research. That the benefits should outweigh the risks and safeguards are included to protect human rights, fundamental freedoms and the welfare of participants, with particular care being given to mitigate risks for vulnerable participants, while recognizing that vulnerable participants may still benefit from research inclusion.

e) The research is **relevant** and will contribute to generalizable knowledge, where a research is defined as "*A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge." The National Academy of Sciences states that the object of research is to "extend human knowledge of the physical, biological, or social world beyond what is already known."* (US Department of Health and Human Services, Office of Research Integrity, What is Research? Available at: https://ori.hhs.gov/module-1-introduction-what-research)

f) **Beneficence**: "*The term* beneficence *connotes acts or personal qualities of mercy, kindness, generosity, and charity. It is suggestive of altruism, love, humanity, and promoting the good of others. "Beneficence" include effectively all norms, dispositions, and actions with the goal of benefiting or promoting the good of other persons*." (Stanford Encyclopedia of Philosophy; Available at: https://plato.stanford.edu/entries/principle-beneficence/

Non-Maleficence: Reviewers are to assess the proposal for risks or harm to research participants. Human participants in research shall not be harmed, physically, psychologically, financially or socially. Research proposals are to be analyzed to see that research protocols will not pose risk or harm to participants. Participants should be protected throughout the duration of their participation in the research.

g) The principle of **justice** to be applied to the selection of participants. Where the selection process is approached with fairness and equality and in accordance with the legal requirements. This process is justified an ethical process.

h) **Voluntariness**: Recruitment practices do not involve coercion. Participation in research is voluntary.

i) **Voluntary Informed Consent** process and forms are presented in a comprehensible and suitable manner for the population where the research is being conducted. Informed consent sought and documented prospectively for each participant. In terms of persons with diminished competency to make an informed decision to participate or not in a research, the international guideline or regulations will apply, for example a surrogate decision maker or proxy or a person who holds the power of attorney, whoever has most appropriate authority may be considered to be included in the voluntary

informed consent process.

j) **Data management procedures** are in place to provide for the reasonable safe, confidentiality and privacy of persons' or people's data collected in the research.

9.6 Ethics Review Exemption

Research projects may be eligible for exemption from an Ethics review, but cannot be exempted from being ethical. For example, content analysis of public documents can be exempted from ethics review but still need to be ethical in their methodology, content and representation of information. Researchers will continue to conduct research and non-research activities responsibly and exercise respect for persons, observe confidentiality and privacy issues, maximize benefits, minimize risks and uphold the principles of justice at all times.

Researchers may apply for an exemption from ethics review. Researchers are requested to apply for an exemption of ethics review and the committee will examine the proposal and give exemption from review where appropriate. The Committee will consider the application for exemption. If the Committee agrees that a proposal does not require review as per set criteria, the proposal will be classified as "*Exempted from ethical review by the Committee*" and the researcher is informed. The researcher is informed on the grounds of exemption and reminded that, any changes are made in the design or execution of the activity, the secretariat must be informed.

In consultation with the Chairperson, the Secretariat will submit the list of all the proposals that were considered for exemption from review and "expedited review" to the next meeting of the Committee. Any member of the Committee may request a re-assessment of the proposal(s) with the classification of "exemption" or "expedited review". The Secretariat shall notify the PI, on the same day following the Committee meeting, **not** to proceed with the research project until the Committee has reviewed the matter and makes a decision. Only then the PI will be informed of the outcome of the re-assessment. If the Committee decides to override the determination made by the Chairperson and the Secretariat, it shall then determine the type of review the proposal shall undergo.

The following types of data collection methods and activities may be eligible for exemption from ethics review.

- Research does not involve human participants
- Administrative data collection and analysis
- Data (including healthcare records and specimens) that publicly available and are unidentifiable.
- Clinical case reports
- Descriptive case studies
- Histories: Interviews, personal viewpoints, institutional histories

- Public officials who are interviewed in their official capacity on issues that is in the public domain;
- Secondary analysis of non-sensitive, non-identifiable data from institutional data repositories/ databases
- Quality assurance, Quality Improvement, Program Evaluation activities or clinical audits Quality assurance activities that are for internal use and will not be published?
- Research practicum and classroom or clinical Learning and Teaching activities
- Research using publicly archived materials
- Research is limited to public health surveillance, disease outbreak investigations, or routine evaluation of health programs based on routinely collected data from health facilities requiring no additional procedures than ordinarily encountered during routine clinical care
- Research proposals which do not involve human participants or data pertaining to them. For example, Research on microbes cultured in the laboratory, analysis of data freely available in public domain. Source: http://www.deakin.edu.au/research/researcher-support/integrity-secure/human-ethics/dheg/g2 - 2-3-2

9. 7 Criteria for expedited review:

Expedited review may be considered when:

When a study protocol is fully approved by an educational institution with high reputation. This case may be considered for an expedited review e.g. a study proposal approved by a renowned university.

a) A study that adopts a WHO toolkit or study protocol can be considered for an expedited review with specific focus of review on assessment of the research protocol for cultural/religious and contextual appropriateness to Fiji context.

b) The research proposal follows an internationally accepted research protocol that has been used extensively previously both in the Republic of Fiji and or outside (researcher has to prove that at the time of submission) and the current research proposal does not depart significantly from that accepted and widely used research protocol. Has to specific its low risk only.

c) A research proposal using similar methodology has been reviewed and approved by the Committee in the past.

d) Based on initial screening during the Primary review, the risk involved to research participants is considered low: the proposal does not include studying a health condition which is stigmatizing and may lead to discrimination, not a drug trial or clinical trial on human participants.

e) Uses unidentifiable data collected previously in other research studies that carry no direct risk to the participants.

9.8 Review of Low Risk Research Proposal

The review of low risk proposals will not require an in-person meeting of FHHREC with full quorum. The secretariat will assign two reviewers either from the existing FHHREC members or outside ad hoc experts with relevant expertise in the area covered by the research proposal. The reviewers should be able to review the proposal within 3 weeks of

receiving it and report back the outcome to the Secretariat. The reviewers will assess the proposal according to the review standards developed by FHHREC.

FHHREC shall be able to report back the outcome of the proposals considered for low risk review within 3 weeks of proposal submission, except in the case of a 'reject', the proposal will be tabled in the next Committee meeting and a decision may be made and to communicate to the PI in 21 days.

9.9 Full Review of High Risk Research Proposal

All high risk research proposals will be submitted to the Committee for a full review. The full review may take more than one process to conduct a full review, as follows;

(i) Committee face to face meeting.

(ii) In the absence of scientific expertise to review the proposal the Secretariat will seek expert reviewers externally.

(iii) Assign two members of the Committee scheduled to be present at the meeting as "primary reviewers". The primary reviewers must submit a written feedback to the secretariat on the technical and ethical issues or summarize the proposal at the Committee meeting. The committee will take into account the reviewers feedback while reviewing and deciding on the proposal.

(iv) Notwithstanding the informational role of the primary reviewers, all members participate at the Committee meeting shall be familiar with each proposal and shall participate in the discussion and in the decision to be taken with respect to each proposal. The Secretariat shall send each of the Committee members a copy of the proposals that will be tabled in the Committee meeting, 4 days ahead of the meeting for them to read and prepare to discuss it in the upcoming meeting.

(v) Using an (electronic system) to collect comments from the committee members may be used as monitoring tool for the chair. The chair of the committee is to ensure that all committee members understand about the ethical issue of a study proposal submitted.

(vi) Approval of proposals shall be made by consensus. When consensus cannot be reached, the Chairperson can exercise discretion on the following two options:

a) May decide that additional information or expert advice is required. If that is the case, consideration on the proposal shall be postponed until the next meeting in order to seek additional information or expert advice.

b) If consensus cannot be reached at the second meeting, then a vote on the Committee decision shall be taken. Committee action shall require a two-thirds majority.

c) If the committee wishes to questions about the technical components of a study proposal submitted, the Chair may invite the principal investigator to attend the Committee meeting to explain the study being reviewed in lay

terms.

d) Processes involved to be communicated to investigator.

9.10 Possible review outcomes

The secretariat and chairperson will consider the reviewers' recommendations and based on that will provide one of the following decisions

- Approved: The research proposal is approved as submitted. This does not preclude the Committee from sending recommendations for the consideration of the research team.
- Endorsed pending minor changes – based on reviewers' comments and requires the PI to revise the proposal and submit a revised version.
- Conditional approval**:** The research proposal has not yet been approved; it requires the PI to address reviewers' comments and/or the completion of one or more requirements before approval can be granted. When the requirements are met, a letter of approval will be issued. The Committee will determine who will review the response submitted (i.e. Secretariat, Chairperson, special reviewers or the Committee) and will be so recorded in the decision and meeting minutes. Notwithstanding the manner of a final review of a proposal that has been conditionally approved, the Secretariat shall confirm a final approval in writing and have the approval signed off by the Chairperson.
- Not approved and need revision and resubmit. The research proposal is not approved as submitted either because there is insufficient information to make a decision or the proposal is **unethical**. However, the proposal can be revised by the research team and re-submit for further consideration by the committee.
- Reject: If the proposal is considered for rejection, the Secretary in consultation with the Chair may consider the proposal for submission to full committee before communicating to the researcher.

9.11 Communicating the outcome of the review to the researcher

The outcome of a review shall be communicated by the Secretariat to the PI in writing with an explanation of the reasons for the decision. Each communication must include:

- Committee's research proposal ID and date the proposal was received;
- names of the principal and co- investigator(s)
- title of the research proposal;
- date (s) of review and decision and the name of reviewing body (i.e. expedited review or full Committee)
- the decision; and
- Any non-binding suggestions or recommendations for the consideration of research team.

10. Monitoring of Approved Research Proposals

All researchers are required to submit an annual progress report to the Committee. When the research project is completed, then a final report of the research must be submitted to Committee. All researchers are required to submit the final report of the research within

one year of the planned completion date as stated in the timeline of the approved research proposal.

An automatic reminder will be sent to the researcher from the national health research Portal to submit the progress/final report through the online system to the secretariat six months after the planned completion date of the research.

With permission of the PI and research team, the final report will be made externally accessible through the health research portal, unless the researcher requests special exemption on grounds of any forthcoming publications, etc.

All the resulting publications should also be submitted to the Secretariat.

10.1 Substantive Changes to protocol

If any **substantive changes** have been made in the protocol or consent documents, the research team should inform the Committee and depending upon the extent of changes made, exemption, expedited or full review of the research proposal may be carried out.

Should the monitoring process lead to a withdrawal of the continuation of a previously approved study, this determination shall be communicated immediately to the PI and the research team. The PI promptly shall report back to the Committee concerning the date the enrolment of new participants was halted and the manner in which the research project is dealing with the previously enrolled participants.

11. Reporting of Adverse Events

11.1 The Responsible Researcher for each approved research shall promptly report to the Committee any developments in the project that might have ethical implications.

11.1.1 When the Secretariat receives a report of changes that are proposed to be made in the protocol or consent documentation of a research project that the Committee has previously approved, a determination shall be made by the Chairperson and the Secretariat whether the proposed changes should be subject to review by the Committee in accordance with these rules. Pending the Committee's decision, which it shall endeavor to produce in a timely manner, the changes proposed for the research project shall not be instituted, with the exception of any modifications urgently needed to protect the well-being or important interests of participants already enrolled in the study.

11.1.2 Any deaths as well as any serious adverse events or unexpected events that occur to participants during their participation in any approved research project shall be reported immediately by the Responsible Researcher to the Secretariat and Chair, including the feedback from other review bodies, if any.

11.1.3 The Secretariat shall review all such reports and determine whether the information reported warrants another review of the research project, with particular attention to the benefit-risk ratio, the adequacy of the steps taken to

minimize risk and the information provided to prospective participants. Such determinations will be reported to the Committee at its next meeting.

11.1.4 If the Secretariat determines that another review should occur, it shall take place as soon as possible (including through an extraordinary Committee meeting, if necessary under the circumstances). The results of the second review will be promptly conveyed to the Responsible Researcher. It shall remain the obligation of the Responsible researcher, rather than of the Committee, to ensure that adverse event reports, and the determinations reached by the Committee in a second review, are filed with all appropriate people and agencies.

12. Procedures on completion of a research project

12.1 The responsible researcher is requested to submit a final report upon completion of the research project. The final report also should include information about how the results have been used and disseminated to relevant stakeholders. The researcher will also clearly specify whether the submitted final report can be made available in public domain, and if not why.

12.2 The Responsible researcher will also submit a copy of any reports that were published in the public domain or any publications in any peer reviewed journals, which will be linked with the FHHREC ID in the electronic national health research registry.

12.3 The responsible researcher will also be required to submit a copy of the raw data used in final analysis of the report, if the study involves collection of data that may have wider and long-term value beyond its original purpose. The data will be submitted within 24 months of the planned completion date of the study (refer *to the data sharing policy for health research in Fiji).*

13. Evaluation and Improvement of the Committee

13.1 Quality Improvement

All members of the Committee and the Secretariat are mandated with the continuous analysis of the operations of the Committee in order to identify problems and to offer suggestions for improving the quality of the Committee's work.

Such suggestions should typically be presented to the Secretary, who will review the suggestions and consult with the Chairperson. If such suggestions may improve the functions of the Committee, the Secretariat shall either place the suggestion on the agenda of the next meeting for discussion or, if it merely amounts to an administrative adjustment, institute it and provide appropriate notification of the change to all affected parties.

Suggestions requiring formal changes in these SOP shall be considered under Section 14.2 below. The secretariat will prepare an annual report summarizing the work of the Committee each year.

14. Adoption, Amendment and review of the SOP

14.1 Adoption of SOP

The SOP will be approved by the Permanent Secretary of Health Medical Services for adoption by the Committee. This will be available publically on the MHMS website under the "Health Research" web page, human health research portal and national health research registry website. This SOP will supersede any other publications/guidelines in this regard, including the provisions mentioned in heath research guide (2007) and in National Health Information Policy (2011).

14.2 Amending SOP

Any member of the committee and secretariat can propose an amendment to this SOP. The proposed amendment shall be submitted in writing to the secretariat to be placed on the agenda of the next available committee meeting for consideration and possible adoption by a majority of the committee members present and voting. The amendment shall come into effect once approved by the Permanent Secretary of Health Medical Services. The approved amendment shall be regarded as an Addendum which shall be numbered and year amendment approved included and amended section clearly noted.

Glossary

Adverse events*:* Undesirable and unintended consequences of, or reactions to, procedures experienced by the research participant and subject.
Annual Report: An annual synoptic document that outlines and analyzes activities, especially summarizing the research proposals reviewed over the last year**.**

Beneficence: Ethical obligation to maximize benefits and to minimize harms (Website: http://www.cioms.ch/ , CIOMS)
Clinical trial: Any research study that prospectively assigns human participants or group of humans to one or more health-related interventions to evaluate the effect on pre-defined health outcomes**.**
Conditionally approved: The research proposal has not yet been approved; it requires the completion of one or more requirements before approval can be granted**.**
Conflict of Interest: A conflict between a person's private interests and public obligations.
The Council of International Organizations of Medical Sciences (CIOMS): An international, non-governmental, not-for-profit organization established jointly by WHO and UNESCO in 1949. CIOMS serves the scientific interests of the international biomedical community in general and has been active in promulgating guidelines for ethical conduct of research, among other activities. CIOMS promulgated guidelines entitled "International Ethical Guidelines for Biomedical Research Involving Human Subjects" for the first time in 1982, revised in 1993 and 2002, and are designed to be of use, particularly in low-resource countries, in defining national policies on the ethics of biomedical research, applying ethical standards in local circumstances, and establishing or redefining adequate mechanisms for ethical review of research involving human subjects. The latest version published in 2002 supersedes that of 1993 and consists of a statement of general ethical principles, a preamble and 21 guidelines which address issues including informed consent, standards for external review, recruitment of participants, and more. Website: http://www.cioms.ch/
Declaration of Helsinki: Adopted in 1964 by the 18th World Medical Assembly (WMA) at Helsinki, Finland, as a set of ethical principles for medical research involving human subjects, including research on identifiable human material and data. The original guidelines have been revised six times since then, with the latest revision in 2008 by the 59th WMA General Assembly for Physicians conducting biomedical research. The declaration outlines clinical trial procedures required to ensure patient safety, consent and ethical committee review in human subjects. The declaration of Helsinki can be found at http://www.wma.net/en/30publications/10policies/b3/17c.pdf (last accessed on October 12, 2010).
Individually identifiable information: Data records or biological materials that contain or are linked to a personal identifier (such as a person's name or a patient number) either directly or through a code, even when the key to the code is held by someone other than the investigator, Records or materials are considered ***unidentifiable*** when they lack any personal identifiers (such as samples taken from repositories that do not possess information on the individuals from whom the samples originated, or records that have been anonymized by the removal of any information, including any code, that could link them to any particular person).
International Clinical Trial Register Platform: A platform set up by WHO (meta-register) that collates information from selected registers of research studies (clinical trials or intervention trials) that prospectively assign human participants or a group of human, participants to one or more health-related interventions to evaluate the effects on health outcomes. Website: http://www.who.int/ictrp/en/ (last accessed on October 12, 2010)
Legally authorized representative*:* An individual or a judicial or other body with the authority under applicable law to give permission for participation in research to a person who lacks the capacity to decide whether to consent for him or herself.
Multi-centre study: Research conducted at multiple sites using a common research protocol.
Principal Investigator (PI): The lead scientist for a particularly well-defined social science, biomedical, behavioral or epidemiological research project; responsible and accountable for the appropriate conduct of the research.
Quorum: A fixed minimum percentage or number of members of committee who must be present before the members can conduct valid business.
Regional Director: An elected chief executive of the WHO Regional Office for the Western Pacific who controls and governs the affairs of that office.
Research*:* Any social science, biomedical, behavioral, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new *generalizable* knowledge.
Research *involving human participants* (sometimes termed "human subjects") when human beings:
(1) are exposed to intervention, manipulation, observation, or other interaction with
investigators, either directly or through alteration of their environment; or (2) become individually identifiable through investigators' collection, preparation or use
of medical or other records or of biological material from human beings.
Research Team: The group of qualified personnel that implements a research proposal; it typically includes a principal investigator, additional investigators, a research coordinator and research assistants.
Research Proposal*:* A document written for the purpose of obtaining funding for a research project. In addition to including the research protocol, it also includes information on the investigators (e.g. their CVs and institutional affiliation), approvals from various relevant organizations and persons, budgets, dissemination plans, etc.
Research Protocol*:* A document describing in detail how a research study is to be conducted in practice, including the study design and methodology, data analysis plan, and a budget. A research protocol is part of a research proposal.
Responsible Regional Office Staff Member: A staff member of the Regional Office responsible for representing its involvement in the research (e.g. contracting with investigators to implement such a project, or who have provided direct technical or logistical support to such investigators) and liaising with external parties on matters involving a specific research proposal.

Private information: Individually identifiable data that have been provided by a person, or obtained through observation of or interaction with a person, under circumstances in which the person could reasonably have believed either that the data (such as contained in medical records) would not be made public or shared with others, or that the data were not being recorded.

Generalizability: A research finding may be entirely valid in one setting but not in another. Generalizability describes the extent to which research findings can be applied to settings other than that in which they were originally tested. For example, the result of a study which focused only in the greater Suva or Central Division cannot be applied to the other parts of Fiji, such as the Western and /or Northern Division.
United Nations Convention on the Elimination of All Forms of Discrimination against Women: See http://www.un.org/womenwatch/daw/cedaw/ as accessed on October 21, 2010.
United Nations Convention on the Rights of the Child: See http://www2.ohchr.org/english/law/crc.htm as accessed on October 21, 2010.
MHMS funded Research: Research conducted by the investigator(s) under a contract with MHMS, which provides, or serves as a conduit for, direct financial support for research project.
MHMS-supported Research: Research activities in which MHMS staff organize and coordinate the research, participate significantly in the design of the research, or provide significant review of, or technical advice on, the research project as a whole, **but not when:**
(1) MHMS staff have provided technical advice only on portions of a research project; (2) the investigators working on the project and seeking advice are neither employed under a contract with MHMS to formulate the research proposal or carry out the research; and (3) the MHMS staff have notified those investigators in writing that the project has not been formally reviewed by MHMS and the technical advice provided by MHMS staff do not constitute endorsement of, or support for, the research project by MHMS and should not be construed or portrayed as such.
Fiji Human Health Research Ethics Committee (FHHREC): A 15 -member Committee established and appointed by the PSHMS/DIRECTOR HEALTH RESEARCH AND INNOVATION UNIT to ensure the highest ethical standards in research supported by MHMS. It is mandated to review all research projects that involve human participants, and are supported either financially or technically, by MHMS.
Website: Fiji Health Research Portal: http:// *(www.health.gov.fj/fijihrp) Fiji National Data Repository: http:// (www.health.gov.fj/fijindr)*

Appendix 1

Guidelines for Accreditation of Ethics Committees in Fiji

Accreditation of Human Research Ethics Committees

The FHHREC provides this guideline[5] for HRECs and their governing bodies to guide the application for accreditation. This section will present the process of accreditation of Ethics Committees in Fiji by the FHHREC.

Rationale for HREC accreditation

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

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

Roles to be performed by FHHREC as the national accreditation body

The FHHREC will

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

Accreditation quality standards

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

[5] Acknowledging the Health Research Council of New Zealand, 2012, HRC Guidelines for Approval of Ethics Committees as sources of information that assisted the development of the accreditation guideline of FNRERC.

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

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

Criteria for eligibility to apply for HREC accreditation

To award an accreditation certificate to a HREC the FHHREC needs to be assured that the HREC has the capacity to offer protection to human participants in research.
HRECS operate under a governing institution registered in the Republic of Fiji.
HRECS must have a Standard Operating Procedure (SOP) that may be submitted together with the application for evaluation.

HRECS Membership

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

Fiji is a multi-ethnic society and therefore the composition of members in the HREC should include members familiar with implications of cultural and religious diversity.
The quorum for meetings will be 50% of membership, including the Chairperson or Vice Chairperson.

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

How to obtain HREC Accreditation

1. Applications for accreditation are sent to the FHHREC by the governing institution of its HREC. An application cover sheet is provided (Appendix A).
2. Attach the SOP of the HREC to the application for accreditation. The SOP should have a description of the following
    - HREC functions
    - Terms of Reference of the HREC
    - Review process
    - Process of submitting an application for ethics review, expedited review or exemption of an ethics review
    - Responsibilities of the ethics committee to the governing institution
    - Complains procedure
    - Ethical standards that the HREC has accepted for the conduct of research. The ethical standards section of the SOP will include sections on processes of voluntary informed consent, minimization and management of risks, protection of privacy and confidentiality of participants in research
    - Policy on cultural and religious sensitivity.

Duration of Accreditation and Dates for Annual Reporting

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

Reaccreditation Procedures

- Applications for re-accreditation should be made 3 months ahead of the anniversary of the accreditation term of 3 years. The following points need to be considered: Number of meetings
- Numbers of proposals received, reviewed, approved, and rejected and their low or high risk status.
- Changes to membership composition?
- Review process changes.
- Problems encountered in reviews.
- Any other items that HREC require guidance or assistant from FHHREC.
- Capacity building activities.
- Cultural and religious sensitivity
- Any complaints and how they were resolved.
- Other information that the HREC wishes to include in the report

Failure to renew accreditation

Failure to seek a renewal of the accreditation status of a HREC means that the HREC's accredited status lapse at the end of the accredited period.

For further Information, please contact the Secretariat of the FHHRERC, Research Unit, Ministry of Health and Medical Services
Telephone: (679) 3306177 ext. 340170 or email: fijihealthresearch@gmail.com

Fiji Human Research Ethics Committee

Application for the Accreditation of Human Research Ethics Committee

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

(Please tick (√) the appropriate description.)

1. Name of HREC…….....

2. Name of Governing Institution……...

3. Name of Chairperson of HREC …….

Name of Administration Officer

4.

5. Year of establishment of HREC……

6. Contact address

   Postal address…….……

   Telephone……..

   E-mail: …….....

   Webpage address: …….

7. Guiding Principles and Standards for HREC.
   …….. (Add more space if needed)

8. HREC Annual report. Please attach.

Ethics committee composition

9.1 Membership Profile

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

9.2 How often does your HREC meet? (

10. Does the governing Institution offer any support (staffing or financial) to the HREC?
    Yes [ ] No [ ]

11. If yes, please specify the nature of support the institution provides to the HREC
    ……..
    ……
    ……

12. If not already included in the SOP, attach document describing the HREC Review process.

13. Are there details of how the HREC protects the rights, safety and wellbeing of research participants in the SOP? Attach a document.

14. Attach the Standard Operating Procedure of the HREC.

15. Do you have a database of ethics applications reviewed, record keeping and archives of HREC activities? Briefly describe it.

16. Do you have a complains policy? Please attach.

Submitted by……

Signature……

Date: ……..

Appendix 2

Classification of Risk

Risk is the likelihood of harm or discomfort or inconvenience to research participants and researcher as a result of conducting the research. If the researcher anticipates any risks, a description of how the risk(s) will be managed or minimized must be included in the research proposal. CHREC will assess whether the researcher has thought of risks involved in the research and propose ways of managing the risks so that they are minimized. Researchers must also assess the benefits of the research and CHREC will assess whether benefits out-weigh the risks before approving the research project. The Ethics Review Checklist can assist researchers to assess their own proposals. (Ethics Review Checklist. Research Unit: College of Medicine Nursing & Health Sciences, 2016.)

Low Risk Research

Research is „low risk" where the only foreseeable risk is one of discomfort such as one of the following shall be subjected to expedited review. (National Statement on Ethical Conduct in Human Research and ethical review and research involving only low or negligible risk. Available from https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/ethics/human_research/NS_low_risk_flow_cha rt.pdf)

Research involving de-identified data, documents or specimens that have been collected except for genetic testing.

Questionnaire based survey that does not include collection of any sensitive information.
What is discomfort? Discomfort is not harm but can include inconvenience, physical discomfort of body and mind: for example, very minor side effects of medication, the discomforts related to measuring height and weight, measuring blood pressure, collecting **routine** blood samples or specimens and mild anxiety experienced by the person during an interview or focus group discussion.
What is sensitive information? Sensitive information refers to any information which when divulged may cause levels of harm such as at the individual, communal and other levels. Examples of harm include anger, bitterness, embarrassment, fear, humiliation and shame. Such information may also lead to discrimination, rejection, retaliation and stigmatization amongst others.

High Risk Research

The aim of categorizing a study as „High risk Research" is not to demotivate/discourage the researcher from conducting the study but to do the study in an ethical manner and, only after taking all the necessary precautions. ***Box 1*** below provides an example of how proposals are written when addressing high risk issues in a research proposal.
This section is divided into 3 sub-sections comprised of indicators of High Risk Research based on
(i) types of "person(s)" involved in research considered as High Risk

(ii) "issues" involved in research

(iii) "research methods" considered as High Risks

Researchers will be required to consider these issues in research and state in the research proposal the methods of managing the risks so that participants are not exposed to any risk(s) and are at the very minimal OR benefits are greater than risks in the research project proposed.

Research projects that involve the following activities may be considered "High Risk Research".

- Deferentially vulnerable groups (those in respectfully trusting relationships or biased power relationships) e.g., Doctor and patient, Teacher and Student, Hostel warden and Boarder
- Economically vulnerable populations (due to poverty)
- Institutionalized populations e.g. prisoners and persons dependent on support
- Medically vulnerable e.g., sick patients and the needy who are unfit to give an informed consent
- Physically or cognitively disabled persons
- Pregnant women and their foetus
- Socially vulnerable groups e.g., People who are involved in illegal activities, for example, gambling, drug trafficking, sex work, People Living with HIV (PLWH) and other stigmatized groups.
- Children 18 years and below. Concerns are about their capacity to comprehend the nature of the research project, whether they have conflicting agendas with parents and if they are coerced to participating without proper parental consent.
- Elderly persons (65 years and over) who are unable to make an informed decision because of illnesses.

Research projects that involve the following issues will be considered "High Risk Research".

- Anticipated harm (or risk of harm) to individuals
- Abortion
- Clinical and non-clinical trials
- Collection of information from identifiable sources without the consent of the identified person
- Drug abuse
- Ethnic identity
- Fertility
- Gender identity
- Grief, death or serious/traumatic loss
- Information that may be regarded as "culturally sensitive"
- Parenting styles
- Personal information that may be regarded as sensitive
- Psychological disorder, including anxiety, mood swings, depression
- Sexuality, sexual orientation
- Studies involving active disease states (Especially Communicable Diseases)
- Suicide
- Audio or Visual recording without permission
- Inflicting pain on participants or invasive physical procedures Psychological experiments
- Recruitment via a third party
- Secret observations
- Use of personal information from unknown sources
- Using medical information of identifiable persons or possibility of linking to the person
- Using medication or drugs or placebos
- Withholding from one group specific treatments or methods of learning, from which they may „benefit" (e.g. in medicine or teaching)

Addressing High Risk Research when Writing Research Proposals

An Example of a High Risk Research and ways of minimizing risks for participants in research

Research Project: Researching female survivors of childhood sexual assault. Pilot qualitative study to investigate early mothering with women who had experienced childhood sexual abuse. Second study to investigate how primary care could be improved with survivors of childhood sexual abuse.
Recruitment of Participants - Research information is placed in an advertisement for community notice boards or hospital outpatient notice boards or local newspaper, stating researcher's contact phone number or email. Participants contact the researcher to discuss any queries regarding the research before interview is confirmed. The researcher is not associated with the medical care, but may refer the participant for medical care if needed.
Research design to include benefits: Research as healing. Research as breaking the silence. Research as helping others. Research to Empower participants as much as possible. Allow participants time to consider the implications of participating in research. Remove any researcher coercion as much as possible. Offer an „opt out" opportunity for participant at multiple stages of the research – evidence of opt out in the questionnaire e.g. "I am now going to ask you about your sexual abuse experience, please feel free to not answer any q question if it is too difficult for you."
Ethical issues to be included:
Confidentiality and Privacy
Ensure safety of all participants. If needed, ensure safety of the researcher(s) Maximize benefits and reduce or eliminate risks for all concerned Ensure that the research is justified and that benefits are weighed for all stakeholders and participants Show evidence that the support of a psychiatrist will be provided if needed by the participant.

Appendix 3

SUMMARY SHEET AND CHECKLIST OF REQUIRED DOCUMENTS

1		Principal Investigator Prof/Dr/Mr/Ms. FAMILY NAME (SURNAME): FIRST NAME: OTHER NAMES:
	1.1	Title of post, position or appointment presently held by principal investigator
	1.2	Complete postal address: Email:
2		*Institution responsible for the research proposed* *Name and address (including website address, if any)*
3		*Title of health research proposed* (should be brief, precise and informative to workers outside your field)
	3.1	Objectives of research proposed (clearly and concisely list specific objectives of the proposed study)
	3.2	Duration of research from preparations for field work till analysis and compilation of final research results From (date): To (date): Total (years):
	3.3	Funds required (FJD$)

	3.4	Any conflict of interest by research institute/PI/funding source declared Yes☐ No☐
4	4.1	Informed consent documentation included in the proposal Yes☐ No ☐
	4.2	Questionnaires for collection of data included in the proposal Yes ☐ No☐
	4.3	If the study design involves a clinical trial, proof of Registration in a database linked to Search Portal of International Clinical Trial Register Platform of WHO is attached Yes☐ No ☐ Not a clinical trial ☐
5	5.1	<u>Institutional and national ethical clearance</u> Name and contact details of the local ERC/IRB/ERB in the country of research where the proposal has been reviewed/submitted: Name of local ERC/IRB: Contact details including email address:
	5.2	Institutional/national ethical clearance enclosed Proposal under review by institutional/national ERC☐ Yes ☐ No ☐ (proof of submission to local ERC enclosed)
6		<u>Approval of national Ministry of Health or national Medical Research Council (or equivalent body)</u> National approval document enclosed Yes ☐ No ☐
7		<u>Institutional endorsement (can be attached as a separate document also)</u> Head of Institution Title:_____ Name: _____ Date: _____ (print) Signature:
8		Curriculum Vitae of Principal Investigator attached Yes☐ No ☐
9		Applicant's signature Date: Signature:

Appendix 4

Research Proposal Template

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

Appendix 5

Format for presenting Budget

	ITEM		Amount (FJD $)
1	**PERSONNEL** (allowances to be paid)		
	1.1	Professional scientific staff (name and functional title)	
	1.2	Technical staff (name and functional title)	
	1.3	Other staff (name and functional title)	
	Subtotal		
2.	**MAJOR EQUIPMENT** (over FJD$ 1000) (include specifications, shipment and freight insurance costs; comment on local provision for maintenance and service		
	Subtotal		
3	**SUPPLIES**		
	3.1	Chemicals	
	3.2	Glassware	
	3.3	Minor equipment (less than FJD$ 1000 each)	
	3.4	Animals	
	3.5	Other supplies	
	3.6	Operating cost (specify maintenance of equipment, gasoline, etc)	
	Subtotal		
	TRAVEL (specify domestic and international)		
	Subtotal		
5.	**DATA ANALYSIS COST**		
	Subtotal		
6.	**COST OF DISSEMINATION OF RESULTS**		
	Subtotal		
7.	**MISCELLANEOUS EXPENDITURES**		
	Subtotal		
8.	SUMMARY		
	(1) Personnel		
	(2) Major equipment		
	(3) Supplies		
	(4) Travel		
	(5) Data analysis cost		
	(6) Cost of dissemination of results		
	(7) Miscellaneous expenses		
	TOTAL		

Appendix 6

Template for all FHHRERC minutes

(The order in which agenda items are reviewed is at the discretion of FNHRERC Chairperson)

Minutes of the FNHRERC Meeting Held on (date) at (venue)

Members Present: _____(Chairperson) _____

(indicate who is a non-scientist, non-MOHMS office affiliated, etc.)

_____ _____

_____ _____

_____ _____

_____ _____

Members Absent:

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Guests:

(include affiliation)

_____ _____

_____ _____

_____ _____

The meeting convened at --:-- (a.m./p.m.) with a quorum present.

(1) MINUTES OF THE MEETING HELD ON (DATE). (The minutes must be voted on and any changes documented.)

(2) ANNOUNCEMENTS

(3) INITIAL REVIEWS.

A. Principal Investigator:
Responsible MOH Technical Officer:
Protocol Title:

Protocol summary:

(a) Discussion:
General discussion:
Specific discussions: (include the following headings

- Scientific design (discuss and note that Institute pre-scientific review has been done)
- Risks/benefits (assign a level of risk here or at the time of the decision and vote, [(d) below] consistent with page 2, FNHRERC Protocol Review Standards form.
- Subject selection (discuss populations to be studied and recruitment plan)
- Additional safeguards for vulnerable subjects
- Minimization of risks to subjects
- Privacy and confidentiality.
- Consent document (document that all required elements are present)
- Status of approval from ERC of the country where research is proposed to be carried out
- Additional considerations (e.g. multi-centre research; collaborative research; nested study. State if these considerations do not apply)

(b) Stipulations (number the stipulations)

(c) Recommendations (number the recommendations)

(d) FNHRERC Decision and Vote: State whether the vote is unanimous; if not, state how many members voted for, against or abstained. Document in or attach to the minutes the reason(s) for the minority opinion(s).

If the protocol is approved with stipulations and/or recommendations, the minutes must state whether the Committee votes that the stipulations and/or recommendations are to be reviewed by the Chairperson, by the Secretariat, by a subcommittee of the FNHRERC, or by the full FNHRERC.

B., C., etc. (Follow same format as above for additional new protocols)

(4) CONTINUING REVIEWS OR a second review of proposals submitted earlier either due to proposed AMENDMENTS or otherwise.

A. Principal Investigator:
Title and type of expedited action:
Date approved by FNHRERC Chairperson or designee:
Description of expedited action: (Expedited actions must be listed separately in the minutes. The Chairperson should provide a brief explanation of any expedited actions. A vote is not required but the Committee has the prerogative to discuss, rescind or amend expedited actions.)

B., C. etc. (List additional expedited actions following the above format

(5) CONTINUING REVIEWS (it is useful for the primary or secondary reviewer or the Committee Secretariat to have the entire protocol file available for reference at the meeting)

A. Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:
Protocol Summary (if not provided in discussion at (a) below):
(a) Discussion:
(b) Stipulations (number the stipulations)
(c) Recommendations (number the recommendations)
(d) FNHRERC Decision and Vote (Include Committee reaffirmation of the level of risk or establishment of a new risk level consistent with the Protocol Review Standards form, page 2)

B., C. etc. (Follow the same format as above for additional continuing reviews)

(6) AMENDMENTS to a research proposal approved earlier

A. Principal Investigator:
Protocol Title:
Protocol Number:
Expiration Date:
Description of the amendment:
(a) Discussion:
(b) Stipulations (number the stipulations)
(c) Recommendations (number the recommendations)
(d) Committee Decision and Vote (include a statement indicating whether the protocol's level of risk is altered by the amendment)

B., C. etc. (Follow the same format as above for additional amendments)

(7) REPORT OF ADVERSE EVENT(S)
Principal Investigator:
Protocol Title:
Protocol Number:
Date of Adverse Event(s):
Description of the adverse event(s):
Document the Committee's acknowledgement of receipt of the adverse event report(s) and discussion. Discussion of serious adverse events occurring on an protocol should include immediate actions taken as a result of the event by the PI; recommendations for further actions, if any, by the Committee (e.g.

suspension of subject accrual, etc.), and any necessary recommendations for further reporting .

If the adverse events are reported from the divisions for the Committee's information only, and no action is required by the Committee, acknowledgement of the report(s) should be documented.

8. INFORMATION ITEMS
   (a)
   (b)
9. ADJOURNMENT The meeting adjourned at --:-- (a.m./p.m.).

Appendix 7

MINISTRY OF HEALTH AND MEDICAL SERVICES

Fiji Human Health Research Ethics Review Form

NOTE TO REVIEWERS

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

Fiji Human Health Research Ethics Review (FHHRER); Reference Number. _____

Research Title: _____

	COMMENTS
Title	
Relevance	Is the proposed research relevant to Fiji Context? Yes. No. Not Sure. Unclear. Comments to investigator(s)
Contribution to new generalizable knowledge	Will the research contribute to new generalizable knowledge to improve health of Fiji people? Yes. No. Not Sure. Unclear. Comments to investigator(s)
Introduction & Background	
Statement of the Problem	
Rationale of the study	
Benefits of Study	
Research Question, Aim, Hypothesis/ese	
Objectives	
Review of Literature	
Study Methods	
Study design	

Study Setting	
Study Population or Sample.	
Selection of participants	
Sampling, sample size & Power of Study	
Method for Recruitment of Participants (where appropriate not in secondary data analysis type of research)	
Data Collection Techniques & Instruments	
Cultural Sensitivity (where appropriate)	
Reliability & Validity of Methods & Tools	
Data Management	
Data Storage	
Data Analysis Plan	
Pretest or Pilot Study where appropriate	
ETHICAL CONSIDERATIONS	
Confidentiality	
Privacy	
Voluntary Informed Consent	
Provision of debriefing, counselling, referral for treatment and processes to enhance duty of care for participants	
Anticipated Risks of research & planned methods of management of risks	
Work Plan	
Timelines/ Gant Chart	
Budget	
Activities, Equipment, Personnel etc	
Source of Funds	
Plan for Administration, Monitoring and Utilization of Results	

Administration Monitoring Utilization(including Publication)	
References	
References included	
Appendices	
Data Collection Form, Tools, Surveys, Questionnaires, FGD & Interview Guides	
Secondary Data De-identification/ Coding Forms	
Information Statement(s) (Written in a language that will be understood by prospective participants.)	
Consent Form(s)	
Third Party Consent	
Assent Forms	
Translated versions of above if applicable	
Facility Approvals	
Other Country Research & Ethics Approvals	
General Comments:	
Recommendation:	

Please tick (√) as appropriate.

Fully Endorsed: No Changes Required: ☐

Endorsed pending Minor Changes: ☐

Resubmit (Major Changes Required: ☐

Acknowledgement

The information used in this review form was sourced from the FNU College of Medicine Nursing and Health Sciences, College Health Research Ethics Committee Review form, 2017 and Fiji National Human Health Research Ethics Reviewer Feedback Form.