

Te Kāwanatanga o Aotearoa New Zealand Government



2025 Rangahau Hauora Māori Project Full Application Guidelines

October 2024

Use with the 2025 Rangahau Hauora Māori Project Full Application Form



Table of Contents

	1: HRC 2025 RANGAHAU HAUORA MÃORI (RHM) PROJECTS GRANT – NFORMATION AND REQUIREMENTS
1.1	DESCRIPTION
1.2	HRC PRIORITIES
1.3	VALUE4
1.4	PROJECT CATEGORIES4
1.5	ELIGIBILITY
1.6	KEY DATES
1.7	APPLICATION PROCESS OVERVIEW
	2: GENERAL INFORMATION ON SUBMITTING AN APPLICATION TO THE
	RANGAHAU HAUORA MĀORI PROJECT GRANT ROUND
2.1	PREPARATION
2.2	FORMATTING YOUR APPLICATION
2.3	ALLOWED CHANGES BETWEEN THE EXPRESSION OF INTEREST AND FULL APPLICATION STAGE
2.4	PRIVACY PROVISIONS
2.5	ENQUIRIES
2.6	ADDITIONAL ELIGIBILITY REQUIREMENTS
APPL	3: INSTRUCTIONS ON COMPLETING AND SUBMITTING YOUR ICATION TO THE 2025 RANGAHAU HAUORA MÃORI PROJECT GRANT ID
3.1	THE PROJECT APPLICATION FORMS
3.2	MODULE 1: GENERAL INFORMATION 11
3.3	MODULE 2: RESEARCH
3.4	MODULE 3: REFERENCES16
3.5	MODULE 4: CONTRACT INFORMATION AND BUDGET16
3.6	MODULE 5: NZ STANDARD CV
3.7	MODULE 6: CLASSIFICATION (ADDITIONAL INFORMATION IN HRC GATEWAY).22
3.8	APPLICATION CHECKLIST
	NDIX 1: RANGAHAU HAUORA MĀORI PROJECT APPLICATION SSMENT PROCESS26
1.	OVERVIEW
2.	ASSESSING FULL APPLICATIONS
3.	REVIEW SUMMARY AND FEEDBACK TO APPLICANTS

APPENDIX 2: SCORING CRITERIA AND ANCHOR POINT DESCRIPTORS 30

CRITERIA FOR ASSESSING AND SCORING RANGAHAU HAUORA MĀORI PROJECT APPLICATIONS BY ASSESSING COMMITTEE	
APPENDIX 3: PROPOSALS INCLUDING RANDOMISED CONTROLLED TRIALS (RCTS)	. 32
APPENDIX 4: APPLICANT REBUTTAL: FULL PROJECT STAGE	. 34
APPENDIX 5: FULL ASSESSING COMMITTEE REVIEW SUMMARY: PROJECT APPLICATION	. 35

Part 1: HRC 2025 Rangahau Hauora Māori (RHM) Projects Grant – key information and requirements

Part 1 sets out the requirements for the Rangahau Hauora Māori Project Grant, including:

- information about the grant, including the maximum value and duration
- information about HRC's priorities
- eligibility criteria that applicants must meet
- an overview of the application process and requirements, including key dates
- an overview of the assessment process and assessment criteria.

Parts 2 and 3 contain instructions for applicants on submitting an application, including administrative requirements and how to demonstrate that the requirements for funding are met.

1.1 Description

The Health Research Council of New Zealand (HRC) funds research projects that have the potential to vastly improve the health of New Zealanders. Projects can cover a range of areas, including biomedical, public health, clinical, Māori focused, and Pacific health research.

1.2 HRC Priorities

All HRC investment must have a clear line of sight to improving health outcomes for all New Zealanders, with a focus on areas of highest health need and communities with the highest health needs¹.

New Zealand's investment in health research must contribute to achieving the goals of the health system and the Science, Innovation and Technology (SI&T) sector. It is important to consider and identify how your research programme will add value and contribute to these goals and wider system performance. The vision for the health system is timely access to quality healthcare². A key focus for the science system is to harness the benefits of research and innovation to drive economic transformation.

1.3 Value

- The HRC expects to fund and encourages a range of grant values and durations.
- The HRC offers contracts worth \$400,000 per year.
- Most projects have a term of three years with a budget of \$1,200,000.
- The budget cap for randomised controlled trial project applications is \$1,440,000 if required and justified in the application.
- You can negotiate terms of up to five years. Shorter contracts are offered pro rata (e.g. a two-year project may have a budget of up to \$800,000).
- The requested budget needs to be justified and reflect the activities being proposed.

1.4 Project Categories

When applying for a Project Grant, you need to select one of the following project categories:

General: Supporting excellent ideas and innovations proposed by researchers, designed to improve health outcomes for New Zealanders.

Rangahau Hauora Māori: Supporting Māori health research that contributes to Māori health gains, upholds rangatiratanga and utilises and advances Māori knowledge, resources, and people.

¹ Areas of highest health need and communities with the highest health needs are identified in the Government Policy Statement on Health 2024-2027.

² The Government Policy Statement on Health (2024-2027) outlines 5 priority areas; 5 non-communicable diseases; 5 modifiable behaviours; 5 health targets; and 5 mental health targets.

Pacific: Making significant improvements in, or developing knowledge contributing to, Pacific health outcomes.

Note: The Health Delivery Research Project Grant round is run out of cycle via the Health Delivery Research Investment Round. This round includes a range of different grant types, in addition to project grants.

Project applications can only be submitted to one category (i.e. you cannot submit the same application for both the General Project category and the Rangahau Hauora Māori category). The HRC does not provide advice on which project category you should choose. You cannot change the project category between the Expression of Interest (EOI) and full stage application.

1.5 Eligibility

If you are applying as the 'first named investigator', who is the lead researcher, on a Project application, you must:

- 1. Have New Zealand as your principal domicile (see definition in the HRC Rules) and your principal place of employment. **Note:** Host organisations are responsible for ensuring that this criterion has been met.
- 2. Submit only 1 or 2 project applications as the first named investigator/co-first named investigator. The HRC will withdraw any applications once this limit has been reached.
- 3. Complete all progress or end of contract reports that are due from previous contracts in HRC Gateway. You cannot submit a new application in HRC Gateway if you have any outstanding reports.

The HRC welcomes proposals for 'co-first named investigators' to create a research team of exceptional strength, such as interdisciplinary work. In addition, early and mid-career researchers who have not previously held a project contract are encouraged to apply as co-first named investigator with a mentor/experienced researcher. Eligibility criteria apply to both first named investigator and co-first named investigator.

Event	Description	Date
Full stage Applications open	Applicants to submit their full application	1 October 2024
Full stage Applications close	Complete Project full application via HRC Gateway	12 November 2024
	Peer review	Dec 2024 to Feb 2025
Assessment	Applicant rebuttal	Early March 2025
	Review by HRC Assessing Committee	April 2025
Results	Outcomes confirmed	3 June 2025
Results	Deadline for commencing research	1 September 2025

1.6 Key Dates

1.6.1 Submission deadline

Please submit your application to HRC Gateway by **1pm on Tuesday 12 November 2024**. Your application will not be accepted after 1pm unless you have **written** authorisation from the HRC.

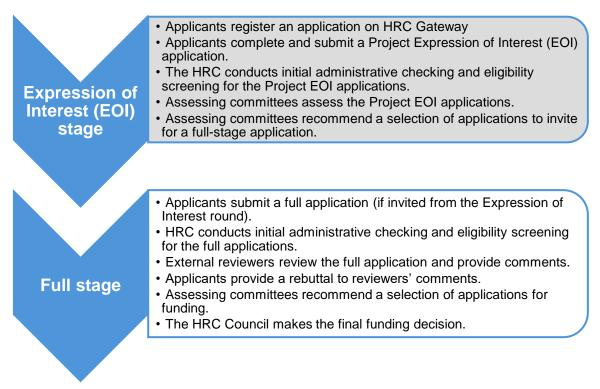
Important note: Your application will be released to the HRC only after it has been approved by your host organisation's Research Office or equivalent. **You should submit your application before your host organisation's internal submission deadline**, which is usually several working days before the HRC closing date. If your host organisation does not have a Research Office, your application will be forwarded directly to the HRC.

1.6.2 Commencement date

Your project needs to start by Monday 1 September 2025.

1.7 Application process overview

Refer to <u>Appendix 1: Rangahau Hauora Māori Project application assessment</u> process for further information on the assessment process.



Part 2: General information on submitting an application to the 2025 Rangahau Hauora Māori Project Grant Round

This section sets out general information for applicants to the 2025 Rangahau Hauora Māori Project Grant.

The information provided in this section includes:

- instructions for using HRC Gateway to submit an application
- formatting requirements for applications
- guidance about the privacy of application content
- contact information if you need assistance with your application.

Please follow the instructions set out in this section.

2.1 Preparation

2.1.1 HRC Gateway account

You will need an HRC Gateway account to apply for a Project grant. Use your existing account or create a new one if you do not have one, via the following URL: <u>https://gateway.hrc.govt.nz</u>. If you have issues logging into your HRC Gateway account, contact <u>info@hrc.govt.nz</u>.

Note: All members of your research team must have an HRC Gateway user account so that their details can be included in the online form. Individual HRC Gateway accounts should be updated annually.

2.1.2 Before submitting an application

Before submitting an application, please read the following resources:

- 2025 Rangahau Hauora Māori Project Full Application Guidelines (this document)
- Government Policy Statement on Health (2024-2027)
- New Zealand Health Research Strategy (2017-2027)
- New Zealand Health Research Prioritisation Framework
- HRC Research Ethics Guidelines
- Guidelines for Researchers on Health Research Involving Māori
- HRC Maori Health Advancement Guidelines and supporting resources
- <u>Guidelines for Pacific Health Research</u>
- HRC Research Impact Slideshow
- Rangahau Hauora Māori Investment Stream details
- <u>ARRIVE guidelines for animal research</u> (if applicable)
- •
- HRC Peer Review Manual (accessed via the 2025 Projects information page on HRC Gateway)

Click on the document name to access the file. These documents can also be found on HRC Gateway.

2.1.3 Forms

You will need to download and complete two different forms when submitting a Rangahau Hauora Māori Project full application:

- 2025 Rangahau Hauora Māori Project Full Application Form (Microsoft Word template)
- 2025 Project Budget Form (Microsoft Excel template)

Note: If you are applying for a General Project or Pacific Project, please use the specific General or Pacific Project Full Application Forms and Guidelines, respectively.

The HRC templates for these forms must be downloaded from the 2025 Projects information page on HRC Gateway. Do not use any other templates; these have special features required for HRC to process them. The application form should be completed in Microsoft Word, and the budget form should be completed in Microsoft Excel. Once completed, upload these documents to your application in HRC Gateway.

Note: The application form must be uploaded as a PDF, while the budget form must be uploaded in both Excel (.xlsx) and PDF formats. When converting your budget form into a PDF format, make sure all Excel spreadsheet tabs are included.

2.1.4 Host organisations

The host organisation is the organisation, institution or company that will be offered a contract with the HRC to deliver the activities described in your application if it is successful. The host organisation will be responsible for ensuring that the activities are completed according to the contract, the HRC Rules, and the HRC Project grant requirements.

If your organisation has not been previously funded as the host organisation by the HRC and your application is successful, your organisation will need to provide due diligence information before a contract can be offered. The HRC will provide you with information and the relevant forms for your organisation to complete.

2.2 Formatting your application

2.2.1 General formatting

Please write your application in a clear, concise manner with sufficient detail. The assessing committee reviewing your application includes a broad range of expertise. It is important that they can understand the scope and implications of your application.

Applications must be in English or te reo Māori; if in te reo Māori, a translation in English must also be provided (any translation will not be included in the page limit).

Please:

- use Arial 10-point type font or larger
- use default margins
- use single line spacing
- keep to the page limits

2.2.2 Compliance

The HRC will not process your application if you do not use the correct HRC application forms or follow the stated page limit and font sizes/styles. Your application may be withdrawn.

Please avoid these common pitfalls:

- 1. Only submit your application using HRC Gateway. Do not send applications or supporting documents to the HRC via email or any other means.
- 2. If your host organisation has a Research Office (or equivalent), your application must be approved by the Research Office first. The application will then be released to the HRC. Please allow enough time for this approval process before the HRC's closing deadline. All queries regarding applications should be directed to the host's Research Office rather than to the HRC directly.
- 3. Ensure you complete all modules, including Module 1 which must be completed in HRC Gateway. Incomplete applications after the closing date will be considered withdrawn and deleted from HRC Gateway.
- 4. Do not include any additional material (e.g. slides, protocols) as 'supporting documents' on HRC Gateway, and avoid using hyperlinks in the application form. All additional material and hyperlinks will be removed from your application.

 Do not send digital files directly to the HRC. Independent researchers and research providers requiring assistance with using HRC Gateway should contact the HRC in the first instance

2.3 Allowed changes between the Expression of Interest and Full Application stage

Please do not make any significant changes to the research team or research plans outlined in your Expression of Interest (EOI) form. Significant changes may result in your full application being disqualified. Slight modifications can be made to the lay summary, please refer to section 3.2 for further information.

Generally, you cannot add any named investigators to the team at the full stage, except:

- for statistical expertise in clinical trials
- for applications submitted to the Rangahau Hauora Māori or Pacific Project category
- if specifically in response to feedback from an EOI assessing committee
- to replace an existing member due to unforeseen circumstances.

The form to request an additional named investigator, or to replace or remove an investigator is available from your research office. If your organisation does not have a research office, please directly contact the HRC.

In the EOI form, named investigators indicated their FTE commitment by selecting from one of the following 'FTE bands':

- 3% 10% (Low FTE)
- 11% 40% (Medium FTE)
- 41% 100% (High FTE)

In the full application, please enter a defined FTE value for each named investigator. This value should fall within the band that was selected in the EOI application.

Note: The HRC will consider changes of FTE between EOI and full application that move to a different band; however, these must be justified and the HRC will need to be notified of these changes. The form to request a change of FTE is available from your research office. If your organisation does not have a research office, please directly contact the HRC.

2.4 Privacy provisions

2.4.1 Statistical and reporting purposes

The information you provide will be used to assess your application. In a non-identifiable form, some information will be used for HRC's statistical and reporting purposes. The HRC stores all applications in a secure place, which may include the New Zealand Research Information System (NZRIS) curated by the Ministry of Business, Innovation and Employment (MBIE) with details provided by funders of the science sector.

2.4.2 Personal information

Personal information in your application will be available to members of the HRC assessing committees and to external reviewers reviewing your application.

2.4.3 Media release

The HRC publishes details of research contracts including named investigators, the host organisation, research title, lay summaries and funding awarded for public interest purposes and to meet the statutory requirements of the *Health Research Council Act 1990*.

2.4.4 Official Information Act

Official Information Act requests for information about an application or research contract, beyond information that has already been publicly disclosed, will be discussed with the host organisation

and programme director before responding to the request. Where appropriate, the request may be transferred to the host organisation.

2.5 Enquiries

If you have any questions about HRC applications, please contact your host organisation's Research Office.

You can contact the HRC at info@hrc.govt.nz if:

- your organisation does not have a Research Office
- your organisation's Research Office cannot assist you
- you have any technical difficulties (i.e. with HRC Gateway)

HRC Gateway will show the status of any application. Please do not contact the HRC for an update on your application status.

2.6 Additional eligibility requirements

2.6.1 Eligibility restrictions on publicly funded research

The HRC cannot accept applications made by a public service department, as listed in Schedule 2 of the Public Service Act 2020. Named investigators from these departments may not claim salary support.

As part of the New Zealand Government's broader response to Russia's invasion of Ukraine, a new eligibility criterion has been implemented for government research funding. For proposals to be eligible, they must not benefit a Russian state institution (including but not limited to support for Russian military or security activity) or an organisation outside the government that may be perceived as contributing to the war effort.

This is not a broad ban on collaborations with individual Russian researchers. The focus is on ensuring that government funding does not support scientific research collaborations that could further Russia's ability to continue its aggression in Ukraine. As a Crown Agent, investing in health research for the public good with taxpayer funding, the HRC reserves the right to make ineligible any funding application that will benefit a state institution or other organisation identified for exclusion by the New Zealand Government.

2.6.2 Trusted Research Guidance

Please familiarise yourself with the <u>Trusted Research Guidance for Institutions and Researchers</u>. New Zealand has an open and collaborative research and innovation system and values academic freedom and research conducted independently by individuals and organisations. As part of preserving trust, the HRC screens proposals for risk related to sensitive technologies³ and may require funded projects to identify, mitigate, and monitor risks as part of the contractual conditions of the project.

³ Technologies become sensitive when they: are or could become dual-use i.e., have both a civil and military/security application; or, underpin, or have the potential to underpin, significant economic value for New Zealand.

Part 3: Instructions on completing and submitting your application to the 2025 Rangahau Hauora Māori Project Grant Round

This section contains instructions for completing and submitting your application. It includes prompts for providing certain information that will be used to score your application.

A full application for a 2025 Rangahau Hauora Māori Project Grant consists of six modules.

Module 1 'General information' must be completed in HRC Gateway. You need to register your application to receive an HRC Reference ID#. This registration step must be approved by your host organisation's research office (if it has one) to complete and submit the full application.

Complete Module 2 'Research', Module 3 'References', and Sections 4A-C 'Contract information and budget' in the **2025 Rangahau Hauora Māori Project Full Application Form** (Microsoft Word template). Refer to **Sections 3.2-3.5** for detailed guidance on how to complete each module.

Please upload all letters of collaboration/supporting documents/memorandums of understanding to HRC Gateway. HRC Gateway will automatically generate a list of uploaded documents under Module 4D.

Complete Sections 4E-H 'Research proposal budget, 'Subcontract budget', 'FTE summary', and 'List of collaborators' in the **2025 Project Budget Form** (Microsoft Excel template). Refer to **Section 3.4** for detailed guidance on how to complete the budget form. Please complete all sections and upload the budget form in both **.xlsx and PDF formats** to HRC Gateway. Please make sure all budget tabs are included in the PDF.

A NZ standard CV is required for all named investigators. Upload these to HRC Gateway; they will be compiled in Module 5.

Module 6 Research classification is for HRC evaluation purposes only and is completed on HRC Gateway.

The completed application form should be uploaded to HRC Gateway as a PDF file. Before submitting your application, refer to the application checklist at the end of Part 3.

3.1 The Project application forms

The form is compatible with most Windows PC and MAC computers. The form has default formatting that conforms to HRC requirements. Figures and tables are best pasted in from a draft document instead of created directly in the form. Please:

- Use the original HRC document templates as it contains special features
- Complete all sections following the instructions on the form and described in these guidelines
- Enter the HRC reference ID# and first named investigator surname on the coversheet (HRC Gateway will remove the coversheet from the final system-generated PDF).
- Enter information only in the indicated form fields.
- Do not reformat Module and Section headings.
- Do not delete spreadsheet columns/shaded rows; you may insert more unshaded rows.

3.2 Module 1: General information

Module 1 is completed in HRC Gateway, and most information will have been provided at the EOI stage. Most fields cannot be edited or updated from the EOI stage. Update Module 1 in HRC Gateway to include the following information.

3.2.1 Research title

The research title should be succinct, written in plain language, and clearly describe the proposed research without using metaphorical terms. The title must not exceed 80 characters, including spaces and punctuation (e.g. 'growth factors' contains 14 characters). Please use sentence case. The HRC reserves the right to amend the title of the funded proposals.

3.2.2. Lay summary

Ensure your lay summary includes a clear statement covering the following key elements

- 1) purpose of the research, why it is needed and how it contributes to priorities
- 2) how the research will be undertaken including the methodological approach
- 3) anticipated health benefits, expected outcomes; and value for money.

This information will be used to inform the Council in the final approval process if the application is recommended for funding. The lay summary will also be publicised through the HRC's communication channels (e.g. website) and should be easily understood by members of the public (150-word limit). The HRC reserves the right to amend the lay summary of funded proposals.

3.2.3 Support personnel

Support personnel can be added if applicable. Examples of support personnel include individuals who will help you upload your application to HRC Gateway. Do not list named investigators or your host institution's research office staff (or equivalent) in this section. All support personnel need to have an HRC Gateway account to view and edit your application.

3.2.4 Named investigators

All named investigators must have an HRC Gateway account before they can be added to the application. Each named investigator will need to sign-in to HRC Gateway and update their details before you submit your application. Certain information (i.e. ethnicity, gender, and whether the researcher is a clinician) is used for HRC information purposes only and will automatically populate from the individual's profile.

3.2.5 FTE for named investigators

Enter a defined FTE value for each named investigator. Use the FTE value for the first year of that investigator's involvement (from the budget spreadsheet).

Role is a dropdown field with the following options:

- Named investigator
- Application support
- Contract support
- Other

Role in project should include brief information on what the investigator will undertake in the project (1-2 sentences max).

You may wish to designate a hapū, iwi or Māori organisation conducting the research to be acknowledged in their own right as investigators on the application. It is still essential to list supporting named investigators.

3.2.6 Research costs

Click the 'Update' button to enter the totals for staff costs, overhead, working expenses and the total cost of research. The totals entered must match the totals in the uploaded budget form.

3.2.7 Unacceptable peer reviewers

You can identify up to two individuals who are not acceptable as peer reviewers for the application. Click the 'Update' button to enter the name, organisation, and reason for exclusion.

3.2.8 Objectives and milestones

Objectives and milestones are assessed, included in a resulting research contract, and used for contract monitoring in progress and end of contract reports. Objectives and milestones must be measurable and achievable within the term of a contract.

Objectives

Briefly describe the intended objectives of your Project application. Objectives should relate to the overall goal or aim of the research. The HRC suggests a minimum of 3 objectives, with sufficient standalone operational detail and scientific information to assess your performance in subsequent years.

All objectives must be added before milestones can be added. There is no limit to the number of objectives and milestones.

Milestones

Provide key milestones that you aim to achieve by the end of each year of a resulting contract. Each milestone must relate to one or more of the objectives previously added.

For contract monitoring and HRC accountability reporting, if the research requires ethics and/or regulatory approval (human, animal, or biological safety), and/or clinical trial registration, these should be identified as separate Year 1 milestones, even if you expect to gain these approvals before starting the proposed research award.

Example milestones:

Year	Milestone	Objective(s)
1	Gain animal ethics approval	Objective 1
1	Complete animal study, data collection, and analysis	Objective 1
1	Register clinical trial prospectively in ANZCTR	Objective 2
1	Gain ethics approval for clinical trial	Objective 2
2	Publish results of lab-based study	Objective 1
2	Recruit 200 participants to clinical trial	Objective 2
3	Complete recruitment to clinical trial (300 total)	Objective 2
3	Complete statistical analysis of clinical trial	Objective 2
4	Submit manuscript to NZMJ	All objectives

3.3 Module 2: Research

3.3.1 Section 2A: Summary of proposed research (1-page limit)

This section should clearly summarise the research proposal. Reviewers use this section to get an overview of your application and as a quick reference. Include all the important points of your application but keep this section to only **one page** long. The content should be similar to your EOI. Use the suggested headings and add subheadings if required.

3.3.2 Section 2B: Description of proposed research (10-page limit, excluding references)

Give an overall description of your research project.

Your audience includes discipline-specific peer reviewers and a more broadly experienced assessing committee. Therefore, not all members will have specialist knowledge of your research topic. It is in your best interest to structure your writing clearly and logically. Using graphics and tables is an efficient use of space (please ensure font type and size are easily legible). Ideally,

seek feedback from a colleague outside your immediate research area. Please refer to <u>Appendix</u> <u>2: Scoring criteria and anchor point descriptors</u> for the scoring criteria for these categories.

Ensure that the format of non-text content is compatible with PDF conversion software. In the application form, the section headings provided must be used. They correspond to the assessment criteria used to assess the Project Grant applications.

Rationale for research

Outline why your research is important, worthwhile and justifiable to New Zealand. Strongly demonstrate the research gap and how your research plans to address it. Include your research's purpose and aims, hypothesis, and anticipated new knowledge, technical advance or innovation.

Consider the following when responding to this section:

- Have you adequately reviewed what is already known in the area and shown that there is a clear case for further research? For example, you can refer to systematic reviews or an otherwise robust demonstration of a research gap.
- What is the significant/important gap in knowledge? Include essential information to help reviewers appreciate or understand why your proposed research should be undertaken.
- Do your hypotheses build on existing knowledge? Demonstrate the potential to advance knowledge in the relevant field, health issue, policy, practice or service delivery.
- How does your research contribute to, or align with, research being undertaken nationally or internationally?
- Where does your proposed research fit relative to the world-wide perspective? For example, is it unique to New Zealand?
- How original is the approach?
- What is the significance of the health issue for New Zealand health and society?
- Does your research address a significant health issue that is important for Māori?
- Do the aims, research question and hypotheses build on existing knowledge, address a knowledge gap, and contribute to the creation of Māori health knowledge?

Research design and methods

Include sufficient details of your study design and methods so reviewers can assess its appropriateness, robustness and innovativeness. Cleary state what will be done, how, by whom, where and when.

Consider the following when responding to this section:

- Subject recruitment and characteristics (including number, gender and ethnicity where relevant)
- Study methodology, and proposed methods of data collection and analysis. Where
 appropriate, provide power calculations, an estimate of the likely effect size and the
 sample size required to detect this (power analysis). The HRC recommends that a
 statistician is involved in this process.
- An indication of timelines for your research. The HRC recommends that you consult with specialists, such as methodologists, statisticians and health economists before finalising your research design. Where possible, detail the validity of the proposed analyses and the feasibility of attaining the statistical power sought.
- Clinical trial applications (<u>see Appendix 3: Proposals including randomised controlled</u> <u>trials (RCTs)</u>) should include a description of statistical guidelines for early termination and a description of data and safety monitoring arrangements, where appropriate.
- Basic science applications are encouraged to provide control data to help the assessing committee. In addition, please provide evidence that mouse models have been generated (even if not in-house) and are viable if transgenic/knock out mice.
- If your research is patent-protected, provide the patent number and a summary of information available (if no technical information can be provided).

The HRC provides an independent data monitoring committee that has appropriate trial-specific expertise and follows best international practice if required. For general information on trial monitoring and the HRC Data Monitoring Core Committee (DMCC), see http://www.hrc.govt.nz/about-us/committees/data-monitoring-core-committee.

Research impact

This section includes two components: 1) a description of how your research might be used and the anticipated benefits for Māori and New Zealand, 2) the action plan to address all 6 goals of the Rangahau Hauora Māori investment stream to maximise the use and benefits of the research. Refer to the <u>HRC's Research Impact Slideshow</u> for additional guidance on completing this section.⁴

- 1. What types of benefits are expected to arise from your research, and who will benefit? Consider the following when responding to this question:
 - Provide a realistic description of how research findings could contribute to improved Māori health or other societal benefits over time (a 'line of sight' or 'pathway' to impact).
 - Identify the more immediate benefits and the users of the research plan who will form a focal point for your action plan.
 - The balance between describing short-term benefits and potential longer-term impacts will be dependent on the specific research context, with emphasis on your sphere of influence throughout the life of the research project.
 - Research-related benefits, such as capacity and capability gains for New Zealand, and influence on future research agenda-setting, may be included where relevant.
- 2. What specific activities have been, or will be undertaken throughout the life of the research project, to address **all six** goals of the Rangahau Hauora Māori investment stream to maximise the use and benefits of your research?

Note: You must address all six investment signal goals. Please cross-reference sections written under other headings to avoid repetition.

Consider the following when responding to this question:

- Describe what targeted actions have been, or will be, taken to improve the likelihood of
 research uptake and impact, and to ensure that the next users or end users (identified in
 the previous question) can meaningfully contribute to or benefit from the research.
- Provide information on how the proposed research contributes to:
 - o Māori health knowledge and the translation of knowledge into health gains
 - The utilisation of Maori health research and ethics processes
 - o The contribution to Māori health research workforce development and leadership
 - Responsiveness to and partnership with Māori stakeholders and communities
- Describe planned dissemination activities that are designed to reach broader audiences. Include details of who can enable the uptake of your research and how they are involved in your research. Identify uncertainties to uptake, or systematic/institutional barriers, and your mitigation strategies (where relevant).
- Provide details of your team's track record in transferring knowledge. Outline your existing links, relationships, or networks with relevant research next-users or end-users. Give examples of knowledge mobilisation or changes in health outcomes or societal impact generated from similar research. This component is considered relative to opportunity.

Note: The <u>HRC's Research Impact slideshow</u> discusses elements that should be covered in this section, including the types of benefits and research users, and the geographical distribution of benefits (such as how contributing to international research efforts will benefit New Zealand).¹

⁴Consult the <u>HRC's Research Impact Slideshow</u> for further discussion on the types of benefits that can arise from health research, and where these benefits might be expected to occur along a pathway to impact.

Expertise and track record of the research team

Provide evidence that the team has the experience, qualifications, knowledge, networks and infrastructure to deliver the proposed research. Outline the role of each team member.

Consider the following when responding to this section:

- Demonstrate that the team has the qualifications, experience, and knowledge in the proposed research area; right mix of expertise, and appropriate networks and collaborations; history of productivity and delivery; and the right research environment/infrastructure to deliver the research and disseminate results.
- The expertise and track record of each member of the team (i.e. named investigators) must be described. Reviewers consider the FTE of senior investigators on each proposal and weight their scoring on the expertise and track record of the research team accordingly, i.e. high scores should not be allocated for a senior named investigator who has a small percentage FTE involvement in the research. Briefly describe the team's track record related to the proposal area, to demonstrate the ability to deliver proposed study outcomes. Highlight important skills, expertise and previous collaborations in the team that would support delivery of the proposed research. A justification for staff roles should be provided.
- Describe any career disruptions, and their impact, that may be relevant to your career history. A career disruption is defined as a prolonged interruption to your capacity to work due to pregnancy, major illness/injury, parental leave, and/or carer responsibilities.

The HRC recognises that applicants with experience in sectors other than public sector research may have gained valuable expertise or produced outputs (e.g. patents) relevant to research translation, and this may have limited the applicant's opportunity to produce more traditional research outputs.

The research team in the full application must be included in any subsequent contract.

3.4 Module 3: References

Please start this module on a new page. There is no page limit.

Citations for key references in the text in Module 2 should be supplied. Details must include a full list of all author(s), title of article, journal, year, volume and page numbers. Endnote lists must be copied into a plain text editor before pasting it in this section. Place an asterisk beside named investigators' publications.

A reference to Māori terms in the application with brief interpretation should be included here.

3.5 Module 4: Contract information and Budget

Sections 4A-4C are part of the **2025 Rangahau Hauora Māori Project Full Application Form.**

Section 4D are letters of collaboration/supporting documents/memorandums of understanding. These documents will need to be uploaded to HRC Gateway; a list of uploaded documents will be automatically generated under Module 4D.

Sections 4E-4H should be completed in the separate Microsoft Excel budget spreadsheet – **2025 Project Budget Form**.

Please complete all modules and then upload the budget form as both **.xlsx and PDF formats** to your application in HRC Gateway.

3.5.1 Section 4A: Justification of expenses

Justification of research staff

Use this section to justify the role and FTE of the named investigators and any other research staff listed in Section 4E. Please include the following (if applicable):

- An explanation of each person's role (named or un-named, funded or not funded by the proposal), who will be actively associated with the research. These may be research assistants, technicians, medical staff, interviewers and support staff or similar, whose names or position titles are listed in the budget under 'research staff' and who have specific FTE involvements. Time-only staff require clear justification.
- A justification for un-named postdoctoral fellows. Named postdoctoral fellows should be included as named investigators and provide their CVs.
- Evidence that biostatisticians, data managers and health economists are integrated into the team as appropriate, e.g. sufficient FTE is allocated for each year of the contract.
- Roles in mentoring junior team members
- Details on whether staff will be promoted during the project and a clear justification for this

Funding requests may be declined for roles that are not fully justified or are only described as a 'training opportunity'. It is your responsibility to ensure that no personnel in this section will exceed 100% FTE of their combined commitments during the term of the contract. The roles of students and casual staff should be justified in the next section 'Justification of working expenses and casual staff'.

Justification of working expenses and casual staff

All items listed under 'Materials and research expenses' in the budget should be justified. Provide costs per item unit and full costs per item for the number of units requested. Costs associated with knowledge transfer activities can be included. Quotes must be provided to support discretionary costs, where available.

The assessing committee will consider the appropriateness of the budget and working expenses. If there are exceptional requests for working expenses, ensure they can clearly understand why the requested materials, travel, research tools or significant one-line items are necessary.

Justify the roles of students and casual staff so that the assessing committee can appreciate how these individuals are necessary for the proposed research. For students, stipends must be included at the per annum values approved by the HRC: \$30,000 for PhD students, \$20,000 for Masters students and up to \$7,500 for summer students, or pro-rata for part-time students.

Students should be named if they have been identified at the time of application, along with a description of how their expertise relates to their role. Unnamed students can be included in the application budget, e.g. "PhD student (not yet appointed)". Once you have appointed an unnamed student, please advise the HRC of the student's name and relevant expertise. If you include an unnamed student, you cannot include any information about your intention to recruit and appoint a student with any particular expertise or other characteristic, such as ethnicity or gender. Any such detail on unnamed students is considered unjustified and will be disregarded in the assessment process.

It is your responsibility to ensure that students do not exceed 100% FTE on their combined commitments with the host organisation during the term of the contract.

3.5.2 Section 4B: Previous/Current contracts and awards

List contracts awarded to the first named investigator within the past 5 years

Using the table provided, outline current and previous funding contracts from any agency that has been received in the last 5 years by **the first named investigator (and co-first named investigator if applicable) as principal investigator**. Copy the table and repeat for each received grant as required. This section provides the HRC reviewers and assessing committees with an overall summary of your abilities to secure funding for research.

For 'Nature of support', indicate whether the funding supports salaries only, working expenses only, both salary and working expenses, equipment, a junior research fellow, etc.

Note: You can replace the table with an Excel spreadsheet. If doing so, please use the same layout as the original table.

3.5.3 Section 4C: Other support

Other research applications awaiting decisions

List any relevant research applications pending with other funders that might alter the project's budget. If applicable, indicate in the spaces provided any overlap (research, resources and personnel) that the listed application might have with this application. By providing this information, you agree that the HRC may seek clarification details from the other funders if required.

Co-funding

Provide details if you have approached other funders to co-fund this research. If applicable, detail the joint funding arrangements.

Financial or other interest(s)

For HRC funding applications, a financial or other interest is anything of economic value or a political/philosophical perspective, including relationships with entities outside of the research host organisation. While not an exhaustive list, examples of financial interests include positions such as consultant, director, officer, partner or manager of an entity (whether paid or unpaid); salaries; consulting income; honoraria; gifts; loans and travel payments. Examples of other interests include aligning with special interest groups seeking to advance or promote a particular worldview or policy.

Please disclose and provide details of any significant relationship to third parties (e.g. commercial sector entities contributing to project costs, equipment, staff joint appointments). Clearly describe how the current application relates to those relationships. Assessing commercial links is **not** part of the HRC peer review process.

A conflict of interest is a situation in which an individual's financial relationships or interests may compromise, or have the appearance of compromising, the individual's professional judgment in conducting or reporting research. If you can identify financial or other interests in your funding application, outline the specific details of your proposed conflict management strategy.

3.5.4 Section 4D: Letters of collaboration/support documents

Any additional documentation (including subcontracts/Memorandum of Understanding (MOU), letters of collaboration/support, appendices, and other supporting documents) should be uploaded as separate PDF files under the 'Letters of collaboration/support documents' on HRC Gateway.

HRC Gateway will automatically generate a list in the order the documents are uploaded.

A letter of collaboration should outline how the interested party intends to implement the findings of the research upon its completion, or provide material or actual support for the research, **not simply state that the research is necessary**. Please ensure that any organisation providing a letter of collaboration recognises their intended commitment to conduct the proposed research and the timeline of their involvement.

3.5.5 Section 4E: Research proposal budget

The budget spreadsheet in Section 4E can be used for different types of applications. Select 'Project' from the drop-down list. Further instructions are contained in the Notes tab of the file.

The guidelines below should be considered only as summary of the HRC's funding rules. For more information, please refer to the *HRC Rules* document, which is available on HRC Gateway.

Budget calculations and spreadsheet

All calculations should be **GST exclusive and in whole dollar amounts**, i.e. no cents or decimals.

'Salary', 'Working expenses' and 'Total cost of this research' are components of Section 4E. The spreadsheet automatically calculates totals for each year of costs. Insert more rows into the table if required.

The 'Total cost of research' shaded section automatically calculates all the figures in this box.

Do not enter any details into the shaded areas as these are completed automatically.

Salary

Only enter **contract research staff** employed or to be employed by the host organisation in this section. This includes academics.

All positions should specify grade and level, FTE and salary; time only is permissible. The monetary value (\$) should be the **actual** salary amount that the named staff member is expected to receive for their part each year.

The budget form does not accept FTE less than 3%. The HRC Assessing Committees do not favour listing numerous investigators with a very low FTE, and salary requests should only be for significant input and involvement in the project. Advisory groups of contributors, who have FTE commitments less than 3%, may be a consideration for the research team.

Do not enter salary associated costs (i.e. amounts requested for employer's contribution to approved superannuation schemes and accident compensation levies) for research staff in this 'Salary' section. Instead, enter them in the 'Working expenses' section.

Note: Overheads will be paid at a negotiated rate for each institution on all eligible contracts.

Staff that must not be entered into the 'Salary' section of the budget are subcontracted staff, named or unnamed Masters and PhD students on stipends, and casual staff.

- Subcontracted staff are those who are **not** employees of the host organisation. The salary and all other expenses for these staff should be broken down into appropriate categories on a detailed subcontract/memorandum of understanding (MOU) between the host organisation and non-host organisation using Section 4F. The total GST-exclusive dollar figure for the subcontract/MOU should be all-inclusive, including overhead calculations. Note: the HRC does not cover overheads for overseas-based organisations. The subcontract/MOU total should then be entered under 'Working expenses subcontracts' for each year.
- If you request funding to provide a stipend for a PhD student (\$30,000 per year) or Master's student (\$20,000 per year), enter these into 'working expenses – materials and research expenses'. Students should be named if they have been identified at the time of application. Unnamed students can be included in the application budget as e.g. "PhD student (not yet appointed)". The HRC must be advised of the student's name once appointed.
- Casual staff (those persons without an ongoing role or commitment to the research but providing one-off services to the research on a part-time, hourly or per diem basis, e.g. interviewers) should also be requested under 'Working expenses - materials and research expenses'.

Working expenses

Working expenses include 'direct costs' only. The only exception is in the case of subcontracts, as described above. Estimates of costs should be expressed in current prices **exclusive of GST**.

Materials and research expenses

The direct costs of the research include all the disbursements that can be identified, justified and charged to a contract. They may include the following:

- Research consumables. These should be itemised at the current cost per unit and full cost for the number required.
- Other costs **directly** related to the research (e.g. telephone calls/communications, mail and freight).
- Computer-related license fees for research-specific software; access to High Performance Computing infrastructure (NeSI).
- Minor research equipment to a total of \$5,000.
- A proportionate part of new specialised equipment (i.e. equipment to be acquired). This cost must be justified in your application and supporting documentation should be uploaded to HRC Gateway).
- Depreciation on specialised equipment if your host organisation's auditors have certified that it will be excluded from your organisation's overhead rate. This cost must be justified in your application and supporting documentation should be uploaded to HRC Gateway. For all other equipment, depreciation and capital costs are included in your organisation's overhead rate.
- Expenses relating to research participants.
- Costs associated with knowledge transfer activities.
- Travel costs **directly** related to conducting the research. Contract funds may be used to assist with overseas travel provided the HRC is satisfied that this travel is directly relevant to conducting the research and that alternative funding sources are not available. This is not intended to relieve your host organisation of its obligation to assist with the costs of overseas travel by its employees.
- Costs for stipends can be requested for Master's and PhD students. Stipends must be included at the HRC-approved rates (Master's \$20,000 per annum; PhD \$30,000 per annum). Both named and unnamed students can be included; in both cases, describe the student's research project/contribution to the research activity in Section 4A. Funding for stipends will be conditional upon the host organisation arranging a tax-free stipend that satisfies the Inland Revenue Department and host organisation's rules. **Note**: students' fees and thesis costs cannot be claimed.
- Disseminating research results. Contract funds can be used to pay fair and reasonable charges to publish HRC-sponsored research in journals, reports, monographs or books. Also, costs incurred from other forms of dissemination, such as meeting with community groups, or conference dissemination can be claimed if reasonable and justified.
- Conference allowance: The maximum allowance for conference attendance is \$1,000 per annum per named investigator if **fully supported at 100% FTE** by the grant and must be fully justified. The allowance cannot be distributed proportionately between grants. This allowance is distinct from the cost to disseminate findings from this proposed research; this cost must also be fully justified. Fares and allowances should be calculated following the host organisation's regulations and scales.

Note: If you intend to ask the HRC's Data Monitoring Core Committee (DMCC) to monitor this study, there is no cost involved. However, your application must include adequate provision for statistical support to provide the DMCC with all data and analysis they request to carry out their monitoring including the preparation of biannual statistical reports. Also, costs for members of the study team (including the study statistician) to attend the meetings need to be included in the application's budget. If you have any questions, please contact the DMCC secretary at dmcc@hrc.govt.nz.

Subcontracts/Memorandum of Understanding (MOU)

Subcontract staff are not employees of the host organisation. The salaries for these staff and all other expenses (e.g. working expenses) requested for the subcontract should appear in a detailed subcontract/MOU between the host organisation and non-host organisation. A MOU should also include overhead calculations for salaries (**note:** the HRC does not cover overheads for overseas-based organisations). A *pro forma* MOU is available upon request from the HRC. If a subcontract/MOU is greater than \$50,000, all expenses requested should be broken down into the appropriate categories in Section 4F (MOU budget).

Please provide MOUs for time-only subcontracted staff who are not employed by the host

organisation. If MOUs cannot be provided, you can include a support letter that describes the individual's role and level of involvement. If your application is successful, copies of MOUs that were not provided for any time-only individuals may be required at the contracting stage. Please upload all MOUs and letters of support as separate PDF files on HRC Gateway. Refer to section 3.5.4 in these guidelines 'Section 4D: Letters of collaboration/support documents' for further details.

Salary associated costs

Amounts requested for the employer's contribution to approved superannuation schemes and accident compensation levies for research staff should be entered in the 'Working expenses' section. Enter the amounts for each year separately in the budget form. The percentage rates for both ACC and superannuation should be noted for each individual (and justified in Section 4A where required, i.e. for non-standard rates).

International expenses

The HRC does not contribute to the overhead of overseas investigators. The total proportion of the contract budget allocated to overseas investigators must not exceed 20%.

Total cost of research

Enter the appropriate overhead rate (OHR) in the budget. Seek advice from your host organisation's Research Office on the costing of their research applications and the overhead rate negotiated with the HRC.

After entering the appropriate overhead rate, the total cost of the research will be automatically calculated. Enter the overhead and total cost of research from the budget form into the HRC Gateway section named 'Research costs'.

3.5.6 Section 4F: MOU budget

If a large proportion of the total budget is contained in a subcontract/MOU, the expenditure must be itemised in the same way as the overall application's budget. Use Section 4F to provide budget details for all MOUs requesting more than \$50,000; add a copy of Section 4F for each subcontractor. Use the overhead rate for the subcontracted staff member's host organisation, not your main host organisation. The total dollar amount for each year should then be entered under 'Working expenses – subcontracts' and a copy of the subcontract/MOU should be uploaded separately to HRC Gateway.

A CV must be provided in Module 5 for all named investigators on MOUs. This helps the assessing committee determine whether their expertise is appropriate and necessary. Without this information, the assessing committee may not support the budget for the MOU. CVs are not needed for employees of commercial enterprises providing service for fees.

If there are no subcontracts/MOUs for this application, or none requesting more than \$50,000, you can ignore Section 4F.

3.5.7 Section 4G: FTE summary

When completing this section, please:

• List the time involvement of **all** personnel (including those on a subcontract/MOU) in fulltime equivalents, e.g. 10% FTE. Half percentages (e.g. 4.5%) are not allowed. Ensure the FTE figures match the budget, MOU budget sections (Sections 4F and 4G), and Module 1.

- Give all names (for unnamed positions, indicate as 'technician', 'research nurse', 'postdoctoral fellow', etc.). Indicate when named investigators are 'time only' (i.e. not receiving salary for their involvement in the project).
- Identify all postgraduate students by 'Masters' or 'PhD'.

Note: Heads of department will need to provide workload relief for research staff working on HRC contracts (principles of full cost funding).

3.5.8 Section 4H: List of collaborators (national and international)

Please complete the collaborators (not named investigators) table by providing full name, organisation, and country (the location where the organisation is based, and the collaborators undertake their research).

For 'collaboration purpose', select one of the following options: research; commercialisation; knowledge transfer.

For 'support', indicate the value of any funding for this research provided by the collaborator in NZ dollars or list any in-kind support.

3.6 Module 5: NZ Standard CV

Upload a CV for all named investigators (including those on a Memorandum of Understanding). HRC Gateway will automatically compile CVs under Module 5 of your application.

CVs must be completed on the NZ Standard CV template, which you can download from HRC Gateway. Please use the default font and stay within the page limits. The HRC will not accept any other forms of CV.

The information provided in your CV **must match** the information provided elsewhere in the application and in your HRC Gateway profile.

Your CV may indicate when career breaks (including pandemic-related disruptions) have taken place as your track record will be assessed relative to opportunity.

3.7 Module 6: Classification (additional information in HRC Gateway)

Click the 'Update' button next to each of the classifications required. Classification of research is for HRC evaluation purposes only. The information is not used in allocating funding. The required details must be entered in HRC Gateway.

3.7.1 ANZSRC and keywords

Categorise the proposed research using the ANZSRC codes for the Fields of Research (FOR) and Socioeconomic Objective (SEO). Enter the percentage to the nearest 10% for each category to a total of 100%.

Enter keywords that categorise the area of health or health research that your application is connected to.

3.7.2 Economic benefits

Briefly describe any potential economic benefits which may arise from your research. If you do not anticipate any direct economic benefits, please state this rather than leaving the field blank. The HRC's interpretation of economic benefits is broad and includes:

- contributing to maintaining a healthy and productive population
- contributing to an efficient and cost-effective health system, and
- value generated from IP and innovation.

3.7.3 Health issues

Enter the requested information on HRC Gateway. Select the health issue that best describes your research and, if required, one secondary health issue.

3.7.4 Mapping category

Select the category that best describes the starting point for your research. The following table provides a description of each category.

Mapping	Description
category	
Biomedical	
Gene	Research into the genetic basis of disease or identification of genes involved.
<u> </u>	Linkage analysis falls here and not under clinical studies.
Cell biology	Analysis of molecular-level interactions. This includes protein-protein interactions, determination of the function of genes involved in diseases, and
	whole cell studies (e.g. immunological studies, transfections, etc).
Physiology	All physiology and anatomy, including animal models of disease and studies on host-pathogen interactions.
Diagnostics	Innovations and the development/refinement of new or existing diagnostic tools.
Pharmaceuticals /treatments	The development of new pharmaceuticals (drug design and development), as well as new treatments for diseases (e.g. vaccines, other therapies).
Clinical	
Clinical studies	Research involving human subjects. This excludes research in which samples from human subjects are used for fundamental biomedical research, such as genetic linkage analyses.
Clinical trials	Randomised clinical trials, usually randomised controlled clinical trials.
Health services	
Health economics	Research into the cost-effectiveness of treatments/services, etc.
Clinical services	This includes primary and secondary care services. Access to and appropriateness of services are also included, and safety of services and compensation. Macro-level analysis of health system changes falls into this area.
Public health	
Knowledge resources	All epidemiology, underpinning social science (qualitative and quantitative), development of tools and new methodologies, and development of indicators.
Risk factors	Research linking life experiences, behaviours, exposures etc. with health outcomes.
Interventions	Research that includes the design and evaluation of interventions.
At-risk populations	Includes research on specific population groups. These groups may be based on age, ethnicity, occupation, etc. Includes research using diagnostics in a particular group.
Community services	Research around community-run services and community groups, e.g. marae-based healthcare services.

3.7.5 Research methodology categorisation

This information will be used to inform HRC's assessment process and policy analyses. We are trialling capturing this data and the information we receive will assist in developing our approach going forward.

We appreciate there are a range of different research methodologies and that these can be described in different ways. The research methodology keywords entered in this section should be descriptive and provide more detail than simply 'quantitative', qualitative' or 'trial'. Only enter

single words or terms in this section – we are not expecting a detailed written description of the methodologies to be used.

Possible examples of research methodology keywords may include terms such as participatory action research; cluster randomised controlled trial; kaupapa Māori methods; systematic review; meta-analysis; implementation science; animal model studies; epigenetics.

3.8 Application checklist

Before submitting your application, please check that you have completed all tasks outlined in this checklist.

- The application is written in Arial 10-point type font or larger, using default margins and single line spacing.
- Module 1 has been completed in HRC Gateway.
- Module 2, Module 3, and Sections 4A-4C in Module 4 have been completed in the 2025 Rangahau Hauora Māori Project Full Application form (Microsoft Word template).
- In Module 2, Section 2A fits within 1 page and Section 2B fits within 10 pages.
- The 2025 Rangahau Hauora Māori Project Full Application form has been converted to a PDF format. All figures, tables and text have been converted intact.
- The 2025 Rangahau Hauora Māori Project Full Application form has been uploaded to HRC Gateway in the 'Uploads' section of the application.
- In Module 4, Sections 4E-4H have been completed in the 2025 Project Budget form (Microsoft Excel template).
- The 2025 Project Budget form has been converted to a PDF format and all spreadsheet tabs are included.
- Both the .xlsx format and PDF format of the 2025 Project Budget form have been uploaded to HRC Gateway in the 'Uploads' section of the application.
- All named investigators' CVs use the HRC template and have been uploaded to HRC Gateway.
- All letters of collaboration/support documents have been uploaded to HRC Gateway as separate PDF files in the 'Uploads' section of the application (maximum of 15 documents).

Appendix 1: Rangahau Hauora Māori Project application assessment process

1. Overview

Two-stage process

Project applications are processed through a two-stage process. Stage One is an Expression of Interest (EOI), which identifies the area of research and gives an overview of the proposed study, methodology, potential research impact, and a description of the research team.

Stage One: EOI application

All Rangahau Hauora Māori Project EOI applications, unless withdrawn due to compliance, will proceed to assessment by a Māori assessing committee. At the Assessing Committee (AC) meeting, applications are discussed and scored. Only highly ranked applications will be invited to submit full applications.

Stage Two: Full application

Full applications are reviewed initially by external reviewers and the primary Committee Reviewer (CR1). Applicants can provide a rebuttal to the reviewer reports. Each application, with the reviewer reports and the applicant's rebuttal, is considered at the AC meeting. AC members discuss and score the applications using the criteria described below.

Ranked applications from the AC are collated and may be considered by the Grant Approval Committee (GAC), a sub-committee of the HRC Council, before being presented to Council to make the final funding decision.

2. Assessing full applications

Assessing committee membership

Individuals assessing the full applications may differ from those who assessed the Expression of Interest (EOI) applications. Full applications will be assessed by a committee of extended expertise, members from the EOI assessing committee, and experts matched to the applications. The number and make-up of the assessing committee depends on the scope of the applications and declared conflicts of interest, in consultation with the committee chairs.

To minimise potential conflicts of interest, the HRC has specific guidance for assessing committee membership.

Anyone who is a **first named investigator** or a **named investigator** on an application should not sit on the committee that is reviewing their application. However, they may sit on or chair a different committee.

Before the full application assessing committee meeting

Reviewers

Reviewers (external reviewers and the primary committee reviewer (CR1)) score the full applications on a 7-point scale, provide comments, and ask questions for each of the following criteria:

- Rationale for research
- Research design and methods
- Research impact
- Expertise and track record of the research team

The 7-point scale corresponds to a word ladder of descriptors:

Score	Criteria descriptor
7	Exceptional
6	Excellent
5	Very good
4	Good
3	Adequate
2	Unsatisfactory
1	Poor

Criteria	Points
Rationale for research	7
Design and methods	7
Research impact	7
Expertise and track record of the research team	7
Total	28

Reviewer reports are available for applicants' rebuttals and are submitted on HRC Gateway. Both are sent to the assessing committee before the meeting. The HRC aims to obtain 3-4 reviewer reports for each application. Once the HRC has received 4 reviewer reports, any additional reports will be cancelled on the following basis: where a clear major conflict of interest exists, the report is of exceptionally poor quality, or the report was the last received by the HRC. A fifth reviewer report may be accepted if the reviewer's expertise was explicitly needed for a specific component of the research application (and a peer review report covering that component had yet to be secured). It is the HRC's role to coordinate and oversee all communications with the reviewers. Committee members and applicants should **not** contact reviewers.

The applicant rebuttal (<u>Appendix 4: Applicant rebuttal: Full project stage</u>) is an opportunity for applicants to respond to comments or questions raised by the external reviewers. The rebuttal should address the main issues raised by the reviewers, remain objective and avoid emotional responses.

Applicants do not know who provided the external reviewer reports. However, this information is available to the assessing committee.

Assessing committee meeting procedure

The chairs are responsible for ensuring assessments are fair and balanced. General discussion by all committee members is essential for a balanced committee opinion, not unduly influenced by one committee member and should not be cut short nor unduly extended.

The discussion time for each application is 25-30 minutes, as follows:

- Declaration conflicts of interest 1 minute
- Committee Reviewer 1 and Committee Reviewer 2 comments 5 minutes
- Discuss the application 15 minutes
- Scoring 2 minutes
- Committee Reviewer 1 notes for the written review summary 2 minutes

Assessing committee meeting scoring criteria: Rangahau Hauora Māori category

The meeting scores are submitted via HRC Gateway and collated confidentially by the HRC staff. Applications in the Rangahau Hauora Māori category are scored from 1 to 7 against the same criteria used for the Expression of Interest applications. The scoring categories are listed below; refer to <u>Appendix 2: Scoring criteria and anchor point descriptors</u> for a full description.

- Rationale for research
- Research design and methods
- Research impact
- Expertise and track record of the research team.

The 7-point word ladder assists scoring. Committee members may only allocate whole scores. The criteria are scored using a 7-point scale of equal weighting, as listed in the table. The total maximum score is 28.

Score	Criteria descriptor
7	Exceptional
6	Excellent
5	Very good
4	Good
3	Adequate
2	Unsatisfactory
1	Poor

Criteria	Points	% score
Rationale for research	7	25
Design and methods	7	25
Research impact	7	25
Expertise and track record of the research team	7	25
Total	28	100

The assessing committee also considers and may make recommendations on:

- the appropriateness of the timeline for the proposed research
- · the appropriateness of the milestones and objectives
- the appropriateness of the requested FTE involvement of the researchers and any direct costs requested, and
- the total cost of the research Project with respect to 'value for money'.

The HRC Investment Process Coordinator will inform the assessing committee on whether the application's budget aligns with HRC policy. However, it is the committee's responsibility to determine whether the budget is appropriate for the application.

Re-ranking procedure

Once all applications have been scored, the assessing committee reviews the ranked applications. Re-ranking is possible on a case-by-case basis to address significant inconsistencies that can affect the overall funding outcome. Any assessing committee member may put forward an application for re-ranking. If the whole committee agrees, the application's scores can be changed by adding up to 0.5 points to one or two scoring criteria. This will move the application up one place. The new ranking and adjusted total scores are then presented for consideration at the next stage. Scores cannot be added to an application's score without re-ranking the application.

The re-ranking procedure is managed carefully by the committee chair(s) and the HRC Investment Process Coordinator to avoid re-litigating applications and to prevent bias. Conflicts of interest are notified and managed appropriately. Any changes are recorded in the meeting score sheet and notes.

Fundable and not fundable line

The committee, noting conflicts of interest, then:

- identifies the applications assessed as not fundable (NF), by starting at the bottom of the ranked list and going up the list based on quality
- identifies the applications assessed as fundable (F).

Applications above the fundable/not fundable line are considered of sufficient quality and are suitable for funding. Applications below the fundable/not fundable line are of insufficient quality and, irrespective of available budget, should not be funded.

Once the applications have been scored and re-ranked, scores cannot be further reviewed or adjusted. Any concerns about the process are identified by the committee and will be forwarded to the relevant Research Committee.

3. Review summary and feedback to applicants

At the end of the funding round, you can access your application outcome via the HRC Gateway. You will receive a review summary <u>Appendix 5: Full Assessing Committee review summary</u>: <u>Project application</u>) from the assessing committee, which is designed to give you a brief, balanced and objective statement of the committee's response to your application.

Review summaries should be constructive and include:

- key strengths of the application
- key areas for improvement and/or further consideration
- other comments (e.g. budgets, FTE, objectives).

Review summaries should not mention scores or reveal who the reviewers or committee members were. The assessing committee chairs are responsible for approving the content of all review summaries. The HRC is responsible for ensuring they are forwarded to your research office/host organisation.

Appendix 2: Scoring criteria and anchor point descriptors

Criteria for assessing and scoring Rangahau Hauora Māori Project applications by assessing committee

The 7-point word ladder is used for all scoring categories (listed A-D).

Note: You do not have to address all the points outlined below; they are included to help guide the assessment for each of the scoring categories.

Score	Criteria descriptor	Criteria	Points	% score
7	Exceptional	Rationale for research	7	25
6	Excellent	Design and methods	7	25
5	Very good	Research impact	7	25
4	Good	Expertise and track record of the research team	7	25
3	Adequate	Total	28	100
2	Unsatisfactory			

A. Rationale for research

Poor

1

The research is important, worthwhile, and justifiable to New Zealand and considers the international context, because:

- It addresses a significant health issue that is important for Māori
- The aims, research questions and hypotheses build on existing knowledge, addess a knowledge gap, and contribute to the creation of Māori health knowledge (Goal 1)
- The research findings are original and innovative.

B. Design and methods

The study has been well designed to answer the research questions because it demonstrates:

- A comprehensive and feasible study design that is achievable within the timeframe
- An appropriate study design to address the objectives of the research
- Awareness of statistical considerations/technical or population issues/practicalities
- · Evidence of availability of materials/samples
- Māori health research processes (Goal 3)
- Māori ethics processes (Goal 4)
- Partnership with, and responsiveness to the needs of, Māori stakeholders and communities (Goal 6)
- Plan for dissemination of results
- Sound data management and data monitoring arrangements
- Well-managed patient safety issues

C. Research impact

The proposed research is likely to add value and benefit Māori and New Zealand because:

- Applicants have described a credible pathway for how their research will:
 - o result in benefits or opportunities for future research in New Zealand, or

- influence policy, practice, or health services or technologies in New Zealand, leading to improved health or other social/economic impacts.
- The research team are undertaking steps to maximise the likelihood of impact by:
 - contributing to the creation of Māori health knowledge (Goal 1)
 - contributing to the translation of findings into Māori health gains (Goal 2)
 - o incorporating Māori health research processes (Goal 3)
 - o incorporating Māori ethics processes (Goal 4)
 - o contributing to building a highly skilled Māori health research workforce (Goal 5)
 - responding to the needs of, and working in partnership with, Māori stakeholders and communities (Goal 6)

D. Expertise and track record of the research team

The team, relative to opportunity, can achieve the proposed outcomes and impacts because they have demonstrated:

- Appropriate qualifications and experience
- Right mix of expertise, experience and FTEs, including consideration of capacity building
- Capability to perform research in current research environment
- Networks/collaborations
- History of productivity and delivery on previous research funding.

Appendix 3: Proposals including randomised controlled trials (RCTs)

The Controlled Trials Assessing Committee (CTAC) is responsible for assessing randomised controlled trials (RCTs) across all disciplines, except for Rangahau Hauora Māori Projects and Pacific Projects which are assessed by the Rangahau Hauora Assessing Committee and Pacific Projects Assessing Committee, respectively. The purpose of establishing this committee was to ensure consistency in assessing RCTs and to improve the quality of HRC-funded RCTs. CTAC members are selected for their knowledge and experience of RCTs and have expertise in disciplines reflecting the nature of applications assigned to the committee. Member(s) of the Data Monitoring Core Committee may also be represented on CTAC.

Generic weaknesses that have been highlighted by CTAC include issues with methodological quality and poor knowledge of clinical trial conduct. To improve the rigor and completeness of clinical trial proposals, please refer to SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials)⁵ when developing your trial protocols and applications.

In addition, consider all 33 items on the SPIRIT checklist. Pay particular attention to the items listed in the Methods section (items 9–23). Addressing these can improve methodological quality and enhance knowledge of clinical trial conduct. Furthermore, consider designing phase III trials with 90% power to detect well-justified minimum important differences. Exceptions would include research questions of importance to New Zealanders that can only be addressed in New Zealand, and the trial size is limited by the pool of patients and the pressure for a timely answer.

Consider the broad expertise of their audience (CTAC) when describing your trial protocol. For example, when describing sample size (SPIRIT item 14) in Section 2B/Design and methods of the application form, justify all information in the calculation and clearly describe the minimum important difference and how this translates into meaningful clinical benefit.

A significant number of clinical trial research proposals request funding for the New Zealand arm of an international study. Clear administrative information relating to funding (SPIRIT item 4) is required in Section 4C/Co-funding of the application form, including the status of all sources of funding and whether the proposal is dependent on international funding. Roles and responsibilities (SPIRIT item 5) should be stated explicitly in Section 2B/Expertise and track record of the research team, including the specific role of the New Zealand investigator (e.g. as distinct from the site co-ordinator role) and any New Zealand-led trial components. Additionally, address New Zealand-specific health significance and impact on clinical care in New Zealand (in Section 2B), rather than replicating generic information from the international protocol.

Clinical trial registration

As part of our commitment to supporting best practice in clinical trials, the HRC is a signatory to the World Health Organization (WHO) Joint Statement on Public Disclosure of Results from Clinical Trials (the Joint Statement). The Joint Statement sets out policy and monitoring requirements for mandatory timeframes for prospective clinical trial registration and public disclosure of the results of clinical trial research.

The Joint Statement reflects the ethical and quality standards that must be met by HRC-funded clinical trials. This will enhance the evidence base for clinical medicine, both in New Zealand and internationally, while providing easily accessible information to the public, patients and their whānau.

The HRC's full policy statement on clinical trial transparency can be found here.

All RCTs funded by the HRC, either wholly or partly, are required to be registered on an established clinical trials registry (e.g. ANZCTR; Clinicaltrials.gov). Registration should be

prospective and should be added to the application as a Year 1 milestone, even if you expect registration to be achieved before starting a resulting contract.

Appendix 4: Applicant rebuttal: Full project stage

Applicant surname	HRC reference #	
Funding round	Due date	
Title of research		

Instructions (delete after reading): Project application rebuttal has a 2-page limit, which includes references. Do not change the default margins and font (size 11), although you should use bold and underlining for emphasis. Try to leave spaces to improve legibility. Please ensure you address all the issues raised by reviewers and remain objective in your response.

This form is provided on Gateway.

Appendix 5: Full Assessing Committee review summary: Project application

HRC reference #	Applicant surname	
Title of research		
Host		

Note to committee reviewers (CR): Please use **brief bullet points** and give careful consideration to the information and wording provided below as it will be useful for both successful applicants (in helping to shape their research) and for unsuccessful applicants (in preparing future research applications). Comments should be clearly worded, reflect the committee's discussion, and ideally be no more than one-page or 4-6 bullet points total. Please delete this text before you submit the completed form to the HRC.

With regard to the criteria for assessing and scoring research applications:

1. The Assessing Committee noted the following key strengths of the application

2. The Assessing Committee noted the following aspects that could be improved and/or considered further

3. Other Comments/suggestions (e.g. budgets, FTE, objectives)