Turanga Ti`amā e te Tau no te Ranga Pōkai i te Ipukarea

The Cook Islands Research Ethics

Guiding principles for research with notes on research involving animals and natural heritage

The Cook Islands Research Ethics
Guiding principles for research involving human participants and other ethical aspects

36 p. 29cm

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Guiding principles for research with notes on research involving animals and natural heritage

Central Policy and Planning Office *Te Kōutu Mana Tūtara O Te Ipukarea* Office of the Prime Minister Government of the Cook Islands Rarotonga, Cook Islands

Contents

Introduction

The Cook Islands government is committed to developing research excellence in the Cook Islands by ensuring that all research conducted in the Cook Islands meets the highest research ethical standards. All research involving human participants must apply for research ethics approval from the Cook Islands Research Ethics Committee (CIREC) prior to undertaking research in the Cook Islands[1]. Research involving experimentation of animals and traditional knowledge must also go to the CIREC for review.

The intent of this document is to provide guidance to:

1. Researchers as they are primarily responsible for conducting ethical research in the Cook Islands. The term researcher broadly is used in this document to define all those responsible for the conduct of research
2. The Cook Islands Research Ethics Committee in their assessment of research ethics applications for approval.

The objectives of the ethical principles in this document are to:

- Safeguard the rights and interests of Cook Islands participants in research
- Promote high-quality ethical research for social, cultural and economic development of the Cook Islands and its people
- Foster awareness of ethical principles and practices amongst, researchers and the wider Cook Islands community
- Help researchers to think about and take responsibility for the ethical issues in their studies
- Help researchers give consideration to Cook Islands community views and perspectives
- Support the consistent ethical review of research in the Cook Islands
- Protect and reassure the community, animals, and the environment.

Research with human participants is defined broadly as every interaction between a researcher and another human, and other aspects of any information relating to a human. It also includes research involving anonymous questionnaires (National Ethics Advisory Committee [NAEC], 2019).

Cook Islands research encompasses various approaches to integrating cultural worldviews, beliefs, practices and concepts, including Cook Islands Māori knowledge systems and conceptual frameworks such as Tivaevae (Maua-Hodges, 2000) and Pu Ara (Herman, 2013).

The guiding principles in this document are derived from various documents published by the Health Research Council of New Zealand[2] and the National Ethics Advisory Committee of New Zealand.

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[1] Note: Further to ethics approval a research permit will be required

[2] See HRC: Guidance notes for health researchers and ethics committees; Guidelines for Health Research with Children; Guidelines for Researchers on Health Research Involving Māori; Pacific Health Research Guidelines; Research Ethics Guidelines; Collection and use of human materials; Te Ara Tika Guidelines for Maori Research Ethics.

Legislation and conventions that may be relevant to researchers include (but are not limited to) the:

- United Nations Convention on the Rights of Persons with Disabilities 2006
- United Nations Declaration on the Rights of Indigenous Peoples
- Declaration of Helsinki (WMA 2017)
- International Ethical Guidelines for Health- related Research Involving Humans (Council for International Organizations of Medical Sciences (CIOMS) and WHO 2016)
- Universal Declaration on Bioethics and Human Rights 2005
- The WIPO copyright Treaty (WTC)
- WIPO performers and phonograms Treaty (WPPT)
- Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled
- Beijing Treaty on Audiovisual Performances
- Seabed Minerals Amendment Act 2020
- Ministry of Marine Resources Legislation Act 2019
- Seabed Minerals Act 2019
- Maritime Zones Act 2018 o Marae Moana Act 2017
- Family Protection and Support Act 2017
- Statistics Act 2015–16
- Copyright Act 2013
- Ministry of Health Act 2013
- Traditional Knowledge Act 2013
- Narcotics and Misuse of Drugs Amendment Act 2009
- Biosecurity Act 2008
- Disability Act 2008
- Official Information Act 2008
- Disaster Risk Management Act 2007
- Marine Resources Act 2005
- Public Health Act 2004
- Environment Act 2003
- Te Reo Māori Act 2003
- Cook Islands Natural Heritage Trust Act 1999
- Antiquities and Artefacts Act 1994
- Cultural and Historical Places Act 1994
- Ministry of Cultural Development Amendment Act 1993

This document contains the Terms of Reference for the CIREC.

This document is a living document and should be reviewed annually by CIREC for relevancy.

This document has been peer reviewed by the World Health Organization Asia-Pacific National Ethics Committees.

`Akapapa`anga – Our Heritage

` Akapapa`anga is a cornerstone of Cook Islands Māori society. It shapes the foundation of our social structure and the collective enterprise of our people. It underpins our connection to the land, defines our rights and responsibilities in its management, and records the interrelation of our islands across generations. It also informs our relationships with our kin both in the Ipukarea and beyond.

The relationships inherent in papa` anga (genealogies) drive our preparations, serving as an impetus to build a strong future for our society, our ` enua, and the generations to come. It is essential that our ` Akapapa`anga and values guide us in navigating ethical matters.

Akapapa`anga is central to understanding Cook Islands Māori world views and the connections which binds us together, including, the Moana (sea), Enua (land) and Mareva (air) and includes the following:

To tatou Iti Tangata – Our People

Our people are our greatest treasure, and we must nurture and protect them. We have a responsibility to act as Tiaki (guardians) for future generations and to care for one another.

To Tatou Reo Māori e to tatou Akono`anga Māori – Our Culture and Identity

Our unique Cook Islands languages, dialects, cultural traditions, and heritage unite us as a people. They must be protected and celebrated, as they are an integral part of our national identity and legacy for future generations.

To tatou Aorangi – Te Moana, Te Enua, Te Mareva – Our Environment

As a proud large-ocean state, we are committed to protecting and sustainably utilizing Te Moana Nui o Kiva. We strive to be at the forefront of innovation, advancing the blue economy for the benefit of our people, environment, and culture.

Our 15 islands, spanning Te Pae Tokerau and Te Pae Tonga, form the heartbeat of our nation. Each island represents a connection between our land, our traditional titles, and our genealogical heritage.

The sky and the air that surround us bind our environment, emphasizing the importance of preserving its pristine condition for future generations. We will continue to adapt and mitigate environmental challenges through technology and innovation.

To tatou Tua Tāpapa – Our History and Legacy

Our nation` s history and pre-history connect us through shared experiences and milestones. We are committed to preserving and protecting our history, ensuring it remains accessible and beneficial for all our people. Our history also links us regionally and globally.

Recognizing colonialism as part of our past, we move forward with aspirations for our future as a nation.

To tatou Mana Pou e Toru – the three Pillars of Authority

Our society has traditionally been guided by three pillars of authority: **Aronga mana** (Traditional Leaders), **Evangelia** (Religious Advisory Council), and **Kavamani** (Government).

For the well-being of our nation, it is vital that these three pillars work together in unity,

collaboration, and implementation of national well-being. Our strong governance structures will be crucial for sustainable development.

As we move into the future, our identity as a nation will continue to evolve, guided by our heritage, values, and shared vision.

Vaerua Ti`amā – Ethical Principles

There are a number of common principles that guide research that involves human participants [3]. These principles shape and inform ethical standards and professional expectations for researchers and include, but are not limited to, the following:

Respect for human dignity

The guiding principle for all research conducted within the Cook Islands is respect for human dignity. This principle means that protecting the welfare of research participants takes precedence over the self-interest of researchers and possible benefits to society at large. A researcher` s obligations to its research participants extend to ensuring that the outcomes of the research and an account of the methods used are made accessible through appropriate dissemination channels for research participants, the public as well as to the scientific community (Health Research Council [HRC], 2017).

Respect for when extracting research related materials

Mutual agreement must be sought when conducting research related to genetic engineering, the creation of transgenic life forms, and the human genome to investigate genetic diversity in the Cook Islands. This is particularly important in relation to how samples are handled, including their storage in tissue banks, the establishment of cell lines, the transfer of tissue overseas for genetic studies, and any potential future use.

For Cook Islanders, the human body is tapu and is considered the embodiment of spirituality and sacredness. In the context of 'Ākonoʻanga Māori, bodies are not merely biological entities but are part of a broader genealogical system that forms the foundation of a kinship group's identity. The body represents the socio-cultural and spiritual continuity between the past, present, and future.

The consent of the research participant, their family, and their kōpū tangata should be obtained. Adherence to the ethical guidelines of relevant host institutions and the Cook Islands must be ensured before the extraction of human tissues and genetic materials (see Appendix 01: Material Transfer Form).

Selection of study population and recruitment of research participants

In the recruitment of research participants in the Cook Islands, researchers should consider whether their recruitment processes are appropriate for their potential participants in the study.

[3]For a general statement of the principles, applicants should consult the Helsinki Declaration. These principles include, but are not limited to, the following: International codes of ethics such as the Nuremburg Code (1947), the Helsinki Declaration (1964), the Belmont Report (1979) and, more recently, the UNESCO Universal Declaration on Bioethics and Human Rights (2005).

In determining appropriate recruitment methods, researchers should consider the characteristics of participants they are seeking to recruit; and the research methods they intend to use to collect data.

The person who contacts potential research participants should be knowledgeable about the study, and able to discuss study details and answer questions in plain English language or in Reo Māori Kuki Airani.

Any incentive offered for participation in research should not unduly influence an individual` s decision to participate. Researchers should ethically justify costs to participants to an ethics committee[4]. All recruitment efforts must respect personal rights to privacy and confidentiality.

Free and Informed consent

Participants must be provided with clear and comprehensive information about the research, including its purpose, potential risks and benefits, and other relevant details necessary for informed consent. The fundamental principles of informed consent, as outlined by the Health Research Council (HRC, 2017), are as follows:

1. **Understanding of Benefits** – Participants should be made aware of both the direct and indirect benefits that new knowledge from the research may provide to the study group.

2. **Capacity for Informed Decision-Making** – Participants must have the ability to comprehend essential information before giving their consent. This includes information presented through various formats, such as written materials, creative outputs, audio, and audio-visual documentation.

3. **Clarity and Context-Appropriate Language** – The research must be explained in language that is clear and appropriate for the context, whether in **plain English** or **reo Kuki Airani Māori**. This standard should also be applied to the **Participant Information Sheet (PIS)** and **Consent Form (CF)** to ensure participants fully understand the anticipated outcomes of their participation.

4. **Voluntary Consent** – Consent must be given freely, without undue influence from financial incentives or coercion. Special measures should be in place to protect vulnerable groups from exploitation.

5. **Right to Withdraw** – Participants must have the right to withdraw from the research at any time without consequence. They should not be required to provide reasons, and their data must also be withdrawn upon their request.

6. **Proxy Consent for Vulnerable Participants** – If a participant is unable to provide informed consent themselves, such as in the case of children or individuals lacking legal capacity, consent must be obtained from a legally authorized representative.

[4]As a guide $20 per hour minimum

Research involving vulnerable populations

Research involving vulnerable individuals[5] is often essential in addressing social, economic, and health inequities experienced by these groups. Researchers must ensure that such individuals or groups are not merely a convenience sample but stand to benefit from the knowledge, practices, or interventions resulting from the research.

Diminished capacity to consent

There are two other groups of people to consider when seeking informed consent:

1. Those who need assistance to give informed consent
2. Those who are unable to give informed consent

Diminished capacity may result from various factors, including early dementia, brain disease, trauma, intoxication, pain, distress, mental illness, disability, or reduced intellectual capacity (National Ethics Advisory Committee [NEAC], 2019). Researchers must assess an individuals' capacity to consent based on the complexity of the study. Where capacity is diminished, individuals still have the right to make informed choices and give informed consent, to the extent appropriate. The following approach should be used when seeking informed consent - if the individual is unable to read or write, use verbal or other alternative methods of communication to convey information and record informed consent. Consider involving members of the individual` s kopu tangata or support network.

Research involving persons with disabilities

Ensuring equitable access to research is crucial for persons with disabilities and should be given every opportunity to participate. There is a distinction between:

- **Disability research,** which focuses on societal barriers and enables disabled individuals to take leadership roles in removing them; and has the ability to empower disabled researchers and participants (United Nations Convention on the Rights of Persons with Disabilities, 2006).
- **Research involving disabled people,** which may be medical or rehabilitative by nature.

Researchers must engage disabled people early in the study design process to enhance ethical outcomes, well-being, and avoid bias. Recruitment should accommodate different needs and lifestyles.

To facilitate participation, researchers should:

- Allow adequate time for informed consent
- Provide necessary support for decision-making
- Communicate information in an appropriate format

[5]See Disability Act; Welfare Act 1989 and Welfare Act Amendment 2019

- Involve support networks where needed
- Maintain permanent records of the consent process

Researchers should also ensure accessibility by making study results available in both digital and physical formats, including large print and open-access journals. Assumptions should not be made regarding participants' access to phones or email.

Research involving children

Children[6] as research participants in research are particularly vulnerable. It is important to safeguard their interests, and to protect them from harm by ensuring that special ethical considerations be in place for reviewing research involving children. The following notes on ethical guidelines on research with children have been adapted from Research Involving Children developed by Nicola Peart and David Holdaway[7] for health research (HRC, 2017). Research involving children is important for the benefit of all children and should be supported, encouraged and conducted in an ethical manner:

1. Children are not small adults; they have their own unique set of interests
2. Research should only be done with children if the purpose of the research is to obtain knowledge relevant to the needs of children
3. Legally valid consent should be obtained from the child or from a parent or caregiver who is legally entitled to give consent on behalf of the child. When parental or caregiver consent is obtained the assent of the children should, wherever possible, also be obtained by the researcher.

Research design

Before undertaking research with children, the researcher must ensure that:

- The purpose of the research is to obtain knowledge relevant to the needs of children
- If a choice of age groups is possible, older children should be involved in preference to younger ones
- The research is designed or supervised and carried out by people experienced in working with children
- The number of children involved is limited to the number which is scientifically essential.

[6] See Welfare Act 1989 and Welfare Act Amendment 2019; A child is 0 – 16 years

[7] For full references refer to the original article) 1 and updated in 2007 by Nicola Peart. For further information on issues relating to research with children refer to: Peart N, Holdaway D. 2000. Ethical Guidelines for Health Research with Children. New Zealand Bioethics Journal 1 (2): 3-9.
(a) Peart N, Holdaway D. 1998. Legal and ethical issues of health research with children. Childrenz Issues 2:42-6.
(b) Peart N. 2000. Health research with children: the New Zealand experience. Current Legal Issues 3:421-39. The principles are taken from the Guidelines of the Royal College of Pediatrics and Child Health 1999 and the European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine 1996.

Informed consent for children

When inviting children to participate in any research the researcher must ensure that the children, and their parents or caregivers, have been fully informed about the research:

1. Each child must be given full information about the research in a form that he or she can readily understand
2. Children must be advised of their right to decline participation and their right to withdraw from the research at any time without giving a reason
3. Parental or caregiver consent is required and the person giving consent must also be given full information about the research and be advised of the child` s right to decline participation or withdraw from the research at any time
4. Before undertaking research with children, the researcher must ensure that legally valid consent is sought on the basis of the information provided:
    - Only one parent or caregiver is required to give consent. However, if there is more than one parent or guardian, there is an expectation that the person giving proxy consent will consult all of the other parents or legal guardians
    - Written consent should take into consideration the age and competence of the child.

Protection of research participants` privacy and confidentiality

The privacy and confidentiality of research participants must be respected. In particular, researchers must safeguard the privacy and confidentiality of research participants by ensuring that they advise the extent to which their participation in the research will/may be known to others. This means that the researcher must store data and disseminate results in a manner consistent with what the researcher has told participants about their privacy. This duty extends to the appropriate use of third parties to provide information about potential participants (HRC, 2014).

Data sovereignty[8]

Data collection for research purposes is increasingly integrated into routine processes, such as healthcare procedures or interactions with both private and public sector agencies in the Cook Islands. As digitization advances, more data is being collected from sources like administrative records and electronic systems.

In the Cook Islands, data exists in both analogue (paper) and digital (electronic) formats. With the rise of digitization, data collection is becoming more common from sources such as administrative data and electronic records.

Cook Islands data[9] is **tapu** (sacred), and highly valued. As such, Cook Islanders possess an inherent right to exercise guardianship over Cook Islands data and data ecosystems. All data collected in the Cook Islands is subject to the laws and government policies of the Cook Islands[10]. The protection, access and use of Cook Islands data shall be grounded in **Tika`anga `akano`ono`o`anga** (protocols) and **Kite pakari** (knowledge). Cook Islanders will decide which data should be tāpu (restricted) or noa (unrestricted) access (HRC, 2014).

Data storage, use, access and destruction

Researchers must reach mutual agreement with their collaborative Cook Islands researchers or the CINRC on the storage, use, access and destruction of data prior to any data collection. Data shall be stored in the Cook Islands where possible. Copies of the research will also be stored with the Central Policy and Planning Office and the Cook Islands National Library and/or Cook Islands National Archives.

Data disaggregation

Data shall be collected and coded using categories that prioritise Cook Islands social, economic and cultural needs and aspirations. The collection, use and interpretation of data should always uphold the dignity of Cook Islands communities, groups and individuals. Data analysis that stigmatises Cook Islanders can result in collective and individual harm and should be actively avoided.

Future use of data

Current decisions regarding data collection can have long-term consequences, both positive and negative, for future generations of Cook Islanders. A core goal of Cook Islands data governance should be to protect future generations from harm.

Individuals and organisations responsible for creating, collecting, analysing, managing, accessing, securing, or disseminating Cook Islands data are accountable to the communities, groups, and individuals from whom the data originates. Data ecosystems should be designed to enable Cook Islanders to derive both individual and collective benefits (NAEC, 2019; HRC,

[8] See Indigenous data sovereignty: Towards an agenda by Kukutai and Taylor

[9] Cook Island data: Data from Cook Islands people (individual and collective), data about Cook Islands people, and data from/about Cook Islands resources

[10] See Public Health Act 2004; Cook Islands Government Official Information Management Policy; Ministry of Health Act 2013; Cook Islands Natural Heritage Trust Act 1999; Copyright Act 2013

2014).

Benefits and harms

Data has the potential to generate significant benefits for both individuals and Cook Islands communities, now and in the future. In some cases, it may be unethical not to use data, as failure to do so could deny potential benefits, and a failure to use it may also cause harm. Researchers must identify the possible benefits and even cause harm. Researchers must identify and carefully weigh the possible benefits and risks of data use. This includes considering how to minimise and mitigate any harms resulting from data use. Studies involving data should strive to minimise risks and maximise benefits. This applies to both newly collected data and previously collected data being used by third parties (NAEC, 2019).

Privacy and confidentiality

The principles of privacy and confidentiality must be applied to all data at every point in its lifecycle[11]. Researchers must respect and record the restrictions that participants place on the use of their data. They must protect participants` data and only disclose it to those who are authorised by the participants. The only exceptions are when disclosure of the data is required by law[12], or if the researchers believe, on reasonable grounds, that there is a serious and imminent threat to public health, public safety or the life or health of an individual (HRC, 2017).

Sending and or storing data overseas

Currently, research conducted in the Cook Islands is predominantly carried out by researchers based outside of the Cook Islands. While it is highly preferable that data collected in the Cook Islands be stored in the Cook Islands, this may not always be practicable at the time of writing of these principles due to the following reason:

- The standard retention period for research data is typically six years[13], and researchers are responsible for ensuring data security and destruction. As such, research data is often stored in the country where the researcher resides.

Therefore, participant information sheets and consent forms must clearly inform participants in the Cook Islands about:

- The country where their data will be securely stored and the duration of storage
- Who will have access to their data
- When and how they can withdraw their data[14]. If a participant withdraws from the study, their data must be destroyed or returned. It is highly unethical to use data collected from

[11] See Ministry of Health Act 2013
[12] See Ministry of Health Act 2013
[13] This is the standard in New Zealand and applicable in the Cook Islands
[14] Participants in the Cook Islands can withdraw from a research study at any time

a participant after they have withdrawn from the study[15]..

Participants must also be informed that their data will be governed by the laws and standards of data security and privacy in the country where it is stored, and they must consent to their data being sent, stored and destroyed in that country (NEAC, 2019).

Non-identifiable data may be sent overseas without explicit consent if it is not possible, appropriate or practical to obtain consent due to the nature of the information. In cases where non-identifiable data is sent overseas by a public or private sector agency in the Cook Islands, specific conditions for the use of the data should be stipulated. For example, care should be taken to avoid a deficit model when discussing health data related to Cook Islands peoples (NEAC, 2019).

Storage, governance and management of data

Data storage must meet the following standards:

1. Data should be stored in a secure manner. For example: locked file cabinets; password protected databases located on computers in locked rooms; password protected databases via password protected computers.
2. Researchers should assess the benefits and risks of keeping identifiable information linked to stored data. In some cases, maintaining identifiers or links to identifiers (for e.g. tracking participant identity or to re-use the data) may be justified.
3. Data should not be stored longer than necessary for its intended purpose, but it must be retained for the minimum period required for health-related data concerning identifiable individuals[16].
4. Robust policies, processes, and procedures must be in place to manage data throughout its life cycle. This requires high-quality, transparent data governance and data management especially when the consent requirement for data use has been waived; where there is data linking; or when unspecified future use is intended.

Data-linking

Data-linking is a technique for connecting pieces of information that are thought to relate to the same person, family, place or event. If these different pieces of information can be connected to a person in a way that does not breach their privacy or cause harm, linking them can create a rich resource for research to answer complex questions and improve social and health outcomes (Data Linkage Western Australia, 2019).

When data sets are linked, the risks of identification are high especially when the different data sources (which may apply to individual people, households or organisations), may have been

[15] This includes data from focus groups. The researcher must ensure that they record the names of participants and the information of each participant during focus group interviews
[16] Te Marae Ora Ministry of Health has a 10-year period for the storage of Health data

designed and collected without the intention of using them together. The process may give rise to concerns that the combined format produces a detailed picture of individuals that they did not consent to when they supplied the data. Privacy is a major consideration in data linkage work. Researchers involved in data-linking must weigh the potential benefits of their research against the risk that individuals will be identifiable within their results. Researchers must:

- Either seek consent from participants or obtain a waiver from the CIRC for research that involves data- linking with identifiable and re-identifiable data
- Respect any conditions concerning data-linking expressed within participants and/or individuals' existing consent. In the absence of direct participant consent, a waiver must be sought from the CIREC
- Ensure that the data that is linked should be fit-for-purpose. Researchers must be able to justify re-use of requested data
- Must account for the storage and destruction of any linked data. They must submit for review by the CIREC. Researchers must a detailed plan of linked data storage, an accounting of the risks of storage, and plans to mitigate the risk of storage. Researchers must work within established data organisational governance structures, as well as develop specific data management plans that ensure the data is being accessed and linked in an appropriate and responsible manner
- Address the privacy risks of linking data by analysing the primary and secondary uses of the data, considering not just re-identification risks but also inference risks
- Take into account in their analysis whether a person can be directly associated with a particular attribute; and also, the extent to which attributes that may be revealed or inferred depend on an individual` s data and the potential harm that may result.

Databanks

Databanks provide a major resource for quantitative and epidemiological research activities, ranging from disease prevention to resource allocation. For example, researchers can use them to significantly accelerate understandings of health and the effectiveness of health interventions. However, databanks raise issues of dignity, autonomy, privacy, confidentiality and discrimination. Researchers should address these issues in accordance with the following general principles:

- Research using databanks should benefit the Cook Islands, particularly in terms of its public health priorities
- Researchers have ethical and legal obligations to respect the dignity, autonomy, privacy and confidentiality of individuals when using data from databanks.

For research studies that use identifiable or re-identifiable data from databanks and combine it with other data (example data collected from participant via questionnaires), researchers must obtain participant consent or if it is not practical to do so, seek a waiver of consent from an

ethics committee. When planning to contact people because their data is included in a databank, researchers must be aware that some people may not know that their data was submitted to a databank or may be unfamiliar with the process by which researchers gain access to such data.

Researchers must seek a waiver or obtain participant consent to submit their data to databanks, paying particular attention to the parameters of consented future uses. Researchers must respect any conditions that participants have placed on the use of their data stored in databanks (NEAC, 2019).

Data collection

When collecting new data from research participants, researchers must ensure that participants are informed of, and consent to, the collection and use of their data for the study. Researchers must:

1. Only collect data necessary for the specified purposes of their study; and to answer their research question
2. Obtain consent from a participant from whom data has been collected for third party use.

Health research

Cook Islands communities have an integrated and holistic perspective of health and wellbeing. Cook Islands concepts of health include an interconnectedness between beliefs and values, as well as between cultural, spiritual, emotional and social aspects. There is also a view that health and wellbeing are often influenced by family and community, specifically in relation to health and illness (Herman, 2013). Cook Islands health research must be underpinned by an understanding of these concepts, and should be aimed at obtaining data that identifies and reduces inequity across populations, improve Cook Islands health outcomes and strengthen the Cook Islands health and disability workforce (HRC, 2014).

Cook Islands health research should create knowledge and understanding essential for improving the health of Cook Islands peoples.

Human tissue

Human tissue is commonly used in health research. Tissue is a broad term that refers to any biological material obtained from a living person or a body, including tissue, blood, urine, sputum, hair, nails and any derivative from these, including cell lines. It does not include non-human biological material, such as micro- organisms that live on or in a person. Blood serum is acellular and not considered a material subject (NEAC, 2019; HRC, n.d).

Research involving human tissue has special ethical considerations because of the way that tissue is obtained. For example, it may be collected prospectively with consent from individuals

or retrospectively from stored samples with or without consent information that tissue may provide; and the implications of that information for the individual donor, their blood relatives and their community.

Extraction of tissues and genes should be guided by appropriate ethical rules and procedures after prior, free, and informed consent is provided by individuals and communities involved in the research. Genetic materials are part of the broader genealogical complex and identity of Cook Islanders. The participants should be fully aware of how the samples will be used, stored, and disposed of later (HRC, 2014).

It is important to have prior mutual agreement between parties in particular relating to how the samples are kept, ongoing storage in tissue banks, establishment of cell lines, tissue being sent overseas, use within genetic studies, and future use[17].

Cook Islanders hold beliefs about the sacred value of human tissue and researchers must respect these beliefs. Researchers should consider the following in research on human tissue:

- Tissue is Tapu – tissue itself and any associated data are of value, and should be appropriately managed
- Provision of tissue is seen as a form of gifting whereby there is tāpu associated with the gift, and certain conditions therefore apply
- Researchers must consider the ethical issues related to collecting and using human tissue alongside the ethical issues related to the information derived from the tissue.

Genetic research needs careful and specific ethical consideration, because it may reveal information about the predispositions to disease of both an individual and their kopu tangata. Whether or not the disease develops in the individual, information arising from research may have implications for people` s access to employment and education, and to benefits or services, including financial services such as banking, insurance and superannuation. The information may also have important implications for blood relatives and kopu tangata.

At a physical and spiritual level, genealogy is embodied within the deoxyribonucleic acid (DNA) of a person. Therefore, the storage and use of human tissue for genetic or genomic research is a culturally informed activity. When individuals consent to participate in this type of research, the biological material and personal information contributed is considered to be culturally significant by Cook Islanders (HRC, 2014).

Genetic research involves risks that the information arising may be misrepresented or misused in ways that lead to prejudice, stigma, disrespect, discrimination or other harms to participants, their kopu tangata and communities. In designing, conducting and reporting genetic research, researchers must consider the potential psychological, social and cultural significance of their research.

Researchers must plan how to minimise harms, and provide full information about the risks to prospective participants. Researchers must prepare and follow a detailed plan for generating and using genetic material and information (NEAC, 2019).

[17] See Ratuva and Mead (2007)

Researchers must inform participants whether their research might generate information that the participant may be legally required to disclose to a third party (example for the purposes of insurance, employment, finance or education).

Researchers must not use or release genetic material and data for purposes unrelated to their specific research without participants' consent, unless they are required to by law. If their research involves participants' kopu tangata, researchers must consider whether members of the kopu tangata are themselves participants, and whether it is therefore appropriate to seek their informed consent (NEAC, 2019).

Use of tissue

Researchers must treat samples of human tissue as pakau aro`a (gift). They must conduct research involving these samples with respect and transparency:

- Researchers should use existing tissue in an ethical manner, and in accordance with the terms of the original gift or consent.
- Where possible, researchers should give preference to existing sources of tissue, if these fulfil their scientific goals, rather than collecting new samples.
- Researchers must not retain samples of tissue where they cannot justify continued storage. Equally, they should not destroy samples where there is a clear rationale and ethical justification; and cultural grounds for continuing to store them.
- Researchers must have a clear strategy in place for managing health-related findings (expected or incidental) from tissue analysis.
- Those who collect, use and store the tissue must be suitably qualified or experienced (or supervised by those who are).
- Access to tissue obtained for a study must be restricted to those who need it to undertake the study.

Consent and waivers

Researchers must get informed consent from the individual from whom the tissue was or will be collected before they use it for research, unless consent from next of kin family member has been provided in the case of a person being deceased or a waiver of consent is approved by CIREC.

Gaining informed consent to use tissue in research must always be the starting point. Where researchers propose to use tissue without specific consent for research (example where tissue was collected for clinical investigation, or the proposed tissue use is not consistent with the scope of the original research consent), researchers must satisfy CIREC that all of the following conditions for a waiver of consent are satisfied:

- There are scientific, practical or ethical reasons why consent cannot be obtained
- The possible benefits outweigh the possible harms, including to any participant, other

individuals, kopu tangata and Cook Islands community

- Appropriate data and tissue governance plans are in place.

When considering a waiver, researchers should identify if there is any known or likely reason to expect that the individual would not have consented if they had been asked. For example, are there elements which would be upsetting to the people who the tissue belongs? This is not something for researchers to prove beyond reasonable doubt, but the researcher needs to consider this aspect of use of tissue without consent (NAEC, 2019).

When research involves using clinical samples, researchers' use of tissue must not compromise the primary clinical reason for collecting the tissue. Researchers must maintain participants' privacy and confidentiality throughout the period during which they are using and storing the tissue and its associated data. Researchers must consider the potential psychological, social and cultural significance of their use of tissue, and plan to minimise all research harms.

Management plans

When undertaking research involving human tissue, researchers must prepare and follow a tissue management plan that clearly describes the specific purpose of the tissue collection and how the researcher intends to process, store, distribute, use and dispose of the collected tissue. Managing the ethical risks associated with the collection and use of human tissue in research includes:

- Conducting the study according to a detailed and approved tissue management plan
- Managing privacy and confidentiality
- Returning results appropriately and managing incidental findings
- Giving special consideration to the issues involved in sending tissue overseas

The tissue management plan should be annexed in the ethics application, and should specify:

- The methods of collection to be used, volume of tissue to be collected and schedule of collection
- Measures taken to de-identify tissue samples and maintain privacy and confidentiality
- Methods, location and duration of storage, planned analyses
- Access to tissue during the study
- What will happen to the tissue after the study is completed, including details of ongoing storage, whether other researchers will have access to the tissue or be able to distribute it, and whether it will be returned to donors

Sending human tissue overseas

Human tissue may be sent overseas for research, if the individual from whom the tissue was collected has consented to it. It may also be sent overseas for analysis, if that is necessary for a study conducted and ethically approved in the Cook Islands.

Incidental findings

Researchers have a duty and responsibility to inform participants, and ensure adequate follow-up is in place after providing feedback on results or incidental findings. In some research situations it may only be ethical to return clinically significant or clinically actionable individual results.

Confirming if follow-up is appropriate may involve a referral to a suitable health professional or specialist. Suitable counselling (clinical, genetic or emotional) may be necessary for participants, depending on the information uncovered. The study protocol should detail these plans.

Researchers should also consider whether any study results relating to human tissue may have direct implications for the health of a participant` s kopu tangata, especially in the case of

genetics research.

Disposal of tissue

Researchers must communicate the contents of the tissue management plan to participants in plain, non- specialist language as part of the process of obtaining their fully informed consent.

In the context of advances in genetic analysis and data-linking, and the prevalence of biobanks that contain identifiable tissue, researchers should always see human tissue samples, in principle, as re-identifiable. However, levels of identifiability do not affect the ethical implications of using tissue in research. Researchers should remove unnecessary identifiers associated with human tissue samples before storage and analysis, to reduce the risk of confidentiality breaches.

Where identifiers on human tissue are necessary (for instance, where researchers test tissue samples provided in clinical trials and report on them for a purpose that is fed back to the clinical team and in some way determines or directs the treatment of participants), researchers should include this fact in the information they give to participants as part of the process of obtaining their informed consent (HRC, n.d).

Genetic research

Genetic research may involve the study of:

- Single or multiple genes, gene-to-gene interaction or gene-environment interaction
- Acquired somatic variation
- Inherited gene sequences and their variants or their products
- Gene expression, including environmental factors, pharmaceutics and other therapeutic products
- The genes of individuals, families or populations
- Epigenetics
- Use of informatics and genetic information
- Clinical phenotypes.

Researchers are increasingly studying genes and genetic information in clinical, epidemiological and social research (HRC, 2014).

Genomic research

Genomic research is research with the potential for hereditary implications (effects on other family members) which may range from single-gene genetic research to whole genome sequencing and other-genomic research (example exosmic or proteomic research) with potential hereditary implications. Researchers undertaking genomic research involving

identifiable kopu tangata should consult with collective groups early in the research planning phase, and throughout it (Hudson et al 2016).

Incidental genetic results

Genetic material and information collected for genetic research may be significant for research participants, their blood relatives and kopu tangata. Research may have complex and socially significant implications for Cook Islands communities. It may potentially inform people` s life decisions, including health decisions. Genetic research can reveal information about previously unknown paternity or maternity. It has uses outside health, such as for tracing migration patterns and in studies of cultural relatedness (NEAC, 2019).

Where research generates information of potential importance to the future health of participants or their kopu tangata, researchers must prepare and follow a detailed protocol, which takes into account the clinical relevance of the research information, the types of genetic tests used in the research and the significance of those results for participants. The plan should:

- Enable participants to decide whether they wish to receive the information, and who else may be given the information
- Detail the degree to which information would remain re-identifiable
- Either provide for access to genetic and clinical advice and counselling about information of health significance, or clearly recommend to participants that they seek these services from professionals with appropriate training, qualifications and experience
- Detail special provisions in place to protect the privacy and confidentiality of genetic information
- Record any circumstances under which participants may be statutorily or contractually obliged to disclose the results of genetic tests or analysis to third parties (example insurance companies, employers or financial and educational institutions)
- Detail any restrictions in place on the release of stored data or material, especially in the context of studies of rare genetic disorders, where it may be possible to identify individuals, kopu tangata or members of a community even if information is given to others in non-identifiable form.

Where participants or relatives choose not to receive genetic information that could be important for their health, researchers should advise them that they will approach them again to confirm this decision when the results of the research are available, regardless of what the results show. Before seeking their consent to genetic research, researchers must inform participants:

- About the degree to which confidentiality is possible, and of arrangements to keep genetic information private and confidential with regard to kopu tangata, as well to future researchers who may receive the material or information
- Whether information from or about their kopu tangata, in addition to that provided by participants, is required for the research
- Whether the research may reveal information of potential importance to the participant` s future health, or the future health of their children and other relatives

- Whether the research has the potential to detect previously unknown paternity or maternity, or non- blood relationship to siblings, and whether, how and to whom researchers will disclose this information
- That, if the research discovers that a family member may be at risk of a life-threatening or serious illness for which treatment is available or soon to be available, researchers may offer this information to the family member concerned, with the approval of the CIREC, even if the participant does not consent to this disclosure (NAEC, 2019).

Biobanks

A biobank is a collection of human tissue samples stored for potential use in research beyond the life of a specific study. Some common features of biobanks are:

- They are ongoing and open-ended, which allows for unspecified future research and the donation of tissue that is stored for definite or indefinite periods
- They need tissue and data to remain potentially re-identifiable, even if they are coded, because researchers may need to link tissue and associated data to other sources of health information for studies in the future, or to follow up information added over time
- They focus on the common good, with a greater concern for future public benefit than individual benefit for participants themselves. Currently, many studies that make use of biobanks offer no direct or immediate benefit to individual donors.
- A bio sample is a pakau aro`a. Tika`anga `akano`o`anga (principles) should be considered at every decision-making point to ensure that responsibility towards akono`anga Māori (custom) is being met during at all points during each step involving the donation
- In most situations, the custodian of human tissue will be the individual researcher or agency who collected the tissue.

When a biobank is closed, researchers should appropriately transfer or dispose of the biological material and data.

Informed consent to store tissue in a biobank

When seeking participants` consent for storing tissue in a biobank, researchers should provide information on:

- The purpose of the biobank
- Governance arrangements, including the rules of access to the biobank, how they will protect privacy and confidentiality of participants, commercial use and benefit sharing, intellectual property issues and the transfer of tissue or material to other institutions or countries
- The risks and burdens associated with collecting, storing and using tissue

- The nature of the tissue they will collect and the form (identifiable, re-identifiable or non-identifiable) in which they will store the tissue
- Whether the researcher and/or custodian of the biobank will seek specific or broad unspecified consent for future research or approval from an ethics committee for use of identified or potentially identifiable tissue for research
- The procedures for returning results, including incidental findings

Due to the prevalence of future unspecified research, consent does not protect all the interests of participants. Neither does it set aside the moral duty of care that researchers who can access a biobank owe to participants.

Researchers need to establish a coherent set of measures for protecting the interests of participants in addition to consent procedures, such as removing identifiers on data and adhering to the forms of governance that guide the conduct of professionals in the public interest.

Researchers should establish these measures in relation to underlying moral norms and values, and in relation to an agreed understanding of the hazards, benefits and uncertainties of tissue use in the context of particular tissue initiatives.

The Cook Islands public has an interest in the responsible use of tissue to improve the health and wellbeing of individuals and groups. Research using biobanks may lead to improvements in health care and service delivery, better targeting of services and greater understanding of risk factors.

Misuse of tissue can harm individuals, groups and communities. Such harm may include loss of privacy, stigmatisation, discrimination or financial loss. The broader public interest may come into conflict with individual privacy. Researchers or custodians of biobanks should seek to avoid potential conflicts and violations rather than addressing them retrospectively (NEAC, 2019).

Intellectual property

Cook Islanders continue to assert their cultural and intellectual property (IP) rights through a range of mechanisms such as the Copyright Act 2013 and the Traditional Knowledge Act 2013. Of particular concern to Cook Islanders is research that involves the use of traditional plants and other natural resources. Specific concerns for Cook Islands Māori arise from the claiming of intellectual property over natural and cultural properties, and the exclusionary nature of these IP provisions. Traditional uses should never be impacted by IP patents. Opportunities for the sharing of new intellectual property with Cook Islands communities should be facilitated particularly where Cook Islands Māori analyses have contributed to the development of the intellectual property.

Researchers conducting studies in the Cook Islands must adhere to national IP laws and policies to ensure compliance with copyright, traditional knowledge, and access and benefit-sharing (ABS). This includes compliance to applicable New Zealand IP laws relating to

patents, trademarks, and designs.

The Cook Islands is also a member of the World Intellectual Property Organization (WIPO) and has acceded to several key treaties, which influence the IP landscape and enhance the protections for creators and researchers in the Cook Islands.

By understanding and adhering to these national and international IP frameworks, researchers can conduct their studies responsibly, ensuring compliance with both domestic laws and international standards.

Cultural responsiveness

The value of reciprocal relationships reinforces cultural responsiveness in research and ensures that participants will be treated with dignity and respect by researchers. Research that is responsive to Cook Islands communities and populations involved allows opportunity for participants and cultural groups to voice their viewpoints about research design, its analyses and dissemination of research outcomes (HRC, 2014).

The Cook Islands` traditional knowledge and cultural expressions are valuable intellectual property of its people. This protocol ensures that researchers engaging with Cook Islands communities adhere to ethical, legal, and cultural obligations, safeguarding the rights of knowledge holders (Appendix 02).

Guiding Principles

- **Respect for Traditional Knowledge Holders** – Acknowledging and honouring the custodians of traditional knowledge.
- **Prior Informed Consent** – Ensuring knowledge holders fully understand and agree to the research scope and potential use of their knowledge.
- **Equitable Benefit Sharing** – Where traditional knowledge has commercial or research value, the benefits must be shared fairly.
- **Cultural Integrity** – Protecting the authenticity of knowledge and ensuring it is used in ways that align with Cook Islands customs and values.
- **Transparency and Accountability** – Researchers must provide clear objectives, methodologies, and intended outcomes.

Cultural protocol for Research Approval

1. **Engagement with Traditional Knowledge Holders** – Researchers must approach the rightful custodians of knowledge through community leaders, elders, or designated representatives.
2. **Formal Consent Process** – A documented agreement (Appendix 03) outlining the scope of research, intended use of knowledge, and benefit-sharing arrangements.
3. **Review by a Cultural Authority** – A national cultural body or relevant government agency should review and approve agreements to ensure compliance with this protocol.

4. **Compliance with Local Laws** – Researchers must adhere to Cook Islands intellectual property and cultural heritage legislation.
5. **Ongoing Consultation and Reporting** – Researchers must maintain communication with knowledge holders throughout the research process and provide findings back to the community.

Cultural heritage

Aspects of cultural heritage need to be factored in and advised by the appropriate authority.

- Antiquities and Artefacts Act 1994
- Cultural and Historic Places Act 1994
- The WIPO copyright Treaty (WTC)
- WIPO performers and phonograms Treaty (WPPT)
- Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled
- Beijing Treaty on Audio-visual Performances

Creative output and visual documentation

There are ethical and legal implications in respect of creative output (for example dance, movement, poetry, prose and so forth) and visual documentation. Consent must also be obtained for the use of any creative output, visual images or recordings generated as part of data gathering processes. Separate consent must be sought and obtained for the use of these creative outputs, images and/or recordings if they are to be used for public presentations such as teaching or publication purposes. Participants must be informed if these creative outputs, visual images, and/or recordings will be published in electronic publications, including theses which are stored electronically (Victoria University, n,d).

The period of time during which creative outputs, visual images and recordings can be used for teaching purposes or for public presentations should be stipulated at the time consent is sought. In a general sense, where these involve children and adolescents, it is recommended that this period is no longer than six years, at which point consent for continued use would need to be renegotiated. Where creative outputs, and/or visual images are generated by participants themselves as part of the research or teaching activities, ownership of the images needs to be negotiated and agreed on as part of the consent process (Victoria University, n.d).

Researcher/s must ensure that participants understand how any creative output and/or visual documentation of them will be used, and subsequently destroyed. This includes third parties who may appear in these data generated in the course of the research. It is always appropriate to seek the permission of third parties who may appear in photographs, videos, or films, preferably before taking a photograph or making a recording, or conducting the creative output. Although it is not illegal to film or take photographs in public places, collecting images in public places for the purposes of research may raise ethical issues depending on the topic and context. Visual research practices that capture images of third parties in which people can be identified, raise sensitive legal issues, and laws will vary in different jurisdictions; researchers need to be aware of these in the Cook Islands. Regardless of the legal status of third parties with respect to visual data, researchers are ethically obliged to consider what counts as ethical behaviour, in terms of requesting permission from others, particularly in

relation to reporting or disseminating research data (Cox, Drew, Guillemin, Howell, Warr, & Waycott, 2014).

In the Cook Islands it is highly recommended that images of identifiable participants are not copyrighted. Researchers must also take into consideration any cultural sensitivities participants may have in regards to creative output, written, audio, visual and audio-visual documentation. For example, the blurring of faces or destruction of photographs (including third parties in photographs) has cultural implications for Cook Islanders. It may be more appropriate to return the visual data to the person rather than destroy the image. Other issues that may arise in relation to consent include: if a research participant dies during the research process or subsequently, can (or should) images of, or by, that person still be shown? Cultural protocols may apply to the dissemination of photographs of people who have died and the feelings of kopu tangata and Cook Islands communities may also need to be considered. The researcher is responsible for ensuring they take into consideration any social and cultural issues related to the use and destruction of visual data and that these matters are clearly communicated to the participants (see Cox, Drew, Guillemin, Howell, Warr, & Waycott, 2014).

DOCUMENTARIES

1. Complete the “Harm to Humans, Cultural Awareness, or Intellectual Property” section

2. Submit the application for review by the CINREC for review

3. Decision:

    a. If `Approved`, then application is submitted to the CINRC for consideration
    b. If `Not Approved`, additional justification may be required.

Research involving animals or involving animal experimentation

The CIREC recommends using extreme caution when involving animals in research and advises researchers to ask themselves as to whether or not such a step is necessary. Overall, it is important to clearly outline any use of animals during the research process in the initial research proposal.

Researching animals

While there is currently paucity of research proposals that involve animals in the Cook Islands the following protocols are intended to guide research proposals involving animals. The protocols[18][18] take into account the following assumption:

1. Research of animals in laboratories (experimental) in the Cook Islands at this point in time is highly unlikely
2. The CIREC should seek expert opinion on proposals that involve research on animals.

As animals are sentient creatures with the capacity to feel pain, and the interests of animals must therefore be taken into consideration.

1. Respect for animals' dignity

   Researchers must have respect for animals' worth, regardless of their utility value, and for animals' interests as living, sentient creatures.

2. Responsibility when intervening in a habitat

   Researchers are responsible for reducing disruption and any impact on the natural behaviour of individual animals, including those that are not direct subjects of research, as well as of populations and their surroundings. Certain research and technology-related projects, like those regarding environmental technology and environmental surveillance, may impact on animals and their living conditions, for example as a result of installing radar masts, antennas or other measurement instruments.

3. Responsibility for openness and sharing of data and material

   Researchers are responsible for ensuring that there is transparency about research findings and facilitating the sharing of data and material from research on animals.

4. Requirement of expertise on animals

   Researchers and other parties who handle live animals must have adequately updated and documented expertise on animals. This includes specific knowledge about the biology of the animal species in question, and a willingness and ability to take care of animals properly.

The CIEC will not approve use of an endangered or threatened species unless the findings are expected to assist the management and conservation of that species, and only if approval has

[18] See https://www.forskningsetikk.no/en/guidelines/science-and-technology/ethical-guidelines-for-the-use-of-animals-in-research/

been obtained from the National Environment Services. The RED list with the Cook Islands Natural Heritage Trust to be considered.

Research on natural heritage

Cook Islands environment and eco-systems

For Cook Islanders the land and waters not only sustain life, but are themselves alive and are connected to people. It is essential that researchers undertaking research of the natural heritage of the Cook Islands (environment and ecosystems), familiarise themselves with the legislation and protocols below:

- Ministry of Marine Resources Legislation Act 2019 –Part 1 and Part 8 o Seabed Minerals Act 2019
- Seabed Minerals Amendment Act 2020
- Maritime Zones Act 2018 o Marae Moana Act 2017
- Traditional Knowledge Act 2013 – Part 2 and Part 3 o Island Government Act 2012-2013 – Part 9.
- Biosecurity Act 2008
- Disaster Risk Management Act 2007 o Marine Resources Act 2005
- Environment Act 2003 – Part 5 and 6
- Cook Islands Natural Heritage Trust Act 1999

The following protocols[19] are intended to guide research proposals undertaking research on natural heritage of the Cook Islands:

1. Where possible project (design and methodology) should be developed collaboratively with agencies responsible for the management of said natural heritage and stakeholders
2. Research data, analysis and recommendations should seek to increase local and national capacity to understand and manage the said natural heritage, improve environmental education and knowledge.
3. Local partners should be rewarded appropriately for their contributions, for example through recognition in publications and presentations
4. Where appropriate, opportunity to given for concerned stakeholders, such as local communities, to comment on proposals where the research will significantly impinge on their interests, such as when it would take place on their traditional land or near sacred natural sites.
5. Use of traditional ecological knowledge should be appropriately recognised, with free, prior and informed consent for any information used. If the research process or intended uses change, the rights holders must be re-engaged as part of a continual process of free, prior and informed consent, particularly if traditional knowledge or associated genetic resources could be placed in the public domain.

[19] See https://www.iucn.org/sites/dev/files/content/documents/parks_19_2_hockings_final_draft.pdf

6. Field researchers should supply any useful incidental information collected (on species movement, management problems, illegal activities that may need immediate action by an agency) to agency staff (of said natural heritage) through regular constructive briefings (briefing papers, progress reports and verbal reports) rather than wait until they complete the research, whilst respecting confidentiality of information collected through anonymous interviews and questionnaires
7. Intellectual property rights on data and results must be recognised and research should not infringe local rights in intellectual property (example customary laws and community protocols).

Payments for participation in research

Any out-of-pocket expenses[20] incurred by research participants should be reimbursed. In the Cook Islands as a **pakau aro`a** includes compensation for their time. However, any undue inducement to participate in research through payment, goods or services to a research participant or to a body or organisation assisting in the recruitment of participants is unacceptable (HRC, 2014).

Risks and potential benefits

The risks of the research should be reasonable in relation to the potential benefits. It is important that participants feel protected in the knowledge that the researcher is taking all necessary precautions to minimise any harm and to maximise the possible benefits resulting from their participation.

Beneficence

Beneficence is about acting in the public good. This means that researchers should consider how their research study might be of benefit to Cook Islands participants and communities. There may be direct benefits to the participant, for example through the intervention they receive, or to wider Cook Islands society through the results of the research (HRC, 2014).

Non-maleficence

All research studies carry some risk of harm, but it is the duty of researchers to minimise that risk. Researchers have a responsibility to assess their research and to discuss any potential harm, to individuals or communities, in their application for ethics approval. Whenever there is risk of harm, they should give careful consideration to possible alternative procedures.

[20] Example transport costs, meals

Minimisation of harm

While the safety of research participants cannot be guaranteed by researchers, they are responsible for mitigating potential risks. Researchers must ensure they have informed research participants in the participant information sheet and consent form of all potential risks and process used to address such risks. The researchers themselves must be mindful of their own safety and well-being (HRC, 2014).

Scientific design and conduct of the study

Scientific quality in any research project is important and therefore lack of merit will have ethical implications. Research lacking in scientific merit will waste scarce resources, will abuse the trust and commitment of participants, and may needlessly expose them to risk for no appropriate benefit. For research to be ethical, it must be well designed, and the research question must have the potential to lead to cultural, social and economic development of Cook Islanders. Well-designed research is scientifically robust, and uses a research methodology that takes account of relevant cultural, social and economic factors.

The design of a research study is critical in determining whether the research achieves its proposed outcomes, benefiting participants and communities. Mako refers to what is right or good in any given situation. In this context, it relates to the validity of the research proposal. Researchers must ensure that their study design is appropriate to answer the research question (HRC, 2017).

Conflict of interest

Researchers are responsible for ensuring that any potential or perceived conflict of interest must be declared in the ethics application form and in the participant information sheet. They must state the purpose, nature and funding of the research. If the research is funded, the support and its source must be identified in the participant information sheet and research reports. In addition, the researcher must be sensitive to possible conflicts of interest or power relationship between the participants, such as those that might arise between parents and their children, managers and their staff, or teachers and their students (University of Auckland, 2013).

Deception

In almost all instances, it is expected that any research conducted within the Cook Islands will maintain the highest level of transparency. The true purpose and nature of the research project should be clearly indicated to all concerned. Should the collection of valid research data require a less than full disclosure, then this must be clearly noted to the CIREC before proceeding, and appropriate strategies implemented to protect the short- and long-term safety

of all parties. Any research data collected cannot be used for commercial purposes.

Dissemination of results

The dissemination of research outcomes is an important factor in maintaining reciprocal relationships with research participants and Cook Islands communities. Therefore, the researcher must consider the dissemination of research results and convey findings in a culturally appropriate manner in the Cook Islands to those who participated in the research (HRC, 2014). Researchers are encouraged to publish in open access to journals.

Complaint's procedure

A person wishing to raise a matter of concern or a complaint about research relating to the ethical standards of research on human participants conducted by researchers approved by CIREC, may do so in writing to the Chair of CIREC. The complaints procedure is set out in full in this document. Researchers are obliged to inform research participants of the complaint procedure outlined (UA, 2013).

Exceptions to ethics review

The following exceptions to ethics review will apply:

1. Teaching and course evaluations, including all-approved surveys, that are not for the purpose of research
2. Reviews and similar evaluations
3. A solitary interview with a participant who is asked to discuss his or her area of expertise and who can reasonably be regarded as having sufficient seniority and experience to be aware of, and protect, his or her own interests with regard to the research and its publication. However, a series of interviews with a single person or a number of persons on the same topic does require approval
4. A solitary interview with an individual public figure about public matters. However, a series of interviews with a single person or a number of persons on the same topic does require approval
5. Observational studies in public where participants are not identified
6. Discussions of a preliminary nature that will assist in the development of a research protocol or instrument, but will not provide data to be incorporated into the research dataset
7. Research involving publicly available data.

Cook Islands Research Ethics Committee review processes

Review of applications

1. All applications will be reviewed by committee members via email or video conferencing. Only those with queries are to be discussed at face-to-face[21] committee meetings.
2. The Chair of CIREC will categorise applications into low-risk review and full review. A low-risk research project is one where there is a low risk of physical harm, psychological harm, exploitation or other potential adverse effect. Participants must give full informed consent and must have the right to choose anonymity in all reporting. When any application is considered low risk, it will be pre-screened and reviewed by two members of the CIREC and an outcome provided to the applicant within a week of receipt of the ethics application. Full review applications will be reviewed by the CIREC and the outcome provided to the applicant three weeks from the date of receipt (HRC, 2014).
3. Where an application goes to full review, researchers may wish to attend the ethics meeting to discuss their proposal under review. Such discussion will be documented.

Decision-making process

The CIREC will make decisions based on consensus of the committee. This process is more likely to reflect the full range of views on the committee. Consensus does not require that all members support the decision, but that all members consider the decision acceptable. It is particularly the role of the Chair to ensure this happens. On occasion, individual members may wish to abstain from some or all of the decision-making process because of strong personal, moral or religious reasons. Such abstentions shall not affect the approval process (HRC, 2014).

Conflict of interest

To achieve impartiality, any member of an ethics committee who has a proposal before the committee or who has a conflict of interest whereby the impartiality of that member could be questioned, will declare and withdraw from the deliberations at the meeting (HRC, 2014).

Role, function and membership of the Cook Islands Research Ethics Committee

To ensure that all research with human participants conducted in the Cook Islands meets the highest ethical standards the Cook Islands Research Ethics Committee (CIREC) was established to review and approve the adequacy of protection for human participants.

[21] Includes video conferencing

Prior to commencement of research, all research projects that involve human participants must receive approval from the CIREC unless an exemption applies[22].

The CIREC does not grant retrospective approval.

Terms of reference

The Cook Islands Research Ethics Committee (CIREC) will:

1. Ensure that all research conducted in the Cook Islands complies with the highest ethical standards.
2. Protect the interests of participants, the researcher and wider Cook Islands community.
3. Promote awareness of ethical issues relating to research with human participants and other aspects.
4. Review complaints or provide information made by any interested person.

Function

The CIREC will:

- Assess, ratify ethics applications for compliance with ethical principles
- Advise on ethical issues related to research relevant to the Cook Islands

The CIREC shall meet face to face[23] when required. In reviewing applications, the CIREC reserves the right to seek expert opinion.

Membership

The Committee will compromise of five members appointed by the Office of the Prime Minister in its inaugural year and thereafter by the CIREC. The committee will have:

- At least one member who has a strong background in research ethics[24]
- At least two members who are research active
- At least one representative who has strong background in health research
- At least one community representative

Criteria

Strong background in research:

The applicant must have experience in research ethics and have full knowledge of what this entails. They will be essential in ascertaining what ethics is and what ethics is not. Experience may include but is not limited to chairing ethics committees; writing ethics documents; represented the country on the WHO ethics

[22] See Exemptions
[23] Includes video conferencing
[24] Research ethics is a specialised field

Strong background in health research:

The applicant must understand quantitative research as this discipline is primarily quantitative. Poor research design can become an ethical issue as is data collection methods.

Community representative:

The applicant must be able to provide a layperson voice. This role will allow for a cultural perspective to the discussions.

Fees

A fee may be imposed per sitting for non-government members.

Term of membership

The term of membership is two years. Appointments may be renewed but no member shall serve more than three consecutive terms.

Chair

The Chair is appointed by the Chief of Staff Office of the Prime Minister, in consultation with the CIREC. The term of the Chair is two years which can be renewed, but no chair shall serve more than three consecutive terms. At the conclusion of a term of two years. Committee members can discuss the possibility of the position of chair revolving amongst members.

Quorum

The quorum will compromise 50 percent of the membership and must include the Chair.

Reporting

The CIREC reports to the Chief of Staff Office of the Prime Minister or nominee.

Duties of Secretariat for the Cook Islands Research Ethics Committee

1. Record all official communication between researchers seeking ethics approval and CIREC
2. Prepare and distribute the CIREC agenda
3. Maintain minutes that record discussions and decisions at the CIREC meeting
4. Distribute the CIREC minutes once approved by the Chair
5. Place an electronic copy onto the L-drive and a hard copy into the CIREC Meeting folder
6. Maintain all relevant records for a period of seven years

Resolution process for complaints

A person wishing to raise a matter of concern, or a complaint, about approval relating to ethical standards of research on human participants may do so in writing to the Chair of CIREC. The complaint should have sufficient detail to enable the Chair to identify the research and the issues of concern.

The Chair will determine if the complaint will be investigated and, if so, the process to be followed:

1. The Chair will lead, the investigation. The CIREC will be informed that a complaint has been received. The complaint will be recorded and the documentation held confidentially.
2. To protect the privacy of the complainant, the researchers, and research participants, all complaints will initially be treated as confidential to the Chair.
3. A complainant may request confidentiality, but must understand there will be circumstances where such a request will mean the complaint cannot be investigated. The complainant will be advised if this is the case.
4. The Chair will ask the subject of the complaint for a written response.
5. After considering the response the Chair, may seek such further information, as may be necessary to pursue the resolution of the complaint.
6. If the Chair comes to the view that there has been a breach of conditions set by CIREC or there is evidence of misconduct in research, a response will be sought from the researcher.
7. Complainants should be kept informed about the progress of their complaint.
8. At any stage of the investigation the Chair may determine that in the interests of the welfare of research participants it is necessary for a disclosure to be made to specific persons who can assist those research participants.

9. At the end of an investigation where the matter is resolved the Chair will advise parties of findings and will, where necessary, refer the findings to the appropriate person or host institution for any consequential action.

10. If the complaint is about the Chair, or if the complainant is dissatisfied with the Chair` s response, the complainant should, in the first instance contact the Chief of Staff Office of the Prime Minister.

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APPENDIX

Appendix: List of relevant Research Ethic guides, legislations and conventions'

The guiding principles in this document are derived from various documents published by the Health Research Council of New Zealand and the National Ethics Advisory Committee of New Zealand.

Legislation and conventions that may be relevant that researchers include (but are not limited to) the:

- United Nations Convention on the Rights of Persons with Disabilities 2006 United Nations Declaration on the Rights of Indigenous Peoples
- Declaration of Helsinki (WMA 2017)
- International Ethical Guidelines for Health-related Research Involving Humans (Council for International Organizations of Medical Sciences (CIOMS) and WH2016)
- Universal Declaration on Bioethics and Human Rights 2005. The WIPO Copyright Treaty (WTC)
- WIPO performers and phonograms Treaty (WPPT)
- Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled
- Beijing Treaty on Audio-visual Performances Seabed Minerals Amendment Act 2020
- Ministry of Marine Resources Legislation Act 2019
- Seabed Minerals Act 2019 Maritime Zones Act 2018 Marae Moana Act 2017
- Family Protection and Support Act 2017 Statistics Act 2015-16
- Copyright Act 2013
- Ministry of Health Act 2013
- Traditional Knowledge Act 2013
- Narcotics and Misuse of Drugs Amendment Act 2009 Biosecurity Act 2008
- Disability Act 2008
- Official Information Act 2008
- Disaster Risk Management Act 2007 Marine Resources Act 2005
- Public Health Act 2004 Environment Act 2003 Te Reo Māori Act 2003
- Cook Islands Natural Heritage Trust Act 1999 Antiquities and Artefacts Act 1994
- Cultural and Historical Places Act 1994
- Ministry of Cultural Development Amendment Act 1993

Appendix 01: Material Transfer Agreement (MTA)

Material Transfer Agreement (MTA)

This agreement (hereinafter referred to as "**MTA**") is entered into by and between:

i. ————————————, COOK ISLANDS, represented by ———————————— Secretary for ———————————— (hereinafter referred to as "**Provider**")

AND

ii. ———————————— (hereinafter referred to as "**Researcher**").

Hereinafter, jointly or individually, referred to as "**Parties**" or" **Party**"

SECTION 1 Purpose of the MTA

This MTA sets out the terms and conditions governing the transfer of biological and/or cultural material outside of the Cook Islands, as defined in Section 2.

SECTION 2 Description of Material

2.1 Biological Material

The Biological Material (hereinafter referred to as "Material") covered by this MTA includes any material derived from or produced by biological organisms, such as plants, animals, bacteria, fungi, and other life forms. This includes, but is not limited to, nodules, human remains, bones, and other biologically derived materials.

2.2 Cultural Material

The Cultural Material (hereinafter referred to as "C Material") covered by this MTA includes physical objects such as instruments, tools, weapons, utensils, and buildings, as well as intangible cultural elements such as ideas, customs, languages, value systems, and songs.

2.3 Collection Details

The Material and C Material are collected by _____.

SECTION 3 Status of the Material

The Material originates from biological and cultural resources over which the Provider has jurisdiction. It remains under the sovereignty of the Provider at all times.

SECTION 4 Authorised utilisation of the Material

The **Material** is provided by the **Provider** to the **Researcher** for the specific purpose of:

All authorized activities are outlined in the collaborative agreement appended to this MTA (Annex 1: Approved Research Permit).

SECTION 5 Obligation of the **Researcher**

5.1 The Researcher shall handle the Material in compliance with all applicable national and international laws, regulations, and guidelines.

5.2 The Researcher shall ensure that only individuals with the necessary skills, knowledge, and expertise handle the Material.

5.3 The Provider and its employees shall not be held liable for any loss, damage, claim, or liability arising from the Researcher's use of the Material.

5.4 For the duration of the project and for five (5) years after its completion, the Researcher shall provide the Provider with any results or data obtained from the evaluation or utilization of the Material.

SECTION 6 Publications

1.1 The Researcher shall notify the Provider in writing of any intended publication or communication related to the Material.
1.2 The Provider has one (1) month from receipt of the notification to approve or reject the proposed publication.
1.3 The Researcher shall provide the Provider with a final copy of any approved publication.

SECTION 7 Intellectual Property Rights

The **Provider** is pleased to supply a sample of the **Material** described in Section 2, under the following conditions:

7.1 **Material** is used for strictly non-commercial purposes and will not be used by the **Researcher** for, nor supplied to any other parties for commercial purposes, even if those purposes are being pursued in the same laboratory;

7.2 The **Material** is made available for the purpose of the work performed in Annex 1 and will not be used for any other purpose without the express, written consent of the **Provider**;

7.3 In the event that the **Researcher** makes or observes any new discovery, improvement or invention (hereafter "Invention") relating to the **Material**, whether patentable or not, the **Researcher** will act to ensure that the protection of any rights to the Invention is not destroyed nor endangered by way of disclosure or any other route and shall bring this to the immediate attention of the **Provider**. The **Researcher** will not make any patent or secure other property rights without the express agreement of the **Provider**. A further agreement will be sought to specify the share of any benefits from the exploitation of Invention between the **Researcher** and the **Provider**.

7.4 The **Provider** will, at all times, retain the right to use any such an Invention for non-commercial research purposes only;

7.5 Repatriation The researcher will pay for repatriation of materials as agreed to by the provider

7.6 At any time requested by the **Provider** or in the event that the **Researcher** fails to comply with the conditions and provisions of this **MTA**, the **Researcher** shall immediately return the **Material** where and if possible, to the **Provider** and destroy any copies of the **Material** which may have been made in the course of the Work.

SECTION 8 Guarantee, exclusion of warranty and liability

8.1 The **Material** is experimental in nature and is provided without any warranty or guarantee with respect to its performance or fitness for any particular purpose or to the completeness and accuracy of any information related to the **Material** supplied by the **Provider** or any other source.

8.2 The **Provider** makes no representation and provides no warranty that the use of the **Material** will not infringe any other patent, copyright or any other proprietary right.

8.3 The **Provider** shall not be liable for any direct, indirect, consequential or other damages suffered by **Researcher**or any third parties resulting from the possession or the use of the **Material** pursuant to this **MTA**.

SECTION 9 Duration and Termination

9.1 This MTA shall be effective from the date of signature and remain in effect indefinitely unless terminated as specified below.

9.2 Either Party may terminate this MTA at any time with thirty (30) days' prior written notice.

9.3 Upon termination, the Researcher shall immediately cease use of the Material and dispose of it according to the Provider's written instructions.

SECTION 10 Contact Persons

For the Provider: Phone:	**For the Researcher: Phone:**
Email:	**Email:**
Date:	**Date:**

ANNEX 1

[APPEND A SCANNED COPY OF THE RESEARCH PERMIT APPLICATION]

Appendix 02: Akono`anga Māori – Cultural considerations for Research

When conducting research in the Cook Islands, it is essential to be culturally sensitive and respectful. The Cook Islands have a unique culture deeply rooted in traditions, and understanding these cultural considerations is crucial for building trust and conducting meaningful research. Below are key cultural protocols to observe:

Mana Pou Toru – Three Pillars of Authority: Three sources of power in the Cook Islands which are always consulted and acknowledged. Traditional tribal titles, the Church and Government.

Tutā`aka`aka - Respect for Elders: Elders (Pa Metua) hold a significant role in Cook Islands society and are highly respected. When conducting research, especially involving older generations, it is essential to seek their guidance and approval.

**`Aka`aravei`anga - Traditional Greetings:** A warm welcome is customary. The traditional greeting often involves a kiss on the cheek, especially among close acquaintances. When meeting locals or entering someone`s home, politeness and courtesy are highly valued. Establishing connections through papa`anga (genealogies) is a meaningful way to build rapport.

Uipa`anga - Community Engagement: Community participation is fundamental in research. Engaging with local leaders and seeking permission before conducting research in a particular area is crucial. Informing the community at island meetings is often an essential part of the process.

Kai Vananga - Oral Tradition: The Cook Islands have a strong oral tradition, where storytelling plays a vital role in preserving history and culture. Researchers should be prepared to listen to and respect oral narratives, as they provide valuable cultural insights. Where possible, research methods should incorporate oral traditions to align with cultural practices.

Reo/Talatala - Language: While English is widely spoken, particularly in Rarotonga and for official matters, it is important to acknowledge and respect the use of Cook Islands Māori (Reo Māori) and Talatala in Pukapuka. Learning and using basic phrases in these languages demonstrates cultural respect and appreciation.

Peu Māori - Traditional Values and Customs: The Cook Islands uphold strong traditional values and customs. Some locations are considered sacred (*tapu*), and researchers should always consult local authorities or elders before accessing these sites to avoid causing offense.

Taonga - Gift-Giving: Offering small, culturally appropriate gifts can help build goodwill with local participants and informants. However, researchers must ensure that gifts do not violate local customs.

Rakei tau - Modesty and Dress Code: Dress modestly when interacting with locals, especially in rural and traditional areas. Revealing clothing may be considered disrespectful in some contexts.

Tika`anga – Permissions, Consent, and Ethical Research:
Informed Consent: Always obtain informed consent from participants before conducting research. Clearly explain the purpose of the research and how their information will be used and shared.

Landowner consultations: When working in the outer islands (*Pa Enua*), permission must be sought not only from the Mayor and Island Council but also from relevant landowners.

Local Expertise: Collaborate with local experts or cultural advisers who can provide insights into the nuances of Cook Islands customs and protocols.

Gender and Religious considerations:
Gender Sensitivity: Be aware of traditional gender roles and expectations within the Cook Islands. It`s important to approach research involving sensitive topics related to gender with care and respect.
Religious Observance: Sunday is traditionally a day of worship and rest in the Cook Islands. Most businesses and work activities cease on this day, and researchers should plan accordingly.

Some useful vocabulary

Aro`a and Meitaki: These are defined as Love, kindness and thankfulness. These expressions are very important to Cook Islanders

Akaoki te meitaki: Can be described as (give back) which is through compensation and ensuring that the results of the research are shared as effectively as possible.

Taonga/Atinga – Donation: This custom serve to maintain reciprocal ties within the family and community. There should be some kind of offer to the participants.

***Akapapa`anga:*** A cornerstone of Cook Islands Māori society. It informs the way our society is built and the collective enterprise of our people. It is important that our Akapapa`anga and values guide us through ethical matters. Akapapa`anga is central to understanding Cook Islands Maori world views and the connections which binds us together, including, the Moana (sea), Enua (land) and Mareva (air).

Ranga Pokai or KimiKimi`anga – Research

Uipa`anga or Iriiri Kapua - Consultation

***Pa Metua* - Elders**

Ariki - High chief, ruler over a tribe (paramount chief),

Mataipo/Tutara - The head of a sub-tribe. (Paramount in their matakeinanga),

Rangatira - Hereditary title under the Ariki or Mataiapo.

Te Kopapa Reo Maori - Delegated authority on Cook Islands Maori language.

Please note that the Cook Islands consist of multiple islands, and there may be variations in culture and customs between them. Always be open to learning and adapting to the specific cultural norms of the area you are conducting research in. Building trust and establishing good relationships with the local community is key to successful research in the Cook Islands.

Appendix 03: (SAMPLE) Formal Agreement between Traditional Knowledge Holders and Researchers

1. Parties to the Agreement

This agreement is made between:

i. **Traditional Knowledge Holders:**
   - Name(s): _____
   - Village/Community: _____
   - Representative (if applicable): _____

ii. **Researcher(s):**
   - Name: _____
   - Institution/Organisation: _____
   - Contact Information: _____

2. Scope of Research

- Title of Research Project: _____
- Purpose of Research: _____
- Expected Duration: _____
- Knowledge Areas Covered: _____

3. Consent and Use of Knowledge

- The researcher agrees to respect and acknowledge the knowledge holders as the rightful custodians of the knowledge shared.
- The knowledge holders consent to sharing knowledge for the specified research purposes only.
- Any use beyond the original scope requires further written consent.

4. Intellectual Property and Benefit Sharing

- The rights to the traditional knowledge remain with the knowledge holders.
- If the research leads to commercial applications, the researcher commits to fair benefit-sharing, which may include:
  - **Revenue sharing** (percentage agreed upon)
  - **Co-authorship in publications**
  - **Community development contributions**
  - **Other agreed-upon benefits**

5. Confidentiality and Cultural Integrity

- Certain knowledge may be classified as sacred or restricted. Researchers must not publish, disclose, or use such knowledge without explicit permission.
- The researcher must ensure that findings are represented accurately and respectfully in any publications or presentations.

6. Reporting and Community Access to Research

- A copy of all research findings will be provided to the knowledge holders and the appropriate cultural authority.

- Knowledge holders retain the right to review and approve findings before public dissemination.

7. Dispute Resolution

- Any disputes arising under this agreement will first be resolved through dialogue between parties.
- If unresolved, disputes may be referred to a local cultural authority or mediation body.

8. Signatures

We, the undersigned, agree to the terms outlined in this agreement.

Traditional Knowledge Holder(s):
Name: _____
Signature: _____
Date: _____

Researcher(s):
Name: _____
Signature: _____
Date: _____

Witness (if applicable):
Name: _____
Signature: _____
Date: _____

Kōutu Mana Tūtara o te Ipukarea · The Office of the Prime Minister