FIJI NATIONAL UNIVERSITY

2018

College Health Research Ethics Committee (CHREC)

College of Medicine Nursing and Health Sciences

Standard Operating Procedures

Table of Content

Acknowledgment

We are pleased to present the Standard Operating Procedures (SOP) for the College of Medicine Nursing and Health Sciences (CMNHS), College Health Research Ethics Committee (CHREC).

This SOP was compiled by members of the CHREC committee and Secretariat, 2017. 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 from existing documents to develop the CHREC SOP while ensuring relevance to the CMNHS.

We wish to thank all the CHREC members who have contributed to the compilation of this SOP.

List of Acronyms

CHREC	College Health Research Ethics Committee
CIOMS	Council for International Organizations of Medical Sciences
CMNHS	College of Medicine Nursing and Health Sciences
FNHRERC	Fiji National Health Research Ethics Review 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
WHO	World Health Organization
WHO WPRO ERC	World Health Organization, Western Pacific Region, Ethics Review Committee
WMA	World Medical Association

1. Introduction

Health research has been widely accepted as vital in the endeavour of maximizing health and health gain attainment. 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 principle of "do no harm" 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 undergraduate programs in medicine, dentistry, pharmacy, health, medical imaging, medical laboratory technology, public, nutrition, 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 on the CMNHS can be found at the link: *http://www.fnu.ac.fj/college-of-medicine/*.

3. Overview of College Health Research Ethics Committee (CHREC)

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 review committees.

CHREC is the research bioethics and oversight committee of the CMNHS. The CHREC 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.

3.1 Committees

It is the responsibility of the Chair or the representative of the Chair of the Research Committees to ensure that committees function in accordance with the Fiji National University Research Policy. Research Committees must record all research submitted to the respective committees with records of review, feedback and decisions.

The Research Committees within the CMNHS are the CHREC and the **School(s) Research Committees (SRC).** The SRCs are research committees located in the five schools of the CMNHS. The functions of the SRC focus on nurturing research within their schools for both staff and students and contribute towards the function and activities of the CHREC.

3.2 Constitution of Membership

3.2.1 Chair and Vice Chair

Membership shall consist of the Associate Dean Research (CMNHS) who will be the Chair and constitute 1 voting right. A Vice Chair shall be elected by members of CHREC. The role of Vice Chair is to perform the duties of the Chair in the absence of the CHREC Chair. If the Chair and Vice Chair are not available simultaneously, the Chair shall nominate someone from the CHREC Committee to Chair.

3.2.2 CMNHS Members

The Head of School of each School in CMNHS can nominate three representatives as members of CHREC. These members should be the Chair-School Research Committee

(SRC), the Co-chair SRC and Secretary SRC. However each school represented at CHREC will have 2 voting rights.

Staff of the CMNHS Research Unit will be included as members of the CHREC but together represent 1 voting right.

3.2.3 External Members

As recommended by International Guidelines, includes a clergy, a lawyer, community members (lay persons, a man and a woman), a social worker and representatives from Ministry of Health Fiji National Health Research Ethics Review Committee (FNHRERC).

3.2.4 Ad hoc Committee Members

The CHREC secretariat shall maintain a list of experts on specific health issues. They shall be called upon when required by the CHREC depending on the need and the topic of the research proposal in review. Ad hoc 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 ad hoc members' list. They may be invited to attend a meeting to discuss a research proposal that involve specific vulnerable populations

3.3 Terms of Membership

A member shall serve for a period of one academic year. The CHREC Secretariat shall call for nominations for membership from the Head of School by the end of each academic year. The nomination shall be received by CHREC Secretariat by the second week of December. The nominees shall serve for the next academic year.

It is advisable that newly appointment members of the CHREC are to 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 a general awareness of research ethics principles and the international standards of research ethics. Members can also attend Research Ethics Training sessions offered at the CMNHS.

3.4 Secretariat

The CMNHS Research Unit will provide the Secretariat and support services for CHREC.

3.5 CHREC Meetings

3.5.1 Frequency of Meeting (Modes and Special Meeting)

The CHREC meet on the second Wednesday of every month except for the month of January and December. Special meetings can be convened as and when the need arise at the request of the Chair of the CHREC. When special meetings are convened, notice shall be circulated by the CHREC secretariat along with the agenda.

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 Secretary well before the meeting dates. The Secretary 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 CHREC meeting would mean 50% of full membership. This includes the Chair, School representatives and external members.

3.5.4 Attendance

Attendance of CHREC meetings shall be defined as follows:

i. Not attending meeting without representatives and without apologies will be counted as absent
ii. Apologies without representative will be counted as absent
iii. Apologies with representatives will be counted as active. Representatives are members of School Research Committees with in-depth research and ethics knowledge.
iv. Absent (or apologies) two times without representatives – letter of warning sent to member and copy to supervisor
v. Absent (or apologies) three times without representatives – letter to be sent out to member notifying release from CHREC duties, and letter to Head of School to request for a replacement.

3.5.5 Redundancy

Redundancy is defined as being absent for three consecutive times. To maintain membership, a CHREC member must have an attendance of at least 60% for an academic year. If a member is categorised as redundant a replacement shall be sought from the Head of School.

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.

3.5.6 Confidentiality of Meetings and of Applications for Ethics Review

All CHREC meetings are held in private and members are encouraged to discuss applications for ethics approval of research, freely and raise matters of concerns. All proceedings are confidential.

Appointed members are to sign a declaration of confidentiality.

Attendance of ad hoc members or observers at CHREC meetings shall have prior approval from the Chair and they are required to sign the declaration of confidentiality.

All documents submitted with applications for ethics reviews are to be kept confidential.

CHREC communications shall be made by the Secretariat or the Chair of CHREC 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.

3.5.7 Meeting Records

The CHREC Secretary will record the proceedings of all CHREC meetings, prepares the minutes in consultation with the Chair. The minutes are circulated to all members within five working days after the meeting. The minutes are tabled at the next CHREC meeting. The minutes will reflect each item listed for discussion on the agenda. Confirmation of minutes of previous meeting(s) will be conducted in the next CHREC meeting. **The minutes are confidential to CHREC and are not disclosed to investigators or their sponsors**.

4. CHREC Standard Operating Procedures (SOP)

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

The SOP ensures that CHREC 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 at https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

ii. Council for International Organizations of Medical Sciences (CIOMS) Associate partner of UNESCO in official relation with WHO. This document is available at; www.cioms.ch/index.php/12-newsflash/400-cioms-inernational-ethical-guidelines

iii. WHO Western Pacific Region, Ethics Review Committee, Standard Operating Procedures, Available at:

http://www.wpro.who.int/publications/The_Ethics_Review_Committee_WPRO-ERC/en/

iv. Fiji Ministry of Health and Medical Services, Fiji National Health Research Guide 2015. Available by request to the MOHMS.

v. The University of Queensland, Human Research Ethics Committees: Standard Operating Procedures, 2016, available at www.uq.edu.au/research/integrity-compliance/files/human/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, CHREC will ensure that any staff and students' (and their affiliates) involved as member of the research team involving human participants meets ethical standards in accordance with accepted principles of research ethics, which includes respect for people, beneficence, non-maleficence and justice.

CHREC 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.[1]

4.1 Purpose of CHREC SOP

i. To describe the structure, roles, review processes that guide CHREC functions.

ii. The SOP is applicable to human research conducted by students, staff and their affiliates. Researchers have the responsibilities of abiding by research ethics governance mechanisms of their chosen research setting. An approval from CHREC does not mean an umbrella approval for all ethics committees. A CHREC approval means that CHREC has reviewed the research proposal and addressed any ethical issues identified.

iii. The SOP guides all researchers who are staff or students at the CMNHS, understand whether their proposed health research project is eligible for Low Risk (LR) Ethics Review, High Risk (HR) Ethics Review or is Exempted (E) from ethics review. A checklist of "Concepts" to be used to determine the level of risks posed by a research is found in Annex 2. Researchers are to read and understand in order to make an informed classification of the research project level of risk, as high or low risk.

iv. To map the process of submission of applications for ethics review of research proposals from staff and students through to the College Health Research Ethics Committee (CHREC).

[1] (WPRO ERC SOP, 2011).

a. To guide the roles of College Health Research Ethics Committee (CHREC) and School Research Committees (SRCs).

Principal investigators, leaders of research groups, or supervisors of students' research projects are to study this document before deciding to submit a research proposal for review. Researchers (Supervisors in the case of a undergraduate students) 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 and research bioethics training sessions (Annex 3 has a list of research bio-ethics training conducted by the Research Unit), 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 skillfully 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 Handbook for Research Studies, available at http://www.fnu.ac.fj/new/images/policies-regulations/Handbook_for_Research_Programmes.pdf

5. Submission of New Research Proposals

All proposals must be submitted to the CHREC Secretariat on email CMNHS-RCO@fnu.ac.fj by the

i. primary supervisor (for student research projects),
ii. principal investigator for staff research,
iii. local investigator in case of collaborative research.

A full research proposal submitted in the format of the CMNHS Health Research Proposal Template[2] ***(Annex 4)*** and in accordance with the Guidelines[3] for the Submission of a Health Research Proposal ***(Annex 4)***. The Data Collection Forms, Participant Information Sheets and Voluntary Informed Consent Forms are considered part of the Research Protocol and must be submitted together.

[2] CMNHS Health Research Proposal Template
[3] Guidelines for the Submission of a Health Research Proposal

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 CHREC template. Incomplete applications, which may include missing necessary attachments or not using CHREC template, will be returned to the person who made the submission and copied to all original recipients of the submission via email.

A complete submission is described below.

Students proposal submission: Documentation required

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, co-supervisors, and SRC Secretariat.

i. Full Research proposal using the CHREC Proposal Guideline template. (Annex 4)
ii. Supervisor(s) endorsement letter using the CHREC template. (Annex 5)
iii. Permission from the Medical Superintendent (if data collection involves any Government Hospital) and Person in Charge (e.g. CEO or Owner) in the case of private health facilities.
iv. Permission from the Dean, CMNHS if data collection involves FNU staff and/or students as participants.
v. Permission from Head of Unit/ Division in case of Government, Ministries or Agencies and Non-Governmental Organizations (NGOs) if conducting research in their organizations and premises.
vi. 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.

Example Case Scenarios

Example 1: FNU student conducting a study in their home country will require items (i), (ii), and (vi). Item (iii) if involving hospital and item (v) if involving NGOs.

Example 2: A student conducting a study on Cancer Survivors and wishing to collect the data through the Fiji Cancer Society will require items (i), (ii), and (v).

Example 3: FNU student wishing to collect data involving FNU staff and/or student participants will require items (i), (ii), and (iv).

Staff Proposal Submission: Documentation required

For staff research (independent or collaborative), submissions must be copied to co-investigators, collaborators as appropriate, as well as SRC Secretariat.

i. Full Research proposal using the CHREC Proposal Guideline template. (Annex 4)
ii. Supervisor(s) endorsement letter using the CHREC template. (Annex 5)
iii. Permission from the Medical Superintendent (if data collection involves any Government Hospital) and Person in Charge (e.g. CEO or Owner) in the case of private health facilities.
iv. Permission from the Dean, CMNHS if data collection involves FNU staff and/or students as participants.
v. Permission from Head of Unit/ Division in case of Government, Ministries or Agencies and Non-Governmental Organizations (NGOs) if conducting research in their organizations and premises.
vi. 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.

Example Case Scenarios

Example 1: FNU staff is a ***principal investigator (or co-investigator)*** on a collaborative study involving an ***overseas academic institution*** with data collection occurring in Fiji health care system. Submission will require items (i), (ii) and (v). Item (iii) if involving hospital and item (iv) if involving FNU staff, student as participants.

Example 2: FNU staff is a ***principal investigator*** on a collaborative study involving an ***overseas academic institution*** with data collection occurring in ***Fiji health care system and another country***. Submission will require items (i), (ii) and (v). Item (iii) if involving hospital, item (iv) if involving FNU staff, student as participants and item (vi) if involving health care system of another country.

Example 3: FNU staff is a ***principal investigator*** on a research study with data collection occurring in ***Fiji health care system*** and is undertaking the research as a requirement for the fulfillment of their postgraduate studies**.** Submission guidelines for students will apply (see Section 5.1 above).

Special Conditions

5.3.1 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 CHREC secretariat as described earlier. The CHREC may recommend full review, expedited review or exemption from review. Proposals that also attach already received health ethics review and approval from a recognized **health research ethics committee** elsewhere, is helpful, but does not guarantee approval from CHREC. CHREC will still need to assess the proposal based on its SOP.

5.3.2 Staff research in another country

Where CMNHS staff 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, log research or in certain circumstances obtain ethical approval from CHREC, if the research is conducted in the area of health.
The purpose of submission to CHREC is for the following reasons:

- Ensure any real or perceived risks attributable to the institution through the researchers' involvement in such projects are addressed, eliminated or minimized.
- 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 documentation they deem important) from collaborating institutions to enable the CHREC secretariat to ascertain whether the proposal needs to be tabled in CHREC or recorded in the CHREC database or review through the CHREC process or a combination of the above actions.

5.3.3 Staff as a CHREC member

CHREC members will be required to declare any conflict of interest in all CHREC meetings and when appropriate be asked to leave the CHREC meeting deliberations when proposals or issues relating to themselves, their department or student colleagues are being discussed.

6. ETHICS REVIEWS OF RESEARCH PROPOSALS

6.1 CHREC Reviewers and their Roles

CHREC members and CMNHS staff recommended by CHREC as reviewers are tasked with the review of research proposals. CHREC reviewers will assess proposals for the level of risk. CHREC 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, CHREC 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 for re-submission.

6.2 Review Process

All submissions will be initially vetted for completeness and appropriateness by the CHREC Secretariat. If a proposal submission is complete and appropriate, the CHREC secretariat will refer the proposal and accompanying documents to the research bioethicists in the Research Unit.

The research bioethicists will conduct a preliminary review to determine the level of risk of the proposal. If the preliminary review identifies the proposal to be of **"Low Risk"** (as defined in section Appendix 2) the proposal will undergo an "Expedited Review" conducted by the ethicists and review comments will be sent by the secretariat within seven (7) working days. The turnaround time for a Low Risk proposal is ten (10) working days. This means that a Researcher who has submitted a research proposal that is deemed low risk by CHREC should receive a communiqué from CHREC on the status of their proposal within 10 working days from their date of submission.

Proposals that are deemed **"High Risk"** (as defined in Appendix 2) during the preliminary ethics review will be referred for a "Full Review" process. The proposal will undergo assessment according to the Research Review Form (see Annex 6) and will be guided by requirements in the CMNHS Guidelines for the Development of a Health Research Proposal. The proposal will be circulated to selected CHREC reviewers. The Turnaround time for a high risk proposal is 30 working days. This means that a Researcher who has submitted a research proposal that is deemed 'high risk' by CHREC should receive communiqué from CHREC on the status of their proposal within 30 working days from their date of submission.

6.3 External Expert reviewers (Procedure)

In the case where CHREC is unable to make a decision or if CHREC 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 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 CHREC to make a final decision.

6.4 Expedited Review

Proposals deemed "Low Risk" will undergo Expedited Review. This process involves review by Ethics officers and Research Fellows within the Research Unit. Where required, a content expert may be requested to assist in the review. The expedited review is completed within 7 days of assignment of the proposal to reviewers. The turnaround time for a Low Risk proposal is 10 working days.

6.5 Full Review

Proposals deemed "High Risk" will undergo Full Review. This process involves review by an Ethics Adviser and two independent reviewers who may be members of the

CHREC or SRCs. If reviewer expertise within CHREC or SRC is inadequate, reviewers who are largely content experts will be sough elsewhere including internationally partners. Prospective reviewers will be requested to respond, within 48 hours, on their availability 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 full review is completed within 14 days of assignment of the proposal to reviewers. The Turnaround time for a high risk proposal is 30 working days.

6.6 Ethics Review Exemption

Research projects may be eligible for exemption from an Ethics review, but cannot be exempted from being ethical. For example, content analysis of public documents – can be exempted from ethics review but still need to be ethical in their methodology, content and representation of information.

Faculty members and students 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. Clarification can be sort from the Research Unit on whether ethical review and approval is required. It is advised that staff and students engaging in these activities get a CHREC letter that agrees that their work is exempt from any ethical review of approval.

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

- Donor funded programs. Projects and consultancies may fall in this category, however, it is the professional and ethical responsibility of all CMNHS faculty to identify potential research within this group of activities and refer them appropriately for review and ethical approvals if needed.

6.7 Possible review outcomes

Possible review outcomes for both Expedited and Full review include:

- Fully Endorsed: No Changes Required
- Endorsed pending Minor Changes
- Resubmit (Major Changes Required)

Appropriate response times for Researchers:

- Minor Changes: Researchers to respond with changes within 10 working days upon receipt of review comments
- 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 CHREC 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.

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

6.8 Attendance of the Principle Investigator

The Chair of CHREC may request the principle investigator to attend a CHREC 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.

6.9 CHREC Consideration of Reviews and decision making

All expedited Reviews (review form comments and endorsement of amendments) will be considered by the Chair of CHREC before issuance of the CHREC 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 CHREC meeting for noting.

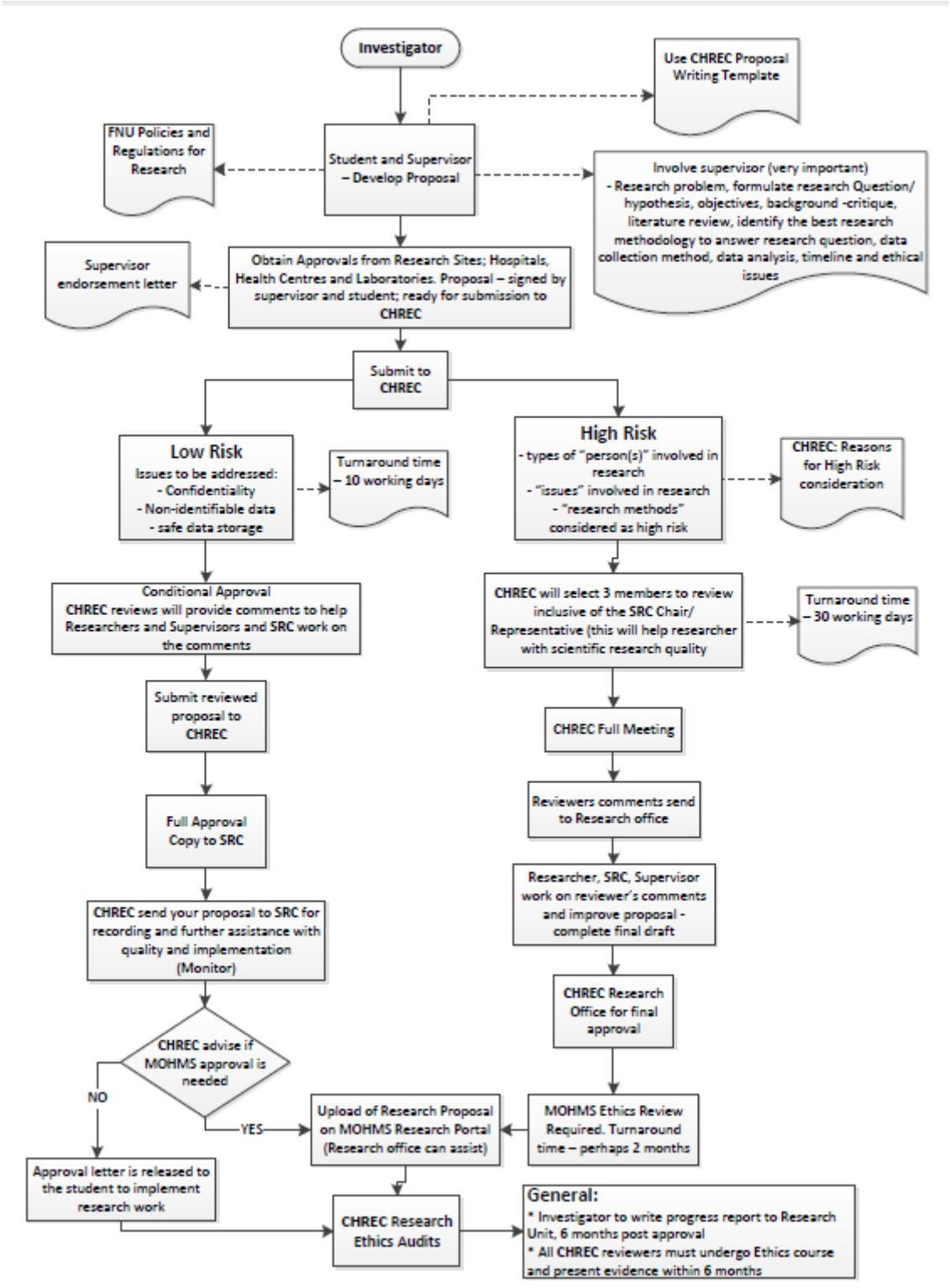
All proposals referred for "Full Review" will be circulated to members prior to the monthly meeting with a justification of the risk stratification and a collation of review comments. Members may review the comments to assess appropriateness of comments and may propose additional comments to improve the technical or ethical acceptability of the proposal. Amended proposals will be sent for endorsement to CHREC members via e-mail for final e-endorsement within 5 working days of receipt of amendments. CHREC 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 CHREC is recorded in the minutes. To encourage free and open discussion and to emphasise the collegiate character of CHREC, 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 CHREC member unable to attend a meeting may submit comments in writing on the proposal to the CHREC 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 CHREC Research Ethics Review Procedure**.

Figure 1: CHREC Research Ethics Review Procedure



7. Monitoring of Approved Projects[4]

It is the obligation of CHREC to ensure continuing oversight of approved research projects. The CHREC Secretariat shall promptly report to CHREC any developments in the project that might have ethical implications. Principal Investigators shall inform the CHREC 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 CHREC by the Secretary. When the Secretariat receives a report of changes that are proposed to be made in the protocol or consent documentation of a research project that the Committee has previously approved, a determination shall be made by the Chair and the ethics officers within the Research Unit on whether the proposed changes should be subject to review by the Committee. If a review by CHREC is required, then the proposed changes will be presented to CHREC 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.

7.1 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 CHREC.

CHREC 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.

7.2 Random Spot-checks on Current Research Activities

School Research Committees may assign members to perform random spot-checks of research being implemented by College students and staff in their respective schools
The random check may include, but not limited to the following:

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

[4] Source: WHO WPRO ETHICS REVIEW COMMITTEE SOP

Where breaches are established during spot-checks (with reference to approved research proposal and protocols), processes to address those breaches will be activated among CHREC, 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 7) discussing the current status of research to CHREC. Periodic reporting will be continued until the successful completion of the research. The report may include but not limited to the following:

- How far research had progressed with reference to the research proposal's Gantt chart?
- What were the challenges/issues/problems that caused delays in research implementation?
- How have those challenges/issues/problems been addressed?
- 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 CHREC research approvals. The following steps will be followed: -

- Initial request for a researcher's progress report for the current period will be communicated by CHREC using e-mail. The e-mail will include the progress report template and a deadline by which signed progress reports are to be submitted;
- Frequent e-mail reminders will be sent to all researchers for submission of progress reports until close of business on the submission day;
- 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.
- Where reason/s are not communicated and attempts to receive progress reports have failed; CHREC 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. Duration of CHREC Approval

- Research projects approvals from CHREC are for specified time period as indicated in the approved work plan and proposed project timeline; taking effect from the approval date
- The approval letter will include the ethics ID number, the approval beginning and end date, and Conditions of Approval;

- 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;
- 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 CHREC 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 a 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 CHREC 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. CHREC will consider the application and will grant an extension to date of approval. The research team will be duly informed of CHRECs decision by writing with the authority of the Chair.

9. 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 CHREC Secretary shall report the final research project outcome (completion or discontinuation) and submit a final report on the study to CHREC. A notation shall be made in the CHREC 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 CHREC electronic registry.[5]

For supervised student research, students and supervisors must provide a clean copy of the Research report for submission to the CMNHS library. An e-copy of the final report, once all assessments are completed, can be given to the CHREC 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.

10. Authorship

[5] Source: WHO WPRO ETHICS REVIEW COMMITTEE SOP

The International Committee of Medical Journal Editors (ICMJE) has developed guidelines to resolve issues related to crediting of authors in publications (Mandal, J., & Parija, S. C. 2013). CHREC may refer to ICMJE for guidance when considering issues of authorship. The article is available at http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.

The ICMJE article includes information about the following topics;

- Defining the Role of Authors and Contributors
- Why authorship matters
- Who is an author
- Non-Author Contributors

11. Conflict Of Interest

11.1 Definition

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

(i) Person's individual interests or responsibilities 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.

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

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

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

11.2 Conflict of Interest for CHREC Members

All CHREC 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.

12. 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 CHREC 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 CHREC which includes the revised protocol. CHREC will conduct an expedited review these amendments. (UQ, HREC SOP, 2016)

13. Suspension or Withdrawal of CHREC Approval

CHREC will make a decision to suspend or withdraw an approval granted to a research project if through the monitoring process of CHREC, 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. CHREC 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 CHREC decision to suspend, unless immediate notification is required for urgent safety reasons. CHREC 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 CHREC. The research team will discontinue research and will comply with the decision made by CHREC. Any other ethics committee involved in the project will be notified of the suspension or withdrawal of CHREC approval. (UQ, HREC, SOP, 2016)

14. Complaints

Complaints about the conduct of an approved research project will be reported to the Secretary of the CHREC and copy to the Chair. The complainant will receive an acknowledgement in writing via email.

The CHREC 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 Bill Summary, parts 5 and 6.**

15. Adoption and Amendments of the SOP

The SOP will be approved by the CHREC Chair after its presentation at a CHREC meeting. Members of the CHREC can propose an amendment to the current SOP by making a written formal submission to the Chair of CHREC. Consultation should be made to relevant stakeholders. The Secretariat will make this submission an item in the agenda of the next CHREC meeting for CHREC consideration and possible adoption by the majority of members who are present. The amendments shall come into effect once approved by the Chair of CHREC. The committee through SRCs will disseminate changes to the staff and students to their respective schools as recommended for implementation.

16. Periodic Review of CHREC SOP

This CHREC SOP is a dynamic document and therefore subject to periodic review. With the understanding that this is the first SOP for the CHREC, it is anticipated that there will be changes along the way to improve CHREC processes towards more robust and timely research from the College. At the initial implementation of the SOP a period of 1year will be allowed for the testing phase of the SOP. During this period any changes and amendments can be made to the SOP after discussion at CHREC and approval by the Chair. After this 1 year period, the CHREC SOP will be reviewed once every two years. The review process will be led and facilitated by the Chair of CHREC.

17. Special Considerations of Research Involving Vulnerable Populations

17.1 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, 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 fetuses
- 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.

17.2 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".

17.3 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. CHREC 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.

17.4 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. CHREC may refer to **Guideline 16 of CIOMS** for further guidance in reviews and to seek clarifications.

17.5 Vulnerability Based on Economic Status or Other Factors

Research participants should not be coerced into participating in a research study because of inappropriate inducements. CHREC will review the consent process and other forms to ensure that inducements offered are appropriate. Additionally CHREC 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.

18. Special Conditions

18.1 Researchers who are CHREC members

Where the researchers are members of CHREC, these members will be excluded from any discussion and reviews pertaining to the said research proposal. This will ensure that there is no conflict of interest of researchers and research reviews.

19. Appeals and Disagreements with CHREC 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 CHREC 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 CHREC 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 CHREC within 14 working days for the final decision. In the situation where after the appeals process both CHREC 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.

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 University 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 CHREC 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 CHREC 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 CHREC for an independent enquiry before referral to the HR policy on staff misconduct.

The Chair of CHREC 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.

21. Auditing

The CHREC shall have a committee regularly involved in monitoring research activities in its effort towards quality assurance of all research at the CMNHS. The CHREC 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 CHREC.

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23. ANNEXES

Annex 1: School Research Committees (SRC)

Annex 1.1: About SRCs

Each School of CMNHS will host its own *School Research Committee* (SRC) and formulate its TOR. The role of the SRC will be to set appropriate benchmarks for research activities within the school and propose research agenda for their respective schools.

SRCs should be responsible for monitoring research timelines and the appropriate supervision, monitoring and assessment of student research. SRCs may contribute to the articulation of research supervision requirements (undergraduate and postgraduate) and may work with Learning and Teaching Committees and College Postgraduate Committee to ensure that the supervision, monitoring and assessment of research programmes are adequate and appropriate. SRCs may, at the discretion of the head of school, also have a role in approving external supervisors: these may be content experts external to the University e.g. Clinicians from Ministries of Health or academics from collaborating universities.

All research proposals submitted to CHREC and correspondence between investigator and the CHREC must be copied to the Chair and secretary of respective SRCs. Student research proposals should be submitted by the Supervisor after duly vetting the scientific and ethical appropriateness of proposed research and appending their signature on the supervisor endorsement form (see Annex 5).

Annex 1.2: Member of the SRC assigned as a Research Reviewer

The reviewer will assess research proposals for technical and ethical merit, critiquing the methodology and offer recommendations on research proposals to both staff and student. CHREC may refer researchers to SRCs for further guidance and assistance to improve the quality of the proposed study. The SRC secretariat will assign appropriate member/s to assist the researchers or student and supervisors to address review comments and make appropriate amendments to address ethical issues. SRCs may specify appropriate internal mechanisms to ensure research projects meet the benchmark levels for the programme. They may also engage in assigning supervisors and co-supervisors who will be able to assist students and staff.

Some points for reviewers to note:

- Relevance of research topic to population, CMNHS research agenda and disciplines/ programs and its importance to the researcher, the school/CMNHS, and the people that the researchers and represent.
- The research design e.g. is it quantitative or qualitative or involves mixed methods? Cross-sectional, Case Control, Cohort, Randomized Controlled Trial, etc.
- Is it feasible in terms of time, finance and skill?

- Will the student/mentee receive appropriate supervision?
- The scientific methods: Is the scientific capacity available to supervise a project which involves specific technical expertise, especially in the Biomedical and Clinical Sciences?
- Significant or new knowledge to be generated by proposed research - will the research outcome inform current practice or influence policy.
- Does the researcher (supervisor in case of undergraduate student) possess the necessary skills and experience to implement the research?
- Does the research design employ any method that may breach internationally accepted research ethics principles?
- Is the budget appropriate for the research?
- Will the outcome of this study be appropriately disseminated?

The SRCs may, through their internal processes as endorsed by their Head of Schools, may decide to assess the acceptability of a research topic and its subsequent development prior submission to the CHREC review process.

Annex 1.3 Student research

The primary objective of student research is to demonstrate their research competencies to meet and fulfil their respective programme requirements. A proposal submitted by a student is expected to be in line with proposal guidelines. A Postgraduate degree student must be able to demonstrate that they are able to apply appropriate scientific research methods to answer a research question or to accept or refute a hypothesis. A PhD student must be able to do the same with the additional provision that the answering of the question or the acceptance or refutation of the hypothesis must make *a contribution to knowledge*. Accordingly, it is necessary that the proposal be reviewed by a content expert.

All student project submissions must identify an *academic supervisor*[6] or co-supervisors with expertise in the project area or in a related area. (Primary supervisor from the full-time staff of CMNHS)

There may be cases where the researcher plans to conduct research in their home country. The research programme must make appropriate arrangements for supervision of research in the country of implementation. The monitoring of such projects may be assigned to members of the SRCs. At the same time, it is critical that each student also obtains research and ethics approval/s from their home country for the study to proceed. Students must be aware that in cases like this, CHREC will only provide partial or provisional approvals pending research and ethics approvals being granted by recognized authorized institutions in the home-country. Once the home-country approvals are received, CHREC will facilitate full research approvals.

[6] Handbook for Research Programmes. Fiji National University, 2014.

A1.3 Staff Research

The objectives for Staff research are to describe a phenomenon, find a definitive answer to a question, or to support or refute the hypothesis they have posed. Accordingly, the review of the proposal should focus on the potential to achieve the objective through the application of scientific methods.

Staff and students are encouraged to discuss their proposals with relevant content experts, and with the SRC, prior to submitting for Ethics Review to the CHREC.

Annex 2: Concepts

Annex 2.1 Principles of Bioethics

The four broad principles stated in this section aim to provide guidance for considering whether a research proposal is ethical or not.

(i) The research project will **NOT HARM** participants and researchers alike. That BENEFITS generated by the research will be maximized in favor of participants over those for the researcher or sponsor alone. More consideration of **BENEFITS** should be directed at participants and people of the country of research, more importantly if they are vulnerable and marginalized populations.

(ii) The research project will **MINIMIZE RISKS** or **MINIMIZE HARMS** that may be inevitable consequences of research activity.

(iii) The participants' **RIGHT TO ACCEPT OR REFUSE** to participate in the research will be respected. The research projects will outline measures to engage voluntarily including the right to withdraw from the study at any point of time, and obtaining informed consent to participate in the proposed research activities.

(iv) That the principles of **FAIRNESS AND EQUALITY** are exercised at all times in the conduct of the research.

Annex 2.2 Health Research

Health research may include, but not limited to, any research project that involves human participation, Health Systems, curriculum development, basic medical sciences involving animals. It may engage several research methods such as surveys, any form of interviews or focus group discussions, conduct of tests on humans, review of personal data from databases, collection or tests on biological specimen are all considered as health research.

Primary research refers to any research where new data is collected; new in the sense that the data has never been collected before. Similarly, secondary research refers to studies conducted using data that has already been collected and is available for use.

Annex 2.3 Risks and Benefits in Research

It is important for researchers to seriously consider and weigh anticipated risks and/or benefits the research project will generate, for the country of research and international partners, all research stakeholders, including direct benefits for research participants and researchers. It is also important to assess the level of involvement of human participants in order to design protocols which appropriately seek voluntary informed consent. In cases where human participation is not engaged but data regarding health indicators of populations are needed, appropriate third party consents and approvals must also be considered and sought.

Annex 2.4 Classification of Risk

Risk is the likelihood of harm or discomfort[7] or inconvenience to research participants and researcher as a result of conducting the research. If the researcher anticipates any risks, a description of how the risk(s) will be managed or minimized must be included in the research proposal. CHREC will assess whether the researcher has thought of risks involved in the research and propose ways of managing the risks so that they are minimized. Researchers must also assess the benefits of the research and CHREC will assess whether benefits out-weigh the risks before approving the research project. The Ethics Review Checklist[8] ***(Annex 2)*** can assist researchers to assess their own proposals.

Low Risk Research

Research is 'low risk' where the only foreseeable risk is one of discomfort[9] such as one of the following shall be subjected to expedited review

- Research involving de-identified data, documents or specimens that have been collected except for genetic testing.
- Questionnaire based survey that does not include collection of any sensitive information.

What is discomfort? Discomfort is not harm but can include inconvenience, physical discomfort of body and mind: for example, very minor side effects of medication, the discomforts related to measuring height and weight, measuring blood pressure, collecting **routine** blood samples or specimens and mild anxiety experienced by the person during an interview or focus group discussion.

What is sensitive information? Sensitive information refers to any information which when divulged may cause levels of harm such as at the individual, communal and other levels. Examples of harm include anger, bitterness, embarrassment, fear, humiliation and shame. Such information may also lead to discrimination, rejection, retaliation and stigmatization amongst others.

High Risk Research

The aim of categorizing a study as 'High risk Research' is not to demotivate/discourage the researcher from conducting the study but to do the study in an ethical manner and, only after

[7] Ethics Review Checklist. Research Unit: College of Medicine Nursing & Health Sciences, 2016.
[8] Ethics Review Checklist. Research Unit: College of Medicine Nursing & Health Sciences, 2016.
[9] National Statement on Ethical Conduct in Human Research and ethical review and research involving only low or negligible risk. Available from https://www.nhmrc.gov.au/_files_nhmrc/file/guidelines/ethics/human_research/NS_low_risk_flow_chart.pdf)

taking all the necessary precautions. ***Box 1*** below provides an example of how proposals are written when addressing high risk issues in a research proposal.
This section is divided into 3 sub-sections comprised of indicators of High Risk Research based on

(i) types of "person(s)" involved in research considered as High Risk
(ii) "issues" involved in research
(iii) "research methods" considered as High Risks

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

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

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

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

- Anticipated harm (or risk of harm) to individuals
- Abortion
- Clinical and non-clinical trials
- Collection of information from identifiable sources without the consent of the identified person
    - Drug abuse
    - Ethnic identity
    - Fertility

- Gender identity
- Grief, death or serious/traumatic loss
- Information that may be regarded as "culturally sensitive"
- Parenting styles
- Personal information that may be regarded as sensitive
- Psychological disorder, including anxiety, mood swings, depression
- Sexuality, sexual orientation
- Studies involving active disease states (Especially Communicable Diseases)
- Suicide

Research projects that involve the following research methods may be considered "High Risk Research"

- Audio or Visual recording without permission
- Inflicting pain on participants or invasive physical procedures
- Psychological experiments
- Recruitment via a third party
- Secret observations
- Use of personal information from unknown sources
- Using medical information of identifiable persons or possibility of linking to the person
- Using medication or drugs or placebos
- Withholding from one group specific treatments or methods of learning, from which they may 'benefit' (e.g. in medicine or teaching)

Box 1: Addressing High Risk Research when Writing Research Proposals

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

Research Project: Researching female survivors of childhood sexual assault. Pilot qualitative study to investigate early mothering with women who had experienced childhood sexual abuse. Second study to investigate how primary care could be improved with survivors of childhood sexual abuse.

Recruitment of Participants - Research information be placed in an advertisements for community notice boards or hospital outpatient notice boards or local newspaper, stating researcher's contact phone number or email. Participants contact the researcher to discuss any queries regarding the research before interview is confirmed. The researcher is not associated with the medical care, but may refer the participant for medical care if needed.

Research design to include benefits: Research as healing. Research as breaking the silence. Research as helping others. Research to Empower participants as much as possible. Allow participants time to consider the implications of participating in research. Remove any researcher coercion as much as possible. Offer an 'opt out' opportunity for participant at multiple stages of the research – evidence of opt out in the questionnaire e.g. "I am now going to ask you about your sexual abuse experience, please feel free to not answer any question if it is too difficult for you."

Ethical issues to be included:

Confidentiality and Privacy

Ensure safety of all participants. If needed, ensure safety of the researcher(s)

Maximize benefits and reduce or eliminate risks for all concerned

Ensure that the research is justified and that benefits are weighed for all stakeholders and participants

Show evidence that the support of a psychiatrist will be provided if needed by the participant.

Annex 3: List of research training workshops conducted by the Research Unit

Research Writing Workshop

Research Supervision

Introductory Excel for Research

Descriptive Analyses in Excel

Advanced Analyses in Excel

Introductory SPSS for Research

Descriptive Analyses in SPSS

Advanced Analyses in SPSS

Reference Management for Research

MS Word for Research

Research Ethics

College Research Processes

Note:
Venue would be announced prior to the scheduled workshop dates.
Certificate of Participation would be given to the participants who will register and attend the workshop.
Video conferencing sessions will be made available for participants from Lautoka and Labasa.

Annex 4: Proposal Template and Guideline

1.0 INTRODUCTION

BACKGROUND TO THE RESEARCH PROBLEM

RATIONALE OR PURPOSE OF THE STUDY (STATEMENT OF THE PROBLEM)

BENEFITS OF THE STUDY

RESEARCH QUESTION, AIM, PRIMARY OBJECTIVE OR HYPOTHESIS

RESEARCH OBJECTIVES

2. LITERATURE REVIEW

3. STUDY METHODS

3.1 STUDY DESIGN

3.2 STUDY SETTING

3.3 STUDY POPULATION OR SAMPLE

3.4 SAMPLING, SAMPLE SIZE AND POWER

3.5 METHOD FOR RECRUITMENT OF PARTICIPANTS

3.6 DEFINITION OF KEY TERMS, CONCEPTS AND VARIABLES

3.7 DATA COLLECTION TECHNIQUES AND INSTRUMENT

3.8 RELIABILITY AND VALIDITY OF METHODS AND TOOLS

3.9 Data Management

3.10 DATA ANALYSIS PLAN

3.11 PRE-TEST OR PILOT STUDY

4.0 ETHICAL CONSIDERATIONS

4.1 CONFIDENTIALITY

4.2 VOLUNTARY INFORMED CONSENT

4.3 PROVISION OF DEBRIEFING, COUNSELLING, REFERRAL FOR TREATMENT AND PROCESSES TO ENHANCE DUTY OF CARE FOR PARTICIPANTS

4.4 ANTICIPATED RISKS OF RESEARCH AND PLANNED METHODS OF MANAGEMENT OF RISKS

5.0 WORK PLAN

(This template can be modified as appropriate to the research)

	Activities	J	F	M	A	M	J	J	A	S	O	N	D
1	Proposal development												
2	Proposal submission for research & ethics review	X	X										
3	Proposed Data Collection			X	X	X							
4	Data Cleaning & Analysis				X	X	X						
5	Report Writing							X	X	X			
6	Open forum presentation								X				
7	Draft Submission: Research Report									X			
8	Final Submission: Research Report										X		
9	Research Report sent to CHREC, and library.											X	
10	Research summary for stakeholder information											X	

6.0 BUDGET

	Item/ Activity	**Unit Cost** (FJD)	**Total Cost** (FJD)
1			
2			
3			
4			
	Total Budget		

7.0 Plan for Administration, Monitoring and Utilization of Results

8.0 References

9.0 Appendices

Annex 5: Sample Supervisor's Endorsement Letter

Date

The Chairperson,

College Health Research Ethics Committee,

College of Medicine Nursing & Health Sciences

Supervisors Letter of Endorsement for Student Research Proposal

Student name ……

Student No……

Title of the research proposal……

Dear Chairperson,

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: Health Research Ethics Committee (CHREC) 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 faithfully,

……..	……..
(Supervisors signature)	(Co-Supervisor Signature)
Name:	Name:
Department:	Department:
Official and alternative Email Contact:	Email:

Annex 6: Research Reviewers Form

College of Medicine Nursing & Health Sciences

Research Review Form

STUDENT ID/ NAME:	
Review Type: □ **Supervisor** □ **DRC 1** □ **DRC 2** □ **CHREC 1** □ **CHREC 2** • *Note to reviewers: Please provide constructive review comments with helpful suggestions/ alternatives. Please refrain from negative and personalized remarks or vague recommendations.*	
Reviewer: **Date Received:** **Date Reviewed:** **Date Returned:**	
	COMMENTS
Title	
Version Number	
Table of Contents	
List of Acronyms	
Glossary of Terms	
Introduction	
Background	
Rationale or Statement of the Problem	
Benefits of Study	
Research Question, Aim, Objective, Hypothesis/ese	
Objectives	
Review of Literature	
Study Methods	
Study design	
Study Setting	
Study Population or Sample	
Sampling, sample size & Power	
Method for Recruitment of Participants	
Definition of key	

Terms, Concepts & Variables	
Data Collection Techniques & Instruments	
Reliability & Validity of Methods & Tools	
Data Management	
Data Analysis Plan	
Pretest or Pilot Study	
4.0 ETHICAL CONSIDERATIONS	
Confidentiality	
Voluntary Informed Consent	
Provision of debriefing, counselling, referral for treatment and processes to enhance duty of care for participants	
Anticipated Risks of research & planned methods of management of risks	
Work Plan	
Activities/ Timelines/ Gant Chart	
Budget	
Activities, Equipment, Personnel etc	
Plan for Administration, Monitoring and Utilization of Results	
Administration Monitoring Utilization(including Publication)	
References	
Harvard/ Vancouver	
Appendices (Only those that are applicable)	
Data Collection Form, Tools, Surveys, Questionnaires, FGD & Interview Guides	
Secondary Data De-identification/ Coding Forms	
Information Sheet(s)	
Consent Form(s)	

Third Party Consent	
Assent Forms	
Translated versions of above if applicable	
Facility Approvals	
Other Country Research & Ethics Approvals	

General Comments:	
Ethical Issues	Technical/Scientific Issues

Recommendation:

□ Fully Endorsed: No Changes Required
□ Endorsed pending Minor Changes
□ Resubmit (Major Changes Required)

Annex 7: Research Progress Report

Research Progress Report

Researcher Name ……

Researcher ID……

Title of the research proposal……

1. How far research had progressed with reference to the research proposal's Gantt chart?

2. What were the challenges/issues/problems that caused delays in research implementation?

3. How have those challenges/issues/problems been addressed?

4. What funding has been used and on what, as well as remaining funds during the period of reporting?

……..	……..
(Researchers Signature)	(Supervisor Signature)
Date:	Date:
Email:	Email:
Phone:	Phone:

Annex 8: ETHICS REVIEW CHECKLIST

1. INTRODUCTION

This ethics review checklist document will help researchers in the College of Medicine, Nursing and Health Sciences (CMNHS) of the Fiji National University, make an assessment whether the research project proposed will be submitted for research review by your Department Research Committee and Research Unit or whether it will require full review by the College Health/(Human) Research Review Committee (CHREC).

It is the responsibility of the researcher to make an assessment of the level of risk associated with the research project by reading this checklist and ticking either YES" or "NO" in the appropriate column. (If researchers need help, please contact the Research Unit staff of the CMNHS Dean's office at Hoodless House.)

The assessment will determine the classification of research involved in a research project, such as Low-Risk (LR), High-Risk (HR) or the research project will be Exempted (E) from research bioethics review. A LR research is one where the foreseeable risk level is no more than discomfort. If there is a 'Yes' answer to any of the items in the checklist, but the researcher feels strongly that the research is LR, then the researcher maintain the LR but include a section of a "special case" assessment. However, the final decision of placement of research proposals in categories will be conducted by the Research Bioethics Reviewers at the Research Unit and CHREC.

A HR research will involve a project where the researcher ticked "Yes" in any of the boxes alongside the description of issues, participants, research procedures or other risk described in the High Risk section.

An E (exemption), is described in Section 3.

Researchers are to identify the risks involved in the research and include in the research proposal a section to explain how the researchers plan to manage the potential risks so that risks are minimized.

After going through the checklist and you assess your research as more than LR or HR you will be required to submit your research proposal through the CHREC for a thorough human research ethics review.

Researchers may also be called upon to defend their proposal or researchers may request an audience with the CHREC committee for them to defend your research proposal.

LOW RISK RESEARCH

Research is ‘low risk’ where the only foreseeable risk is one of discomfort (What is discomfort? Discomfort is not harm but can include inconvenience, physical discomfort of body and mind: for example, very minor side effects of medication, the discomforts related to measuring height and weight, measuring blood pressure, collecting **routine** blood samples or specimens and mild anxiety experienced by the person during an interview or focus group discussion.)

such as one of the following shall be subjected to expedited review

- Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis except for genetic testing.

- Questionnaire based survey that does not include collection of any sensitive information.

2. HIGH RISK RESEARCH

2.1 Topics considered as High Risk research topics

Are any of the following topics included in the proposed research? Please indicate by ticking (√) either Yes or No. If you have answered "yes" to any of the follow items, then it is a high risk research and research proposals should be submitted for a full ethics review by CHRERC.

Description of research topics		
Parenting or parenting styles	YES	NO
Sensitive personal issues or sensitive personal information	YES	NO
Sensitive cultural issues or ethnic identify	YES	NO
Grief, death or serious/traumatic loss	YES	NO
Gambling	YES	NO
Eating disorders	YES	NO
Illicit drug taking or drug abuse	YES	NO
Substance abuse	YES	NO
Self-report of criminal behaviour	YES	NO
Mental disability or any psychological disorder, depression, mood states and/or anxiety	YES	NO
Suicide	YES	NO
Sexuality, sexual behaviour or gender identity or sexual orientation	YES	NO
Race or ethnic identity	YES	NO
Any disease or health problem	YES	NO
Fertility	YES	NO
Termination of pregnancy	YES	NO
Anticipated harm (or risk of harm) to individuals	YES	NO

Studies involving active disease states (Especially Communicable Diseases)	YES	NO
Clinical and non-clinical trials	YES	NO

2.2 If any of the following procedures are to be employed, it will be regarded as High Risk Research.

Description of research <u>procedures</u>		
Use of personal data obtained from Government Department	YES	NO
Concealing the purposes of the research	YES	NO
Covert or hidden observation	YES	NO
Audio or visual recording without permission or consent	YES	NO
Recruitment via 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
Infliction of pain	YES	NO
Administration of drugs or placebos	YES	NO
Administration of other substances	YES	NO
Use of medical records where participants can be identified or linked	YES	NO

2.3 Research projects that involve the following <u>individuals or categories of people</u> will be considered "High Risk Research".

Description of <u>research participants</u>		
Children or young people under 18 years. Concerns are about their capacity to comprehend the nature of the research project, whether they have conflicting agendas with parents and if they are coerced to participating without proper parental consent.	YES	NO
People with a physical disability or vulnerability	YES	NO
People whose ability to give consent is impaired because of mental disability	YES	NO
Residents of a custodial institution (Institutionalized populations) e.g. prisoners and persons dependent on support e.g. orphans or juveniles in retention centers.	YES	NO
People unable to give free informed consent because of difficulties in understanding the research information (e.g. language difficulties).	YES	NO
Members of a socially identifiable group with special cultural or religious needs or political vulnerabilities	YES	NO
Deferentially vulnerable groups (those in respectfully trusting relationships or biased power relationships) OR People in dependent or unequal relationship with the researchers (e.g. lecturer/student, doctor/patient, teacher/pupil, professional/client)	YES	NO
People with existing relationships with the researcher (e.g. relative, friend, co-worker)	YES	NO
People in a workplace setting with the potential for coercion or problems of confidentiality (e.g. employer/employee)	YES	NO
Participants able to be identified in any final report when specific consent for this has not been given	YES	NO
Persons not usually considered vulnerable but would be thought so in the context of the project	YES	NO
Economically vulnerable populations (due to poverty)	YES	NO
Medically vulnerable e.g., sick patients and the needy who are unfit to give	YES	NO

an informed consent		
Physically or cognitively disabled persons	YES	NO
Pregnant women and their foetus	YES	NO
Socially vulnerable groups e.g., People who are involved in illegal activities, for example, gambling, drug trafficking, sex work, People Living with HIV (PLWH) and other stigmatized groups.	YES	NO

2.4 Assessment of research to be conducted in foreign country settings.

Does the research involve any of the following?

Research being undertaken in a politically unstable area	YES	NO
Research involving sensitive cultural issues	YES	NO
Research in countries where criticism of government and institutions might put participants and/or researchers at risk	YES	NO
Risks to the researcher(s), (e.g. research undertaken in unsafe environments or trouble spots)?	YES	NO

3. RESEARCH PROJECTS ELIGIBLE FOR ETHICS REVIEW EXEMPTION (E)

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.

Research shall be exempted from full CHREC review if the principle investigator is not a College (CMNHS-FNU) staff or student; however it has to be recorded at Departmental Research Committee (DRC) and College Research Committee (CRC) if the co-investigators of the same research are college staff or students. It should also be recorded at DRC and CRC if the college staff is doing a research project from any other institution.

The following types of data collection methods and activities are generally **NOT** considered to be research and **may** be eligible for Exemption from ethics review depending largely on the basis that these will not yield generalizable results.

Administrative data collection and analysis	YES	NO
Clinical case reports	YES	NO
Descriptive case studies	YES	NO

Histories: Interviews, personal viewpoints, institutional histories	YES	NO
Secondary analysis of non-sensitive, non-identifiable data from institutional data repositories/ databases	YES	NO
Quality assurance, Quality Improvement, Course or Program Evaluation activities	YES	NO
Research practicum and classroom or clinical Teaching & Learning activities	YES	NO
Research using publicly archived materials	YES	NO
Research proposals which do not involve human participants or data pertaining to them are exempted from ethics review. For example, Research on microbes cultured in the laboratory, analysis of data freely available in public domain	YES	NO
Donor funded programs, exempted from review. Projects and consultancies may fall in this category, however, it is the professional and ethical responsibility of all CMNHS faculty to identify potential research within this group of activities and refer them appropriately for review and ethical approvals if needed.	YES	NO

4. CONCLUSION

Faculty members and students 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.

Acknowledgement: Low risk, High Risk and ethics review Exemption in this checklist were taken from the Low Risk Ethics Review Application form of the Deakin University, Faculty of Health and Development, Melbourne, Australia.