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## Research Policy and Supporting Documents

This National Research Policy provides an overarching framework for managing research that is being conducted within the Cook Islands. The NRP is currently under review to ensure it remains relevant and effective in enabling researchers to contribute to the ever growing knowledge economy and society, and ensure that research is carried out in such a way as to protect our people, environment from possible harm or exploitation.

### a) Cook Islands Research Policy

#### Introduction

1. The Government of the Cook Islands is committed to generation of knowledge and expanding access to it on behalf of its people. It supports developments and strengthening of capacity and capability to do research in the Cook Islands and also recognises the importance of viable research activity as part of its national sustainable development.
2. Access to information and research outputs across the full range of sectors will inspire and assist social, economic, cultural and environmental initiatives.

3. Conduct of research in the Cook Islands and retention of its outputs for use by the country along with access to relevant research information developed overseas are important.
4. In promoting research the Government of the Cook Islands places great emphasis on safeguarding the interests of the Cook Islands people and their unique resources. To do this the Government has the responsibility to provide an environment that promotes integrity, while at the same time encouraging openness, sharing of skills and creativity among researchers as well as their research participants. To enable this to be achieved, the Government of the Cook Islands recognises that a robust research management framework must be put in place.

#### Rationale

5. There are concerns that the absence of a **robust policy framework** and **processes to manage national research activities** will mean that potential benefits will not be obtained. There is also a real risk of exploitation particularly with research into marine and terrestrial resources, indigenous fauna and flora, population health and genetics studies. Loss of rights to intellectual property has been identified as an issue across a range of research activities.
6. To date the oversight of research activities in the Cook Islands has not had the backing of a policy framework, guidelines and processes to protect the rights of the Cook Islands and Cook Islanders and to ensure that benefits from research are maximised. The lack of a policy framework has led to those seeking to conduct research not being clear as to their responsibilities and there has been no ongoing oversight to ensure that external researchers and organisations have met their obligations.
7. The Cook Islands Government also recognises the importance of building capacity to conduct research and to translate the results into evidence to develop informed policies, services, processes and products. Building and strengthening national research capacity in areas of potential research excellence and innovation are identified, encouraged and promoted and that research by Cook Islanders is advanced.
8. The policy provides a framework to manage all research activities conducted in the Cook Islands. It includes research sponsored by donor agencies, research conducted by staff and students to overseas academic institutions, and research conducted under the mandate of a Government Ministry or Department. The policy framework reflects international best practice and seeks to ensure that the interests of the Cook Islands and its peoples are protected and that the research capacity and capability of Cook Islanders is promoted and encouraged.
9. The vision for the national research policy is:

*“Maximum benefits for the Cook Islands through research”*

It is envisaged that a robust research management framework will ensure that this vision is achieved.

#### Definition of Research

10. Research, in this policy, is defined as **“Any creative and systematic work to increase the stock of knowledge or its use or application”**.  
Research should be distinguished from audit which is an activity conducted to

examine practice and outcomes at a particular time and place to inform and improve management rather than provide advancement of knowledge. The research policy does not cover audit unless it is intended that the outcomes of the audit are to be published and thus contribute to advancement of knowledge within a broader community.

## Governing Principles and Objectives of the Research Policy

11.

- a. This policy seeks to provide a robust framework to manage all research conducted in the Cook Islands which will encourage and facilitate the developmental needs of the country. It is well recognised that high quality and useful research requires a facilitating environment and if this does not exist, research will not flourish. It is also important that effective control must also be exercised to build upon and support good research practice.
- b. This policy recognises that the research environments in the Cook Islands have a number of unique features. It is a country that because of its size, location and environment and its culture, attracts researchers. Such an environment requires a strong infrastructure for research. An infrastructure that is liberating to encourage research yet, at the same time, one that protects the Cook Islands and its people from exploitation.
- c. Within the framework is a code of ethics and good research practice. These have been developed by the Cook Islands and are based on the principles described in the Guidelines for Pacific Health Research (HRC NZ 2005). All researchers conducting research in the Cook Islands will be expected to subscribe to the Code a responsibility which is reflected in the conditions for a Research Permit.
- d. The policy will create an enabling environment for the development of national research capacity that is essential to support the sustainable development of the Cook Islands. This will encourage and support Cook Islanders need to undertake research which will contribute to the country's development goals and to the personal advancement and empowerment of its people. The right research environment is a pre-requisite for a flourishing research tradition.
- e. Dissemination of research findings and their translation into evidence informed policies, services, processes and products is essential and must be encouraged and be timely to be effective. Transfer of knowledge to a broad community of interest is important if the benefits of research are to be understood and realised.
- f. Ease of access to research data and its analysis are important if opportunities are to be maximised. The advantages arising from use of modern information technology systems is recognised in the policy.

- g. The policy builds on the existing processes that have been in place for many years. It will seek to add value and will promote research which supports the National Sustainable Development Plan (2011-2014) – The Pathway for Sustainable Development in the Cook Islands.
- h. The policy will provide mechanisms to link researchers across sectors, research areas and communities to build collaborative research programmes and partnerships. The value of regional and international research is also recognised and the Cook Islands will participate in such activities to enhance outcomes for its community.
- i. The policy will formulate, wherever appropriate, the links between research and development to enhance economic, social, cultural and environmental outcomes.

#### Principles for conduct of research in the Cook Islands

The following seven principles are based on those developed by the HRC NZ for conduct of research in the Pacific.

- **Relevance** – Research should contribute to identified priorities and national goals and outcomes e.g. National Sustainable Development Plan (2007 – 2010)
- **Participation** – Cook Islands people should participate at all levels and stages of a research project and also provide support for the Cook Islands member(s) of the research team.
- **Quality** – All research should be of high quality, well-designed and delivering valid reliable results which stand up to peer review. The methodology should be culturally acceptable.
- **Commitment** – Researchers need to make a commitment to work with and for the Cook Islands communities. Where possible this should be sustainable.
- **Relationships** – Establishment of significant and sustainable relationships are essential not only to build capacity but also to ensure research knowledge is translated into outcomes.
- **Reciprocity** – Reciprocity requires that knowledge gained through research will be shared with and used to benefit research participants and where appropriate other people.
- **Capacity Building** – Capacity building through research is essential if research for development is to be successful.

In addition to the above principles that are five others which relate to ethics and where appropriate these requirements should also be met.

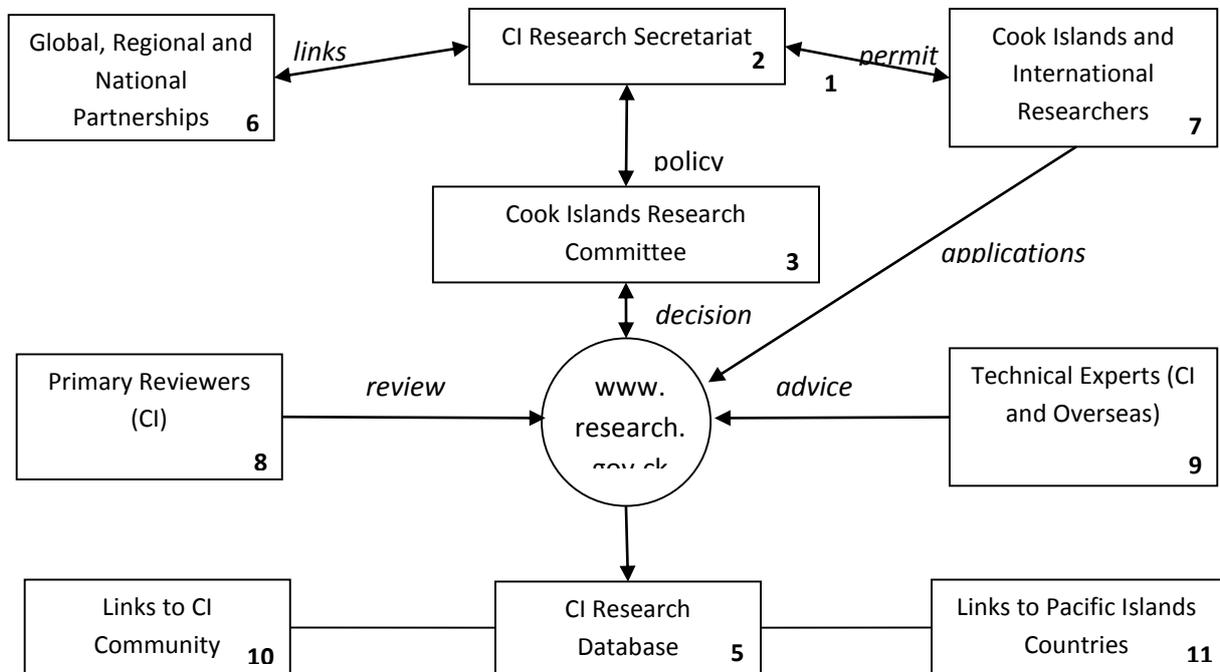
- **Respect** – The researcher and research participants should each respect each other and demonstrate respect.
- **Cultural Competency** – Researchers are required to create safe and enabling research environments that support culturally competent practice. Understanding the beliefs, values and practices of all those involved is paramount.

- **Meaningful Engagement** – All activities must involve meaningful engagement enabling effective consultation and conduct of research.
- **Rights** – All those to be involved in research must have the right and freedom to make an informed choice as to whether to participate.
- **Protection** – Pacific research relationships are often based on structural societal inequalities and care must be taken to protect those less powerful. Indigenous Pacific knowledge and knowledge holders should be protected.

As noted above it is implicit that the results of all research be disseminated widely and utilised to deliver knowledge, economic, environmental, cultural, health and social outcomes for the Cook Islands. Where the results of research are of commercial value the benefits should be shared between the researcher(s) and the Cook Islands.

# The Research Policy Framework

## Section 1: The Policy Architecture



The key features of the Policy Architecture are shown above. The roles and responsibilities of those involved in the administration of all research conducted in the Cook Islands are described below:

1. **Central Policy and Planning Office of the Office of the Prime Minister (Cook Islands Government)** is the host for the Cook Islands Research Secretariat and is responsible for development of policy and administration of the research framework.
2. **Cook Islands Research Secretariat** is responsible for the day to day administration of all research related processes e.g. receives applications, organises reviews, coordinates Cook Islands Research Committee (CIRC) meetings, issues research permits, updates the research database and manages the website and links to national, regional and other stakeholders. The Research Secretariat is the central point of the framework.

3. **Cook Islands Research Committee (CIRC)** has 6 members (3 government sector members and 3 non-government members with an eminent person as chair. Terms of reference for CIRC are available on [www.research.gov.ck](http://www.research.gov.ck). CIRC review all applications for a research permit together with recommendations from the primary reviewer and advice from technical experts (if required). The criteria used by CIRC are as follows:
  - a. potential to address national priorities and deliver benefits;
  - b. funding and cultural arrangements to conduct research are appropriate;
  - c. have primary reviewers recommended approval;
  - d. will the proposed research strengthen research capacity;
  - e. is additional information required.

The CIRC decide if research is to proceed.

4. [www.research.gov.ck](http://www.research.gov.ck) is the focal point of the Research Framework providing the link with researchers and reviewers, Research Secretariat, CIRC and the CI Research Database. The website also provides information on ongoing research activities, conferences and links to the CI Tourism website.
5. **CI Research Database** is the repository of all information relevant to research seeking approval, ongoing or completed. Over time the database will be searchable providing on-line access to all current and past research.
6. **Global, Regional and National Partnerships** with the Cook Islands will, where appropriate, have a link to the CI Research Secretariat to facilitate dissemination of research related news.
7. **Cook Island and International Researchers** will link through the internet to the CI Research Secretariat and also be able to submit applications for a Research Permit on-line.
8. **Primary Reviewers** are a key part of the review process for all research proposals. The reviewers will usually be senior representatives of a relevant Government Ministry or Department but could be associated with another organisation with responsibility for the relevant sectors in the Cook Islands. Confidential reports are provided by reviewers. The criteria used by Primary Reviewers are as follows:
  - a. research to provide benefits to Cook Islands;
  - b. proposed study design and research methods are appropriate;
  - c. research team have appropriate qualifications and experience;
  - d. Cook Islander researcher is appropriate;
  - e. proposed funding arrangements are acceptable;
  - f. plans for analysis and dissemination of results appropriate;
  - g. is new intellectual property likely to be developed;
  - h. are plans to strengthen Cook Islands research capacity acceptable.

9. **Technical Experts (Cook Islands and Overseas)** provide advice to the primary reviewers and/or CIRC by invitation where additional technical expertise is required. For each sector the Cook Islands Research Secretariat has established a link to a major research organisation or government agency in New Zealand as the 'first line' for advice.
  
10. **Links to the Cook Islands Community** are a key part of the Research Framework providing details of past and present research activities and links to the dissemination of results.
  
11. **Links to Pacific Island Countries** will facilitate sharing of information regarding proposed research and uptake and translation of research results to evidence informed policy, services and products.

**b) RAF08 Research Application Form**

**OFFICE USE ONLY**

Application No:

**A. PROPOSAL SUMMARY**

1. Contact Details

a. First Named Investigator

Title	
Surname	
First Name(s)	
Position at Host Institution	
Host Institution	
Department	
Institution	
Address	
City	
State	
Country	
Postal Code	
Telephone number	
Fax number	
Email	

b. Other Named Investigator(s)

Title	
Surname	
First Name(s)	
Host Institution	
Department	
Institution	
Address	
City	
State	
Country	
Postal Code	
Telephone number	
Fax number	
Email	

c. Cook Island Investigator(s)

Title	
Surname	
First Name(s)	
Contact details	
Ministry/ Department/Organisation	
Address	
Telephone number	
Fax number	
Email	

2. Project Details

- a. Title of Research Project (max 20 words)
- b. Lay Summary of Research (max 80 words)

3. Research Sector(s)

Put a  in all research sectors to which the research applies

- Agriculture
- Culture
- Education
- Environment
- Health
- Marine
- Natural Heritage
- Social Development
- Spirituality
- Tourism
- Works
- Other - Please specify \_\_\_\_\_

4. Duration of research

- a. Start Date of Research (dd/mm/yy)
- b. Project duration in months
- c. Number of visits to the Cook Islands

B. DESCRIPTION OF THE PROJECT

1. Rationale for the Project (half page)  
Please explain links to the national priorities of Cook Islands and potential contribution to knowledge and economic, social, environment and health goals.
2. Description of the project (1 page)  
Please describe the proposed project including a description of methodologies to be used and likely research outputs.
3. Dissemination of Research Results (1 page)
  - a. Please explain how the results of the research project will be disseminated.
  - b. What plans will be put in place to ensure that the Cook Islands will benefit from the research.
4. Description of Research Capacity Strengthening (half page)  
Please describe how your research will contribute to research capacity building (e.g. postgraduate research training) in the Cook Islands.
5. Collection of samples (half page)  
Describe what samples (e.g. mineral, marine, fauna, flora, human) are to be taken; where and how will they be used and how will they be dispensed with at the end of the project.
6. Research Funds
  - a. Source of Research Funds
  - b. Estimated total cost of research US\$ \_\_\_\_\_
  - c. Estimated % of expenditure in Cook Islands \_\_\_\_\_%

## C. REGULATORY APPROVALS

1. Research Permit
  - a. Type of Research Permit sought (Please tick relevant box)
    - Cook Islands researcher is First Named Investigator
    - Foreign researcher is First Named Investigator
2. Type of Research
  - a. Type of Research (Please tick relevant box)
    - Research commissioned by a Ministry on the Cook Islands
    - Research commissioned/sponsored by a donor agency
    - Research is investigator initiated
    - Research is initiated by private sector
3. Location of Research (Please tick all relevant boxes)
  - Aitutaki
  - Atiu
  - Mangaia
  - Manihiki

- Manuae
- Mauke
- Mitiaro
- Nassau
- Palmerton
- Penrhyn
- Pukapuka
- Rakahanga
- Rarotonga
- Suwarrow
- Territorial Waters

4. Ethics Approval

a. Proposed research involves use of animals

- Yes       No

If yes – Animal Ethics Committee approval has been obtained   
 applied for

Please provide details of ethics Committee and date of approval.

Animal Ethics Committee	
Contact details	
Date of approval (dd/mm/yy)	

b. Proposed research involves use of human subjects and/or human tissue

- Yes       No

If yes – Human Ethics Committee approval has been obtained   
 applied for

Please provide details of Ethics Committee and date of approval.

Human Ethics Committee	
Contact details	
Date of approval (dd/mm/yy)	

5. Other regulatory approvals

Please specify any other regulatory approvals relevant to the proposed research (e.g. hazardous substances, bio-security, radioactivity and pharmaceuticals).

6. Intellectual Property (Please tick box, if relevant)

The research project has potential to develop intellectual property

Yes     No

If yes – Please describe the steps to be put in place to protect and develop the intellectual property and for sharing of benefits with the Cook Islands.

D. CURRICULUM VITAE

Brief (2 page) CV of First Named Investigator is attached (Required).

Brief (2 page) CV of Other Named Investigator(s) is attached

E. DECLARATIONS

1. Declaration by First Named Investigator

The information supplied in this application is, to the best of my knowledge and belief, accurate. I have considered the ethical issues involved in this research and believe that I have adequately addressed them in this application. I understand that if the protocol for this research changes in any way I must inform the Cook Islands Research Committee.

\_\_\_\_\_  
NAME OF FIRST NAMED INVESTIGATOR (PLEASE PRINT):

\_\_\_\_\_  
SIGNATURE OF FIRST NAMED INVESTIGATOR

\_\_\_\_\_  
DATE

2. Declaration by Institution

If First Named Investigator is an employee of a host institution the signature of an individual designated by the institution to approve research proposals and to provide on behalf of the institution and the First Named Investigator assurance that

research will be conducted in accordance with the Research Permit requirements and conditions.

I have read the application and it is appropriate for this research to be conducted by the host institution and the host institution will take appropriate action to sanction the researcher if they fail to conduct the research proposed in this application in accordance with the Research Permit requirements and conditions.

\_\_\_\_\_  
NAME AND DESIGNATION (PLEASE PRINT):

\_\_\_\_\_  
SIGNATURE

\_\_\_\_\_  
DATE

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### **c) Guidelines for Completion of Research Application Form (RAF-08)**

#### **Introduction**

To conduct research in the Cook Islands all researchers are required to obtain approval from the Cook Islands Research Committee (CIRC). Applications to the CIRC must be made on the approved Application Form (RAF-08). This can be accessed from the Cook Islands Research Unit website ([www.research.gov.ck](http://www.research.gov.ck)). Applications should be made on-line or by downloading and completing a word document. These guidelines are designed to provide assistance to applicants and should be read together with the Cook Islands Research Policy and the Cook Islands Code of Conduct for Researchers (see [www.research.gov.ck](http://www.research.gov.ck)).

Applications should be on Application Form (RAF-08)

#### **A. Proposal Summary**

1. **Contact Details (First Named Investigator)**  
The First Named Investigator should be the project leader and they will be the individual to whom all correspondence will be addressed.
  
2. **Other named Investigator(s)**  
Contact details should be provided for all other Named Investigators.
  
3. **Contact details of Cook Island Investigator(s)**  
All research conducted in the Cook Islands should have at least one Cook Islands person working in partnership with the Named Investigator(s). This individual(s) should be identified prior to submission of the proposal and their experience and expertise should be used in the design of the research project. For further information Named Investigators should contact the National Research Unit ([info@research.gov.ck](mailto:info@research.gov.ck)).
  
4. **Title of Research Project and Lay Summary**  
The title of the project should be no more than 20 words in length and it should describe what the research is about.  
  
The lay summary (max 80 words) will be used by the National Research Unit in its Registry of Research and in media releases. Applicants should note that details of the Project Title, Named Investigator(s) and lay summary will be included on the Cook Islands Research Website, if the proposal is approved.
  
5. **Research Sector(s)**  
To ensure that a research proposal receives appropriate review the Research Sector(s) which describes the research should be checked. Information on the research priorities for each of the sectors is available on the [www.research.gov.ck](http://www.research.gov.ck). If your research falls outside the research sectors listed check the 'other' box and briefly describe the research sector.

## B. Description of the Project

1. **Rationale for Project (max half a page)**  
This section should be no more than half a page and it should explain the links between the proposed research and the Cook Islands priorities for the research area. It should also describe the potential contribution that the research will make to the economic, environmental, social and health goals and to development of knowledge.
  
2. **Description of Project (max 1 page)**  
This section should describe the goals and specific objectives of the research

project. Details of methodologies and proposed methods of analysis should be described. Proposed outputs of the research should be detailed.

3. Dissemination of Research Results (max 1 page)  
This section should describe how the results of the research project will be disseminated to end-users. Plans which describe how the Cook Islands will benefit from the research should also be described.
4. Description of Research Capacity Strengthening (max half a page)  
It is important that research conducted in the Cook Islands contributes to strengthening of the local research capacity. This section should describe how the proposed research will contribute to this goal. Where possible training positions should be supported on the research project.
5. Collection of Samples (max half a page)  
This section should describe what samples (e.g. minerals, marine, fauna, flora or human) are to be collected during the research project. Details of where and how they will be used together with the proposed plans to dispose of the samples at the end of the project should be described.

#### C. Regulatory Approvals

1. Source of Research Funds  
It is expected that all research projects will have received full financial support prior to applying for and receiving a Research Permit. This section seeks details of the funding agency/donor agency supporting the research, together with an estimate of the total costs and the % of the total project costs which would be expended in the Cook Islands.
2. Type of Research Permit Sought (for administrative purposes)  
This section seeks information as to whether the research project is led by a Cook Island researcher or permanent resident of the Cook Islands (i.e. as First Named Investigator) or by a foreign researcher.
3. Type of Research (for administrative purposes)  
This section seeks information on the origins of the research. Is it commissioned by a Ministry in the Cook Islands, commissioned/sponsored by a donor agency (e.g. ADB, WHO, NZAID), investigator initiated or initiated by a private sector agency/organisation (e.g. pharmaceutical company).
4. Research Location (for administrative purposes)  
This section seeks information on the location of the research within the Cook Islands. Applicants should check each of the islands involved. If it is a marine study consider checking box for Territorial Waters.

5. Ethics and Other Regulatory Approvals

All research to be carried out in the Cook Islands is required to have ethics approval (animal and/or human) *before* a research permit is issued. The approving ethics committee(s) for foreign/overseas Named Investigator(s) would usually be that of the host institution. For Cook Islands led projects ethics review approval will be conducted by the relevant Cook Islands Government Ministry (e.g. Ministry of Health). Where necessary the CIRC may seek advice ('second opinion') on ethical issues from international bodies with appropriate expertise (e.g. Health Research Council of New Zealand Ethics Committee).

Where other regulatory approvals are likely to be required (e.g. biosecurity, hazardous substances, clinical trials) investigators should seek advice on requirements from the Cook Islands Research Unit prior to submission of an application.

6. Intellectual Property

The underlying principle of is that benefits arising from development of IP should benefit the Cook Islands. Where IP generation is a possible outcome of a research project the First Named Investigator should describe how protection and development of any project related IP will benefit the Cook Islands.

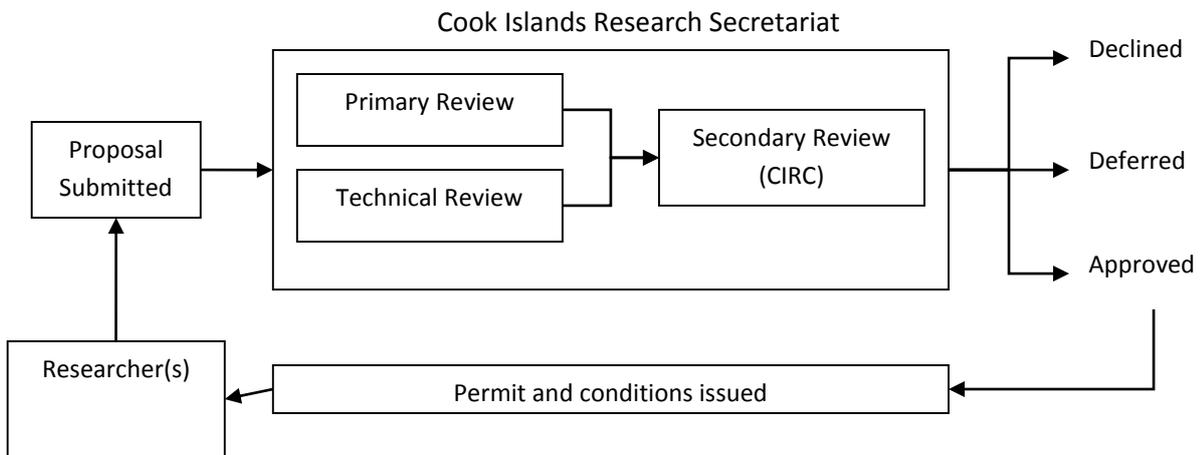
D. Curriculum Vitae

A brief CV (no more than two pages) for the First Named Investigator must be attached to the application. It should include a description of qualifications and expertise relevant to the proposed research. The CV should be dated. Relevant information should also be included for all other named investigators.

E. Declarations

The First Named Investigator and Institutional Authority must sign and date the application. The signed Declaration page should be faxed or sent as a PDF to the National Research Unit if the application is completed online.

#### d) Process to Obtain Approval to Conduct Research in the Cook Islands



## Process

1. Research proposal is submitted on official form to the Cook Islands Research Secretariat at the Central Policy and Planning Office of the Office of the Prime Minister.
2. Primary review conducted by Ministry, Department or Organisation official(s).  
Criteria:
  - Research will contribute to sector priorities.
  - Study design and research methods are appropriate.
  - Research team have necessary expertise and qualifications.
  - Cook Island investigator is appropriate.
  - Study will strengthen research capacity in Cook Islands.
  - Intellectual Property issues have been addressed.
3. Technical review by national and/or international experts may be required.
4. Cook Islands Research Council (CIRC) reviews proposal and recommendations of primary (and technical) review(s) and decides on the outcome. Criteria:
  - Research will benefit the Cook Islands.
  - Cultural issues have been adequately addressed.
  - Plans to disseminate results are appropriate.
  - Proposed research has received a primary review.
  - Research has an appropriate level of funding.
  - Proposed study has regulatory and ethical approvals.
5. If the proposal is approved the Research Secretariat will negotiate any conditions with Researcher and/or Research Team and issue permit.
6. If proposal is deferred the Research Secretariat may seek additional information from the Researcher and/or Research Team and/or decide to seek an additional review(s).

### e) Secondary Review of Research Proposal by CIRC

For use by the Office of the Prime Minister and Cook Islands Research Committee

To be completed by Cook Islands Research Secretariat

1. First Named Investigator:
2. Title of Research Project:
3. Copy of Research Proposal is attached  Yes
4. Copy of Primary Review is attached:  Yes

To be complete by CIRC members

1. Is the proposed research consistent with national priorities and will the research provide benefits to the Cook Islands?  
 Yes  No
2. Are all arrangements, including funding and cultural issues, to conduct the research appropriate?  
 Yes  Not clear  No

If not clear what additional information is required?

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3. Has the Primary Review recommended the proposal be approved?  
 Yes  No
4. Will the proposed research strengthen research capacity in the Cook Islands?  
 Yes  No
5. Recommendations:  
 Research permit **approved**.  
 Research permit **declined**.  
 Research permit **deferred**.

If Research Permit deferred please provide details of additional information required::

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Details of person completing the Primary Review

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Affiliation (Ministry, Department, Organisation): \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## f) Framework for Conduct of Human Genetics Studies in Cook Islands

### Different types of Genetic Studies

#### 1. Personalised Medical Treatment

Due to genetic differences between people a disease can appear slightly differently in different patients. Some of this variability is due to genetic differences between individuals. Personalised medicine refers to the process of analysing a person's genes to identify the type of disease that they have or their response to that disease. This information is then used to create or choose a personalised medicine that is designed to treat the exact form of the disease that they face.

An example of this kind of medicine is Herceptin treatment for breast cancer. Herceptin is a humanised monoclonal antibody that which binds to the HER2/neu receptor that is over-expressed in some breast cancers. If genetic analysis shows that the breast cancer is the type of cancer which over-expresses the HER2/neu receptor, then it can be treated with Herceptin. Herceptin binds to the HER2/neu on the cancer cells and reduces proliferation.

#### 2. Diagnosis of Disease

In some types of disease it is possible to identify the type of disease based on a genetic test, especially in the case of cancers.

For example, if a disease occurs repeatedly within a family and it is suspected that there is a genetic cause for the disease, a number of members of the family might give samples and information about whether they suffer from the disease. These samples could then be compared to one another to locate the genes responsible for the disease, in the hope that this would lead to a treatment for the disease

#### 3. Genetic Epidemiology (Biobanking)

Genetic epidemiology, or as it is more commonly known, biobanking, involves the collection and storage of biological materials, usually human tissue or blood samples. The samples may be accompanied by clinical information from the person who gave the sample. Biobanks may also contain bacterial, plant, animal or environmental samples. The large amount of information stored in biobanks can then be used in research to understand the complex interaction between genes and the environment in the cause of disease.

Biobanks are only currently being formed however it is hoped that they will be used to elucidate the mechanism of disease such as diabetes, heart disease and cancer.

#### 4. Envirogenomic Studies

Some genetic studies are interested in the how the environment interacts with a person's genetic make-up and how these interactions impact the person's health. These studies are known as enviro-genomic studies.

**5. Anthropological Studies**

Anthropology is the study of humanity and some branches of anthropology use genetics in their work. They look at patterns of genetic similarity among different human populations to elucidate information about such things as, the way human beings evolved, patterns of migration, fluctuations in population size and the relationships between populations of human beings on different continents.

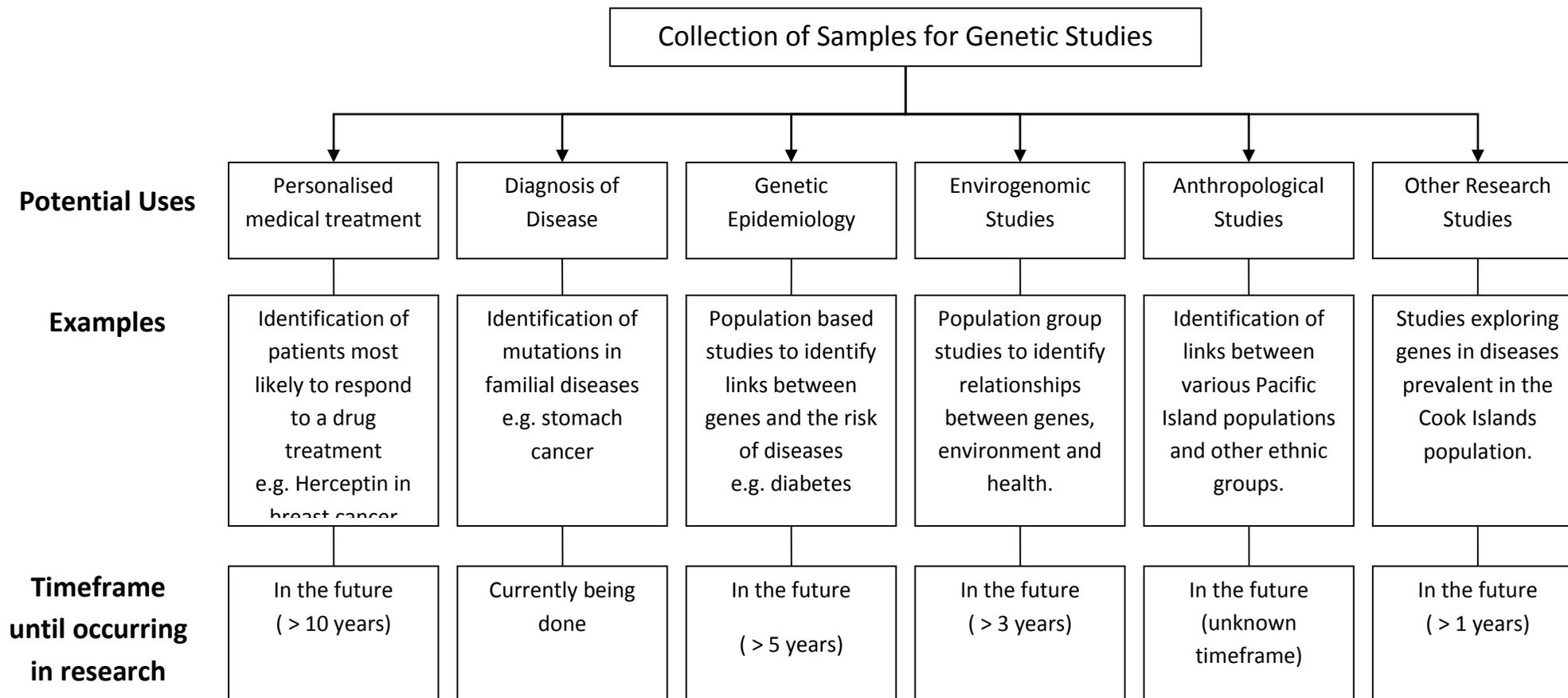
**6. Other Research Studies**

There are lots of applications for genetic studies and there will be studies that fall outside the examples given above, especially with the increasing use and application of genetic information in other fields of study.

**Process for Undertaking Genetic Studies in the Cook Islands**

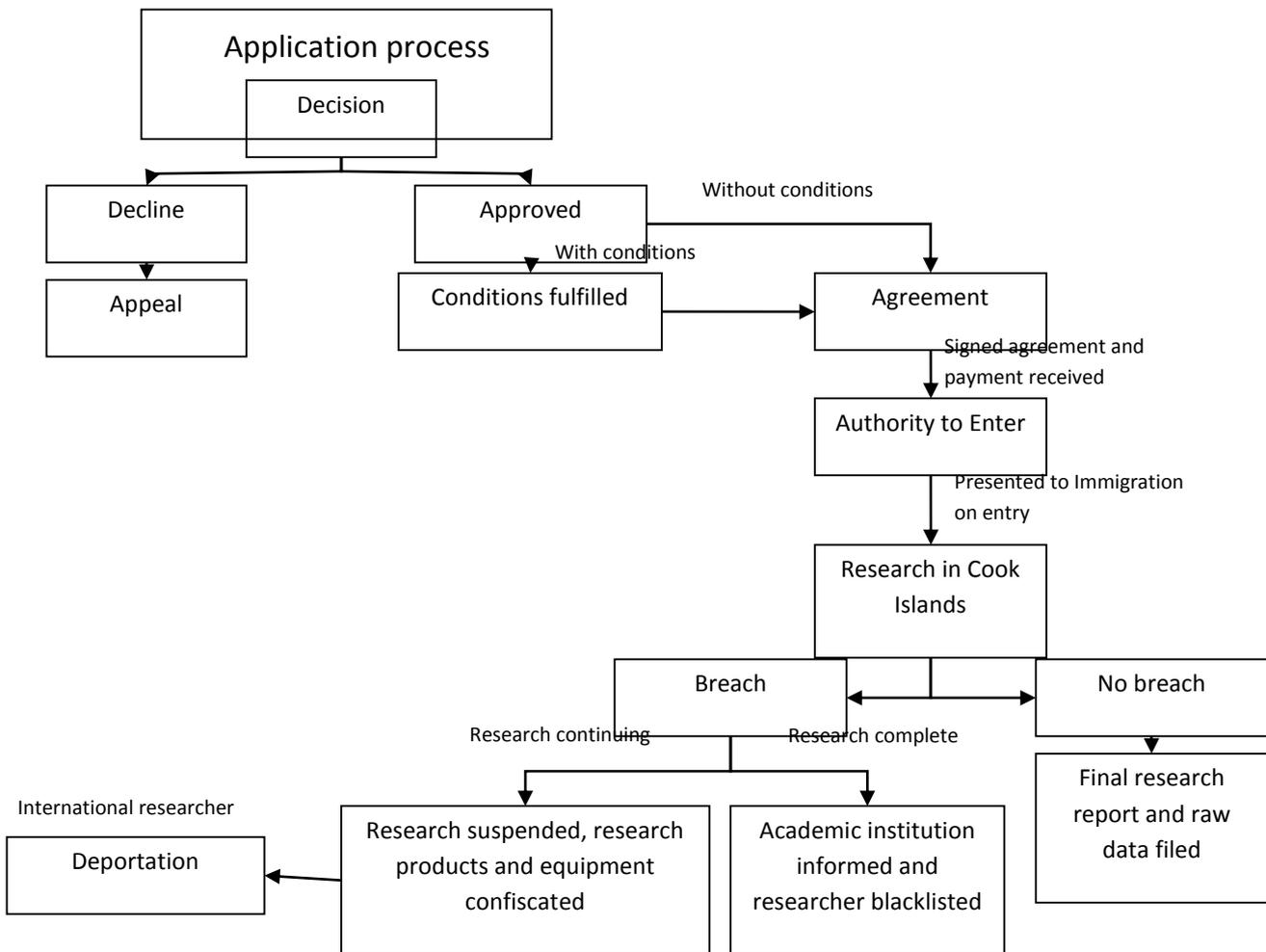
1. All research which occurs in the Cook Islands must be reviewed and approved by the Cook Islands Research Committee (CIRC), including research that involves genetic studies.
2. The CIRC can consult experts, either domestically or internationally, on a research application.
3. Only once approval of the CIRC has been received may research commence in the Cook Islands.

## Framework for Conduct of Human Genetics Studies in Cook Islands



- Need for community consultation on any proposal to involve the Cook Islands population in gene studies. NB Likely that the Cook Islands population in New Zealand may participate in many of the studies identified above.
- All studies would need review (primary review and external technical advice) and the Cook Islands Research Committee.
- All studies would require ethical approval (and external expert advice).
- Where relevant, issues related to indigenous peoples' rights would need to be addressed.

## g) Legislative Framework



*Note: When a proposal is approved, with or without the conditions being met, the proposal is then agreed on, payment is received and the researcher is authorised to conduct their work. The diagram should remove the "with/without conditions" arrows as they serve no purpose.*

*Note: "Final research report and raw data filed" - Under the Research Agreement there should be a clause that ensures the Researcher submits copies of their work for approval before it can be endorsed by the CIRC/CIG, and later published by the 'host institution'.*

This diagram shows the proposed legal framework.

The application process through the Office of the Prime Minister (OPM) and Cook Islands Research Committee results in a decision of either approval or decline of the research proposal. Declined applications can be appealed or the applicant may submit a new application.

Approved application result in a Research Agreement being produced by the OPM, which is a contract between the researcher and the Cook Islands detailing the terms on conditions of doing the research. The Research Agreement will then be sent to the researcher who will need to sign it and get their institution to sign it, if appropriate. The researcher would then return the Research

Agreement with the appropriate fee to the OPM. The OPM would process the Research Agreement and fee and send the researcher a research permit and an authority to enter the Cook Islands for the purposes of doing research.

On arrival in the Cook Islands of an international researcher would be able to elect to enter the country for the purposes of research in their arrival card (changes required to the current arrival card) and present their research permit and authority to enter.

The research would then commence in the Cook Islands.

If there was any breach of the Research Agreement during the course of the research then it would be possible to suspend the research permit until the breach was corrected or to revoke the research permit. If the research permit was revoked this would also revoke the authority to enter and an international researcher could then be deported. There would also be powers to cease research products and equipment, if appropriate.

If the breach occurs after the research is completed then the researcher's institution would be informed and the researcher would be blacklisted.

As the legislation in the Cook Islands on intellectual property is currently under review and development, the mechanisms for dealing with intellectual property are left open and any appropriate clauses could be written into the Research Agreement. However it was envisaged that the Research agreement would take ownership of all intellectual property produced by the research

Parts of this legislative framework tie in with immigration and it is likely that small alterations would be required to the Immigration Act.

#### **h) CIRC meeting procedures**

1. If both reviewers are in agreement (either approve or decline) nothing needs to be done.
2. If the Primary Reviewer approves and the CIRC decide to decline a proposal it would be appropriate for CIRC to meet with the Primary Reviewer to discuss the point(s) at issue. If agreement can not be reached a 'second opinion' should be sought by CIRC. The 'second opinion' would provide advice to CIRC who would then review their original decision. The 'second opinion' does not overturn the CIRC decision.
3. If the Primary Reviewer declines a study and CIRC need clarification as to the basis for the decision they could meet the reviewer or seek clarification by email.
4. All discussion with Applicants on the conditions imposed on the research team are to involve CIRC and, where appropriate, the Primary Reviewer. (See Appeals process).
5. Conflict of Interest is an important issue and any such interest should be declared to the Cook Islands Research Secretariat, if a Primary Reviewer, or to the Chair of CIRC, if a CIRC member, as soon as practicable.
6. The Appeals process would allow an Applicant to appeal against either the outcome of their application for a Research Permit or the conditions imposed by the CIRC. Where an Appeal is to be lodged, a letter should be written to the CIRC (c/o CI Research Office) setting out their concerns. CIRC will consider their letter and may, if appropriate, seek a 'second opinion' prior to responding to the Appeal.

#### **Processes to address differences in Primary and CIRC (Secondary review): For Discussion**

1. CIRC would usually make unanimous decision but could decide to accept a majority decision.
2. Where a decision is made to defer approval pending provision of additional information the Cook Islands Research Secretariat will advise both the Primary Reviewer and CIRC on the issues and the requirements to be met by the Research Team.
3. Where proposals and the review process raise technical, regulatory or ethical issues the CIRC may seek advice from an external body such as the Health Research Council of New Zealand or the Environmental Risk Management Agency of New Zealand.
4. The quorum for CIRC meetings should be 50% + 1 i.e. with 6 members 4 if the quorum. The Chair should have a single vote. Conflicts of interest (COI) should be noted (and recorded in the minutes of meetings).