
FNU
FIJI NATIONAL UNIVERSITY
College Human Health Research Ethics Committee (CHHREC)
STANDARD OPERATING PROCEDURES 2020
Fiji Institute of Pacific Health Research (FIPHR)
College of Medicine, Nursing and Health Sciences

ACKNOWLEDGMENT

We are pleased to present the 2020 revised version of the Standard Operating Procedures (SOP) for the accredited[1] College of Medicine Nursing and Health Sciences (CMNHS), College Human Health Research Ethics Committee (CHHREC). CHHREC was awarded an accreditation certificate by the Fiji Government's National Human Research Ethics Review Committee (FNHRERC) for successfully meeting the international requirements of a Human Health Research Ethics Committee. The award took place during a Fiji National Consultation Meeting on **Governance of National Human Research Ethics in Fiji,** held at the Tanoa International Hotel, Nadi, on 26th March, 2019[2].

The CHHREC committee members identified important issues that needed to be addressed in the original SOP of 2018. The issues were raised as agenda items and the members deliberated over the issues in CHHREC meetings. After the Chair and members reached an agreement then the issues were recommended for inclusion in the SOP. The revisions of the original SOP of 2018 was conducted as the years progressed through 2018-2020. This revision was completed in December, 2020.

The revision of the SOP 2020 was conducted by members of the CHHREC committee and Secretariat 2020. Internationally accepted documents like the World Health Organization, Western Pacific Region, Ethics Review Committee (WHO WPRO-ERC) and the University of Queensland Human Research Review Committee SOP were used to guide the development of this document. Therefore, an adoption process was conducted of existing operating procedures to develop the CHHREC SOP while ensuring relevance to the CMNHS and the Pacific Islands Region.

We wish to thank all the CHHREC members who have contributed to the compilation and revision of this SOP 2020.

[1] See Section 3 - College Health Research and Ethics Committee for a description of the CHHREC accreditation award.

[2] The Accreditation Certificate and an FNU Media Report are attached as Appendix 1: Accreditation of the College Human Health Research Ethics Committee

LIST OF ACRONYMS

CHHREC	College Human Health Research Ethics Committee
CIOMS	Council for International Organizations of Medical Sciences
CMNHS	College of Medicine Nursing and Health Sciences
FHHREC	Fiji Human Health Research Ethics Committee
FNU	Fiji National University
HIV	Human Immunodeficiency Virus
ICMJE	International Committee of Medical Journal Editors
MOHMS	Ministry of Health and Medical Services
NGO	Non-Governmental Organization
PLWH	Person Living with HIV
SOP	Standard Operating Procedures
SRC	School Research Committees
TOR	Terms of Reference
UASR	University Academic Student Regulations
UNESCO	United Nations Educational Scientific and Cultural Organization
UQ HREC SOP	University of Queensland, Health Research Ethics Committee, Standard Operating Procedures
WHO	World Health Organization
WHO WPRO ERC	World Health Organization, Western Pacific Region, Ethics Review Committee
WMA	World Medical Association

Contents

1. INTRODUCTION

Health research has been widely accepted as vital in the endeavour of maximizing health and wellbeing. In doing so, ethical considerations are paramount requiring researchers to conduct research ethically.

Ethics originated from the Greek words *ethos* (habit) and *ethikos (*character). Ethics is associated with the right conduct. Ethics involves reflecting and reasoning on what is the right thing to do. Ethics simply means "right, fair and just".

Research ethics requires researchers to think of the ethical conduct or the right conduct that will guide research. How will the researcher's ethical conduct guide the formation of a research topic question(s), the research methodology and research method? What responsibilities do researchers have towards the research participants? What about their voluntary informed consent? Will the research bring benefits or risks to research stakeholders? The principles of "respect", "beneficence", "do no harm" and "justice" must be strictly adhered to.

Ethical consideration of research is usually ignored or expressed as an afterthought in the discussions of research project plans. However, research methodologies and findings are to achieve and maintain a standard of excellence, trustworthiness and validity. These are all ethical values that all research projects need to maintain.

Research ethics is a critical part of the conceptualization of the research ideas through to the end where the findings will be published. Research, like daily life challenges, may produce ethical dilemmas where agreement on what is right or wrong will be impossible. In such cases, it is important that all involved in the research project and its ethical review, maintain a high level of research ethics awareness which will in turn influence their decision making on how the research project should be designed, implemented, and results disseminated.

2. THE COLLEGE OF MEDICINE NURSING AND HEALTH SCIENCES (CMNHS)

The College of Medicine Nursing and Health Sciences (CMNHS) is a merger of two of Fiji's Oldest Health and Medical Institutions; the Fiji School of Medicine and the Fiji School of Nursing.

The College has the vision to be the leading health workforce academic education and research institution in the Pacific Region. It strives for Excellence and Relevance in all that it does and focuses on graduating compassionate and competent health professionals who will improve the health of people in the Pacific Region.

The College delivers health educational programs at various levels (up to Doctor of Philosophy in selected disciplines) in dentistry, health, medicine, nutrition, medical imaging, medical laboratory technology, pharmacy, public health, physiotherapy, nursing and midwifery. To extend the formal academic program, short courses are offered in areas such as reproductive health, trauma management, advanced life support and disaster management, emergency health, phlebotomy and

treatment of Tuberculosis. More information about CMNHS is available at http://www.fnu.ac.fj/college-of- medicine/

Fiji Institute of Pacific Health Research (FIPHR) is the research arm of the CMNHS and it is an integrated virtual research institute of the CMNHS at the FNU. FIPHR has an overall vision of supporting Pacific Island countries in developing healthier communities by focusing on knowledge creation, exchange integration and application through research as well as innovation and research capacity needed to address their communicable disease, obesity and NCD crises, address sexual health issues, promote, restore and/or maintain population health and wellbeing and reduce their inequalities in health[3]. More information about FIPHR is available at https://www.fnu.ac.fj/college-of-medicine/research-cmnhs/

3. THE COLLEGE HUMAN HEALTH RESEARCH ETHICS COMMITTEE (CHHREC)

While research has been a core academic activity within undergraduate and postgraduate programs and staff career development at CMNHS, the establishment of a formal research ethics review committee was instituted in 2011 and named "College Health Research Ethics Committee" in line with the University policy for Colleges to set up appropriate research ethics committees.

CHHREC is the research bioethics and oversight committee of the CMNHS. The CHHREC term of reference (TOR) is included in this document. The TOR governs the appointment of members as well as defines specific terms of appointment and roles for members and reviewers.

The accreditation of CHHREC means that CHHREC has authority to issue FULL APPROVAL for research proposals submitted for ethics review without sending to FHHREC as per the pre-accreditation process. This calls for the researchers in CMNHS to submit their proposals to CHHREC for ethics review. When a Conditional Approval[4] is granted then the next step is for the researcher to apply for facility approval. When the facility approval is granted, CHHREC will issue a Full Approval[5]. The CHHREC will not conduct any retrospective ethics review of research projects already conducted or completed. The researcher shall not begin data collection before receipt of the CHHREC full approval. Once the CHHREC full approval is received then data collection begins.

3.1 Committees

3.1.1 School Research Committees (SRCs)

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

It is the responsibility of the Chair or the representative of the Chair of the School Research

[3] Source: Fiji Institute of Pacific Health Research (FIPHR) Strategic Plan 2020-2025, p.6.

[4] Refer to section 6.10

[5] Refer to section 6.11

Committees (SRCs) to ensure that committees function in accordance with the Fiji National University (FNU) Research Policy. SRCs must record all research submitted to the respective committees with records of review, feedback and decisions.

3.2 Composition of Membership

3.2.1 Chair and Vice Chair

Membership shall consist of the Associate Dean Research (Naidu, Matadradra, Sahib, & Osborne) who will be the Chair and constitute 1 voting right. A Vice Chair shall be elected by members of CHHREC every two (2) academic years. The role of Vice Chair is to perform the duties of the Chair in the absence of the CHHREC Chair. If the Chair and Vice Chair are not available simultaneously, the Chair shall nominate someone from the CHHREC Committee to Chair.

3.2.2 CMNHS Members

The Schools elect three (3) SRC members as members of CHHREC with consideration of the fact that representatives can serve a maximum of two (2) terms. These members should be the Chair, Co-chair and Secretary of the SRC. The Head of School will nominate interim members. Each SRC represented at CHHREC will have two (2) voting rights.

The research centres in the FIPHR will nominate a representative to be a member of CHHREC. Each research centre will have one (1) voting right.

Staff of FIPHR, including a Bioethicist are members of the CHHREC Secretariat and will have one (1) voting right.

3.2.3 PhD Qualified Research Active Staff

To contribute to the robustness of the review process of CHHREC, the Dean will appoint two (2) PhD qualified staff who are research active in the College as members of CHHREC.

3.2.4 External Representatives

As recommended by International Guidelines, external members in an research ethics committee should include a clergy, a lawyer, community members (lay persons, a man and a woman) and a social worker. External members will have one (1) individual voting rights. They will have equal roles and responsibilities as all members of the CHHREC committee. They are required to submit their Curriculum Vitae and their contact email for records and communication purposes. External members of CHHREC is an honorary and voluntary appointment for which there is no financial remuneration. There is a sitting allowance paid to the external members. They will be notified in advance about CHHREC meetings and meeting agendas. External members are to read and familiarize themselves with the SOP.

In addition, CHHREC requires representative(s) from the Ministry of Health and Medical Services (MoHMS) Fiji Human Health Research Ethics Committee (FHHRERC) to attend the CHHREC meetings.

CHHREC meetings normally provide refreshments during morning tea break and lunch for all CHHREC members attending CHHREC meetings.

3.2.5 Co-opted Committee Members

The CHHREC secretariat shall maintain a list of experts on specific health issues. They shall be called upon when required by the CHHREC depending on the need and the topic of the research proposal in review. Co-opted members may be called upon to conduct reviews and make recommendations but are not voting members nor contribute to the quorum of meetings. Representative of vulnerable population will also be included in the co-opted members' list. They may be invited to attend a meeting to discuss a research proposal that involve specific vulnerable populations.

3.2.6 Duration of Membership

A member shall serve for a period of **two (2) academic years** for a maximum of two consecutive terms. The CHHREC Secretariat shall call for nominations for membership from the Head of Schools at the end of every second year.

External members shall serve for a period of two academic years unless otherwise instructed by the Chair of CHHREC. The Secretariat shall call for Expression of Interest for External members at the end of the two-year period.

3.3 Training

It is mandatory that all members of CHHREC complete the online research bioethics training available on the internet from Office of International Research Ethics FHI 360, available at https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/ for general awareness of research ethics principles and the international standards of research ethics. Members can also attend Research Ethics Training sessions offered at CMNHS which will be conducted by a selected member of the FIPHR Training and Data Repository section. A training advertisement will be circulated to all members of CMNHS staff and staff are to sign up for the training session. A **Certificate of Participation** will be awarded to staff who have participated in the training session.

3.4 Secretariat

Selected members of staff of the Fiji Institute of Pacific Health Research (FIPHR) will provide the Secretariat and support services for CHHREC.

3.5 CHHREC Meetings

3.5.1 Frequency of Meeting

The CHHREC meet on the second Wednesday of every month except for the months of January and December. Special meetings can be convened as and when the need arise at the request of the Chair of the CHHREC. When special meetings are convened, notice shall be circulated by the CHHREC secretariat along with an agenda a week prior to the scheduled special meeting date. Meetings may also be convened virtually when needed.

3.5.2 Agenda

The Secretariat will make a call for agenda items. Members are to submit items for the agenda of meetings to the Secretariat well before the meeting dates. The Secretariat will compile the agenda and circulate to members along with the reminder of the meeting.

3.5.3 Quorum of Meeting

A quorum for the CHHREC meeting would mean 50% of full membership. This includes the Chair, School representatives, Research Centres representatives and External Members.

3.5.4 Attendance

Attendance of CHHREC meetings shall be defined as follows:

i. Members who attend, either in person or virtual will be recorded in the meeting minutes as "Present".
ii. Members who are absent without apologies and without a nominee will be counted as absent.
iii. Apologies without a nominee will be counted as absent.
iv. Apologies with nominee(s) will be counted as active. Nominee(s) are members of School Research Committees with in-depth research and ethics knowledge.
v. Absent (or apologies) two times without nominee will be issued with a letter requesting the member to respond and show the reason(s) why he or she should not be dismissed from CHHREC. The letter will be sent to the member and copy to supervisor and Dean of CMNHS.
vi. Absent (or apologies) three times without nominee(s) will result in the issuance of a letter of dismissal from CHHREC. The letter will be sent to the member and copy to Head of School and Dean of CMNHS. The Head of School will also be requested to nominate a new member.
vii. To maintain membership, a CHHREC member must have an attendance of at least 60% for an academic year. If a member has been dismissed under clause v. or vi. of 3.5.4 a replacement shall be sought from the Head of School concerned.
viii. The Chair may also invite individuals as observers for the purpose of capacity building in the area of Research and Research Ethics. The observer may be requested to participate in the discussion but does not have any voting rights. The Chair may also request the observer to leave the meeting room when decisions are made by voting or other. The observer will sign the CHHREC declaration of confidentiality.

3.5.5 Confidentiality of Meetings and Ethics Review Proceedings

All CHHREC meetings are held in private and members are encouraged to discuss applications for ethics approval of research proposals and research capacity development freely and raise matters of concerns.

All aspects of the **review of students and staff research proposals** by the CHHREC either during the CHHREC meetings or during the review process are to be kept confidential. All documents submitted with applications for ethics reviews are to be kept confidential. CHHREC communications to researchers and/or research team shall be made by the CHHREC Research Officer or a staff of the Secretariat or the Chair of CHHREC in special circumstances. Communication will be addressed to the Principle Investigator or his or her appointed contact persons as indicated in the research proposal. Communications are not to be released to sponsor or any third party.

3.5.6 Disclosure of Information for SRCs from CHHREC meetings

The CHHREC meeting will deliberate over matters or decisions for SRCs for action. Examples, (i) a new document required by CHHREC at point of submission of proposal like the *Supervisors' Endorsement Letter*, or (Suaalii-Sauni & Fulu-Aiolupotea) a change in the review process, for example, the requirement to have "*two supervisors per research student*" and these two supervisors are to both sign the Supervisors' Endorsement Letter or statistical reports of reviews. These sorts of information may be disclosed to the SRCs for information and/or action. The Chair, from time to time, will require the members to communicate certain matters to their SRCs. These matters are to be communicated as appropriate by CHHREC members to their SRCs as per instructions from Chair.

3.5.7 Declaration of Confidentiality

Appointed members are to sign a declaration of confidentiality. Attendance of content experts of research topics or observers at CHHREC meetings shall have prior approval from the Chair and they are required to sign the declaration of confidentiality. The template is attached as Appendix 2.

3.6 Meeting Records

The CHHREC Secretariat will record the proceedings of all CHHREC meetings, prepares the minutes in consultation with the Chair. Action items to be recorded clearly as well as the member(s) responsible.

The minutes are;

i. circulated to all members within seven (7) working days after the meeting
ii. tabled at the next CHHREC meeting
iii. To reflect each item listed for discussion on the agenda.

Confirmation of minutes of previous meeting(s) will be conducted in the next CHHREC meeting. The minutes are confidential to CHHREC and are not to be disclosed to non CHHREC members.

4. CHHREC STANDARD OPERATING PROCEDURES (SOP)

This document provides a Standard Operating Procedure (SOP) for the CMNHS CHHREC to ensure the practice of high ethical research standards and maintain consistent ethical reviews of research processes and associated functions.

The SOP ensures that CHHREC are constituted and operate in accordance with international and national accepted guidelines on ethical conduct of human health research such as the following:

i. Declaration of Helsinki, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964 and amended by the 64th WMA General Assembly, Fortaleza, Brazil, October 2013, available from; https://www.wma.net/what-we-do/medical-ethics/declaration-of-helsinki/
ii. Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Health-related Research Involving Humans, Associate partner of UNESCO in official relation with WHO. This document is available at; https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
iii. WHO Western Pacific Region, Ethics Review Committee, Standard Operating Procedures, available at; https://iris.wpro.who.int/bitstream/handle/10665.1/6769/9789290615170_eng.pdf
iv. Fiji Ministry of Health and Medical Services, Fiji Human Health Research Ethics Policy, available by request to the MOHMS.
v. The University of Queensland, Human Research Ethics Committees: Standard Operating Procedures, 2016, available at; https://research.uq.edu.au/files/18030/UQ_SOPs_for_HRECs_June_2016.pdf

It is also acknowledged that the above documents were the sources of information used to compile this SOP.

In adopting the SOP, CHHREC will ensure that any staff and students (and their affiliates) who are members of research involving human participants do meet ethical standards in accordance with accepted principles of research ethics, which includes respect for people, beneficence, non-

maleficence and justice. CHHREC will also ensure that the proposed research design is scientifically sound and appropriate for addressing the research question(s) and will not unnecessarily expose research participants to risk (WHO WPRO SOP).

4.1 Purpose of CHHREC SOP

i. To describe the structure, roles and review processes that guide CHHREC functions.
ii. To ensure that the SOP review processes are applied when reviewing research proposals of students, staff and their affiliates. Researchers have the responsibilities of abiding by research ethics governance mechanisms of their chosen research setting. An approval from CHHREC does not mean an umbrella approval for all ethics committees. A CHHREC approval means that CHHREC has reviewed the research proposal and addressed ethical and technical issues identified.
iii. To guide all researchers in CMNHS, understand whether their proposed human health research project is eligible for Low Risk (Fehoko, Bellringer, & Fairbairn-Dunlop) Ethics Review, High Risk (HR) Ethics Review or is Exempted (E) from ethics review**. A checklist** to be used to determine the level of risks posed by a research is attached as Appendix 3. Researchers are to read and understand in order to make an informed classification of the level of risk of their proposed research project.
iv. To map the ethics review processes for the information and awareness of researchers of CMNHS.
v. To guide the roles of the CHHREC.

4.2 Build Awareness of SOP

Principal investigators, leaders of research groups, or supervisors of students' research projects are to study this SOP before deciding to submit a research proposal for review. Researchers (Supervisors in the case of a students' research) at the CMNHS are also encouraged to complete the Research Bioethics training and induction opportunities offered by the Research Unit of the CMNHS, from 2016 onwards or complete the online research bioethics training available on the internet from the Office of International Research Ethics FHI 360, available at https://www.fhi360.org/sites/all/libraries/webpages/fhi-retc2/ before completing their research project proposals and applying for research ethics review.

A list of Research Bioethics training sessions also will be provided to all departments and all researchers will be encouraged to make an effort to attend one of these training sessions. After completing the research training, the researchers (and supervisors of undergraduate student research) ought to be well aware of research bioethics in order to place individual research projects in the relevant research bioethics review category and skilfully complete the relevant applications for submission, giving sufficient time for review and feedback processes.
This document is also intended to supplement the Fiji National University Research Policy and the FNU Authorship Policy available from https://www.fnu.ac.fj/research/research-office/research-policies/

5. SUBMISSION OF NEW RESEARCH PROPOSALS

All proposals (Word document) must be submitted to the CHHREC Secretariat on email CMNHS-RCO@fnu.ac.fj by the:

i. Principal investigator (for students' research) with a completed Supervisor's Endorsement Letter in PDF format (A sample is attached as *Appendix 4a)* and a completed CHHREC Research proposal Submission Checklist(*Appendix 4b*)
ii. Principal investigator (for staff research)
iii. CMNHS staff researcher in case of collaborative research.

A full research proposal, submitted in the format of the CMNHS Health Research Proposal Guideline Template (*Appendix 5)* must be submitted via email to the CHHREC officer attaching all relevant documents, for example, research designs that require the collection of primary data must attach relevant documents such as the:

i. Data Collection Forms (*Appendix 6 and/or Appendix 7*)
ii. Participant Information Statement (*Appendix 8*)
iii. Voluntary Informed Consent Form (*Appendix 9*)
iv. Assent form (*Appendix 10* - For under aged participants or participants that may not understand the longer more detailed consent form and does not have the capacity to decide for themselves. An assent form for under aged participants will be accompanied by a parents or guardian consent form. An assent form for participants without the capacity to decide for themselves will be accompanied by a third party consent form. The third party will be a proxy – family member or a person with the power of attorney).
v. For research designs such as those involving use of identifiable secondary data, a **de-identification form** is required to be attached to the research proposal. (A sample is attached as *Appendix 11*)

The secretariat will assess the application for completeness and appropriateness. A complete submission should contain all required documents for an objective review, while appropriateness will imply using appropriate CHHREC template(s).
Incomplete applications, which may include missing necessary attachments or not using CHHREC template, will be returned to the principle investigator or the researcher who made the submission. The principle investigator and/or the responsible staff will complete the application and send to the CHHREC officer.

A complete submission is described below.

5.1 Students Proposal Submission

For students' research (postgraduate, undergraduate and staff conducting research as a student for the award of a degree), submissions must be copied to the students' supervisors, co-supervisor, and SRC Secretary.

All research of CMNHS students, undergraduate and postgraduate, are required to have two (2) supervisors. Out of the two supervisors, one should be a staff of CMNHS appointed formally and endorsed by SRC to be the CMNHS supervisor. The 2nd supervisor may be a site supervisor, for example, research conducted in hospitals and require clinical supervision.

The RCO will include this requirement for CMNHS supervisor in the checklist for receiving research proposals.

i. Full Research proposal using the CHHREC Proposal Guideline template. (*Appendix 5*)
ii. Supervisor(s) endorsement letter using the CHHREC template. This supervisor must be a CMNHS staff appointed as supervisor by SRC. (*Appendix 4*)
iii. Research Proposals from CMNHS staff members who are in collaborative research with researchers from another university or overseas country, must attach an ethics approval from an ethics committee in that university/hospital or national ethics committee of that overseas country.

5.2 Staff Proposal Submission: Documentation required

All staff of CMNHS involving in research must submit the research proposal to CHHREC for ethics review. This ethics review is primarily for the protection of research participants from risks and also for the protection of risks posed to the institution CMNHS/FNU. For staff research (independent or collaborative), submissions must be copied to co-investigators, collaborators as appropriate, as well as SRC Secretary.

i. Full Research proposal using the CHHREC Proposal Guideline Template (*Appendix 5*).
ii. Supervisor(s) endorsement letter using the CHHREC Template (*Appendix 4*).

5.3 Requirements for Facility Approval

After the proposal has been reviewed by reviewers and approved granted a **Conditional Approval** from CHHREC, then the following documents are required before a full approval can be granted.

i. Permission from the Medical Superintendent (if data collection involves any Government Hospital or health facility) and Person in Charge (e.g. CEO or Owner) in the case of private health facilities.
ii. Permission from the Dean of CMNHS if the research involves CMNHS staff or students or both.
iii. The FNU Registrar's permission be sought if the research involves staff and/or students from other colleges in FNU (outside CMNHS).
iv. Permission from Head of Unit/ Division in case of Government, Ministries or Agencies, Non-Governmental Organizations (NGOs) if conducting research in their organizations and premises.
v. Permission from appropriate authority or authorities, for example, in the Ministry of Health or other if the research is to be conducted in health department in countries apart from Fiji.

5.4 Special Conditions

5.4.1 Principal Investigator as non-staff/student

Research where the principal investigator is neither a staff nor student of CMNHS but co-investigators are either staff or students of CMNHS, the proposal will go through the same procedures set out above. The research project has to be submitted to CHHREC Secretariat as described earlier. The CHHREC may recommend full review, expedited review or exemption for review. Proposals that also attach ethics approval from a recognized health research ethics

committee is excellent but does not guarantee approval from CHHREC. CHHREC will still need to assess the proposal based on the SOP and for context relevance.

5.4.2 Research setting in a country other than Fiji

Where CMNHS staff or student is the principal investigator, co-investigator, supervisor/ co-supervisor or mentor in a study conducted in another country, the principal investigator is required to make full submission for ethics review from CHHREC.
The purpose of submission to CHHREC is for the following reasons:

i. Ensure any real or perceived risks attributable to the institution through the researchers' involvement in such projects are addressed, eliminated or risk management strategies are in place.
ii. Ensure that research conducted in countries that do not have properly established/ functional research ethics committees have received due diligence for research ethics review.

Researchers are encouraged to submit proposals, review comments and other institutional ethics approvals (including any other important documentation) from collaborating institutions to enable the CHHREC secretariat to ascertain whether the proposal needs to be tabled in CHHREC or recorded in the CHHREC database or review through the CHHREC processes or a combination of the above actions.

5.4.3 Staff as a CHHREC member

CHHREC members will be required to declare any conflict of interest in all CHHREC meetings and when appropriate be asked to leave the CHHREC meeting deliberations when proposals or issues relating to their research projects/interests are being discussed.

CMNHS staff use of existing data owned by students or other not available in the public domain

Case Scenarios

Example 1*: FNU student conducting a study in their home country will require the following;*

- *Research Proposal*
- *Supervisors' endorsement letter*
- *Appropriate documents relevant to the research design, such as, participants' information and consent and data collection forms.*
- *A facility approval is required. A CHHREC Conditional Approval can help researcher apply for ethics approval and facility approval in the country of research.*

Example 2*: A student conducting a study on Cancer Survivors and wishing to collect the data through the Fiji Cancer Society will require*

- *Research Proposal*
- *Supervisors' endorsement letter*
- *Appropriate documents relevant to the research design such as participants' information and consent and data collection forms.*
- *A facility approval is required from Fiji Cancer Society. (A CHHREC Conditional Approval can help researcher apply for facility approval from Fiji Cancer Society.)*
- *When the approval is granted from Fiji Cancer Society, a full approval will be granted from CHHREC.*

Example 3*: FNU student wishing to collect data involving FNU staff and/or student.*

- *Research Proposal*
- *Supervisors' endorsement letter*
- *Appropriate documents relevant to the research design, participants' information and consent and data collection forms.*
- *A facility approval is required from CMNHS if target population is CMNHS staff or students. If target population is all FNU staff and/or students, a facility approval is to be sought from the FNU Registrar's office. (A CHHREC Conditional Approval can help researcher apply for approval from the FNU Registrar's office).*

6. ETHICS REVIEWS OF RESEARCH PROPOSALS

6.1 CHHREC Reviewers and their Roles

CHHREC members and CMNHS staff recommended by CHHREC as reviewers are tasked with the review of research proposals. CHHREC reviewers will assess proposals for the level of risk and scientific rigour and make recommendations for the improvement of proposals that need improvements. CHHREC reviewers will also conduct ethical review of research proposals and determine whether they should be granted ethical approval, declined, or exempted from ethical review. Where proposals are declined, CHHREC can recommend experts (within or external to the college) to support the researchers or refer them to SRC for appropriate guidance for the improvement of the proposal and/or the re-submission. Research proposals planned to be conducted in Fiji and originated from abroad requires the reviewers to include **cultural expectations** of research and **context specific issues** in the review tasks. The reviewers are to cite the ethics approval from the foreign University or approval from ethics committee overseas.

6.2 Review Process

All submissions will be initially vetted for completeness and appropriateness by the CHHREC Secretariat. If a proposal submission is complete and appropriate, the CHHREC secretariat will issue a CHHREC reference number and then reply to the researcher quoting the reference number. The proposal and accompanying documents will then be assessed for the level of risk. If the preliminary review identifies the proposal to be of **"Low Risk"** (as defined in section Appendix 7) the proposal will undergo an "**Expedited Review**" and review comments will be sent to the secretariat within 10 working days. This means that a Researcher with a low risk proposal should receive a communiqué from CHHREC on the status of their proposal within 10 working days from their date of submission. If required, a content expert may be requested to assist in the review. The expedited review is completed by the reviewer and will send the review comments to the CMNHS-RCO email. The RCO will compile all reviewers' comments onto one Review Form and then prepare other documents as required based on reviewers' recommendations and send to the researcher(s).

6.3 Special Request for an expedited review from School Research Committees

CMNHS Schools can submit a special request for an expedited review of specific students' programme of study research proposals that has strict timelines, such as the School of Medical Sciences Technical Interns' class.

The Process:

Pre-Plan. Members of CHHREC must conduct a planning exercise with CHHREC. Inform CHHREC of the need and the time frame required to conduct the expedited review. Expedited Review plan will be drawn up.

The expedited review processes.

(i) Receive new proposal process.
(ii) Select reviewers to conduct the reviews of students' proposals.
(iii) Send the proposals to the selected reviewers. Indicate a turn-around time – not more than 3 working days and return to CHHREC research officer.
(iv) Proposals that need revisions – to send back to researchers. Researchers to work on revisions and should return to researcher officer no more than 3 working days.
(v) CHHREC Reviewers do the 2nd review – 2 working days. Conditional approvals are to be issued at the end of the 2 working days.
(vi) Researchers get their facilities approval – 2 days. CHHREC issues Full approval at the end of these 2 days.
(vii) Total turn-around time for this specially requested expedited review is 10 days.

Proposals that are deemed **"High Risk"** (as defined in Appendix 8) during the preliminary ethics review will be referred for a "Full Review" process. This process involves review by an Ethics Adviser and two independent reviewers who may be members of the CHHREC or SRCs or external reviewers. If reviewer expertise within CHHREC or SRC is inadequate, reviewers who are largely content experts will be sought externally including internationally partners. Prospective reviewers will be requested to respond, within 48 hours, regarding their availability and acceptance to review the proposal within the allocated timeframe so as not to delay the review process and to seek other reviewers for their assistance. The proposal will

undergo assessment according to the Research Review Form (see Annex 9).

The turnaround time for a full review is 30 working days. The RCO will compile all review comments in one review form and send to the Chair for his comments. The Chair will make recommendations whether to table in CHHREC or to send the comments directly to researcher(s). This process will be conducted before the 30 working days.

6.4 Blinding Process

The RCO will remove the identifiers on research High Risk proposals before sending to the reviewers. This is a double blind process where both researchers and reviewers are not identified in the proposal document.

6.5 Animal Ethics Review Process

Effective from 12th September, 2018, research proposal(s) that involve animals will be send to the FNU College of Agriculture, Fisheries and Forests (CAFF) experts in animal health to review. This process will cease upon the establishment of an animal ethics committee at the CAFF or in Fiji.

6.6 External Expert Reviewers

In the case where CHHREC is unable to make a decision or if CHHREC does not have the expertise to review an application – the proposal will be sent to experts in the subject matter of the proposal for an independent review. The principle investigator will be notified on the need for further review. An expert reviewer(s) is/are identified and contacted by the Chair to see if they are available during the timeframe of review. The expert reviewer(s) must not have any conflict of interest and confidentiality requirements are maintained. The research proposal is sent to the external reviewer(s) for review. Upon completion of review, the expert reviewer(s) will send results of the review to the Chair. These results are presented to CHHREC to make a final decision.

6.7 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. CMNHS researchers are to 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.

Academic and professional activities that are not classified as „Human Research" may apply to other "Non-Health" ethics review committees or "Learning and Teaching" Committees or Executive Committees (Projects and Consultancies) for appropriate Institutional review and approvals.

The following types of data collection methods and activities may be eligible for exemption from ethics review[6]. Clarification can be sort from the CHHREC on whether ethical review and approval is required. It is advised that staff and students engaging in these activities get a CHHREC letter that agrees that their work is exempt from any ethical review of approval.

[6]http://www.deakin.edu.au/research/researcher-support/integrity-secure/human-ethics/dheg/g2-2-3-2

i. Administrative data collection and analysis
ii. Clinical case reports
iii. Descriptive case studies
iv. Histories: Interviews, personal viewpoints, institutional histories
v. Secondary analysis of non-sensitive, non-identifiable data from institutional data repositories/ databases
vi. Quality assurance, Quality Improvement, Course or Program Evaluation activities or clinical audits
vii. Research practicum and classroom or clinical Learning and Teaching activities
viii. Research using publicly archived materials
ix. 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.

6.8 Possible Review Outcomes

Possible review outcomes for both Expedited and Full review include:

i. Fully Endorsed: No Changes Required
ii. Endorsed pending Minor Changes
iii. Resubmit (Major Changes Required)

Appropriate response times for Researchers:

i. Minor Changes: Researchers to respond with changes within 10 working days upon receipt of review comments
ii. Major Changes: Researchers to respond with changes within 30 working days upon receipt of review comments

Resubmissions done within the specified timeframes will be assigned to the original reviewers for their final endorsement of amendments. Inability to meet the specified timeframes (i.e. 10 days, 30 days) must be communicated to the CHHREC secretariat with the justifications. Failure to adhere to these timeframes without any communication can result in the proposal being asked to resubmit as a new proposal and resulting in time delays.

There is no limit to the numbers of times a research proposal is resubmitted to CHHREC for review before a review decision is made. However, in cases of students proposal identified in CHHREC to be facing challenges the Chair or CHHREC representatives may be recommended to assist this student with the reviews of his or her proposals along with the supervisors.

Ethical approval letter will be issued within 5 working days from reviewer's endorsement.

6.9 CHHREC Request the Principle Investigator to attend CHHREC Meeting

The Chair of CHHREC may request the principle investigator to attend a CHHREC meeting in order to make a formal presentation or to respond directly to questions and queries for clarification, provision of further information or reassurance regarding issues raised through ethics reviews. The Principle investigator or his or her representative who is also part of the research team can attend in person. If the principle investigator and his or her representative are not able to be present in person, a phone or video-conference can also be organized.

6.10 CHHREC Consideration of Reviews and Decision Making

All expedited Reviews (review form comments and endorsement of amendments) will be considered by the Chair of CHHREC before issuance of the CHHREC ethics approval letter. A list of expedited reviews with justification of assignment to "Low Risk" and subsequent endorsement of summary amendments will be presented to members at the monthly CHHREC meeting for records. All proposals referred for "Full Review" will be circulated to members prior to the monthly meeting with a justification of the risk stratification and a collation of review comments. Members may review the comments to assess appropriateness of comments and may propose additional comments to improve the technical or ethical acceptability of the proposal. Amended proposals will be sent for endorsement to CHHREC members via e-mail for final e-endorsement within 5 working days of receipt of amendments. CHHREC endeavours to reach a decision concerning the ethical and scientific acceptability of a research project by unanimous agreement.

Where a unanimous decision is not reached, the Chair needs to facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.

Any significant minority view (i.e. 2 or more members) is noted in the minutes. Discussions of significant issues and decisions are recorded in the minutes. Where members wish, a record of their formal dissent from the decision of the CHHREC is recorded in the minutes. To encourage free and open discussion and to emphasise the collegiate character of CHHREC, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded. A CHHREC member unable to attend a meeting may submit comments in writing on the proposal to the CHHREC Secretariat prior to the meeting and this will be recorded in the minutes.

The detailed operational process of the research ethics review process is illustrated in the diagram labelled **Figure 1: CHHREC Research Ethics Review Procedure**.

6.11 Conditional Approval

A conditional approval is granted to the researcher upon recommendation from reviewers that the proposal is ethically and scientifically sound. The condition is for the researcher to sought Facility Approval.

6.12 Facility Approval

This approval is sought from the facility or site in which the research will be conducted, for example, CWMH, Valelevu Health Centre, Vanuatu Hospital, Vaiola Hospital in Tonga, Suva Grammar School. The approval letter should be send to the CHHREC RCO for recording and to send to the reviewers in order to be cleared for a Full Approval.

Categories of Facility approvals: -

(i) **Hospitals:** Example; CWMH, Regional PICTs Main Hospitals. Approvals are granted by the Medical Superintendents or his or her official representative.

(ii) **Divisional Hospitals/Health Centres/Dental clinics**: Lami Health centre, Navua Health Centre. Approvals are granted by the Divisional Senior Medical Officer or his or her official

representative.

(iii) **Private Hospital/Private Clinics/Dental clinics**: Approvals are granted by the owner of the facility or the Chief Executive Officer.

(iv) **Fiji National University:** Example; if FNU staff and students are target populations in the research. The Registrar grants the approval. CMNHS or other FNU Colleges: The Dean of the Colleges grant the approvals.

(v) **Secondary and Primary Schools**: Example, Suva Grammar School, Veiuto Primary School. Ministry of Education grants permission for research in any school in Fiji. Other Pacific countries may vary. The School principals' permission are also to be sought before the data collection takes place in the schools.

(vi) **Fijian Villages**: iTaukei Affairs and the Provincial Offices grant permission for research in iTaukei Fijian villages.

(vii) **Research in Municipal Markets**: The city or town council grant approvals. For example, research to be conducted in Nausori Market therefore Nausori town council grants approvals.

6.13 Full Approval

CHHREC Chair grants a full approval when the facility approval(s) are cited by the Secretariat and representatives of Chair.

6.14 Appeals and Disagreements with CHHREC Review Decisions

In a situation where the researcher disagrees with the outcome of the review decision, the researcher has the right to appeal. The researcher must write directly to the Chair of the CHHREC with clear reasons for the appeal and list the committee decisions being contested. The contested decisions must be accompanied by justifications and any information that the researcher feels is relevant to supporting the appeal. The Chair of the CHHREC will convene an independent sub-committee to review the appeal and the decisions under contest to recommend to the Chair. A researcher may opt to make a presentation to the sub-committee. The sub-committee may institute other processes which may include but not limited to: interviews, discussions, seeking opinion of an independent reviewer. The sub-committee will review the outcome of the processes and make a recommendation to the Chair of CHHREC within 14 working days for the final decision. In the situation where after the appeals process both CHHREC and the researcher are still not able to come to an agreement, the researcher can re-appeal to the Dean of the College for a final decision on the matter.

7. MONITORING OF APPROVED PROJECTS

It is the obligation of CHHREC to ensure continuing oversight of approved research projects. The CHHREC Secretariat shall promptly report to CHHREC any developments in the project that might have ethical implications. Principal Investigator shall inform the CHHREC secretariat of any changes in an approved research proposal or consent documentation proposed to be made before implementation, and these shall be reported immediately to the CHHREC by the Secretariat. When the CHHREC 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 Chair and the ethics officers within the Research division on whether the proposed changes should be subject to review by the Committee. If a review by CHHREC is required, then the proposed changes will be presented to CHHREC for review and approval which it shall endeavour to produce in a timely manner. The changes proposed for the research project shall not be instituted until approval is granted[7].

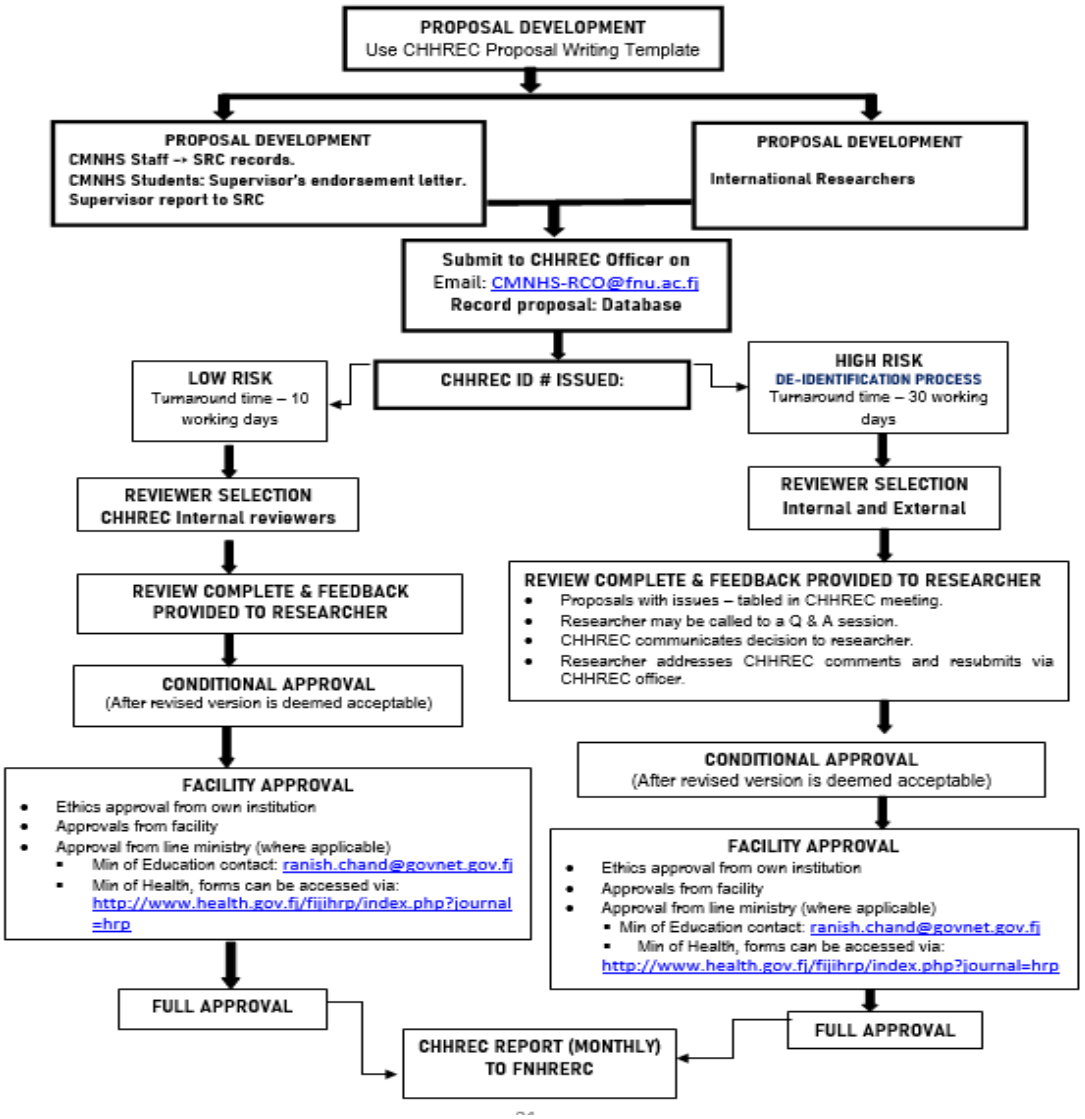
7.1 Adverse Events Reporting

Any harm 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 Principal Investigator to CHHREC.
CHHREC Chair and selected members 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. If the Chair determines that another review should occur, it shall take place as soon as possible (including through a special Committee meeting, if necessary under the circumstances).

The results of the second review will be promptly conveyed to the Principle Investigator.

[7] Source: W HO W PRO ETHICS REVIEW COMMITTEE SOP

Figure 1: CHHREC Research Ethics Review Procedure



7.2 Auditing

The CHHREC shall have a committee regularly involved in monitoring research activities in its effort towards quality assurance of all research at the CMNHS. The CHHREC will maintain quality assurance of all CMNHS research in three ways;

i. Conducting random spot-checks on current research being conducted

ii. Receiving mandatory periodic research progress reports from researchers

iii. Monitoring mandatory timeframe for the duration of each research and ethics approval beyond which, research activities will be deemed expired and redundant except where extension approval processes have been sought and granted by CHHREC.

7.2.1 Random Spot-checks on Current Research Activities

CHHREC members may perform random spot-checks of research being implemented by CMNHS

staff or students. The random check may include, but not limited to the following;

i. Compliance of proposed activities/protocols with implementation and timelines
ii. Utilisation of approved Data Collection Forms
iii. To ascertain the validity of the voluntary informed consent process
iv. To validate data collection procedure and storage
v. To confirm roles and responsibilities of personnel involved in research as stated in the submission.

Where breaches are established during spot-checks (with reference to approved research proposal and protocols), processes to address those breaches will be activated among CHHREC, the supervisor and/or the researcher, whichever is applicable.

7.3 Research Progress Reports

Each researcher will be required to periodically submit a research progress report (see Annex 12) discussing the current status of research to CHHREC. Periodic reporting will be continued until the successful completion of the research. The report may include but not limited to the following:

i. How far research had progressed with reference to the research proposal's Gantt chart?
ii. What were the challenges/issues/problems that caused delays in research implementation?
iii. How have those challenges/issues/problems been addressed?
iv. What funding has been used and on what, as well as remaining funds during the period of reporting?

Where progress reports are not submitted by researchers in spite of several requests, recourse will be sought including rescindment of CHHREC research approvals. The following steps will be followed: -

i. Initial request for a researcher's progress report for the current period will be communicated by CHHREC using e-mail. The e-mail will include the progress report template and a deadline by which signed progress reports are to be submitted;
ii. Frequent e-mail reminders will be sent to all researchers for submission of progress reports until close of business on the submission day;
iii. Those failing to submit reports will be contacted by e-mail and may be followed by phone to establish reason/s for non-submission and to establish agreement on next date of report submission.
iv. Where reason/s are not communicated and attempts to receive progress reports have failed; CHHREC will formally communicate with the researcher through a signed letter to make a final request for a progress report failing which other options will then apply. These include: Communicating with the specific Schools, Departments and Units, through their Heads where applicable or project sponsors and cancelling the research approval after 5 failed requests for progressive report submission.

8. URGENT SAFETY RELATED MEASURES

In the case of immediate unforeseen risks of harm to participants in research, it is the responsibility of the principle investigator to do all that he or she can do in order to eliminate this risk. The safety of the participants is paramount.

The principal investigator will report to CHHREC any of this urgent safety related measures, stating the nature of the safety related issue, the reason for it and how it was handled. A revised research protocol will also be submitted to CHHREC which includes the revised protocol. CHHREC will conduct an expedited review these amendments. (UQ, HREC SOP, 2016)

9. DURATION OF CHHREC APPROVAL

i. Research projects approvals from CHHREC are for specified time period as indicated in the approved work plan and proposed project timeline; taking effect from the approval date.
ii. The approval letter will include the CHHREC ID number, the approval beginning and end date, and Conditions of Approval;
iii. Approval is limited to the research proposal as submitted in the application, and any subsequent changes must also be approved via a request for amendment.
iv. If the researcher thinks that the research project will take longer than the approved implementation timeframe, the researcher should submit an application to the CHHREC stating valid reasons for the delay. Examples of valid reasons for delay includes the following reasons; (i) Approvals sought from research stakeholders in-country of research, (Suaalii-Sauni & Fulu-Aiolupotea) Access to funds via approved grants (iii) Unavailability of data from data source.
v. There may be other reasons that the researchers face and should be written in an application for extension to CHHREC.
vi. The application will be considered on individual case basis.

10. PROGRESS REPORT AND ANNUAL REPORT

Progress reports are expected at routine intervals which will be specified in the ethical approval letters. Requests for annual reports are sent out by the CHHREC at the end of academic year.

Failure to submit annual report following repeated reminders (3 times within the period of 2 months) will mean approval for the project will lapse and a new application will be required. If research is to extend beyond its approved timeline, the researcher is expected to request for approval timeframe with justification.

If the research project is anticipated to be incomplete by the proposed timeframe, then the principle investigator is to write an email to the CHHREC chair to inform him or her of the need for an extended time and the reasons for doing so. This email is to be copied to all research team members. CHHREC will consider the application and will grant an extension to date of approval.

The research team will be duly informed of CHHRECs decision by writing with the authority of the Chair.

11. PROCEDURES ON COMPLETION OF RESEARCH PROJECT

The Principal Investigator is required to submit a final report within six months upon completion of the research project.

The CHHREC Secretariat shall report the final research project outcome (completion or discontinuation) and submit a final report on the study to CHHREC. A notation shall be made in the CHHREC records accordingly and 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 project in CHHREC data base[8] .

For supervised student research, students and supervisors must provide a clean copy of the Research report for submission to the FIPHR data repository. An e-copy of the final report, once all assessments are completed, can be given to the CHHREC secretariat. A clean, de-identified copy of the research dataset must be stored by the Principal Researcher for a minimum period of 5 years.

Researchers are expected to report publications from their research findings to the Research Unit. Datasets are retained for reference and can be useful in cases where issues arise regarding contest of research findings.

12. AUTHORSHIP

CHHREC abides by the FNU Authorship Policy. The FNU Authorship Policy document available at: https://www.fnu.ac.fj/research/research-office/research-policies/.

13. CONFLICT OF INTEREST

Definition: Conflict of interest in the context of research is:

(i) Persons' individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligation in research; or
(ii) An institutions interests or responsibilities have the potential to influence the carrying out of its research obligations (Australian National Statement on Ethical Conduct in Human Research, 2015).

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

[8] Source: WHO WPRO ETHICS REVIEW COMMITTEE SOP

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 *(The Australian National Statement on Ethical Conduct in Human Research, 2015)*.

The guidance on avoidance of conflicts of interest is discussed in details in the WHO WPRO-ERC Standard Operating Procedures pp. 29-31.

13.1 CHHREC Members Declare Conflict of Interest

All CHHREC Members are expected to declare conflict of interest or perceived conflict of interest on each issues of deliberation at all meetings either face-to-face or e-meetings.

14. SUSPENSION OR WITHDRAWAL OF CHHREC APPROVAL

CHHREC will make a decision to suspend or withdraw an approval granted to a research project if through the monitoring process of CHHREC, it was found and reported that safety and welfare of participants are compromised. Suspension or withdrawal may be related to the whole research project or part of the protocols of the research project. CHHREC will specify what aspects of the project will cease and when activities can recommence. The principal investigator will be notified in writing within 3 working days of the CHHREC decision to suspend, unless immediate notification is required for urgent safety reasons. CHHREC will conduct a thorough investigation and prepare a report about the suspended project. The principal investigator will be requested to make a written response to the report. The decision to re-instate a research project will be the discretion of CHHREC. The research team will discontinue research and will comply with the decision made by CHHREC. Any other ethics committee involved in the project will be notified of the suspension or withdrawal of CHHREC approval[9].

15. COMPLAINTS AND GRIEVANCES

Complaints about the conduct of an approved research project are to be reported to the Secretariat of the CHHREC and copy to the Chair. The complainant will receive an acknowledgement in writing via email. The CHHREC Secretariat will investigate the complaint and conduct an audit of the project if necessary. If the matter is related to research misconduct, the matter will be dealt with in accordance with the FNU research policies and if FNU protocols are not sufficient, then the Fiji National Research policies or law will apply, for example, The Fiji National Research Council Act, 2017: Part 5 : Available at http://www.parliament.gov.fj/wp-content/uploads/2017/03/Act-20-National-Research-Council-Act.pdf

[9] Source: University of Queensland, HREC, SOP, 2016

15.1 Grievances Procedures for Researchers

Grievances procedures for students and staff have been documented well in FNU policies, therefore, the repetition of these procedures in the SOP is unnecessary. Reference to the relevant FNU policy documents (below) is recommended.

i. **FNU Policies for the Responsible Practices in Research**
Section 3: Student Supervision, lines 70, 75, 80, 85; Available at: http://www.info.fnu.ac.fj/uniresearch/images/policies/University_Research_Policy.pdf

ii. **FNU Handbook for Research Programmes**
Section III: Supervisor and Student Roles and Responsibilities, 3.3 Handling Disputes; Available at: http://www.fnu.ac.fj/new/images/policies_regulations/Handbook_for_Research_Programmes.pdf

iii. **University Academic and Student Regulations (UASR)**
- Section 6.0: Process for Students to Seek Redress for Grievances Against the University
- Section 6.1: Grievances against Students
- Section 6.2: Grievances against Instructors
- Section 6.3: Grievances against Staff other than instructors/Lecturers

Available at: http://www.fnu.ac.fj/new/images/policies-regulations/University_Academic_and_Student_Regulations_2018-.pdf

iv. **FNU Human Resources Grievance Policy**
- Section 5.0: Grievances Related to Work Performance; (Available at: http://www.fnu.ac.fj/new/images/policies-regulations/hpn.pdf)

16. COLLECTION, STORAGE AND USE OF BIOLOGICAL MATERIALS AND RELATED DATA[10]

The Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) have provided an international guideline for health-related research involving humans. This topic is written in detail as Guideline 11. Click on the link below for online access.

https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

17. ADOPTION AND AMENDMENTS OF THE SOP

The SOP will be approved by the CHHREC Chair after its presentation at a CHHREC meeting. Members of the CHHREC can propose an amendment to the current SOP by making a written formal submission to the Chair of CHHREC. Consultation should be made to relevant stakeholders. The Secretariat will make this submission an item in the agenda of the next CHHREC meeting for

[10] Source: CIOMS and WHO. 2016. *International ethical Guidelines for health-related research involving humans* [online]. Geneva, Available at https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

CHHREC consideration and possible adoption by the majority of members who are present. The amendments shall come into effect once approved by the Chair of CHHREC. The committee through SRCs will disseminate changes to the staff and students to their respective schools as recommended for implementation.

18. PERIODIC REVIEW OF CHHREC SOP

This CHHREC SOP is a dynamic document and therefore subject to periodic review. With the understanding that this is the first revision of the CHHREC SOP, 2020. It is anticipated that there will be changes along the way to improve CHHREC processes towards more robust and timely research from the College. The CHHREC SOP will be reviewed every two years. The review process will be led and facilitated by the Chair of CHHREC.

19. SPECIAL CONSIDERATIONS OF RESEARCH INVOLVING VULNERABLE POPULATIONS

Attached as *Appendix 10*.

19.1 Research Involving Vulnerable Population

The Committee will be guided by Article 17 and Articles 26- 29 of the Helsinki Declaration in reviewing proposals involving vulnerable populations. Article 17 of Helsinki Declaration clearly states that "medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research".

19.2 Research Involving Children

In accordance with the United Nations Convention on the Rights of the Child, special considerations must be made when conducting research involving children (those under 18 years old). These include completion of lay person's information sheet to inform parents or other legally authorized representatives or guardians about the research, informed consent process of parents and assent forms and processes for children. CHHREC may be guided further by **Guideline 14 "Research involving Children" of the International Guidelines for Biomedical Research** (CIOMS, 2002) in reviewing proposals involving proposals involving children.

19.3 Research Involving Women

In a manner consistent with the United Nations Convention on the Elimination of All Forms of Discrimination against Women, pregnant and lactating women are classified as a vulnerable population because their condition leads to risk for both the mother and the fetus or breastfeeding offspring. CHHREC may refer to **Guideline 16 of CIOMS** for further guidance in reviews and to seek clarifications.

19.4 Vulnerability Based on Economic Status or Other Factors

Research participants should not be coerced into participating in a research study because of

inappropriate inducements. CHHREC will review the consent process and other forms to ensure that inducements offered are appropriate. Additionally CHHREC will be guided by **Guideline 7 "Inducement to participate" and Guideline 10 of the International Guidelines for biomedical research (CIOMS, 2002**) as well as **Article 17 of Helsinki Declaration (2008)** in reviewing proposals involving research in population and communities with limited resources.

20. RESPONSIBLE CONDUCT IN RESEARCH

Responsible conduct in research is the responsibility of all researchers. It is also a serious matter and is referred to in the FNU Research Policy, FNU Handbook for Research Programmes, the University Academic Student Regulations (UASR) booklet (2013 revised version; section 4.0 Academic Conduct sub-section 4.1.3-4.1.6 page 57), and the FNU Human Resources (HR) Policy.

Staff and students are obligated to practice integrity in research and to report legitimate instances of research misconduct utilizing the formal processes available under the University Research Policy, HR policy or UASR as above. All instances of research misconduct must be reported to the Chair of CHHREC through a formal letter outlining the nature of the misconduct in line with criteria for misconduct. Student research misconduct should be reported to the Chair of CHHREC for an independent enquiry before referral to the academic disciplinary processes for student academic misconduct. Staff research misconduct should also be reported to the Chair of CHHREC for an independent enquiry before referral to the HR policy on staff misconduct.

The Chair of CHHREC will appoint an independent sub-committee to assess the complaint and launch a process of investigation of facts around the allegation(s). Depending on the seriousness of misconduct, the Human Resources section may also be asked to assist in the investigation. Where possible, the University regulations and processes for appeals and disciplinary actions will apply.

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21. APPENDICES

Appendix 1: Accreditation of Human Research Ethics Committees

Guidelines for Accreditation of Ethics Committees in Fiji by the Fiji National Human Research Ethics Committee, Ministry of Health and Medical Services, Republic of the Fiji Islands

Accreditation of Human Research Ethics Committees

The FNHREC provides this guideline[11] for HRECs and their governing bodies to guide the application for accreditation. This section will present the process of accreditation of Ethics Committees in Fiji by the FNHREC.

Rationale for HREC accreditation

The accreditation process seeks to establish that HRECs are doing their best to fulfil 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 FNHREC as the national accreditation body

The FNHREC will

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

Accreditation quality standards

1. Research proposals submitted to HREC for ethical review will justify the involvement of humans in the research.
2. HREC is based on sound internationally and locally accepted ethical principles.
3. Compliance with national and institutional policies and regulations.
4. A diverse range of research study designs is entertained, (for example, surveys, student projects, and behavioural 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 FNHREC.
10. Reviews of research projects must establish a process for obtaining the voluntary informed consent of participants.

[11] 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.

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

Criteria for eligibility to apply for HREC accreditation
To award an accreditation certificate to a HREC the FNHREC needs to be assured that the HREC has the capacity to offer protection to human participants in research.

HRECS operate under a governing 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 FNHREC 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 FNREC 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 FNHREC subject to satisfactory review by its secretariat or independent persons.

Reaccreditation Procedures
- Applications for re-accreditation should be made 3 months ahead of the anniversary of the 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 FNHREC.
- 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 FNHRERC, Research Unit, Ministry of Health and Medical Services.

Appendix 2: Declaration of Confidentiality

COLLEGE HUMAN HEALTH RESEARCH ETHICS COMMITTEE (CHHREC)
CONFIDENTIALITY AGREEMENT FOR COMMITTEE MEMBERS

In recognition of the fact, that _____ ***(CHHREC member's name and designation***) herein referred to as the "Undersigned", have been appointed as a member of the CHHREC.

TERMS AND CONDITIONS:

1. CHHREC committee members are to participate in CHHREC activities in accordance with the CHHREC Standard Operating Procedures (SOP).
2. Members review both scientific and ethical aspects of research protocols involving human participants in order to ensure that research is conducted in a humane and ethical manner and in accordance with Fiji national research regulations, Fiji National University (FNU) institutional policies and guidelines and the CHHREC SOP.
3. The CHHREC members must meet the highest ethical standards in order to merit the trust and confidence of CMNHS staff and student researchers in the protection of the rights and well-being of human participants in research.
4. A member of CHHREC is expected to meet the same high standards of ethical behavior to carry out CHHREC mandate.
5. This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the CHHREC member (Undersigned) in conjunction with the duties as a member of CHHREC. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.
6. As such, the undersigned agrees to hold all confidential information/ data in confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies) shall remain the sole property of the CHHREC.
7. The undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Confidential information includes any information submitted by Researchers in CMNHS and its affiliates, in connection with Ethics Committee review, whether written or oral, including, but not limited to technical, scientific, financial. Minutes of Meeting of CHHREC where discussions about research project reviews were discussed is confidential.
8. I agree to cooperate with the CHHREC Agreement on Confidentiality. (If the Undersigned agrees with the terms and conditions set forth above, please sign and date this Agreement.)
9. The original (signed and dated Agreement) will be kept on file in the custody of the CHHREC. A copy will be given to you for your records. I agree to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Undersigned Signature **Date**

_____ _____

Chairperson's signature **Date**

Reference: *http://www.nirrh.res.in/SOP/03_Confidentiality.pdf*

Appendix 3: Checklist for Low and High Risk

CHECKLIST FOR LOW AND HIGH RISK

Please complete this checklist if your research is considered to be Low/Negligible Risk (category 1 or 2). Once completed please include the checklist with your ethics application as part of the one pdf file process for submission.

CHHREC ID: (*Office Use ONLY)*

Before starting your application, please read this checklist:

Acknowledge the source of this form, James Cook University (JCU)

Please answer each question of the checklist to determine the "risk" to participants in your research project. Your answers to the questions listed will determine whether your application can be reviewed as a low/negligible risk application.

If you answer "YES" to any of the questions, it may indicate that your research is not low/negligible risk.

A "YES" answer does not immediately exclude your application from review. Any "YES" answers will be considered by the College Health Research Ethics Review Committee and you will be advised if your application has been accepted as a low/negligible risk application or if it has been determined that it must be referred to the next meeting of the CHHREC for a full review.

Low risk research is defined as research in which the only foreseeable risk is one of discomfort. Discomforts include, for example, minor side-effects of medication, the discomfort of measuring blood pressure or the anxiety induced by an interview.

Negligible risk research is defined as research in which there is not foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience. Examples of inconvenience may include filling in a form, participating in a street survey, or giving up time to participate in research.

Are any of the following topics covered in part or in whole in your project?				
Research about parenting issues	☐	YES	☐	NO
Research investigating sensitive personal issues	☐	YES	☐	NO
Research investigating sensitive cultural issues	☐	YES	☐	NO
Explorations of grief, death or serious/traumatic loss	☐	YES	☐	NO
Depression, mood states, anxiety	☐	YES	☐	NO
Gambling	☐	YES	☐	NO
Eating disorders	☐	YES	☐	NO
Illicit drug use	☐	YES	☐	NO
Substance abuse	☐	YES	☐	NO
Self report of criminal behaviour	☐	YES	☐	NO
Any psychological disorder	☐	YES	☐	NO
Suicide	☐	YES	☐	NO
Gender Identity	☐	YES	☐	NO
Sexuality	☐	YES	☐	NO
Race or ethnic identity	☐	YES	☐	NO
Any disease or health problem	☐	YES	☐	NO
Fertility	☐	YES	☐	NO
Termination of pregnancy	☐	YES	☐	NO

Are any of the following procedures to be used in your project?				
Use of personal data obtained from Commonwealth or State Government Department/ Agency	☐	YES	☐	NO
Use of personal data obtained from State Government Department/ Agency	☐	YES	☐	NO
Use of personal information from a non-government organization	☐	YES	☐	NO
Deception of participants	☐	YES	☐	NO
Concealing the purposes of the research	☐	YES	☐	NO
Covert observation	☐	YES	☐	NO
Audio or visual recording without consent	☐	YES	☐	NO
Recruitment of a third party or agency	☐	YES	☐	NO
Withholding from one group specific treatments or methods of learning, from which they may "benefit" (e.g. in medicine or teaching)	☐	YES	☐	NO
Psychological interventions or treatments	☐	YES	☐	NO

Administration of physical stimulation	☐	YES	☐	NO
Invasive physical procedures	☐	YES	☐	NO
Invasive physical procedures	☐	YES	☐	NO
Infliction of pain	☐	YES	☐	NO
Administration of drugs	☐	YES	☐	NO
Administration of other substances	☐	YES	☐	NO
Exposure to ionizing radiation	☐	YES	☐	NO
Tissue sampling or blood taking	☐	YES	☐	NO
Collecting body fluid	☐	YES	☐	NO
Use of medical records where participants can be identified or linked	☐	YES	☐	NO
Genetic testing/ DNA Extraction	☐	YES	☐	NO
Drug trials or other clinical trials	☐	YES	☐	NO

Other Risks?				
Are there any potential risks to the researcher? (e.g. research conducted in unsafe environments or trouble spots)?	☐	YES	☐	NO
Are there any potential risks to non-participants in the research, such as, participant's family members and social community? E.g. effects of biography on family and friends or infectious disease risk to the community)	☐	YES	☐	NO

Does your project specifically target participants from any of the following groups?				
Suffers from a psychological disorder	☐	YES	☐	NO
Suffering a physical vulnerability	☐	YES	☐	NO
People highly dependent on medical care	☐	YES	☐	NO
Children and/or young people without parental or guardian consent	☐	YES	☐	NO
People whose ability to give consent is impaired	☐	YES	☐	NO
Resident of a custodial institution	☐	YES	☐	NO
People unable to give free informed consent because of difficulties in understanding information provided e.g. Language difficulties	☐	YES	☐	NO
Members of a socially and/or culturally identifiable group with special social/cultural/ethnic or religious beliefs or political vulnerabilities	☐	YES	☐	NO
Aboriginal and Torres Strait Islander Peoples	☐	YES	☐	NO
Those in a dependent relationship with the researchers eg. Lecturer/student, doctor/patient, teacher/pupil & professional/client	☐	YES	☐	NO
Participants are identifiable in the final report when specific consent for release has not been given	☐	YES	☐	NO

Does your project involve researching in an overseas country?				
Where research is being undertaken in a politically unstable area	☐	YES	☐	NO
Where research involves sensitive cultural/social/political/ethnic/economic or religious issues	☐	YES	☐	NO
Where criticism of the government and institutions may be a risk to participants and/or researchers	☐	YES	☐	NO

Appendix 4a: Supervisor's Endorsement Letter

College Human Health Research Ethics Committee (CHHREC)
Fiji Institute of Pacific Health Research (FIPHR)
College of Medicine, Nursing and Health Sciences
Fiji National University | Hoodless House| Brown Street |Suva
Tel: (679) 3311700 Ext.: 3018/3020/3024 | Website: www.fnu.ac.fj

Date:

The Chairperson
College Health Research Ethics Committee
College of Medicine, Nursing & Health Sciences

Dear Chairperson,

RE: SUPERVISORS LETTER OF ENDORSEMENT FOR STUDENT RESEARCH PROPOSAL

Student Name:	
Student ID:	
Title of Research:	

As Supervisor of the above student project I have reviewed the research proposal and find it to be scientifically sound and practically feasible.

I forward it to the College of Medicine Nursing & Health Sciences: Human Health Research Ethics Committee (CHHREC) for review and approval. I confirm that I will provide continuous guidance and supervision throughout the research process as required and will inform the committee of any changes in supervisory roles.

Yours Sincerely,

.....	.....
(Supervisors Signature)	**(Co-Supervisor Signature)**
Name:	**Name:**
Department:	**Department:**
Email:	**Email:**

Appendix 4b: CHHREC Research Proposal Submission Checklist

College Human Health Research Ethics Committee (CHHREC)
Fiji Institute of Pacific Health Research (FIPHR)
College of Medicine, Nursing and Health Sciences
Fiji National University | Hoodless House| Brown Street |Suva
Tel: (679) 3311700 Ext.: 3018/3020/3024 | Website: www.fnu.ac.fj

CHHREC RESEARCH PROPOSAL SUBMISSION CHECKLIST

Please use the checklist below to ensure all relevant documents are attached to your proposal prior to submission to the College Human Health Research Ethics Committee. Failure to do will result in your submission not being accepted.

Title of Research:	
Student Name:	
Student ID:	
Student Email Address:	
Department and School :	
Programme of Study:	
Supervisor(s) Name :	
Supervisor(s) Designation:	
Supervisor(s) Email Address:	
Co-Supervisor(s) Name:	
Co-Supervisor(s) Designation:	
Co-Supervisor(s) Email Address:	
(Other information)	

Click in the appropriate box	Yes	No
Supervisor's endorsement letter is attached to the proposal document?	☐	☐
Does this research contribute to a formal qualification? *(For Student Only)*	☐	☐
Has this project been submitted to any other ethics committee?	☐	☐
If yes, is the result of the ethics review attached to the proposal document?	☐	☐
Please attach any other relevant documents and list as Attachments)	☐	☐

Appendix 5: CHHREC Guidelines for Development of a Full Research Proposal

CHHREC GUIDELINES FOR DEVELOPMENT OF A FULL RESEARCH PROPOSAL

The recommended outline for a full research proposal is as follows:

---

1. INTRODUCTION
- 1.1 Background Information
- 1.2 Statement of the Problem
- 1.3 Literature Review

2. AIM & OBJECTIVES

3. METHODOLOGY
- 3.1 Study type, variables, and data collection techniques
- 3.2 Sampling
- 3.3 Plan for data collection
- 3.4 Plan for data processing and analysis
- 3.5 Ethical considerations
- 3.6 Pretest

4. WORK PLAN

5. BUDGET

6. PLAN FOR ADMINISTRATION, MONITORING AND UTILIZATION OF RESULTS

Annex 1. References

Annex 2. List of abbreviations (if applicable)

Annex 3. Data-collection instruments (including questionnaires)

1. INTRODUCTION

1.1 Background Information

1.2 Statement of the Problem

The background information included in the INTRODUCTION should certainly contain some background data about the country, the health status of the population, and health service data related to the problem that is to be studied. This may include a few illustrative statistics, if available, to help describe the ***context*** in which the problem occurs. The background information presented should be ***relevant to the problem at hand*** and should not go into considerable detail in the description of things that are not particularly relevant.

In addition to this relevant background information, and as noted in the criteria for the first assignment, the INTRODUCTION should include a Statement of the Problem, which should include:

- a concise **description** of the nature of the problem (the discrepancy between "what is" and "what should be") and its size, distribution, and severity (who is affected, where, since when, and what are the consequences for those affected and for the services?),
- an **analysis** of the major factors that may influence the problem and a convincing argument that available knowledge is insufficient to solve it,
- a brief description of any solutions that have been tried in the past, how well they have worked and why further research is needed,
- a description of the type of information expected to result from the project and how this information will be used to help solve the problem, and
- if necessary, a short list of definition of crucial concepts used in the statement of the problem.

After reading the Background Information and the Statement of Problem, the faculty supervisor (or for that matter, anybody reading it!) should be able to understand ***the reasons for carrying out the study***.

1.3 Literature Review

The Literature Review should be thorough and should:

- be closely and specifically related to the statement of the problem,
- consist of a coherent discussion of one or two pages in **the student's own words**, using all relevant references,
- organize references in groups through the use of statements related to aspects of the problem that they touch upon, and
- address all important aspects of the problem…. If not, more references are needed…. probably at least 10 for these student projects.

2. OBJECTIVES

As noted in the criteria for the first student assignment, the research objectives:

- should be closely and specifically related to the statement of the problem and the literature review,
- should cover the different aspects of the problem and its contributing factors in a **coherent** way and in a **logical sequence**,
- should be clearly phrased in operation terms, specifying exactly **what** will be done in the study, **where**, and for **what purpose**,
- should be **realistic** considering local conditions,
- should use **action verbs** that are specific enough to be evaluated (e.g. "to determine", "to compare", "to verify", "to calculate", "to describe", and "to establish"),
- should avoid the use of vague non-action verbs (e.g. "to appreciate", "to understand", or "to study"),
- might state, through a *general objective*, what is expected to be achieved by the study, followed by *specific objectives*, which are smaller, logically connected parts,
- should include objective(s) focusing on **how the results will be used** (e.g. recommendations, planning).

3. METHODOLOGY

3.1 Study type, variables, and data collection techniques

In this section of the proposal the following should be clearly stated:

- What study type is being used to address the objectives (e.g. descriptive, cross-sectional, case-control, cohort, experimental). This should describe both quantitative and qualitative aspects of the study, and ***the design as suggested should be able to meet the objectives of the study*** as provided in the previous section.
- What are the study variables? How are they *defined* and how will they be *measured*? This should include a description of all relevant:
  - ***exposure variables,***
  - ***outcome variables,*** and
  - ***Confounding variables***.

  These variables should arise from the "factors" noted in the problem statement, and they should relate directly to meeting the study objectives. "Listing" the variables is not acceptable – it is expected that the methodology should outline exactly how the variables will be measured and what outcomes are expected i.e. methodology "proper".
- The methodology should be constructed in a logical sequence outlining processes that if replicated would yield similar results. Students are therefore encouraged to adopt questionnaires and methodologies that have been successfully tested in other settings and may be applicable to their context.
- How will the data be collected? This should include a specific description of what techniques will be used for data collection (e.g. through a questionnaire, with a data collection form for data extraction from a logbook or clinical records, through audio recording of focus group discussions, etc.) Supervisors and researchers are to ensure that questionnaires are relevant to the study and have been designed to answer the study questions.
- All relevant ***data collection instruments*** should be attached to the proposal as an Annex.

3.2 Sampling

This section should include a clear description of how the researcher intends to select the study participants and it should address the following questions:

- Is there a "sampling frame" for the study population (i.e. a listing of all the units that compose the study population?
- If not, what type of nonprobability sampling method is to be used? (e.g. convenience sampling or quota sampling)?
- If yes, what type of probability sampling method is to be used? (e.g. simple random sampling, systematic sampling, stratified sampling, cluster sampling, multistage sampling)
- Has the total number of participants for the study been chosen?…how?….
- Have sources of selection bias been considered in the chosen method?

3.3 Plan for data collection

This section should include a clear description of how the researcher intends to collect their data (Clear, reproducible and sound, step-wise approach to all aspects involving data collection) and it should address the following questions if applicable:

- Can your methods be reproduced by another research team if they followed your proposed methodology?
- Who will collect what, when, and with what resources (i.e. what are the logistics)?
- If human participation is involved, how will consent to collect the data be obtained from relevant authorities, individuals, and/or the community in which the project is to be carried out?
- What steps are being taken to ensure that the data being collected is of good quality (i.e. that it is reliable and valid)?…. this may involve things like verifying that the data needed is present, that pretesting is done for data collection instruments, that consistency is maintained between different observers, etc.

- Is there a clear procedure for data handling and storing?
- Provide a copy of data collection form/ audit form etc.
- Provide a description of how the researcher will recruit participants. Recruitment process needs to indicate that participants are volunteering to participate and there is no coercion.

3.4 Plan for data processing and analysis

This section should include a clear description of how the researcher intends to process and analyse their data and it should address the following questions:

- How will the data be sorted and processed? …manually or by computer
- Will coding be used (e.g. male=1, female=2)… if so, is a data dictionary being used to keep track of how variables are coded?
- What methods are being used to limit errors and to verify that data entry is accurate?
- How are the study variables to be analysed?… for example:
  - frequency counts for categorical variables → frequency tables,
  - cross-tabulations between exposure and outcome variables → calculations of appropriate measure of association (i.e. odds ratio or relative risk), and χ^2 and p values,
  - calculation of measures of central tendency/variability for numeric variables, and
  - use of ANOVA (analysis of variance) for differences in numeric variables between groups, etc.
- What criteria are used to determine statistical significance? (e.g. p value < 0.05)
- If qualitative data is being collected, how will it be analysed and summarized?

For much of the above the presentation of "dummy tables" might be appropriate.

3.5 Ethical considerations

This section should indicate that the researcher has taken into account pertinent ethical considerations in the development of the study. Relevant questions to be answered in this section might include:

- Who will benefit from the research undertaken?... the community?, individual subjects?, health science?, the researcher?… Along this line, there should be a clear demonstration as to how the ultimate utilization of the results provide a substantial benefit that justifies the efforts undertaken.
- Have adequate steps been taken to identify and minimize potential deleterious effects to study participants… for example:
  - side-effects of interventions,
  - untoward effects of withholding treatments known to be effective,
  - risks from invasive assessment techniques,
  - pain, anxiety, discomfort and embarrassment, and (especially if the activity taken is not part of normal practice)
  - Welfare of laboratory animals.
- Is there adequate consideration of informed consent?. including:
  - have potential risks and benefits of participation been explained,
  - have any procedures to be used been explained,
  - is it made clear to the participant that they have the free choice to either refuse to participate or to withdraw from the study *without* any negative impact on their subsequent care?
- If complete informed consent is not possible, are adequate measures taken to protect the rights and welfare of the participants?
- Have adequate steps been taken to ensure the confidentiality of patient data and the anonymity and privacy of participants?
- Have the values of the community and any potential taboos been considered and respected?
- Has the investigator been careful not to inappropriately raise expectations among the participants and the community as to the outcomes of the study?
- Overall, has there been adequate planning and appropriate design of the study methodology such that the time and effort of the researchers and subjects is not wasted?.

Note: this implies that the legitimate and correct use of research methodology is an ethical necessity.

3.6 Pretest Applicable only to large-scale studies e.g., Community/ Prospective studies

In this section the investigator should describe the components of a pretest or pilot study that will allow for a test of, and if necessary, a revision of the proposed research methodology before starting the actual data collection. In regards to these concepts:

- a pretest usually refers to a small-scale trial of a particular research component (e.g. seeing whether or not a questionnaire is understood by people and yields the type of data expected), and
- a pilot study is the process of carrying out a preliminary study, going through the entire research procedure with a small sample.

In either case, the process serves as a trial run that allows for the identification of potential problems in the proposed study. This process allows for a revision of the methods and logistics of data collection before starting the actual fieldwork. Hence, the use of a pretest or pilot study is important if:

- Difficulties can be anticipated in the implementation of the proposal (e.g. bias in data collection or sampling, ethical problems, etc.),
- the investigator has little experience with a certain data-collection technique (e.g. use of focus group discussions, implementing a new questionnaire, etc.), or

- Parts of the study are particularly costly or time consuming (e.g. the use of questionnaires in large surveys, the translation of a questionnaire or interview schedule, etc.).

If the investigator chooses not to use a pretest or a pilot study, then there should be an explanation as to why this is so (e.g. because the methods have been demonstrated in previous studies to be sound and because the investigator is well versed in the use of all data collection methods and instruments).

4. WORK PLAN

In this section the investigator should present a reasonable work plan for the proposed study. A work plan is a schedule, chart, or graph that summarizes, in a clear fashion, various components of a research project and how they fit together. Such a plan will usually include a schedule that includes:

- the tasks to be performed,
- the dates each task should begin and be completed,
- the personnel assigned to the task, and
- an estimate of the time required to complete the task (e.g. in person-days).

5. BUDGET (if applicable)

In this section the investigator will provide of all expenses *for which they will need support*. The budget should be detailed enough to understand all costs, and should include a justification as an explanatory note discussing why the various items in the budget are needed. Usually, the methodology is used as a guide to predict actual cost to be incurred by the project as the activities will automatically provide a basis for expenditure.

6. PLAN FOR ADMINISTRATION, MONITORING AND UTILIZATION OF RESULTS

In this section the investigator will provide a statement as to how the project will be managed and monitored to ensure its timely progress (e.g. by the investigators use of the work plan and on-going monitoring to make any necessary changes).

Additionally, and most importantly given the "action orientation" of health systems research, this section ***MUST*** include a clear statement as to how the results of the study will be utilized and disseminated. Indeed, the fundamental reason for undertaking health systems research is to obtain results that can be used to improve health and health care. Hence, this statement should outline specific strategies that will ensure that the results will be used. These strategies might include:

- the involvement of relevant authorities, staff, and community members in the design of the study, in the dissemination of the results, and in the implementation of the recommendations,
- a description of the process wherein study recommendations will be presented, and hopefully, acted upon,
- the identification of communication channels that will be used to disseminate the studies results and recommendations, and
- a determination of what materials will be prepared (e.g. reports of findings for different audiences) and what processes will be undertaken (e.g. presentations to the community, involvement of policy makers, etc.) to ensure that the results and recommendations of the study will be used.

7. REFERENCES

All references noted in the INTRODUCTION (or any other section) should be included in this section. References should be consistent with "the Vancouver System" or as required by the program/ agency etc. For detailed resources, please visit the research website. Some examples are provided below:

- For an article, the following information should be noted:
  Author(s) (surname followed by initials). Title of article. Name of journal, year; volume number: page numbers of article.
  Example:
  Gwebu ET, Mtero S, Dube N, Tagwireyi JT, Mugwagwa N. Assessment of nutritional status in pregnancy: use of a reference table of weight-for-height. Central African Journal of Medicine, 1985; 31: 193-196.

- For a book, the following information should be noted:
  Author(s) (surname followed by initials). Title of book. Edition. Place: Publisher, year: number of pages in the book.
  Example:
  Abramson JH. Survey methods in community medicine. 2nd ed. Edinburgh: Churchill Livingstone, 1979: 229.

- For a chapter in a book, the citation can include:
  Author(s) of chapter (surname followed by initials). Chapter title. In: Editors of book (surname followed by initials). eds., Title of book. Place: Publisher, year: page numbers of chapter.
  Example:
  Winikoff B, Castle MA. The influence of maternal employment on infant feeding. In: Winikoff B, Castle MA, Laukaran VH, eds. Feeding infants in four societies: causes and consequences of mother's choices. New York: Greenwood Press, 1988: 121-145.

Appendix 6: Data collection form – for Quantitative Research

Questionnaires and surveys
A questionnaire is a standardised, structured instrument with a focus on closed questions, administered in a standard way to (usually) large numbers of people.

Questionnaires are best used when you:
• have a large sample;
• want straightforward, standardised information; and
• are more interested in what happens, rather than why or how.

They can ask questions about knowledge, attitudes or opinions, behavior, and personal attributes, but are based on self-report – what people remember or report about themselves may not be the same as actual behavior. They are also limited in that they gather superficial information and cannot take into account context or attribute causality.

Questionnaires can be administered by mail, by telephone, by email, over the internet, or face-to-face. Each of these has various advantages and disadvantages in terms of standardisation, cost and response rate. It may be that a relevant and well-validated questionnaire already exists in your area of interest – if so use it, as it will permit comparison between data sets, and should have been thoroughly assessed for reliability and validity. You may need to talk to a number of experienced researchers in your field to identify the questionnaire instruments that exist.

A good quantitative research design involves:
• testing a specific theory
• With a representative sample of a population
• analyzing with appropriate statistical techniques
• In a way that is generalisable to the wider population

For example, data entry sheet for data collection in Excel Format

Participants' Code or Case Numbers	**Variable 1 E.g. Age**	**Variable 2 E.g. Height**	**Variable 3 E.g. Weight**	**Variable 4 E.g. Diabetic (Yes/No)**	**Variable 5 E.g. Taking medication**
001/CWMH_2020	55	170cm	95kg	Yes	Yes
002/CWMH_2020	18	165cm	55kg	No	No
003/CWMH_2020	15	150cm	50kg	Yes	Yes
004/CWMH_2020	25	190cm	96kg	Yes	No
005/CWMH_2020	32	187cm	112kg	Yes	Yes
006/CWMH_2020	43	157cm	60kg	Yes	Yes
007/CWMH_2020	72	159cm	55kg	Yes	Yes

Appendix 7: Interview Guide Questionnaire – for Qualitative Research

In qualitative research our aim is to explore the question under investigation, and work together with participants to gain a shared understanding of meaning. Qualitative researchers need to be especially careful to be reflexive in their practice. This means being highly aware of the role they play in collecting and interpreting data, and how their own backgrounds and views may have an impact on the findings. "Interviewing is data collection in face-to-face settings…" Qualitative interviews can be unstructured (without formal ordering of questions), semi-structured (using a question guide) or structured (using a set of questions). Questions are usually open-ended, that is they require more detail and explanation than a yes or no answer.

Unstructured Interviews
Unstructured or undirected interviews aim for open and frank discussions, led by the interviewees, rather than the interviewer. The researcher has no set questions, but may use a topic list as an aide memoire of areas to cover. This method allows the informant to discuss their experiences in their own way. The researcher needs to be skilled at probing for further detail and clarification, without steering the interview to their own agenda.

Semi-structured Interviews
Semi-structured or focused interviews are conducted with an interview guide or a list of questions or topics to be covered by the interview. The exact order of questions will vary dependent upon the informant. There are different types of semi structured interviews:

- **In-depth Interviewing**
  In-depth interviews look intensely at a topic, to gain a rich, complete understanding from the informant's point of view. The Interviewer uses an interview guide and seeks clarification and amplification as necessary.

- **Case Studies**
  A case study is a very detailed study of a particular case. The researcher collects comprehensive information on a person, an event, an illness-episode, a programme, an Organisation, a time period, a community, etc. Information is gained through loosely structured interviews or participant observation (see below).

  The case study is seen as a single example of many cases, and researchers do not claim that these can be generalized. These provide detailed information about particular cases, in a particular context. They are useful when an in depth understanding is required to develop other research methods such as questionnaires. Case studies are not usually conducted alone, but are used in combination with other qualitative methods.

- **Life Histories**
  Life histories are informants' personal biographies collected over a series of many long interviews (both structured and semi-structured). Researchers examine informants' values, cultural interests and social relationships. Life histories are best used as explanatory and illustrative evidence in connection with other representative data. One drawback is that informants may be atypical as they were willing to be interviewed, and there may be problems of representativeness.

Open Ended Questions - Examples
Change these closed questions to open ended questions:

- Would you agree that nipple piercing should be prohibited?
- Do you like the occupational therapist at the hospital?
- Is it difficult for you to find a doctor out of hours?
- Did the Aboriginal Health Worker explain to you how your diabetes medicine works?

Structured Interviews
Structured interviewing involves asking informants exactly the same questions. These include questionnaires, free listing, pile sorts, rating scales and rank order methods. These methods are usually used to follow-up more open-ended qualitative research.

Group Interviewing Techniques
Group interviews are a way of collecting data from several people in one setting. Group interviewing techniques include focus groups and group discussion. Importantly, the unit of analysis is the group rather than individual group members (i.e. young people as a group, not the individual young people who took part of the interview).

Focus Groups
The usefulness of data from focus groups relies heavily on interaction between participants. Therefore, focus groups work best when participants are comfortable enough to share their beliefs and experiences in the group setting. Groups should be held at a convenient time for informants and in a particular setting where they feel comfortable. This will help encourage candidness and spontaneity. Group members may influence each other by responding to the ideas and comments that come up during discussion. This interaction is a unique feature of focus groups. This data collection method can be used to assess needs, develop interventions, test new ideas or programs and improve existing programs.

Focus groups are also useful for exploratory studies in health issues; solving specific program problems;
and evaluating health programs. They can be used as a 'self-contained' method, or as the primary source of data collection. They are useful as supplementary sources of data to develop questionnaires or interview guides for individual data collection or to validate the findings of

quantitative surveys or other forms of research evidence. Focus groups should typically consist of 6 to 8 people with a shared socio-cultural background (age, sex, socio-economic, education and ethnicity) or shared interest or experience (illness, attitudes). Participants are recruited based upon a shared criteria (for example, young Indigenous women at a high school aged 15-17) (see Example 9.2 below). This shared experience usually creates a comfortable environment for open discussion. Participants in focus group discussions often do not know each other, but sometimes groups of friends may be selected. Separate focus groups may need to be held for men and women.
This also applies for age, ethnic group, etc., depending of course on the subject or your research. You should also hold at least two focus groups for each "type" of respondent (i.e. young versus older; higher vs. lower socioeconomic).

Another good reason for holding separate focus groups for each "type" of respondent is finding a time that ensures participation by a broad spread of people; e.g. daytime meetings might suit retired or unemployed people, while evening meetings might better suit those who work or have small children. If your target group is aged people, then a daytime meeting is likely to suit most invitees. If your focus group consists of a spread of age groups and employment status, for example, then it may be more difficult to find a time that suits all. Thus, your focus group attendees might not reflect your target group well. At least two researchers must be available to conduct focus groups. A moderator, who speaks the local language, facilitates discussion using a topic guide and open-ended questions. They encourage interaction and guide conversations. A note-taker records key issues and other factors such as non-verbal responses and interaction and dynamics. To protect confidentiality, note takers should draw a diagram of the group, allocating each member a number (e.g. M1= Male one). If focus groups are not taped, there should be two note takers. One note taker records the discussion and the other records non-verbal cues. It is crucial that note takers only record facts, not interpretations of what is occurring. Focus groups should last no longer than two hours so as not to tire or bore the participants. Sometimes incentives are paid to participants to thank them for their contribution, transport costs may be covered, food and drink is offered.

Example: Focus Group

Focus group discussion about sexual behavior with 15-17 year old girls in schools

SL: Do you think that boys and girls want to have sex the same amount?

P3: Oh, I reckon it's just the boys first, but then they turn the girls on with the way they talk and act, you know….

Ps [Eagerly, interrupting]: Yeah, they just like put on a show….

P3 and Ps: Yeah, they just put on a show….and once they get you in bed….., and they sneak up to you and stuff like that, with other boys that come to you, they like pull you away, and they're one person, and they're like I'll be back, I'm scoring, and shit like that, and Then they come up to you, and they're like, are you alright, come into the bedroom, we'll just talk, and that's when they turn the lights Out…[general agreement from others]

P2: What do you call it, they…ss…persuade… [Searching for word]

PP: Seduce.. ?

P2: Yeah, seduce you..

P3: Yeah, especially like when they do it really, really kindly, and it just turns you on the way they do it….[others laugh]…oh sorry, and then that's when it happens, but it depends if it's a cute guy you did it with, or if he's well known….then the girls like brag about it at school, and then as soon as you say the name if everyone's saying oh, that's a geek man, then you're like, but he was bad…you know….

Appendix 8: Participants' Information Statement

PARTICIPANTS' INFORMATION STATEMENT

1. **Study title**

Simplify the title to the level of understanding of the potential participants.

2. **Invitation/Information paragraph**

Explain to potential participants that they are being asked to take part in a research study. Identify the aims of the research and its anticipated duration, identify who is funding it, any institutions involved and give the names of the principle researcher.

3. **Why have I been chosen? Do I have to take part?**

Explain how the potential participants are chosen and how many other participants will be involved in the study and that participation is entirely voluntary. You can explain to the participant that they can withdraw from the study at any time without any implications.

4. **What will happen to me if I take part – or don't take part?**

State how long the study procedures will take and what will be done (an interview, survey form completed, observations made, samples taken do). Set down clearly what you expect of them. State that if they choose not to participate in the study that there will be no change in your service response to their needs.

5. **What are the possible disadvantages and risks of taking part?**

Identify any possible disadvantages of taking part. For example, time may need to be set aside, visits may be needed, or samples taken. If an intervention is planned the possible risks should be stated (e.g. a reaction to a new drug, bruising at the site of the needle, possible tensions among new housemates etc.).

6. **What are the possible benefits of taking part?**

Benefits may or may not accrue to study participants. Benefits, for example: maybe for others who suffer from the same disease, maybe for policy advice, for health care management systems improvements, and the benefits for the general population.

7. **Will my taking part in this study be kept confidential?**

Explain the processes used to protect identity and the confidentiality of participants.

8. **What will happen to the results of the research study?**

Explain how the information will be published, how it will be used and how they can obtain a copy of the published results.

9. **Contact for Further Information**

Provide potential participants with names and contact points for further information.

10. **Thanks for Participating**

Thank the potential participants for reading the information sheet and invite them to complete the Consent Form.

Note: The participants' information statement and participants 'consent form should be dated.

Appendix 9: Voluntary Informed Consent Form

VOLUNATRY INFORMED CONSENT FORM

Title of Study:	
Name(s) of Principal Investigator(s):	

This document is to certify that I, *(name of participant);*

- have had the research project and my role in it fully explained to me by (*name of Interviewer)*
- have been given an opportunity to ask questions, and all of my questions and have been answered
- to my satisfaction,
- understand that all data will remain confidential with regard to my identity; and
- Understand that my participation in this research project is voluntary and that I am free to withdraw my consent and discontinue my participation at any time.

I hereby freely agree to participate in this study;

…… ……

Signature of Participant Date

I, the undersigned, have fully explained the research to the above participant.

…… ……

Signature of the Informant/Clinician/Researcher Date

NOTE: When a signed document is used, a copy must be provided to the participant so she/he will have a record of her/his agreement to participate.

Appendix 10: Assent Form

ASSENT FORM

Research Title:	
CHHREC ID:	
Name of Participant:	
Address:	
Age:	

The points below can either be typed as a statement and read and explained to the participant or can be represented diagrammatically or as audio visual aid (e.g., cartoon, video) according to the level of understanding of the participant.

1. Statement of the purpose of the research.
2. Description of the procedures to be applied to the minor
3. Description of potential risk and discomfort of the procedure associated with the research
4. Description of the benefits of the direct benefit to the minor
5. Explanation that the participation is voluntary and that they can withdraw from the study at any time
6. Statement that the minor should discuss whether or not to participate with his/ her parents prior to signing the form

The study and the purpose of my participation have been explained to me. I understand the risks and benefits associated with the study and that I am free to withdraw from this study at any time. I agree to voluntarily participate in the study.

Signature/Thumb impression: | |

Name of researcher taking consent: _____

Signature of researcher taking consent: _____

Date: _____

Appendix 11: Secondary Data De-identification Code – Sample Form

SECONDARY DATA DE-IDENTIFICATION CODE - SAMPLE FORM

Please note this form is only a sample but the researchers can design their forms to be consistent with the research design.

SL no	Name	Age	Address	Ethnicity	Code no
1	Vincy Smith	25	Lot 1, Naulu, Nakasi	Fijian	Sl no- first and last letter of name- age

Appendix 12: Progress Report Form

College Human Health Research Ethics Committee (CHHREC)

PROGRESS REPORT FORM

Approval of research projects by the CHHREC requires the provision of a progress report within 12 months of approval. Please provide an electronic copy to the CHHREC Secretariat on email: CMNHS-RCO@fnu.ac.fj

CHHREC ID:	
Research Title:	
Principal Investigator:	
Supervisor(s):	

Please list current research team members

Name	Role	Other Notes

STATUS OF PROJECT:

Date of Commencement:	
Proposed Completion Date:	

Progress Report:

Give a brief statement on progress so far. Please include original aims and a summary of work completed and/or findings to date.

Please answer the following: (☒ mark the appropriate box)	Yes	No	Not Applicable
Have you encountered any problems in the following areas? ☐ Study Design ☐ Ethics ☐ Finance ☐ Recruitment of Participants ☐ Facilities, equipment If YES to any of the above, please provide summary of problems encountered. …… ……	☐	☐	☐
Have any participants withdrawn from the study since the last approval? If YES, please provide details. …… ……	☐	☐	☐
Have any adverse events, unexpected side effects, complications or other issues observed or any new ethical issues emerged since the last approval? If YES, please provide details. …… ……	☐	☐	☐
Has any information come to light from this, or other similar studies which might affect the CHHREC's perception of the risks/benefits assessment conducted about this study? If YES, please provide details. …… ……	☐	☐	☐
Has written informed consent been obtained, and will continue to be obtained, from all	☐	☐	☐

participants? If NO, please provide an explanation. …… ……			
PUBLICATION: (☒ mark the appropriate box) - *Please attach copies and links of all publications.* …… ……..			
Have you published your findings? If YES, please indicate the details of your publication (listing the full reference e.g. authors, title, journal, date, pager numbers etc.). …… ……..	☐ Yes ☐ No		
If NO, do you intend to publish your findings?	☐ Yes ☐ No		
PRESENTATIONS: (☒ mark the appropriate box)			
Have you presented your data at a scientific meeting? If YES, please provide details. …… ……	☐ Yes ☐ No		

I confirm that this project is being conducted as originally approved by the College Human Health Research Ethics Committee (CHHREC), subject to any changes subsequently approved and that all adverse events are reported to the Committee according to the guidelines for reporting of adverse events.

…….. ……..

Signature of Principal Investigator Date

SELF ASSESSMENT CHECKLIST:

Please (☒ mark the appropriate box)	YES	NO	N/A

All documentation for this project is up to date and are accessible.	☐	☐	☐
Recruitment of potential participants have been made only by the project team members.	☐	☐	☐
The project team meet regularly to discuss project progress. There is a regular meeting of the study team including the Principal Investigator/s to discuss the progress of the study and a record of these meetings is maintained.	☐	☐	☐
All project staff are trained in the study protocol before being involved in the study.	☐	☐	☐
Ethics and Governance	YES	NO	N/A
The study is being conducted in accordance with the protocol approved project proposal. Any modifications have been reported to CHHREC and the relevant documents updated.	☐	☐	☐
All adverse incidents have been reported to CHHREC.	☐	☐	☐
Participant Information and Consent Form	YES	NO	N/A
Signed consent forms have been obtained from all participants (where applicable) and reconsented if necessary. They are stored securely and are available for audit.	☐	☐	☐
Participants know who to contact if they have a question, complaint or an emergency.	☐	☐	☐
All study participants have been provided with a copy of the Participant Information Template approved by the CHHREC.	☐	☐	☐
A translator and/or a translated copy of the Participant Information Template in his/her own language has been provided to all non-English speaking participants.	☐	☐	☐
Data Integrity and Privacy	YES	NO	N/A
Any personal identifying information that has been transferred to portable drives including USB sticks or portable computers has security measures in place to ensure no unauthorised access.	☐	☐	☐
All computer files containing study data are passwords protected.	☐	☐	☐
All principal computer files containing study data are stored on a secure network drive where they are regularly backed up.	☐	☐	☐
All paper-based questionnaires have the identifying information removed immediately after processing and are then identifiable only by a code. The 'code-key' is stored separately under	☐	☐	☐

lock and key at all times.			
Comments			

FORM COMPLETED BY:

Principal Investigator:	
Student ID/Staff ID: (as appropriate):	
Program:	
School:	
Signature:	
Date:	

Appendix 13: Definition of Vulnerable Populations

DEFINITION OF VULNERABLE POPULATIONS

Vulnerable populations are those that are relatively (or absolutely) incapable of protecting their own interests, either because of insufficient power, intelligence, education, resources (including financial resources), strength or other needed attributes to protect their own interests (CIOMS, 2002). They may include but are not limited to:

- Children, including newborns and minors who are (under 18 years old); fertilized ova, pregnant women and viable foetuses
- People whose judgment or capacity to make free-willed, informed decisions is limited or compromised. This includes cognitively-impaired people with conditions that affect their decision-making abilities.
- Participants with limited civil freedom, such as wards of the state, residents or clients of institutions for the mentally ill, populations under judiciary care and people in long-term care facilities, among others.
- Participants recruited from emergency medical facilities, intensive care units, older people in long-term care facilities, life threatening situations or the like.
- Participants whose economic conditions predispose them to certain incentives
- Populations subject to stigma and discrimination.

Fehoko, E. S., Bellringer, M. E., & Fairbairn-Dunlop, P. (2022). Culture, church, and collective: a qualitative study about gambling harm prevention and reduction in Aotearoa/New Zealand-a Tongan male perspective. *Harm reduction journal, 19*(1), 134-134. doi:10.1186/s12954-022-00717-2

Naidu, V., Matadradra, A., Sahib, M., & Osborne, J. (2013). Fiji: The challenges and opportunities of diversity.

Suaalii-Sauni, T., & Fulu-Aiolupotea, S. M. (2014). Decolonising Pacific research, building Pacific research communities and developing Pacific research tools: The case of the talanoa and the faafaletui in Samoa. *Asia Pacific Viewpoint, 55*(3), 331-344.