Health Research Council of New Zealand
Te Kaunihera Rangahau Hauora o Aotearoa

October 2020

2021 PROJECT FULL APPLICATION GUIDELINES

To use with forms:

2021 Project Full Application Form

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Part A: What is a Project?

1. Project introduction

HRC Projects should address well-defined research questions with the aim of making significant improvements in, or developing knowledge contributing to, 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.

Applicants who submit randomised controlled trial project applications are able to request an increase in budget cap to a maximum of no more than 20% ($1,440,000), if required. At the Expression of Interest (EOI) stage applicants are advised to include a comment in their application that they anticipate seeking an increase in budget cap (should the EOI be successful) but no specific budget details are required at this stage. At the full application stage, applicants must provide full budget details and justification for an increase in budget cap in their application. Final approved budgets will be subjected to full assessment processes.

The HRC reserves the right to allocate funds from the contestable funding pool to Programmes and Projects in an appropriate strategic mix.

2. Research investment streams

The HRC has established four Research Investment Streams (RIS) for the annual funding round:

- Health and Wellbeing in New Zealand: Keeping populations healthy and independent throughout life
- Improving Outcomes for Acute and Chronic Conditions in New Zealand: Improving outcomes for people with illness or injury
- Rangahau Hauora Māori: Supporting Māori health research that upholds rangatiratanga and utilises and advances Māori knowledge, resources, and people.
- New Zealand Health Delivery: Improving health and disability service delivery outcomes over the short-to-medium term

Note: For the 2021 annual funding round, the New Zealand Health Delivery investment stream will be run separately and out of cycle to the other investment streams.

For Project applications, the RIS cannot be changed between the EOI and Full stages.

3. Previous funding round success rate

Success rates for the 2020 funding round in each RIS are presented below:

RIS	EOI	Full	Funded
Health and Wellbeing in NZ	108	30	14
Improving Outcomes for Acute and Chronic Conditions in NZ	231	72	37
Rangahau Hauora Māori	14	7	4
Total	353	109	55

4. Rules regarding named investigators on Programme contracts

A ‘named investigator’ (NI) may lead only one HRC research programme at a time but may collaborate and be funded as a NI on other HRC research contracts.

5. Rules regarding named investigators on Project contracts

There is a limit of **three** project applications for any one first named investigator.

6. Important note – use of forms

Use these guidelines and the 2021 Project Full Application Form when submitting a Project full application for the Health and Wellbeing (HW) and Improving Outcomes for Acute and Chronic Conditions (IOACC) RIS.

Use the separate guidelines and form (2021 RHM Project Full Application Form) when submitting a Project full application for the Rangahau Hauora Māori RIS.

Use the separate guidelines and form (2021 Pacific Project Full Application Form) when submitting a Project full application for a Pacific Project.

For the New Zealand Health Delivery (NZHD) RIS, use the separate guidelines and forms (document titles not known at time of publication) when submitting a NZHD application.

7. Project assessment process

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

- An assessing committee meeting to assess EOI applications and select applications to invite for full applications.
- Review of the full applications by external reviewers.
- An assessing committee meeting to assess full applications.
- Grant Approval Committee (GAC) meeting to make the final recommendation for Council approval.
- Funding decisions by HRC Council.

For more details please refer to the HRC Peer Review Manual which can be found on HRC Gateway.

8. Project timetable

Event	Description	Date
EOI opens	EOI round opens in Gateway	Opens 10 June 2020
Registration closes	Registration deadline in Gateway	Closes 10 July 2020
EOI closes	Complete online sections & upload 2021 Project EOI Form	Closes 17 July 2020
EOI assessment	Review by HRC Assessing Committee	During September 2020
EOI results	EOI results	6 October 2020
Full Stage Opens	Invitation to submit	6 October 2020
Full Stage Closes	Complete online sections & upload 2021 Project Full Application Form	Closes 23 November 2020
Assessment	Peer review	Dec 2020 to Feb 2021
	Rebuttal / Response	Early March 2021
	Review by HRC Assessing Committee	During April 2021
	Council approval	Late May 2021
Results	Outcome	8 June 2021

Part B: General rules for submitting a Project full application

1. Use of 2021 Project Full Application Form

1.1 When to use the 2021 Project Full Application Form

The 2021 Project Full Application Form must be used when submitting a full project application for the Health and Wellbeing and Improving Outcomes for Acute and Chronic Conditions investment streams. Use the 2021 RHM Project Full Application Form for applications to the Rangahau Hauora Māori Research Investment Stream. Use the 2021 Pacific Project Full Application Form for Pacific Health Project applications.

1.2 Prior to submission

The HRC only accepts applications on HRC Gateway. Prior to any submission, named investigators must have a current Gateway account, that must be updated annually. Key opening and due dates are in Section 4 below.

Before submitting this application form, applicants should read:

- This document for eligibility and specific instructions
- Research Investment Stream details
- The appropriate Peer Review Manual to understand application assessment
- Guidelines on Ethics in Health Research
- Guidelines for Researchers on Health Research Involving Māori
- Guidelines for Pacific Health Research
- HRC Research Impact Slideshow
- The Māori Health Advancement Guidelines.

The regularly updated reference documents and forms are on HRC Gateway.

2. Format

2.1 General formatting

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.

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).

Use the correct HRC form as it contains special features.

Applicants must:

- Use Arial 10-point type font or larger
- Use default margins
- Use single line spacing
- Not exceed any page limits.

2.2 Compliance

The HRC **will not process** any application that does not comply with stated page limits and font sizes/styles.

2.3 Additional documents

No other documents are to be included.

3. Copies of Project full applications required

3.1 Electronic copy

Submit the form as a PDF file. Ensure that the PDF version meets page limits and that graphics and tables are converted correctly from the Word version.

Submit the budget information file in both xlsx and PDF formats. Use the HRC file as it contains special features used for HRC processes.

HRC Gateway will allocate file names.

Important

The application is submitted to the host Research Office when the applicant uploads the files through HRC Gateway. The application will be forwarded to the HRC after host Research Office approval. Always allow sufficient time before the HRC closing date for this approval step.

3.2 Do not send files

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.

4. Closing dates for full application

4.1 Submission of full application online

Upload the 2021 Project Full Application Form using HRC Gateway.

Submit the form as a PDF file created by using the PDF function in MSWord or another PDF generator. Ensure that the PDF version meets page limits and that graphics and tables are satisfactorily presented. HRC Gateway will allocate file names.

The closing date for invited full applications to be submitted online to the HRC is **1pm, 23 November 2020**. Full applications are released to the HRC only after approval by the applicant host Research Office or equivalent, which will require access to the full application several days before the HRC closing date. Paper copies of applications are NOT required.

4.2 Incomplete applications

Incomplete applications will be regarded as withdrawn.

4.3 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 NIs 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 RHM RIS or Pacific project round
- if specifically in response to feedback from an EOI assessing committee, or
- to replace an existing member due to unforeseen circumstances.

In the full application, if the replacement of a named investigator, or an addition of a named investigator is required, please notify the HRC **before 11 November 2020** to justify the change. 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.

4.4 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 in order to make the changes in our system. Please notify the HRC **before 11 November 2020** to justify the change. The form, to request a change of FTE, is available from your research office.

5. Privacy Provisions

5.1 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 National Research Information System (NRIS) curated by MBIE with details provided by funders of the science sector.

5.2 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.

5.3 Media release

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

5.4 Official Information Act

Official Information Act requests for information about an application or research contract will be discussed with the host institution and investigator before responding to the request. Where appropriate, the request may be transferred to the host institution.

6. Enquiries

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

Where the Research Office cannot assist, or for technical enquiries relating to applications, contact the HRC's staff:

https://www.hrc.govt.nz/contact-us

Email addresses are "firstnameinitial+surname@hrc.govt.nz", eg. Jane Smith, jsmith@hrc.govt.nz.

Part C: Submitting a full application – Completion of the 2021 Project Full Application Form

Applicants should confirm that they have been invited to submit a Project full application.

Module 1 of the application was completed on HRC Gateway at the EOI Stage. This form contains a Coversheet, Module 2, Module 3, Sections 4A-4D of Module 4 and Section 6D of Module 6. Supporting documents (as listed in Section 4D) are now required to be uploaded separately in HRC Gateway. The contract information and/or budget Excel file for Module 4 must be uploaded separately. Module 5 contains NI CVs that are uploaded separately. Module 6 is the research classification of the research that must be completed online (with the exception of Section 6D).

This form must be downloaded and completed by applicants before being uploaded to HRC Gateway as a pdf file. The complete application with all Modules will be generated by HRC Gateway for downloading and printing.

Note: By submitting an application to the HRC on Gateway the applicant is confirming that the submitted application complies with all requirements including formatting and page limits. The HRC will not accept changes after the closing date.

1. Use of the 2021 Project Full Application Form

Use the original form and contract information file as these contain special features.

The form is compatible with 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.

Remember:

- Enter information only at the indicated form fields.
- Do not reformat Module and Section headings.
- Do not delete spreadsheet columns/shaded rows, but you may insert more unshaded rows.
- Use the original HRC document templates. Do not copy and paste into a new document as this can drastically change fonts and remove other features required for HRC processes.
- Input HRC Ref ID# and NI surname on the coversheet.
- HRC Gateway will remove the coversheet from the final system-generated PDF.

2. Module 1: General information

Module 1 is completed entirely online and is not part of the uploaded form. 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 (NIs)

All NIs 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).

Please note that the HRC allows some changes and/or additions of named investigators between EOI and full application; however, these must be as per the requirements described in Part B, section 4.3 (and outlined below).

As a general rule, no additional NIs can be added to the team, with the following exceptions:

- for statistical expertise in clinical trials

- for applications submitted to the RHM RIS or Pacific Health Project round
- if specifically in response to feedback from an EOI assessing committee, or
- to replace an existing member due to unforeseen circumstances.

FTE for named investigators (NIs)

A defined FTE value will need to be entered for each named investigator (and for the first named investigator) and this value should fall within the FTE band that was selected for each investigator in the EOI application. **The FTE value should be the value for the first year of that investigator's involvement (from the budget spreadsheet)**.

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 in order to make the changes in our system. Please notify the HRC **before 11 November 2020** to justify the change. The form, to request a change of FTE as stated above, is available from your research office.

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 EOI applications are submitted.

You may wish to designate a hapū, iwi or Māori 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 NIs.

Research costs

Enter in the relevant totals for staff costs, overheads, working expenses, and total cost of research (from the Excel budget spreadsheet).

Note that this field is not required to be completed at the EOI stage (only required at the full application stage).

Milestones and objectives

Milestones and objectives are **assessed** along with budget requests, included in an awarded research contract and used for contract reporting templates. This section is now inserted immediately after the list of named investigators in the final system-generated PDF.

Poorly described objectives and milestones can affect application scoring, delay or rejection of the application from processing and/or requests for further details at contracting stage.

Objectives

Briefly describe the intended deliverables of this research application. Objectives should be **clear** and **measurable** to allow evaluation of research performance of an awarded contract.

Note that the HRC suggests a minimum of three 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. Each milestone must relate to one or more of the objectives, e.g.:

Year	Milestone	Objective(s)
1	Recruit 200 patients for study	Objective 2
1	Complete data entry and analysis (lab study)	Objective 1
2	Complete statistical analysis (clinical study)	Objective 2
3	Submission of manuscript to NZMJ	All Objectives

Remember that any contract will be monitored, and progress measured against the milestones and objectives provided in this proposal.

For contract monitoring, and HRC accountability reporting, if the research requires **ethical consent**, this should be identified as a milestone.

3. Module 2: Proposal

3.1 Section 2A Summary of 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 Science Assessing Committee members. Use the suggested headings and add subheadings if required.

3.2 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, so not all members will have working knowledge of every research topic. Write the proposal for scientists 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.

Rationale for research

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

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 sample 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 Science 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. Science Assessing Committees are also reassured when methodologies have been used/trialled before.

Research impact

*Note: applicants for all investment streams are no longer required to link their impact section to the Goals of the relevant investment signal. This is to encourage applicants to consider all potential ways in which their proposal can add value for NZ, and what actions within their influence can help achieve this potential. Assessment of Impact for these streams has been restructured to include two components: 1) a **description** of how your research might be used and the anticipated benefits for NZ, 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 (below). 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 distribution of benefits** (such as how contribution to international research effort will benefit NZ). Research-related benefits, such as capacity and capability gains for NZ, 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?

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. 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

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[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.*

[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.*

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.

Māori Health Advancement

For the 2021 funding round, an additional scoring criterion has been added for Project assessment: Māori Health Advancement.

The HRC expects applicants for HRC research funding to consider all potential ways in which their proposal will advance Māori health, and to outline what actions they will undertake to help achieve this potential. Assessment of Māori health advancement will explicitly consider two components:

- An outline of contributions the research may make to advancing Māori health.
- Specific actions that have been, and will be, undertaken to realise the contribution to advancing Māori health through the life of the project and also beyond it.

All applicants for HRC funding will be required to address these two questions in their proposals. In responding to these questions, applicants should consider how their research is informed by the four domains of Māori health advancement (see the Māori Health Advancement Guidelines for more details). Researchers are encouraged to consider the domains during development of their research, as this may identify aspects of the research not previously considered. It is not a requirement that all four domains are specifically addressed in the proposal, but researchers are advised to consider each in formulating the strongest rationale for the application. Consideration of Māori health advancement is context-specific, as determined by the nature and scope of the research.

Alignment of the response to the 'Māori health advancement' criterion and other assessment criteria will strengthen an application.

1. **How will the outcomes of your research contribute to Māori health advancement?**

Provide a realistic description of how this research could contribute to improved Māori health outcomes or reductions in inequity over time. Consideration should be given to potential short-term and/or longer-term Māori health gains, within the specific context of the research and where it is positioned along the research pathway (cf. potential 'line of sight' or 'pathway' to impact). In addition, more immediate users and beneficiaries of the research who can utilise the research findings for Māori health gain should be identified.

2. **What activities have you already undertaken (that are relevant to this project), and what will you undertake during this project, that will realise your research contribution to Māori health advancement?**

Describe specific actions that have been, and will be, undertaken (from the development of the research idea through to the completion of the project) to maximise the likelihood that this research will contribute to Māori health advancement. Outline actions taken to ensure that the next users or beneficiaries of the research can utilise the findings for Māori health gain.

If the research is not expected to make direct contributions to Māori health, identify actions that will be undertaken throughout the life of the project to contribute to other facets of Māori health advancement. Identify barriers to actioning your aspirations for advancing Māori health, and your mitigation strategies (where relevant). Identify elements of the team's track record that provide confidence that this research will optimally contribute to Māori health advancement. For example: existing links, relationships, or networks with relevant Māori communities and next-users or end-users of research; demonstrable examples of knowledge translation and uptake; or changes to practice or policy that have enhanced equity and advanced Māori health. This component is considered relative to opportunity (i.e. stage of career progression, nature of research, and institutional capacity and capability).

Expertise and track record of the research team

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., NIs), 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 NI 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.

4. Module 3: 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 lists generated by bibliographic software may need to be first copied into a blank Word document, and then copied into the form.

5. Module 4: Contract information and budget

Sections 4A – 4D are parts of the form.

Sections 4E – 4H are to be completed on the separate Excel file (2021 Project Budget.xlsx).

5.1 Section 4A: Justification of expenses

Justification of research staff

Use this section to justify the role and FTE of the NIs and any other research staff listed in section 4E. Also explain the role of all other personnel (named or un-named, funded or not funded by the proposal), who will actively contribute to this 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. Un-named postdoctoral fellows should be justified but it is recommended that named postdoctoral fellows should be included as NIs and should provide a CV. Science 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 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 under 'Research Working Expenses'. Any promotion of staff or increase in salaries over the term of the contract (beyond 3% annually) **must be clearly justified** in Section 4A. Note: the HRC does not consider annual scale increments or across-the-board wage increases as promotions.

Justification of working expenses and casual staff

All items listed under ‘Materials and Research Expenses’ in the budget should be justified, with costs broken down per item, and full costs 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 Science Assessing Committee will clearly understand why the requested materials, travel, research tools and significant one-line items are necessary for the successful completion of the research. Clearly justify the role of students (must be named) and casual staff so that the Science Assessing Committee can appreciate how these persons are necessary for the proposed research. It is the responsibility of the applicants to ensure that no students in this section will exceed 100% FTE on their combined commitments with the host institution 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 Index) and upload separately via HRC Gateway.

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 support from any agency that has been received by **the first named investigator 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’ reports

End of Contract or Final reports for recently completed HRC contracts are part of this application.

- Ensure that reports are for the first named investigator of this application, when they were also the principal pnvestigator for a previously funded contract, awarded in the last 5 years.
- Programme contract reports for the senior named investigators who were the principal investigator can also be included, for contracts awarded in the last 6 years.
- Do not upload full deliverable reports from HRC Research Partnerships contracts; only upload the executive summary of deliverable reports.

Note. Submission of annual reports are an HRC contract requirement. Delayed submission without justification will result not only in contract suspension but also will prohibit the submission of new research applications.

5.3 Section 4C: Other support

Other research applications awaiting decision and co-funding

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**.

Co-funding

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

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.

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**.

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

List any subcontracts/MOU, letters of collaboration, appendices and any other supporting documents. Please see the sub section 'Subcontracts/Memorandum of Understanding (MOU)' in Section 4E below for further details.

The documents themselves must be uploaded separately into Gateway as PDF files.

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.

5.5 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.

For more information refer to the *HRC Rules* which are available on the HRC website.

Budget calculations and spreadsheet

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

The 'Salaries', 'Research Working Expenses' and 'Total Cost of 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 of the figures in this box.

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

Salary

Only enter c**ontract research staff** employed or to be employed by the host institution (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 the research proposed. **Salaries for year 2 and year 3 may be increased by a maximum of 3% per annum each year**, or by more if specific details of expected promotion are provided and **fully justified** in Section 4A. Note: the HRC does not consider annual scale increments or across-the-board wage increases as promotions.

The budget form does not accept FTE less than 3%. The HRC and Science Assessing Committees do not favour applications listing numerous investigators with a very low FTE. 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 'Research Working Expenses' section.

Staff that must **NOT** be entered into the Salary section of the budget are subcontracted staff, named Masters and PhD Students on stipends and casual staff.

a) Subcontracted staff are those who are NOT employees of the host institution. The salary and all other expenses for these staff should be broken down into appropriate categories on a detailed subcontract/MOU between the host institution and non-host institution 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 'Research Working Expenses - Subcontracts' for each year.

b) If funding to provide a stipend for a PhD ($30,000 per year) or Masters Student ($20,000 per year) is requested, the student must be named. Enter Masters and PhD stipends (for named students only) into 'Research Working Expenses – Materials and Research Expenses'.

c) Casual staff (those persons without an on-going 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 'Research Working Expenses - Materials and Research Expenses'.

Note: The proportion of contract budget allocated to overseas Investigators must not exceed 20% for Projects.

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 **fully** justified on research applications (upload budgetary supportive documents separately via HRC Gateway and list in Section 4D).
- 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 institution of its obligation to assist with the costs of overseas travel by its employees.
- Costs for Masters ($20,000 pa) or PhD ($30,000 pa) named students only can be claimed if a description of the student's research project is provided in Section 4A. Funds will be conditional upon the institution arranging a tax-free stipend that satisfies the Inland Revenue and host institution's rules. Ensure that PhD students requested are supported for three years of PhD study, either entirely or partly through this project. **Note: students' fees and thesis costs cannot be claimed**.
- 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 institution.
- Note: If you are intending to ask the HRC's Data Monitoring Core Committee (DMCC) to monitor this study, there is no cost involved in using the HRC's DMCC. However, if the DMCC agrees to monitor the trial, costs for members of the study team (including the study statistician) to attend the meetings (and preparation of biannual statistical reports) will need to be included in the budget for the application. If you have any questions please contact the Secretary to the DMCC, info@hrc.govt.nz.

Subcontracts/Memorandum of Understanding (MOU)

Subcontract staff are not employees of the host institution. The salaries for these staff and all other expenses (e.g. working expenses) requested for the subcontract must appear in a detailed subcontract/MOU between the host institution and non-host institution. 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 MOUs separately via HRC Gateway (see Section 4D above).

MOUs must also be provided for 'time only' subcontracted staff. In the event that MOUs are unable to be provided for 'time only' subcontracted staff, it is acceptable to include a support letter with 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 'Research 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 online section of the research application.

5.6 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 'Research 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 NIs on MOUs to enable the Science Assessing Committees to determine whether the investigator's expertise is appropriate and/or necessary. Without this information the Science 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 index). If there are no subcontracts/MOUs for this application, or none requesting more than $50,000, you may delete or ignore Section 4F.

5.7 Section 4G: FTE summary

List the time involvement of ALL personnel (including those on a subcontract/MOUs) 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 NIs are 'time only' (i.e. **not** receiving salary for their involvement in the project). Identify all Postgraduate students by 'Masters' or 'PhD' as well as by their names. Ensure the FTE figures are the same as those in the budget and MOU budget sections (Sections 4E and 4F), as well as in 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).

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

Please complete the Collaborators section (not named investigators) 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.

6. Module 5: NZ standard CV template

Upload a CV for all named investigators (include those on MOU).

Use the NZ Standard CV template with default font from the HRC website. 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 Gateway profile.

CV may indicate when career breaks have taken place as track record will be assessed relative to opportunity.

7. Module 6: Research classification

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.

7.1 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.

7.2 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.

7.3 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.
Community services	Research around community-run services and community groups, e.g. Marae-based healthcare services.

7.4 Section 6D: Research methodology categorisation

This information will be used to inform HRC assessment process and policy analyses. We are trialling this as part of the 2021 annual funding round project full stage and the information we receive this year will assist in developing our approach to capturing this information 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 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; kaupapa Māori methods; systematic review; meta-analysis; implementation science; animal model studies; epigenetics; etc.

Appendix 1: Improving the rigour and completeness of clinical trial proposals

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. In order to improve the rigour and completeness of clinical trial proposals, applicants are encouraged to refer to SPIRIT 2013 Statement (Standard Protocol Items: Recommendations for Interventional Trials)* 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, a research question of particular 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 4G/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 NZ investigator (e.g. as distinct from the site co-ordinator role) and any NZ-led trial components. Additionally, it is expected that applicants will address NZ-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.

*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.