MINISTRY OF HEALTH AND MEDICAL SERVICES

FIJI HUMAN HEALTH RESEARCH POLICY

2020

POLICY OWNER: RESEARCH INNOVATION & DATA ANALYSIS MANAGEMENT DIVISION

CONTENTS

1.0 POLICY GOALS/OBJECTIVES

1.1 Goals (intended outcomes)

1.1.1 To ensure that all proposed human health research projects in the Republic of Fiji is appropriately designed to address the needs of the people and is in alignment to the objectives of the National Research Council Act 2017.

Objectives

1.2.1 Develop a national health research ethics vetting group with the establishment of the Fiji Human Health Research Ethics Committee (FHHREC) to monitor the quality and effectiveness of human research ethic applications, reviews and implementation strategies in Fiji.

1.2.2 To develop and implement a framework for a Standard Operating Procedure (SOP) in human health research under the Ministry of Health & Medical Services (MHMS).

1.2.3 To strengthen human health research activities and capacities at the Ministry of Health and Medical Services to support achievement of strategic objectives, evidence based decision-making and policy development.

1.2.4 To promote or advocate for the ethical conduct of human health research in Fiji.

2.0 POLICY STATEMENT

This policy;

2.1 is aligned to the processes and principles described by the National Research Council Act 2017;

2.2 establishes the Fiji Human Health Research Ethics committee (FHHREC) to review, endorse research ethics applications and have oversight over the standards/SOPs used to conduct human research in Fiji;

2.3 is responsible for the conduct of human health research, to set standards on the appropriate human health research governance and management systems in Fiji to ensure prioritization, accessibility and transparency of research activities, and adherence to sound scientific, ethical and technical quality human health research review systems and processes;

2.4 govern the accreditation of human health research for relevant stakeholders that includes academia, government departments, NGOs and international

entities;

2.5 follows the ethical principles described in the report "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" also known as "The Belmont Report".

3.0 BACKGROUND

The Fiji Human Health Research Ethics policy is a strategy developed to assist and facilitate the Fiji National Health Research Unit, Fiji Human Health Research Ethics Review Committee, reviewers and researchers alike to abide and comply with the necessary research procedures in order to strengthen and promote a robust human health research culture in Fiji.

Fiji encourages the scientific human health research and values its contribution to better health for all Fijians through evidence- informed policies and programs. It strives to maximize efficiency, transparency and accountability in health research to improve the quality, use and impact of human health research applications. The progress and excellence of research is dependent on our vigilance in maintaining the highest quality and conduct in every aspect of science.

This policy provide a framework for the fair, open, and responsible conduct of human health research in Fiji without inhibiting scientific freedom or creativity. These set forth the general principles concerning the responsibilities of researchers in the collection and recording of data, confidentiality of information, human research subjects protection, sharing of final research findings and other research outputs including the data.

4.0 DEFINITIONS

Ethics - is the study of what we ought to do. The terms 'ethics' and 'morality' are often used interchangeably.

Fiji Human Health Research Ethics Committee (FHHREC) - a 15 member Committee is established and appointed by the Permanent Secretary of Health & Medial Services (PSHMS) to ensure the highest ethical standards in research supported by MHMS. It is mandated to review all research projects that involve human participants, and are supported either financially or technically, by MHMS.

Human Health Research - when human beings: (1) are involved in research and are exposed to intervention, manipulation, observation, or other interaction with investigators, either directly or through alteration of their environment; or (2) become individually identifiable through investigators' collection, preparation or use of medical or other records or of biological material from human beings.

Intellectual property (IP)[1] - is the overall term for property in the creation of the mind, including inventions, literary and artistic works, but also images, and designs. There are two distinct categories of IP: copyright, which includes literary and artistic works and industrial property, which includes inventions protected by patents, trademarks, industrial designs, and geographical indications.

Principal Investigator - The lead scientist for a particularly well-defined social science, biomedical, behavioural or epidemiological research project; responsible and accountable for the appropriate conduct of the research.

Acronyms

AOP - Annual Operational Plan
CHREC - College Health Research Ethics Committee
FHHREC - Fiji Human Health Research Ethics Committee
FRCS - Fiji Revenue and Customs Service
HHR - Human Health Research
MEHA - Ministry of Education, Heritage and Arts
MHMS - Ministry of Health and Medical Services
MTA - Material Transfer Agreement
PI - Principal Investigator
PSHMS - Permanent Secretary of Health & Medial Services
RIDAM - Research, Innovation, Data Analysis and Management
RIU - Research and Innovation Unit
SOP - Standard Operating Procedure

5.0 RELEVANT LEGISLATIONS & AUTHORITIES

- Copyright Act 1999
- Declaration of Human Rights Article 17 (Right to Privacy)
- Fiji National Health Research Guide 2015
- Fiji National Human Research Ethics Committee Standard Operating Procedures
- Information Act 2018
- International Ethical Guidelines For Health-Related Research Involving Humans, 2016
- National Research Council Act 2017
- World Medical Association Declaration of Helsinki 1964

[1] World Health Organisation. (2020, March 30). Intellectual property. Retrieved 10:36, March 30, 2020, from https://www.who.int/topics/intellectual_property/en/

6.0 POLICY IN THE HEALTH SYSTEM

6.1 Leadership/Governance

6.1.1 Role of Permanent Secretary Health & Medical Services (PSHMS)

6.1.1.1 The PSHMS shall spearhead and support the FHHREC through its Research and Innovation Unit (RIU); in alignment to recommendations by the National Research Council (NRC).

6.1.1.2 The PSHMS shall appoint the FHHREC committee upon recommendation or nomination by the RIU, as outlined in the processes described in the SOP.

6.1.2 Role of FHHREC

6.1.2.1 The FHHREC has the mandate of overall governance and management of human health research in Fiji and ensure the highest ethical and research standards is maintained in practise in all related activities.

6.1.2.2 The FHHREC shall ensure stakeholders are informed on the guidelines, and intervene by addressing the issue with the relevant authorities if any research is conducted outside the ambit of the guidelines.

6.1.2.3 The FHHREC shall describe and administer the process for accreditation of aligned institutions to independently review local human health research and monitor its activities.

6.1. 2.4 The FHHREC shall address any issues or complaints raised by the general public on the conduct of human health research in Fiji by raising it with the relevant authority or institutions.

6.1.2.5 The FHHREC may appoint or delegate to a separate specialized subcommittee to conduct for an expert review of complex research proposals such as clinical trials and interventional studies or make recommendations on important ethical issues and events e.g. pandemics.

6.1.2.6 The Senior Health Research Officer of the MHMS shall serve as the secretariat of the FHHREC.

6.1.2.7 The secretariat of FHHREC shall develop and report on indicators to monitor the progress of activities and its work plan.

6.1.3 The RIU shall develop an implementation plan and review guidelines with relevant stakeholders in accordance with the MHMS Annual

Operational Plan (AOP), Strategic Plan and National Development Plans of government.

6.1.4 This policy is aligned to the other research policies and strategic plans of other Government ministries and institutions (including, but not limited to Higher Education Commission, Ministry of Education, Heritage & Arts, Department of Immigration, Ministry of iTaukei, etc.).

6.2 Financing

6.2.1 To ensure this policy is implemented, the MHMS shall provide the secretariat support and human resources to administer FHHREC on an annual basis for the sustainable implementation of the FHHREC Guidelines and Policy.

6.2.2 The MHMS RIU shall provide the policy and technical oversight for implementation of this policy, including developing annual budget submissions and operational plans.

6.3 Workforce/Human Resources

6.3.1 All stakeholders involved in the governance of the Human Health Research Ethics process shall undertake essential capacity building activities.

6.3.2 The MHMS RIU and partners shall organize and facilitate training for the FHHREC and this includes the Annual Human Health Research Symposium.

6.4 Medical Products/Technologies

6.4.1 All medical products and technologies introduced in human health research in Fiji need to comply with relevant standards, policies and regulations for that specific medical product/technologies in Fiji.

6.4.2 All biological materials collected in Fiji from human health research for transfer internationally should be conducted within the ambits of Material Transfer Agreements (MTA) from FHHREC or FRCS.

6.4.3 The FHHREC must ensure that intellectual property matters have been properly addressed by Principal Investigators and discussed with relevant agencies.

6.5 Health information systems

6.5.1 Access to data from MHMS Health information system is through a defined Data Request Process of the MHMS.

6.5.2 All research related information/report generated by healthcare workers and data/articles gained from any Human Health Research conducted in Fiji should be submitted to the MHMS and to be uploaded into the MHMS Research Repository Database.

6.5.3 All applications for ethical review should be submitted through the Health Research Portal of the MHMS.

6.5.4 To ensure data is protected the Data Repository shall use high quality, security-conscious databases, software or encryption.

6.6 Service delivery

6.6.1 Any access to health facilities, staff and patients to conduct Human Health Research activities shall require prior Human Health Research Ethics approval either partial or complete by FHHREC or an accredited institution of FHHREC.

6.6.2 Any international research or researcher(s) intending to conduct activities within Health facilities or collate information from employees of the MHMS should seek formal approval from the PSHMS through the FHHREC process and preferably engage a MHMS staff as a co-investigator.

6.6.3 However, access to health facilities by local researchers (students, lecturers, CSOs) shall only need to seek approval from the head of the facility or institution with the prior provision of the necessary information on the research project.

6.6.4 Human Health Research conducted outside Health facilities e.g. schools and village communities must go through the FHHREC guidelines and ensure that relevant authorities' protocols are followed.

6. 6.5 All research conducted within health service delivery points with staff, patients and public must be conducted in a cohesive, non-disruptive and ethical manner at the discretion of the head of facility.

7.0 IMPLEMENTATION PLAN

7.1 The FHHREC with MHMS RIU shall develop, monitor and evaluate its implementation plan in alignment with relevant operational and strategic plans.

7.2 The FHHREC shall update the progress of its activities and formulate an

annual report to the NRC and the PSHMS.

7.3 The FHHREC and RIU may consider providing feedback on its outputs through newsletters, social media, journals, and website.

7.4 The RIU within the MHMS shall assess and give accreditation to local ethics committees. All higher education institutes involved with research in Fiji are invited to apply for accreditation.

8.0 EFFECTIVE DATE

This policy is effective from the date of signed endorsement in section 11.0 below.

9.0 REVIEW DATE

This policy should be assessed in accordance with all guidelines and shall be reviewed every *5* years or as and when deemed necessary by the MHMS.

10.0 KEY SEARCH WORDS

human health research ethics. ethics, research, data repository, intellectual property

11.0 APPROVED BY:

Acting Permanent Secretary for Health and Medical Services

..... 20/10/20

Signature Date

Honourable Minister for Health and Medical Services

Minister for Health & Medical Services

..... 20/10/2020

Signature Date