

National  
Hauora Coalition



# RESEARCH COLLABORATION GUIDELINES

NATIONAL HAUORA COALITION

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This document outlines procedures associated with research collaboration requests from Internal and External Researchers

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## Document Control

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1.2	Final version	Reviewed by Rachel B
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## 1. Purpose & Use

### 1.1. Purpose

The purpose of these guidelines are to outline the process for any research and/or health service evaluation collaboration requests that are formally made to the National Hauora Coalition (NHC), from internal or external researchers. These guidelines ensure that appropriate measures are undertaken to safeguard the National Hauora Coalition and whānau Māori and that the research aligns with the kaupapa and values of the organisation.

The Research Collaboration guidelines describe:

- Key terms and definitions;
- NHC Research Principles;
- Research review process and approval;
- Research implementation;
- Publication and acknowledgments;
- Research close-out and dissemination; and
- Risks and issues.

All Applicants and Approved Researchers should adhere to the principles and processes described in this document.

### 1.2. Use

These guidelines should be used and followed by Applicants, Approved Researchers and NHC team members when conducting activities related to any research collaboration between internal and external researchers.



## 2. Key Concepts and Definitions

Concept	Definition
Applicant	Any researcher who wishes to engage with the NHC in a formal research collaboration.
Approved Researcher	Any internal or external Applicant who satisfies NHC's criteria for research collaboration.
Data	Any personal, organisational or health information collected about individuals as part of a research initiative.
Identifiable Information	Any information that has the potential to reveal the personal identity of an individual (e.g., first name, last name, DOB, NHI)
Te Rōpū Rangahau o National Hauora Coalition	An internal committee tasked with reviewing all incoming research requests and advising on research activity.
Publications	Any formal writing that includes NHC data obtained in the respective research initiative, that may be accessed by the public, as well as internal and external stakeholders.
Research Collaboration Agreement	A formal agreement that outlines terms and conditions of a research collaboration between NHC and an Applicant.
Research Request	A formal request made by researchers to collaborate with the NHC on a research project.
Serious Adverse Event	Any harmful event associated a research product that results in hospitalisation or death.
Study Site	An organisation actively involved in research conduct or clinical trial delivery (i.e., participant recruitment, intervention/treatment delivery).
Suspected Unanticipated Serious Adverse Event	Any harmful event not associated with a research product, but occurs during a research study, that results in hospitalisation or death.



### 3. Background

The National Hauora Coalition (NHC) began operating as a Primary Healthcare Organisation (PHO) in 2011. It was formed when a group of committed Māori service providers decided to pursue a vision focused on the health and wellbeing of their communities. Built on the belief they could achieve more by standing together and working together than by acting alone, the NHC was born.

Since then, we have attracted a clinical network of 57 practice locations, serving an enrolled population of 230,787 (42% of which are high-need populations) across five District Health Boards (as at 1st December 2019).

To build healthier whānau and communities, it takes an unwavering commitment to addressing inequity in health and social outcomes. and drive change at all levels – individual, whānau, hapū, iwi community and New Zealand.

Our responsibilities of Mana Whānau, Whānau Ora are built around family values and consequently aims at empowering family groups to decide and pursue the best way forward for their health and wellbeing. This is our reason for existing and shapes the way our services are designed and delivered, contracts arranged, and the way our providers work together. It's a courageous undertaking and is cloaked in ō mātou tikanga (our values).

#### NHC Core Values

 <p><b>WHĀNAU WHAKATAURANGI</b> <b>KEEP OUR WORD</b></p> <p>What we say we are going to do, we do. We build trust and confidence by delivering on our promises to customers, staff and whānau.</p>	 <p><b>WHĀNAU WHAKAARO TIKA</b> <b>THINK LIKE WHĀNAU</b></p> <p>Whānau well-being is our priority. We succeed when whānau succeed. Therefore whānau defines who we are and what we're about.</p>	 <p><b>WHAKANUIA TE WHĀNAU</b> <b>CELEBRATE INDIGENEITY</b></p> <p>Indigeneity is woven into the fabric of this organisation, it is a part of who we are. We celebrate and create indigeneity, and we privilege indigenous ways of knowing and being.</p>
 <p><b>MAHIA KIA EA, KIA TOA</b> <b>A "CAN DO" ATTITUDE</b></p> <p>We are a 'can do', not a 'make do' organisation. We get things done. Consequently our willingness to attempt the impossible will mean we accomplish extraordinary things.</p>	 <p><b>WHĀNAU WHAI HUA</b> <b>OUTCOMES MATTER</b></p> <p>Because the status quo isn't acceptable, and we are intolerant of inequities. We are performance and results focussed, &amp; will prove our contributions make a difference.</p>	 <p><b>WHĀNAU AUAHA</b> <b>EVERYONE AN INNOVATOR</b></p> <p>We all have the courage to innovate. Our adventurous, creative &amp; open-minded spirit will challenge the status quo to be at the 'cutting edge' of everything we do.</p>

We are Kaupapa Māori. In our leadership capacity, we will continue to challenge policy makers to better align the New Zealand health system with its Treaty of



Waitangi obligations. We believe a radical change is required, certainly one that is grounded in the partnership guaranteed to Māori through Te Tiriti o Waitangi.

We acknowledge that we are in a privileged position to influence system change that significantly reduces health inequities for whānau Māori. A key avenue for system change is collaborating on innovative research projects. We have therefore engaged in a formal process to review and collaborate with health researchers whose initiatives innovate to reduce inequities and privilege Mana Whānau; Whānau Ora.



## 4. NHC Research Principles

All applicants and approved researchers should adhere to the principles described below.

### 4.1. NHC Values & Capacity

- 4.1.1. The NHC will only engage with research that adequately aligns with NHC core values, principles of Te Tiriti o Waitangi, pro-equity approaches, and research that privileges mana whānau; whānau ora.
- 4.1.2. The NHC will only engage with research that has the potential to provide measurable benefits to whānau Māori.
- 4.1.3. Research funding should appropriately reflect the input of NHC resource, people and material costs, funding, infrastructure, professional development and service outcomes.
- 4.1.4. Research should provide opportunities to the people within our organisation.

### 4.2. Ethical Considerations

- 4.2.1. Research will not be initiated until the appropriate ethical approval has been sought and approved (if applicable). Evidence of ethics approval must be provided to the NHC prior to research implementation.
- 4.2.2. All data accessed will be de-identified unless approved by an applicable ethical committee (e.g., New Zealand Health and Disability Ethics Committee) and agreed in writing with the NHC. The option of de-identification of qualitative data should be offered to participants when appropriate.
- 4.2.3. If informed consent is required by participants in a research project, wording must be culturally tailored to Māori and Pacific whānau, where applicable.
- 4.2.4. Ethical considerations will be reviewed by the NHC prior to approval of research requests.
- 4.2.5. The NHC must be notified of any amendments of ethical applications, in writing, prior to submission.
- 4.2.6. The NHC must be notified of any Serious Adverse Events (SAE) or Suspected Unexpected Serious Adverse Reaction (SUSAR) that occurs on an approved research project, in writing, within 7 days of Approved Researchers being notified of the event.

### 4.3. Data Considerations

- 4.3.1. NHC data is not publicly accessible.



- 4.3.2. Ethnicity data must be collected in accordance with the latest Health Information Standards Organisation (HISO) Ethnicity Data Protocols
- 4.3.3. The NHC hold Data Governance responsibilities over patient data collected within NHC provider networks.
- 4.3.4. All data must be stored in a secure environment protected from access by any unauthorised person(s).
- 4.3.5. All data must be held in compliance with the New Zealand Privacy Act 1993, Health Information Privacy Code 1994 and any other relevant New Zealand legislation.
- 4.3.6. All data must be used for research purposes only.
- 4.3.7. Data must be securely stored, managed and governed in accordance with the latest National Ethical Standards for Health and Disability Research and Quality Improvement and any other applicable legislation.
- 4.3.8. Data cannot be shared with any persons external to the research team unless approved by applicable ethical committees (i.e., New Zealand Health and Disability Ethics Committee) and agreed in writing.
- 4.3.9. The NHC Executive Leadership Team (ELT) has overall responsibility and accountability for governance for NHC's involvement in any research collaborations. This includes data governance over NHC data. The Executive Leadership Team may delegate work associated to research to Te Rōpū Rangahau o NHC.
- 4.3.10 The NHC may provide Māori data governance advice to any research the NHC engages with.

#### **4.4. Publishing Considerations**

- 4.4.1. Any written articles or publications ("Publications") that are publicly available (including submissions to academic journals and technical reports) that incorporate or make reference to any NHC data must be submitted to Te Rōpū Rangahau o NHC for review and approval at least 30 days prior to submission for publication.
- 4.4.2. Te Rōpū Rangahau o NHC reserves the right to make recommendations as to the form and content of any publications that incorporate or refers to any NHC data. Researchers may accept or decline recommendations made; however agreement must be made in writing between the Approved Researcher and the NHC prior to publishing.
- 4.4.3. Publications must positively raise and promote the awareness and profile of the NHC. Publications that do not fulfil this criterion will not be granted approval from Te Rōpū Rangahau o NHC.



- 4.4.4. Data that is analysed, interpreted, reported and published must be done so in culturally appropriate and mana enhancing ways.
- 4.4.5. All publications should include suitably worded acknowledgment of National Hauora Coalition. Acknowledgments should include the following wording:

*“We would like to acknowledge the National Hauora Coalition for their support and contribution to this research.”*

- 4.4.6. All presentations that incorporate NHC data must include the National Hauora Coalition’s organisational logo in (as a minimum) in the opening or closing presentation slides.

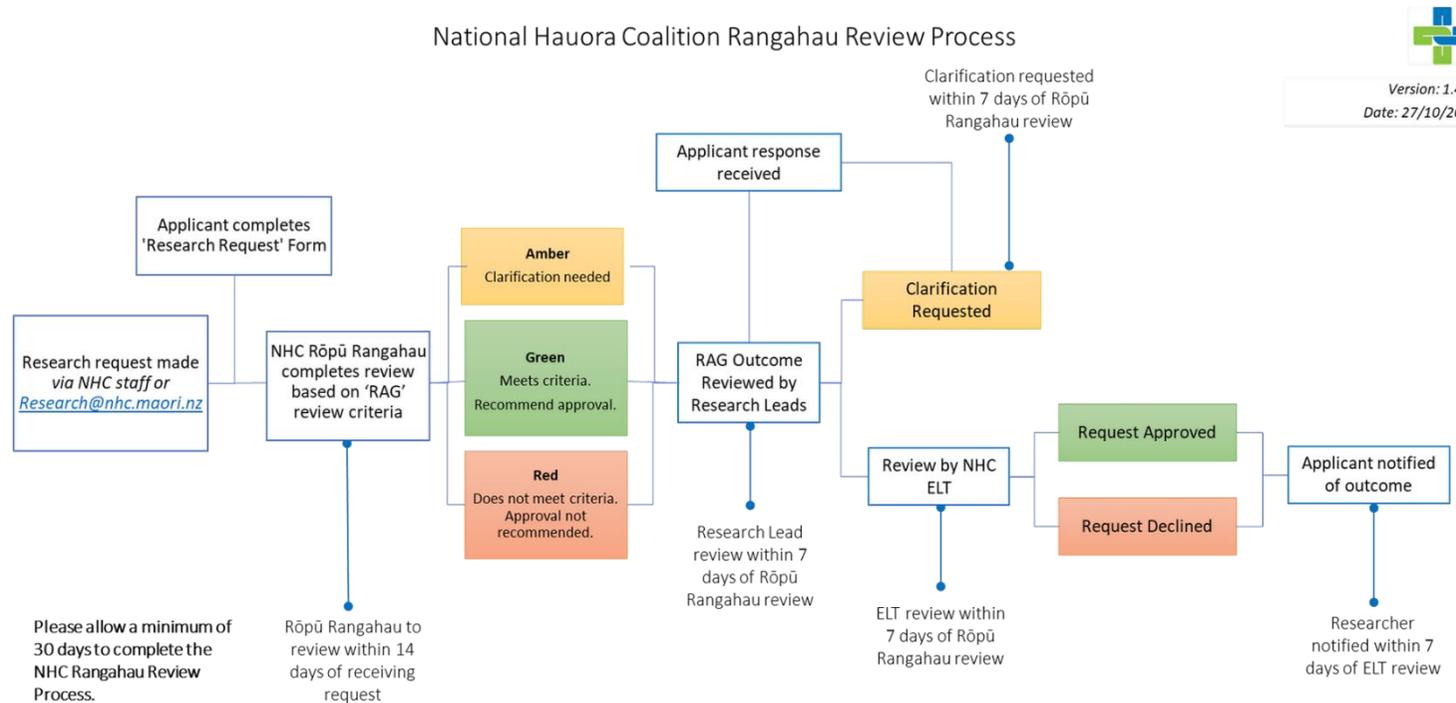
### **Contractual Considerations**

- 4.4.7. As part of the Research Collaboration Process, all Approved Researchers will engage with the NHC in a formal agreement.
- 4.4.8. The NHC reserves the right to protect any contractual obligations stated under agreement with any of their Providers/Contractors.
- 4.4.9. In the event research may put contractual obligations at risk, the NHC ELT will take any steps necessary to mitigate or remove any risk or threat. This may include the immediate withdrawal of the NHC’s involvement with the Approved Researcher, at any stage of the research process. Approved Researchers will be notified in writing in the event this occurs.

## 5. Rangahau Review Process

This section describes the NHC's Research Review Process. A summary of the review process is shown in **Figure 1**.

FIGURE 1. NATIONAL HAUORA COALITION RANGAHAU REVIEW PROCESS FLOWCHART



## 5.1. Research Requests

Expressions of interest for research collaboration can be made through a variety of channels. Researchers can express interest in collaborating by emailing [research@nhc.maori.nz](mailto:research@nhc.maori.nz). Our research team will then email a research request form to the interested researcher. Alternatively, Researchers can submit a Research Request Form online via the NHC's website.

From here, the interested researcher becomes an 'Applicant'.

## 5.2. Research Review

Research Requests will be reviewed by the NHC's Te Rōpū Rangahau within 14 days of receipt. This will be coordinated by the NHC Research Manager.

### 5.2.1. Rōpū Rangahau 'RAG' Review

Te Rōpū Rangahau will assess all requests based on the below criteria:

1. Alignment with NHC values, capacity and timing;
2. Ethical considerations;
3. Data considerations; and
4. Other professional development or network capabilities.

Alignment with the above criteria will be assessed and discussed. At the end of the review, one of below "RAG" options will be agreed and selected:

<b>Red</b> Does not meet criteria. Significant concerns. No approval recommended.	<b>Amber</b> Clarification needed.	<b>Green</b> Good fit with the criteria. Recommend for approval.
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### 5.2.2. Research Lead Review

NHC Research Lead/s will review recommendations put forward by Te Rōpū Rangahau and will progress the request depending on RAG criteria. If the request is 'Amber' the Research Lead/s will request clarification, then perform a re-review prior to progressing to ELT.

### 5.2.3. NHC ELT Review

The Research Lead will provide a summary of recommendations at the next NHC ELT weekly meeting following Te Rōpū Rangahau's review. At the hui, ELT will discuss and make a formal decision regarding the request. One of the following decision options will be decided:

<b>Request Declined</b> Applicant notified of outcome via email.	<b>Clarification Requested</b> Applicant contacted for clarification.	<b>Request Approved</b> Progress to Research Collaboration Agreement.
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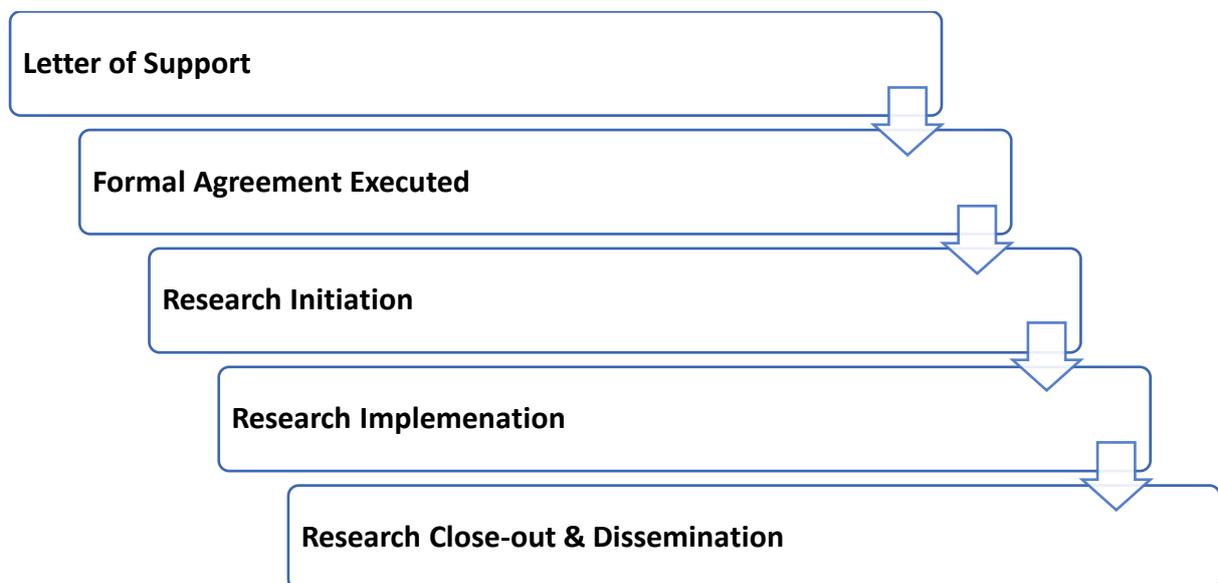


Applicants will be notified of the outcome of their request via email within 7 days of NHC ELT decision. If Approved, the Approved Research will receive a letter of support. A Research Implementation Process is then undertaken in collaboration with the Approved Researcher. This is facilitated by the NHC Research Manager.

## 6. Research Implementation Process

This section describes the process carried out for all Approved Researchers and how risks and issues will be managed by the NHC. A summary of the implementation process is shown in **Figure 2**.

FIGURE 2. NHC RESEARCH IMPLEMENTATION PROCESS



### 6.1. Letter of Support

Applicants with approved Research Requests are now considered to be Approved Researchers moving forward.

Approved Researchers will initially receive a Letter of Support from the Clinical Director of the NHC. This will be facilitated by the NHC Research Manager. The Letter of Support is provided to indicate the NHC's intent to collaborate with the researcher.

The Letter of Support will be distributed to the Approved Researcher within 7 days of NHC ELT Decision (described above).

### 6.2. Formal Research Agreement

Depending on the nature of the research collaboration, we may engage in a Memorandum of Understanding, Research Collaboration Agreement or Data Access Agreement.

#### **Memorandum of Understanding and Research Collaboration Agreements**



A Service Schedule and Implementation Schedule will be negotiated between the NHC and the Approved Researcher.

The Approved Researcher should review, sign and return the signed agreement to the NHC Research Manager within 30 days of receipt.

### **Data Access Agreement**

If the Approved Researcher is seeking data access only, the Approved Researcher will be required to sign the NHC Data Access Agreement. This will be provided to the Approved Researcher by the NHC Research Manager.

The Approved Researcher should review, sign and return the signed Data Access Agreement to the NHC Research Manager within 30 days of receipt.

### **6.3. Research Initiation**

The activities described below should be carried out as part of research initiation process.

#### [6.3.1. Study Master File](#)

The Approved Researcher should provide the NHC with a Study Master File. This study master file should contain official and supporting documentation, including:

- Research contact list
- Ethics applications submissions, submission supporting documentation and approval letters
- Case Report Forms (if applicable)
- Grant proposals
- Participant Information Sheet and Consent Form
- Any participant-facing promotional materials
- Research protocols
- Responsibilities assignment matrix
- Any other applicable guidelines or supporting documentation

#### [6.3.2. Research team onboarding](#)

If staffing resource is required, the NHC Research Manager will coordinate activities between the Approved Researchers, relevant NHC Business Unit Managers.

#### [6.3.3. Research initiation hui](#)

A research initiation hui should be held with all team members involved with the research project. This includes with internal NHC team members and any Study Sites/external team members (e.g., GP clinics).

#### [6.3.4. Training](#)

Any applicable training should be provided to all team members (internal NHC and at Study Sites) involved with the research prior to research implementation.



#### 6.3.5. Statistical Analysis Setup

We recommend engagement with a Statistician prior to research implementation to provide a statistical analysis plan and outline any data requirements needed for analysis.

#### 6.3.6. Dissemination Plan

A dissemination plan should be shared with the NHC Research Lead prior to research implementation.

### 6.4. Research Implementation

The activities described below should be carried out as part of the research implementation process.

#### 6.4.1. Data Access

If applicable, data access to NHC data will be made via the NHC Mōhio team. Data access will be granted in accordance with Mōhio data access policies and procedures.

#### 6.4.2. Research Project Management

Approved Researchers should use project management techniques (e.g., Gantt charts) to monitor progress against research deliverables or milestones. The NHC Research Manager will set up relevant project management tools and supporting documentation related to NHC involvement with the research project.

### 6.5. Research Close-out & Dissemination

The activities described below should be carried out as part of the research close-out process.

#### 6.5.1. Close-out

A site close-out hui should be conducted with all internal NHC team members and study site's involved with the research project.

#### 6.5.2. Research Dissemination

A final research report should be submitted to the NHC Research Lead upon completion of the Research Project. The NHC may request a presentation of findings to the NHC ELT as part of dissemination.

#### 6.5.3. Publication Review

Approved Researchers must submit all draft publications to the NHC Rōpū Rangahau for review at least 30 days prior to publication submission. Draft publications can be submitted via email to the NHC Research Lead or Manager. The NHC Research Manager will distribute the publication to the Rōpū Rangahau for review and feedback.

The NHC Rōpū Rangahau may make recommendations as to the form and content of any publications that incorporate or make reference to any NHC data. Approved Researchers may accept or decline recommendations made, however agreement



must be made in writing between the Approved Researcher and the NHC prior to publishing.

The applicant is not permitted to proceed with publishing until approval to do so is received in writing by a NHC Rōpū Rangahau representative or a representative of NHC ELT.

## **6.6. Risks and Issues**

### **6.6.1. Risk & Issues Register**

The NHC Research Manager will create and maintain a Risk and Issues Register from research initiation to research close-out. This will include contingency planning, risk mitigation activities and relevant escalation pathways.

### **6.6.2. Withdrawal from Research**

The NHC reserves the right to withdraw involvement from a research project in the event of a serious breach in the terms and conditions of the Research Collaboration Agreement.