October 2022

2023 PACIFIC PROJECT FULL APPLICATION GUIDELINES

To use with the following form:

2023 Pacific Project Full Application Form

Table of Contents

Part A: What is a Pacific Project?

1. Project introduction

Health Research Council (HRC) Pacific Projects should address well-defined research questions with the aim of making significant improvements in or developing knowledge contributing to Pacific health outcomes. The HRC will offer contracts worth $400,000 per year to a maximum value of $1,200,000 for a three to five-year term, or pro rata for a shorter contract. For example, a two-year project may have a budget of up to $800,000 or a five-year project may have a budget of up to $1,200,000 but most projects have a term of three years with a budget of $1,200,000. The first named investigator must be of indigenous Pacific descent.

The budget cap for randomised controlled trial project applications is $1,440,000, if required and justified in the full application.

The HRC expects to fund a range of grant values and durations.

2. Project categories

Note: the 'General' project category replaces the previous 'Health and Wellbeing in New Zealand' and 'Improving Outcomes for Acute and Chronic Conditions in New Zealand' research investment streams (RIS) which are not applicable for the 2023 Project funding round.

Applicants **must** select:

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

Note: Health Delivery project investment 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.

The same proposal cannot be submitted to different categories, i.e. General Project, Rangahau Hauora Māori research investment stream, or Pacific Project, as this creates avoidable duplication of both application and assessment effort.

The HRC does not provide advice on choice of project category, as that decision is best made by the investigator. Applicants may change their final choice of project category by creating duplicate applications and making a decision for the most appropriate project category before the closing date for registration. The project category cannot be changed between the Expression of Interest (EOI) and full stages.

3. Rules regarding named investigators on Project contracts

A 'first named investigator' (i.e. lead researcher) on a Project application must have New Zealand as their principal domicile (see definition in the HRC Rules) and their principal place of employment. Note: Host organisations are responsible for ensuring that New Zealand is the principal domicile and principal place of employment for the applicant. By submitting an application, the host is satisfied that this condition has been met).

The HRC welcomes proposals for 'co-first named investigators' under circumstances that would result in 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 in combination with a mentor/experienced researcher. Residency conditions apply to both first named investigator and co-first named investigator.

There is a limit of **two** project applications per first named investigator/co-first named investigator. Failure to comply with this limit will result in the withdrawal of the application(s) (i.e. all applications submitted after the limit was reached).

4. Important note – use of forms

Use these guidelines and the **2023 Pacific Project Full Application Form** when submitting a **Pacific Project** full application.

5. Project assessment process

Project applications are assessed through several steps, via a two-stage process:

Stage 1

- An assessing committee assesses EOI applications and recommend applications to invite for full application.

Stage 2

- External review of the full applications and applicant rebuttal/reply.
- An assessing committee assesses full applications.
- Funding decisions by HRC Council.

6. Project timetable

Event	Description	Date
Full stage opens	Invitation to submit	4 October 2022
Full stage closes	Complete Project full application via HRC Gateway	Closes 30 November 2022
Assessment	Peer review	Dec 2022 to Feb 2023
	Applicant responses	Early March 2023
	Review by HRC Assessing Committee	During April 2023
	Council approval	Late May 2023
Results	Outcome	Early June 2023

Part B: Rules for 2023 Pacific Project full applications

1. Pacific Project full application components

All 2023 Pacific Project full applications must be created, completed, and submitted via HRC Gateway. For some modules of the application, forms need to be downloaded from HRC Gateway, completed, and then uploaded to the application in HRC Gateway. Other required supporting documents also need to be uploaded to the application in HRC Gateway.

Once all components of the application are complete and all supporting documents attached, the application must be compiled and submitted via HRC Gateway.

Also note that prior to submission, all named investigators must have a current HRC Gateway account (updated within 12 months prior to submission).

Forms

These two forms must be used for Pacific Project full applications:

- 2023 Pacific Project Full Application Form (Word template)
- 2023 Project Budget Form (Excel template)

The HRC templates for the above must be downloaded from the 2023 Pacific Projects information page on HRC Gateway. Do not use any other templates; these have special features required for HRC processing.

The forms should be completed in Word and Excel, respectively, and then uploaded to the application in HRC Gateway. Note that the application form must be uploaded as a PDF, while the budget form must be uploaded as both Excel (.xlsx) and PDF formats.

2. Guidelines

Before submitting an application, applicants should read:

- this guideline for eligibility and specific instructions for 2023 Pacific Project full applications
- Guidelines on Health Research involving Māori
- Māori Health Advancement Guidelines
- Guidelines for Pacific Health Research
- Guidelines on Ethics in Health Research
- HRC Research Impact Slideshow
- ARRIVE guidelines for animal research (if applicable)
- Peer Review Manual

3. 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 the application, if it is successful. The host organisation will be responsible for ensuring that the contracted activities are completed according to the contract, the HRC Rules, and the requirements of this grant type.

Organisations that have not previously been funded as the host organisation on a research contract with the HRC will be required to provide due diligence information before a contract can be offered. The HRC will provide further information and relevant forms for the organisation to complete following a successful outcome for the application.

4. Proposals

Proposals must be written in a clear, concise manner with sufficient detail to enable the reviewers to understand the scope and implications of the proposal. Please note assessing committee membership is composed of a broad range of expertise.

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).

Applicants must:

- use Arial 10-point type font or larger
- use default margins
- use single line spacing
- not exceed page limits.

The HRC will not process any application that does not comply with the above.

5. Application submission

5.1 Submission

The closing date for submitted applications to be released to the HRC, in HRC Gateway, is **1pm on 30 November 2022**. No applications will be accepted **after 1pm** on the closing date unless **written** authorisation has been received from the HRC.

Important: Applications are released to the HRC only after approval by the application host organisation's Research Office or equivalent. Applicants should submit their application before their host organisation's internal submission deadline, which is usually several working days before the HRC closing date to allow for host internal processing.

For host organisations without a Research Office, the application will be forwarded directly to the HRC.

5.2 Cautions

The HRC manages an assessment process that benefits greatly from the contributions of a large number of experts who act as peer reviewers and committee members. The HRC values the time of these very busy experts, as well as the effort of our applicants, and is not able to accept applications that do not meet our requirements or timelines. Please avoid these common pitfalls:

Do not send applications or supporting documents to the HRC via email or any means other than submission in HRC Gateway.

Researchers at host organisations with a Research Office (or equivalent) must have their application approved for it to be released to the HRC and must allow the appropriate time for that prior to the HRC's closing deadline. All queries regarding applications should be directed to the host's Research Office rather than to the HRC directly.

Independent researchers, researchers whose host organisation does not have a Research Office, and Research Office staff requiring assistance with using HRC Gateway should contact the HRC in the first instance.

Incomplete applications will be deleted from HRC Gateway after the closing date.

5.3 Significant changes between EOI and full application

Applicants may not make significant changes in the research team and research plans submitted in the EOI. Significant changes may result in the full application being disqualified.

As a general rule, no additional named investigators can be added to the team at the full stage, with the following exceptions:

- 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; or
- to replace an existing member due to unforeseen circumstances.

The form, to request an additional named investigator, replacement or removal of investigator, is available from your research office.

The EOI lay summary can be slightly modified in the full application.

5.4 Changes to FTE between EOI and full application

The HRC has updated how it captures FTE in the EOI application. In the EOI, 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, a defined FTE value will need to be entered for each named investigator, and this value should fall within the band that was selected in the EOI application.

Please note that 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 to make the changes in our system. The form, to request a change of FTE, is available from your research office.

6. Privacy provisions

6.1 Statistical and reporting purposes

The information provided in an application will be used for assessing that application and, in a non-identifiable form, some information will be used for HRC statistical and reporting purposes. The HRC undertakes to store 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 with details provided by funders of the science sector.

6.2 Personal information

Personal information contained in the application will be available to members of the HRC committees, and to external reviewers relevant to the review of the application.

6.3 Media release

The HRC publishes details of research contracts including named investigators, 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.

6.4 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 institution and investigator before responding to the request. Where appropriate, the request may be transferred to the host organisation.

7. Enquiries

All enquiries related to HRC applications should be directed in the first instance to the Research Office of the applicant's host organisation.

If your organisation does not have a Research Office or where the Research Office cannot assist, or for technical enquiries relating to applications, contact the HRC: info@hrc.govt.nz

Part C: Completing and submitting a 2023 Pacific Project full application

Module 1 of the application was completed in HRC Gateway at the EOI stage.

Module 2, Module 3, Module 4, and Module 6 section 6D are completed in forms that are then uploaded to the application in HRC Gateway.

Module 5 contains named investigator CVs that must be uploaded separately in HRC Gateway.

Module 6 is the research classification of the research that must be completed in HRC Gateway (with the exception of section 6D).

The complete application with all modules and uploaded documents will be compiled by HRC Gateway and can be downloaded and printed for checking prior to submission.

1. Module 1: Application details, investigators, objectives & milestones

This module is completed entirely in HRC Gateway. Most information will have been completed at the EOI stage. Some fields will not be able to be edited or updated from EOI stage. Additional information required for the full application is outlined below.

Support personnel

Support personnel are additional HRC Gateway users who can view and edit the application and **are not** named investigators or research office staff.

Named investigators

All named investigators must be registered users of HRC Gateway with a current profile, that must be updated annually by the researcher (HRC will not update profiles without direct request from the researcher).

In the case of co-first named investigators, the co-first named investigator must be listed as the **second** named investigator on the application.

FTE for named investigators

A defined FTE value will need to be entered for each named investigator (and for the first named investigator). **The FTE value should be the 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).

Information on ethnicity, gender, and whether the researcher is a clinician (and is practicing) is used for HRC information purposes only. Please note ethnicity, iwi, clinician, or practising clinician are not required to be entered as these details will automatically populate from the individual person profiles. Each named investigator will need to sign-in to HRC Gateway and check and update their details before applications are submitted.

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

Research costs

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

Unacceptable peer reviewers

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

Objectives and milestones

Objectives and milestones are assessed, are included in research contracts, and are used for contract monitoring in progress and final reports.

Objectives

Briefly describe the intended objectives of this research application. Objectives should be **clear** and **measurable** to allow evaluation of research performance of an awarded contract. All objectives must be added before milestones can be added.

The HRC suggests a minimum of 3 objectives, with sufficient standalone operational detail and scientific information included to be able to inform progress assessment in subsequent years. 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 approval (human or animal), and/or clinical trial registration, these should be identified as separate Year 1 milestones, even if the applicant(s) expect to gain these approvals prior to commencement of 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	Submission of manuscript to NZMJ	All objectives

2. Modules 2, 3 and 4

These modules are completed in forms that are then uploaded to the application in HRC Gateway. Detailed guidance on how to complete these modules in the forms provided is included in **Part D** of this guidelines document.

Uploads

Upload the following documents into the 'Uploads' section of the application in HRC Gateway:

- **Full application proposal**: This is the completed 2023 Pacific Project full application form, converted to PDF format. This contains Module 2, Module 3, Module 4 sections 4A-4D, and Module 6 section 6D. Please check the PDF before uploading to ensure that all figures, tables, and text have converted intact, and that the application meets all other requirements detailed above.
- **Budget PDF**: This is the completed 2023 Project budget form, converted to PDF format. This contains Module 4 sections 4E-4H that will be included in the compiled application. Please check the PDF before uploading to ensure that all sections are included.
- **Budget spreadsheet**: This is the completed 2023 Project budget form, in .xlsx format.
- **Letters of collaboration/support documents**: Each letter or document listed in Module 4 section 4D of the application form should be uploaded here as a separate file in PDF format, up to a maximum of 15 documents.

3. Module 5: NZ standard CV

Use the NZ Standard CV template with default font from HRC Gateway. Do not exceed the page limits. The HRC will not accept any other form of CV.

The information provided in the CV **must be the same** as that provided elsewhere in the application and in the investigator's HRC Gateway profile.

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

4. Module 6: Classification

Click on the 'Update' button adjacent to each of the classifications required:

Classification of research is for HRC evaluation purposes only. The information is not used in allocating funding. Required details must be entered in HRC Gateway.

4.1 Section 6A: 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 research.

4.2 Section 6B: Economic benefits

Please provide a brief description of any potential economic benefits you consider may arise from your research. If no direct economic benefits are anticipated, 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.

4.3 Section 6C: Health issues and mapping category

Health issues

Enter the requested information on HRC Gateway. Applicants need to select the health issue that best describes their research and, if required, one secondary health issue.

Mapping category

Enter the requested information on HRC Gateway (select one). Applicants need to select the category that best describes the starting point for their research. The following table provides a description of each category.

Mapping category	Description
Biomedical	
Gene	Research into the genetic basis of disease, identification of genes involved. 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	This includes all physiology and anatomy. Animal models of disease are included in this category, and studies on host-pathogen interactions.
Diagnostics	This includes innovations, and the development/refinement of new or existing diagnostic tools.
Pharmaceuticals / treatments	This includes 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	This includes 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.

Mapping category	Description
Community services	Research around community-run services and community groups, e.g. Marae-based healthcare services.

Part D: Completing the 2023 Pacific Project full application and budget forms

The **2023 Pacific Project Full Application Form** (Word template) contains a Coversheet, Module 2, Module 3, Module 4 sections 4A-4D, and Module 6 section 6D. This must be downloaded and completed by applicants before being uploaded as a PDF file.

Section 4D is the Letters of collaboration/supporting documents. List the name of the documents in this form and upload each letter or supporting document as a separate file.

The **2023 Project Budget Form** (Excel template) contains Module 4 sections 4E-4H. All sections must be completed and then the budget file uploaded to your application in HRC Gateway in both .xlsx and PDF formats.

1. Module 2: Research

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

This section should clearly summarise the research proposal. The content should not be significantly different from the EOI. The summary must be no more than **one page**. A clear and succinct summary including all the important points of the application can help reviewers get an overview of the proposal and is useful as a quick reference for assessing committee members. Use the suggested headings and add subheadings if required.

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

The section headings provided must be used. The assessing committee membership is broadly discipline-based, matched to the range of applications assigned to that committee, therefore not all members will have specialist knowledge of every research topic. It is advised to write the proposal for members with a general understanding of the research area.

The use of graphics and tables is an efficient use of space (please ensure font type and size are easily legible). Ensure that the format of non-text content is compatible with PDF conversion software.

The section headings correspond to the four equally weighted score criteria which form the basis of assessment (Rationale for research, Research design and methods, Research impact, Expertise and track record of the team).

Rationale for research

Provide the research rationale with a robust demonstration of the research gap and a statement of purpose or research aims for scientific enquiry, hypothesis, new knowledge, technical advance, and innovation.

Demonstrate that you have adequately reviewed what is already known in the area and that there is a clear case for further research. For example, refer to systematic reviews or an otherwise robust demonstration of a research gap. Include information that you feel is essential for the reader to better appreciate or understand why you feel your proposed research should be undertaken. What is the significant/important gap in knowledge or what is the potential to advance knowledge in the field or health issue, policy, practice or service delivery that your research will address? How does your research contribute to, or align with, research currently being undertaken either nationally or internationally? Where does your proposed research fit relative to the world-wide perspective? For

example, is it unique to New Zealand? Do your hypotheses build on existing knowledge? How original is the approach? What is the significance of the health issue for New Zealand health and society? Has responsiveness to Māori been considered?

Research design and methods

Provide sufficient details for technical assessment of scientific protocol, feasibility and validity of data.

Include sufficient detail of study design and methods so that an assessment can be made of its appropriateness, robustness and/or innovativeness. This might include a description of subject recruitment and characteristics (including number, gender and ethnicity where relevant), study methodology, and proposed methods of data collection and analysis. Where appropriate, it is essential to provide power calculations and an estimate of the likely effect size and the sample size required to detect this (power analysis), after consultation/involvement with a statistician. Clinical trial applications (see Appendix 1) are to 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 aid with committee assessment. In addition, applicants should provide evidence that mouse models have been generated (even if not in-house) and viable if transgenic/knock out mice. When research is patent-protected, applicants are encouraged to provide the patent number and a summary of information available (if no technical information can be provided).

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

Indication of timelines for the research should be included. Consultation with specialists such as methodologists, statisticians and health economists before finalising research design is recommended. Where possible, detail the validity of the proposed analyses, and the feasibility of attaining the statistical power sought (if appropriate).

The assessing committees need this information to judge and appropriately score this criterion, so ensure that the practicalities are clearly stated, i.e. what will be done, how, by whom, where and when. Assessing committees are also reassured when methodologies have been used/trialled before.

Research impact

Note: applicants for all project categories are not required to link their impact section to the goals of the investment signal for the previous research investment streams. This is to encourage applicants to consider all potential ways in which their proposal can add value for Pacific communities and New Zealand, and what actions within their influence can help achieve this potential. Assessment of Impact now includes two components: 1) a ***description*** *of how your research might be used and the anticipated benefits for Pacific communities and New Zealand, and 2) the* ***action plan*** *to maximise the use and benefits of the research. See the HRC's Research Impact Slideshow on the HRC website for additional guidance on completing this section.*[1]

What types of benefits are expected to arise from your research, and **who will benefit?**

This section should provide a realistic description of how research findings could contribute to improved health or other societal benefits over time (a 'line of sight' or 'pathway' to impact). Importantly, it should also identify the more immediate benefits, and users of the research who will form a focal point for your Action Plan. The balance between describing short-term benefits and potential longer-term impact will be dependent on the specific research context, with emphasis on considerations within your sphere of influence throughout the life of the research project.

The HRC's Research Impact slideshow includes discussion of elements that should be covered in this section, including the **types of benefits and research users**, and the **geographical**

[1] Consult the HRC's Research Impact Slideshow (https://www.hrc.govt.nz/resources/2020-hrc-impact-assessment-slideshow) 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.

distribution of benefits (such as how contribution to international research effort will benefit New Zealand). Research-related benefits, such as capacity and capability gains for New Zealand, and influence on future research agenda-setting, may be included where relevant.

What specific activities will you undertake, throughout the life of the research project, to maximise the use and benefits of your research for Pacific?

Describe what targeted actions have been, or will be, taken[2] to improve the likelihood of research uptake and impact, and to ensure that the next users or end users (identified in the previous section) can meaningfully contribute to, and/or benefit from, the research. Information must be provided about the contribution of the proposed research to: Pacific health knowledge and the translation of knowledge into health gains; the utilisation of Pacific health research and ethics processes; the contribution to Pacific health research workforce development and leadership; and, responsiveness to, and partnership with, Pacific stakeholders and communities. Describe other planned dissemination activities that are designed to reach broader audiences. Who can enable the uptake of your research, and how have they been involved in your research? Identify uncertainties to uptake, or systematic/institutional barriers, and your mitigation strategies (where relevant).

What elements of the **team's track record of knowledge transfer** provide confidence in the likelihood of research uptake? For example: existing links, relationships, or networks with relevant research next-users or end-users; demonstrable examples of knowledge mobilisation, or changes in health outcomes or societal impact generated from similar research. This component is considered relative to opportunity.

Expertise and track record of the research team

Evidence that the team has the experience, qualifications, and infrastructure to deliver the research. The role of each team member is required.

Provide evidence 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.

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 an applicant's capacity to work due to pregnancy, major illness/injury, parental leave, and/or carer responsibilities. The expertise and track record of each member of the team, (i.e. named investigators), must be described. Committees 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 on the basis of a senior named investigator who has a small percentage FTE involvement in the research. Include a brief description of 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. Justification for staff roles should be provided.

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.

CVs must be completed on the NZ Standard CV template provided. Applicants are encouraged to note when career breaks, such as parental leave, occurred as track record is assessed relative to opportunity.

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

See Appendix 1 for further information on clinical trial applications.

[2] Consult HRC Guidelines and funding rules for information on support of knowledge transfer activities and include these activities in objectives/milestones where appropriate. Progress against implementing the action plan will form part of the milestones HRC monitors with respect to contractual compliance and delivery.

2. Module 3: References

References

Ensure this section starts on a new page.

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. Asterisks are to be placed beside applicant's publications. If references are multi-authored, there is discretion to limit the author list to a more convenient number to fit any space limitations.

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

3. Module 4: Contract information and budget

Sections 4A-4D are parts of the Word application form.

Sections 4E-4H are to be completed on the separate Excel file.

3.1 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 for whom CVs have been provided, including roles in mentoring of junior team members. Also explain the role of all other personnel (named or un-named, funded or not funded by the proposal), who will be actively associated with the research and for whom you are seeking funding. 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. Un-named postdoctoral fellows should be justified here, but it is recommended that named postdoctoral fellows should be included as named investigators and should provide a CV. Assessing Committees may decline funds for roles that are not fully justified or are simply described as a 'training opportunity'. Provide 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. It is the responsibility of the applicants to ensure that no personnel justified 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 following 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 must be justified, with costs broken down per item unit, and full costs per item for number of units requested. The application review process will consider the appropriateness of the budget and working expenses. If there are exceptional requests for working expenses, ensure that the Assessing Committee will clearly understand why the requested materials, travel, or research tools and significant one-line items are necessary for the successful completion of the research.

Clearly justify the roles of students and casual staff so that the Assessing Committee can appreciate how these roles contribute to the proposed research activity.

For students, stipends must be included at the per annum values approved by the HRC: $30,000 for PhD students and $20,000 for Masters students, and up to $7,500 for summer students, or pro-rata for part-time students.

Students should be of Pacific indigenous descent and named at the time of the application, and their expertise relevant to their role should be described in the justification.

It is the responsibility of the applicants to ensure that no students justified in this section will exceed 100% FTE on their combined commitments with the host organisation during the term of the contract. The HRC encourages the inclusion of allowable costs associated with knowledge transfer activities.

Quotes must be provided to support discretionary costs, where available.

List all supporting budget documents in Section 4D (Letters of collaboration/supporting documents list) and upload separately into HRC Gateway.

3.2 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 support from any agency that has been received 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 is intended to provide the HRC reviewers and committee members with an overall summary of the first named investigator's abilities to secure research funding for this type of 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.

If applicable, please detail how this previous/current contract relates to and/or overlaps with the application.

Note: The table and text after the heading of this subsection can be deleted and replaced by an Excel spreadsheet using the layout and required information in the original table.

Previous HRC end of contract report(s)

The HRC no longer requires, or accepts, the submission of previous HRC contract reports to be uploaded as part of the application process.

Please note that the submission of progress and end of contract reports are an HRC contract requirement. For existing HRC contracts, delayed submission without justification will result not only in contract suspension but also will prohibit the submission of new research applications.

3.3 Section 4C: Other support

Other research applications awaiting decisions

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

Applicants should disclose and provide details of any significant relationship to third parties (e.g. commercial sector entities contributing to project costs, equipment, staff joint appointments). A clear description of how the current application relates to those relationships is desirable but assessment of commercial links is **not** part of the HRC peer review process.

Co-funding

Provide details if the applicant has approached other funders for co-funding of this research. If applicable, detail the joint funding arrangements.

Financial or other interest(s)

For the purposes of 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 institution. 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 alignment with special interest groups seeking to advance or promote a particular world view or policy.

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. In the event that an applicant has identified financial or other interests in a funding application, the applicant should also outline the specific details of their proposed conflict management strategy.

3.4 Section 4D: Letters of collaboration/Supporting documents list

List any subcontracts/MOU, letters of collaboration, appendices and any other supporting documents.

The documents themselves should be uploaded separately into HRC Gateway.

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 to state that the research is necessary**. Please ensure that any organisation providing a letter of collaboration recognises their intended commitment to the conduct of the proposed research and timeline of their involvement.

3.5 Section 4E: Research proposal budget

The budget spreadsheet in Section 4E can be used for different types of applications. Select from the dropdown list the application type you wish to submit. Further instructions are contained in the Notes tab of the file.

The guidelines below should be considered only a 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 be in whole dollar amounts, i.e. no cents or decimals.

The '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 any shaded areas as these are completed automatically.

Salary

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

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

The budget form does not accept FTE less than 3%. The 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.

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

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.

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.

a) 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/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 doesn't cover overheads for overseas-based organisations). The subcontract/MOU total should then be entered under ‘Working expenses - subcontracts’ for each year.

b) If funding to provide a stipend for a PhD student ($30,000 per year) or Masters student ($20,000 per year) is requested, enter these into 'working expenses – materials and research expenses'. Students should be named at the time of application.

c) 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 and may include the following:

- Research consumables (these should be itemised at current cost per unit and full cost for number required).
- Other costs **directly** related to the research – 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 (equipment to be acquired) may be included and justified on research applications (insert all budgetary supportive documents at the end of Module 4 with the printed application).
- Depreciation on specialised equipment: depreciation and capital costs on existing equipment are included in the overhead rate. If an institution's auditors have certified that specific items of equipment have been excluded from the research rate, then depreciation on the excluded equipment can be included in research applications and justified in the same manner as other direct costs.
- Expenses of research participants.
- Costs associated with knowledge transfer activities.
- Travel costs **directly** related to the conduct of the research. Contract funds may be used to provide assistance with overseas travel provided the HRC is satisfied that such travel is directly relevant to the conduct of the research and that alternative sources of funding are not available. This is not intended to relieve the applicant's host organisation of its obligation to assist with the costs of overseas travel by its employees.
- Costs for stipends can be requested for Masters and PhD students. Stipends must be included at the HRC approved rates (Masters $20,000 pa; PhD $30,000 pa). Named students can be included; a description of the student's research project/contribution to the research activity should be provided in Section 4A. Funding for stipends will be conditional upon the organisation arranging a tax-free stipend that satisfies the Inland Revenue and host organisation's rules.
- Dissemination of research results (fair and reasonable charges associated with the approved publication of the results of HRC-sponsored research in journals, reports, monographs or books may be paid from contract funds. 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 in accordance with the regulations and scales of the host organisation.
- **Note**: If you are intending to ask the HRC's Data Monitoring Core Committee (DMCC) to monitor this study, there is no cost involved. However, the proposal must include adequate provision for statistical support to provide the DMCC with all data and analysis they request

to carry out their monitoring including 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 budget for the application. If you have any questions, please contact the secretary to the DMCC, ethics@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 doesn't 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). Upload the MOU with this form.

MOUs should also be provided for time only subcontracted staff not employed by the host. If MOUs are unable to be provided for time only subcontracted staff, it is acceptable to include a support letter with a description of the level of involvement and role of these individuals in the application. If the application is successful, copies of MOUs for any time only individuals not provided in the application may be required at the contracting stage.

Salary associated costs

Amounts requested for employer's contribution to approved superannuation schemes and accident compensation levies for research staff – these are not to be entered in 'salary' but in the 'working expenses' section. The amounts for each year should be entered separately in the budget form and the percentage rates for both ACC and super should be noted for each individual (and justified in Section 4A where required, i.e. for non-standard rates).

International expenses

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

Total cost of research

Enter the appropriate overhead rate (OHR) in the budget. Researchers should seek advice from their host institution 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 this amount in the HRC Gateway section of the research application.

3.6 Section 4F: MOU budget

When a substantial proportion of the total budget of a research proposal is contained in a subcontract/MOU, the expenditure must be itemised in the same way as the overall research proposal budget (see above). Use Section 4F to provide budget details for all MOU requesting more than $50,000; add a copy of Section 4F for each subcontractor. The overhead rate used should be that for the host institution of the subcontracted staff, not that of the main host institution of the applicant (**note: the HRC doesn't cover overheads for overseas-based organisations**). 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 in HRC Gateway.

A CV must be provided in Module 5 for all named investigators on MOUs to enable the assessing committees to determine whether the investigator’s expertise is appropriate and/or necessary. Without this information, the assessing committees may decide not to support the budget for the MOU. CVs are not necessary for employees of commercial enterprises providing service for fees.

All subcontracts/MOUs must be listed in Section 4D (Letters of collaboration/supporting documents list). If there are no subcontracts/MOUs for this application, or none requesting more than $50,000, you may delete or ignore Section 4F.

3.7 Section 4G: FTE summary

List the time involvement of **all** personnel (including those on a subcontract/MOU) in terms of full-time equivalents, e.g. 10% FTE. Give all names (for un-named positions, indicate as 'technician', 'research nurse' and 'postdoctoral fellow' etc.). Half percentages (e.g. 4.5%) are not allowed. Indicate when named investigators are 'time only' (i.e. **not** receiving salary for their involvement in the programme). Identify all postgraduate students by 'masters' or 'PhD'. Ensure the FTE figures are the same as those in the budget and MOU budget sections (Sections 4E and 4F), as well as Module 1. Heads of department will be required to agree to provide workload relief for research staff working on HRC contracts (principles of full cost funding).

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

4. Module 6: Classification

4.1 Section 6D: Research methodology categorisation

This information will be used to inform HRC assessment process and policy analyses.

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 a greater level of detail than simply ‘quantitative’, qualitative’ or ‘trial’. However, only single words or terms should be entered 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; Pasifika methods; systematic review; meta-analysis; implementation science; animal model studies; epigenetics; etc.

Appendix 1: Proposals including randomised controlled trials (RCTs)

The Controlled Trials Assessing Committee (CTAC) is responsible for the assessment of randomised controlled trials (RCTs) across all disciplines. The purpose of establishing this committee was to ensure consistency in the assessment of 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.

Issues with methodological quality and poor demonstration of knowledge of clinical trial conduct are generic weaknesses that have been highlighted by CTAC. To improve the rigor and completeness of clinical trial proposals, applicants are encouraged to refer to SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials)[3] when developing their trial protocols and applications to the HRC should reflect protocols that conform to the SPIRIT 2013 guidelines.

With regard to the content of HRC applications, consideration should be given to all 33 items on the SPIRIT checklist, with particular attention to the items listed in the Methods section (items 9–23). Addressing these items is likely to improve methodological quality and enhance the demonstration of knowledge of clinical trial conduct. Furthermore, applicants should give consideration to 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.

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

It has also been noted that a significant number of clinical trial research proposals are requests for 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, it is expected that applicants will address New Zealand-specific health significance and impact on clinical care in New Zealand (in Section 2B/Rationale for research and Research impact, respectively), 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.

We endorse the requirements of the Joint Statement as reflective of 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 simultaneously providing easily accessible information for the public, patients and their whānau.

The HRC's full policy statement on clinical trial transparency can be found here in our Resource Library: https://www.hrc.govt.nz/resources/clinical-trial-transparency-policy-statement

[3] *Chan A-W, Tetzlaff JM, Altman DG, et al. SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Ann Intern Med* 2013; 158: 200-07. This guidance builds on ICH GCP E6 guidance regarding protocol items. The CONSORT Statement (2010) for clinical trial reporting should also be considered at the protocol design stage.

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 the applicant expects registration to be achieved prior to commencement of a resulting contract.

Appendix 2: Pacific Project application assessment process

1. Overview

1.1 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. EOI applications are assessed and ranked with the intention that those invited to Stage Two Full applications will have an overall success rate of approximately forty per cent.

1.2 Stage One: EOI application

At the AC meeting, the proposals are discussed and scored using the criteria described below and ranked by total score.

Only highly ranked applicants will be invited to submit full applications.

1.3 Stage Two: Full application

Full applications are reviewed initially by external reviewers and the Committee Reviewer 1 (CR1). Applicants have the opportunity to comment on the reviewer reports. At the AC meeting each application, with reviewer reports and applicant response, is considered and AC members discuss and score the proposals 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 funding decisions.

2. Assessment of EOI

At the EOI AC meeting committee members confidentially score the proposals.

2.1 Scoring criteria: Pacific category

Applications are scored on a 7-point word ladder using the following equally weighted criteria for the General category. These are listed below with full description in Appendix 3:

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

The 7-point word ladder assists AC scoring according to the descriptors rather than other considerations such as success rates of applications. Reviewers may only allocate whole scores.

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

The criteria are scored using a 7-point scale of equal weighting, as listed in the table, so that the total maximum score is 35

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

2.2 EOI assessing committee meeting procedure and scoring

The chair is responsible for ensuring that a fair and balanced assessment is reached. General discussion by all 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 allocated to each EOI is up to 20 minutes, for example:

- declaration of conflicts of interest - 2 minutes
- CR comments - 2 minutes
- general discussion of the proposal - 12 minutes
- scoring - 2 minutes
- CR1 notes Review Summary points – 2 minutes.

The scores are submitted via HRC Gateway and collated confidentially by the HRC staff.

The scoring criteria and descriptors used at the EOI AC meeting are the same as those used for the preliminary scoring prior to the meeting (Appendix 3: Scoring criteria and anchor point descriptors).

2.3 Re-ranking procedure

After all applications have been scored, the ranked applications are considered by the AC for possible re-ranking of applications on a case-by-case basis to remedy significant perceived inconsistencies with a material effect on the outcome. Applications cannot have points added to the score for the purpose of strengthening the score without re-ranking the application. This procedure will allow any application in the ranked table to move up or down by one position at a time. The re-ranking procedure is managed carefully by the committee chair(s) and the HRC research investment manager to avoid re-litigation of any applications and to mitigate against any bias affecting the process.

Any AC member may bring forward an application for re-ranking.

Conflicts of Interest are notified and managed in the appropriate manner.

The application under consideration would have its scores modified, after appropriate discussion and agreement, by adding up to 0.5 points to one or two of the scoring criteria of choice to move the application up one place under consideration.

The new ranking and new adjusted total scores would then be put forward for consideration at the next stage.

Re-ranking of other applications can be done using an iterative process until a final ranked list is reached.

Any changes are recorded in the meeting scoresheet and notes.

2.4 Selection for the full applications list

At the EOI assessing committee meeting, the proposals are ranked according to the total score. The committee then considers the ranked EOI and recommends those that should submit full applications. The recommendation of applications to be invited to the full stage is a quality decision

that is made without consideration of or reference to the likely number of applications to be invited to the full stage.

In making this recommendation, the AC draws a line on the ranked EOI list so that those below the line should not proceed to the full stage (NF) and all others should proceed to the full stage (F).

Statistical normalisation may be applied to minimise the effect of scoring variation between committees. Statistical normalisation calculates the z-score of a number using the mean and standard deviation of a distribution (AC total scores) corrected for the mean and standard deviation of the larger distribution (all AC total scores). The HRC, after consideration of the results from all AC meetings, will complete the process to prepare the final lists of full applications for General, Rangahau Hauora Māori (RHM), and Pacific Projects.

2.5 EOI review feedback

Applications that are discussed by an AC will receive brief qualitative feedback in the review summary (Appendix 4: EOI outcome and feedback).

Outcomes will be published on HRC Gateway after the announcement of EOI results.

3. Assessment of full applications

3.1 Assessing committee membership

The AC membership required to assess full applications may differ from the EOI AC. Full applications will be assessed by a committee that may have extended expertise, members from the EOI AC, and experts matched to the applications. AC members will be provided with documents relating to the work of each committee. The number and membership of AC depends on the scope of the applications, taking into account conflicts of interest, in consultation with the chairs.

To minimise potential conflicts of interest, the following specific HRC guidance for AC membership has been developed:

> an AC member should not sit on a committee if they are a first named investigator or a named investigator on an application under consideration by that committee.

This means that anyone who is a **first named investigator** or a **named investigator** on an application under consideration in that round should not sit on the committee that is reviewing their application; however, they may sit on or chair a different committee.

3.2 Before full application assessing committee meeting

3.2.1 Reviewers

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

- Rationale for 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

Reviewer reports, available for applicants' responses, are submitted on the HRC Gateway. Reviewer reports and applicant responses are sent to the AC prior to the meeting. The HRC aims to obtain 3-4 reviewer reports for each proposal. If this number is exceeded, additional reports will be cancelled on the following basis: where it is clear that a major conflict of interest (COI) exists, the report is of exceptionally poor quality or the report was the last received by the HRC. There may be scope for including a fifth reviewer report for an application, if that 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 role of the HRC to coordinate and oversee all communications with the reviewers. Committee members and applicants should **not** contact reviewers.

Note that the applicant response (see Appendix 5) is an opportunity for the applicants to respond to the comments or questions raised by the external reviewers. The applicants are advised to address the main issues raised by the reviewers, remain objective in addressing reviewers and avoid emotional responses. The applicant response, together with the reviewer reports will be made available for the AC at their meetings.

External reviewer reports are anonymised for applicant response or response, but not for the assessing committee.

3.3 Assessing committee meeting procedure

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

Applications to be discussed by the committee will be in random order.

The discussion time allocated to each proposal is 25-30 minutes, e.g.:

- declaration of conflicts of interest - 2 minutes,
- CR1/CR2 comments - 5 minutes,
- general discussion of the proposal - 15 minutes,
- scoring - 2 minutes,
- notes for review summary - 2 minute.

The meeting scores are submitted via HRC Gateway and collated confidentially by the HRC staff.

3.4 Assessing committee meeting scoring criteria: Pacific category

In the AC meeting, applications in the General category are scored from 1 to 7 against the same criteria used for EOI (Appendix 3: Scoring criteria and anchor point descriptors). These are listed below; refer to Appendix 3 for a full description.

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

The 7-point word ladder assists AC scoring according to the descriptors rather than other considerations such as success rates of applications. Reviewers may only allocate whole scores.

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

The criteria are scored using a 7-point scale of equal weighting, as listed in the table, and that the total maximum score is 28

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 Committee also takes into consideration 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 research investment manager will provide the committee with information on the budget with regard to HRC policy. However, it is the responsibility of the committee to determine whether the budget is appropriate for the proposal.

3.5 Scoring procedure

The scores are submitted via HRC Gateway and collated confidentially by the HRC staff.

3.6 Re-ranking procedure

After all applications have been scored, the ranked applications are considered by the AC for possible re-ranking of applications on a case-by-case basis to remedy significant perceived inconsistencies with a material effect on the outcome. Applications cannot have points added to the score for the purpose of strengthening the score without re-ranking the application. This procedure will allow any application in the ranked table to move up or down by one position at a time. The re-ranking procedure is managed carefully by the committee chair(s) and the HRC research investment manager to avoid re-litigation of any applications and to mitigate against any bias affecting the process.

Any AC member may bring forward an application for re-ranking.

Conflicts of interest are notified and managed in the appropriate manner.

The application under consideration would have its scores modified, after appropriate discussion and agreement, by adding up to 0.5 points to one or two of the scoring criteria of choice to move the application up one place under consideration.

The new ranking and new adjusted total scores would then be put forward for consideration at the next stage.

Re-ranking of other applications can be done using an iterative process until a final ranked list is reached.

Any changes are recorded in the meeting scoresheet and notes.

Fundable and not fundable line

After scoring and re-ranking discussion, the applications are ranked according to total score.

The committee, noting conflicts of interest, then:

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

The fundable/not fundable line refers to the position in the ranked list of applications below which all applications are of insufficient quality that, irrespective of available budget, they should not be funded.

Note: Once the proposals have been scored following discussion by the committee, no scores are permitted to be further reviewed or adjusted at or after the conclusion of each proposal discussion. Any concerns about the process are identified by the committee and are taken by the AC chair(s) to the chair of the relevant research committee.

3.7 Score normalisation

If there are two or more AC appointed to assess applications within a category, statistical normalisation will be applied to minimise the effect of scoring variation between committees. Statistical normalisation calculates the z-score of a number using the mean and standard deviation of a distribution (AC total scores) corrected for the mean and standard deviation of the larger distribution (all AC total scores). Projects and Programmes are included in the normalisation process. The normalised score will be used for consideration by the GAC and Council alongside other factors as described in the GAC terms of reference.

4. Review summary and feedback for applicants

4.1 EOI application

All applicants will receive feedback based on AC outcome (Appendix 4: EOI outcome and feedback). For the applications that are discussed at the meeting, applicants will also receive qualitative feedback in the form of a review summary (see Appendix 4: EOI outcome and feedback). Review summaries for EOI will be brief and may identify several strengths and areas for improvement.

4.2 Full application

At the conclusion of the funding round, applicants receive an AC review summary and can access their application outcome via the HRC Gateway. The CR1 writes a brief review summary of the AC discussion for each of their assigned proposals (see Appendix 6: Assessing Committee review summary). The intent of the review summary is to provide the applicant with a brief, balanced, objective statement of the committee's response to the research proposal.

Review summaries should be constructive and may 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 include reference to scores or the identity of reviewers or committee members.

The AC chair(s) is/are responsible for approving the content of all review summaries. The HRC is responsible for ensuring they are forwarded to research offices/the host institution.

Outcomes will be published on the HRC Gateway after the funding round.

5. Additional eligibility requirements

5.1 Eligibility restrictions on publicly funded research

As part of the New Zealand Government's broader response to Russia's continued assault on 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 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 application for funding that will provide benefit to a state institution or other organisation identified for exclusion by the New Zealand Government.

Appendix 3: Scoring criteria and anchor point descriptors

Criteria for assessing and scoring Pacific Project applications by assessing committee

The same 7-point word ladder containing criteria descriptors is considered against each of the following assessment outlines below (listed A-E).

Note:

- The "Adequate" anchor point is 3 points.
- Applicants do not necessarily have to address all the points in the outlines below; they are included to help guide assessment under each of the scoring categories.

Score	Criteria descriptor
7	Exceptional
6	Excellent
5	Very 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

A. Rationale for research

The research is important, worthwhile, and justifiable to New Zealand, with consideration to the international context, because it addresses some or all of the following:

- it addresses a significant health issue that is important for health/society
- the aims, research questions and hypotheses build on existing knowledge and address a knowledge gap
- the research findings should be original and innovative.

B. Design and methods

The study has been well designed to answer the research questions, because it demonstrates some or all the following:

- comprehensive and feasible study design that is achievable within the timeframe
- 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
- culturally appropriate methodology
- sound data management and data monitoring arrangements
- patient safety issues well managed.

C. Research impact

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

- Applicants have described a credible pathway for how their research will:
- result in benefits or opportunities for future research in NZ, or
- influence policy, practice, or health services or technologies in NZ, leading to improved

health or other social/economic impacts for Pacific communities.

- The research team are undertaking steps to maximise the likelihood of impact by: contributing to the creation of Pacific health knowledge; contributing to the translation of findings into Pacific health gains; incorporating Pacific health research processes; incorporating Pacific ethics processes; contributing to building a highly skilled Pacific health research workforce; and responding to the needs of, and working in partnership with, Pacific stakeholders and communities.

D. Expertise and track record of the research team

The team, relative to opportunity, have the ability to 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 4: EOI outcome and feedback

The number of applications and the relatively short time available makes extensive feedback to applicants difficult. The review summary will be written to briefly reflect the assessing committee discussion and focus on key strengths and potential areas for improvement, which may aid completing the full application.

Project EOI review summary

HRC reference #		**Applicant surname**	
Title of research			
Host			

Applicants who have been invited to submit a full application must note that responding to or addressing the points noted in this review summary does not mean that the full application will be funded.

Note to committee reviewers (CR): Please give careful consideration to the information and wording provided below as it will be useful for both applicants progressing to the full application stage (in helping to shape their research) and for unsuccessful applicants (in preparing future research applications). Comments should be clearly worded, reflect the panel's discussion, and ideally be no more than one-page or 5-6 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 proposals:

1. The assessing committee noted the following key strengths of the application (brief bullet points)

2. The assessing committee noted the following aspects that could be improved and/or considered further (brief bullet points)

3. Other Comments/suggestions (brief bullet points)

Appendix 5: Applicant response

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

Instructions (delete after reading): Programme applications have a 3-page limit. All other applications have a 2-page limit. The page limit 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. Ensure to address all the issues raised by the reviewers andremain objective in your response.

Appendix 6: Assessing Committee review summary: Full Project application

HRC reference #		**Applicant surname**	
Title of research			
Host			

Note to committee reviewers (CR): Please 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 proposals:

1. The assessing committee noted the following key strengths of the application (brief bullet points)

2. The assessing committee noted the following aspects that could be improved and/or considered further (brief bullet points)

3. Other Comments/suggestions (brief bullet points)

Appendix 7: Assessing Committee chair's report

Committee name	
Chair(s)	
Date(s)	
Research investment manager	
BM/Clin/PH/MH/PacH	

Please provide brief comments or bullet points in the following sections, which represent the consensus views from the committee. This confidential information will be forwarded to the HRC statutory committees and used for the continuous improvement of HRC processes.

1. Administration and communications

2. Committee membership, expertise and working relationship

3. Integrity of the process

- Management of COIs
- Maintaining confidentiality
- Mitigating against bias

4. Assessment of applications

- Virtual meeting environment
- Key recommendations

5. Comments about HRC Gateway

6. Other comments