

# Guidelines



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

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## Programme Application Guidelines (PA218)

## Table of Contents

<b>Part A: What is an HRC Research Programme? .....</b>	<b>3</b>
1. Introduction.....	3
2. Research Investment Streams .....	3
3. Programme Director Requirements .....	3
4. Research Programme Qualifying Parameters .....	4
5. Negotiation of Contract Details .....	5
6. Overview of Assessment Process for HRC Research Programmes .....	5
7. HRC Research Programme Funding.....	5
<b>Part B: Rules for Submitting the PA218 Application Form.....</b>	<b>6</b>
1. Use of PA218 Form.....	6
2. Format.....	6
3. Copies of Applications Required.....	7
4. Closing Dates .....	7
5. Privacy Provisions .....	7
6. Mailing Address .....	8
7. Enquiries .....	8
<b>Part C: Guidelines for Completion of the PA218 Application Form.....</b>	<b>9</b>
1. Use of PA218 Form.....	9
2. Module 1: General Information .....	9
3. Module 2: Research .....	10
4. Module 3: References.....	11
5. Module 4: Contract Information and Budget.....	12
6. Module 5: NZ Standard CV.....	17
7. Module 6: Research Classification .....	17
Appendix 1: Improving the Rigour and Completeness of Clinical Trial Proposals. ....	19
Appendix 2: Presentation and Interview of Shortlisted Applicants at PAC.....	20

## Part A: What is an HRC Research Programme?

### 1 Introduction

HRC research Programmes, with a 5-year term and a budget up to \$5M, are intended to provide support for the long-term development of a research field by a group of established investigators, with an outstanding track record of achievement. Collaboration between research groups and institutions is encouraged. Programmes will focus on specific research objectives that deliver outputs and outcomes rather than inputs. The HRC supports research Programmes with strategic, long-term visions that promote development of knowledge relevant to the health needs of New Zealand.

Programmes require three or more established researchers who are responsible for the scientific direction and quality of the research. A successful funding history of peer reviewed contracts by the proposed Named Investigators is required. Named Investigators will also be expected to have had an outstanding track record of achievement in health research and to provide support for those seeking training in health research. Salaries of investigators within a research Programme need not be funded by the Council, but each Named Investigator is expected to devote a substantial and specified portion of time to the research Programme.

A Programme application not meeting the criteria will sometimes be accepted on the basis of the nature of the proposed research, e.g., when the budget for a clinical trial exceeds the Project budget maximum. Written approval for this exception must be obtained from the HRC prior to submission of the application.

If the HRC already has a significant investment in a research area, particularly if it already has a Programme in the area, consideration will be given to whether increased capacity and additional long-term commitment of funds to this research area is warranted. The appropriateness of Programme investment in any research area shall be assessed on a case-by-case basis.

The New Zealand Health Delivery Research Investment Stream will **not** support Programmes because the medium-term or 5-year requirement in the stream is not compatible with the term of a Programme.

### 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
- New Zealand Health Delivery: Improving health and disability service delivery outcomes over the short-to-medium term
- Rangahau Hauora Māori: Supporting Māori health research that upholds rangatiratanga and utilises and advances Māori knowledge, resources, and people.

Applicants **must** select one of the HRC RIS. Assessing committees may score out of scope applications at the bottom of the scale for Research Impact (*HRC Peer Review Manual*) because those applications will not advance the goals or priorities of the RIS. This applies to applications that are **clearly** out of scope, not those that could be considered to fall within a 'grey' area (are relevant to more than one investment stream).

The HRC will not provide advice on choice of RIS, as the final decision is that of the investigator. Applicants may change their choice of RIS by creating a new application for the appropriate RIS in the HRC Gateway provided that the registration or submission dates have not passed.

### 3. Programme Director Requirements

Resourcing a team with \$5 million of tax payers' investment requires a significant degree of accountability to be demonstrated with regard to managing the size and complexity of an HRC Programme. A proven

record of managing projects of a sizeable nature is therefore required. We will revise these criteria from time to time. Specified dates are to allow clarity in decisions on what funding meets the requirements.

A proposed Programme Director must meet one of the following requirements **at the due date of application (11 October 2017)**:

- 1) Director on an HRC Programme with no more than one year to run, i.e., Director of a Programme contract that will expire before 11 October 2018;
- 2) Director of an HRC Programme in the last five years, i.e., Director of a Programme contract that expired after 11 October 2012;
- 3) First Named Investigator on at least two HRC, or comparable national or international agency. Project contracts that are current or have expired in the last 24 months since 11 October 2015; i.e., a track record of current or recent research funding and experience in managing several research activities with other researchers;
- 4) First Named Investigator on one HRC, or comparable national or international agency, Project contract, that is current or completed in the last 12 months before 11 October 2017, and proposing to lead a Programme team of at least two other First Named Investigators on Project contracts from the HRC, or comparable national or international agency, that are current or completed in the last 24 month since 11 October 2015; i.e., has recent or current research funding, teamed with at least two other researchers with recent or current funding and collectively managing several projects with related themes.

In this context, any health research Project of similar value and term to an HRC Project, typically \$1.2 million for 3 years, from an agency that allocates funds using internationally accepted contestable processes and peer review, e.g., Marsden fund, MBIE Endeavour fund, NHMRC, NIH and MRC. Only HRC Projects awarded in the annual contestable round, similar value HRC Partnership projects, but **not** Feasibility Study Grants, Emerging Researcher First Grants, HRC Fellowships and awards less than \$500,000, qualify for inclusion in these requirements. Grants valued at around \$800,000 due a lower overhead could also be considered for inclusion.

The Programme funding round is competitive with a complex application and assessment process. The requirements are to give guidance with respect to the calibre of research teams most likely to succeed. These requirements are not applicable for a proposed Director resubmitting an application that was shortlisted and assessed fully by the Programme Assessing Committee in the previous round.

An HRC Programme Director must assign at least 20% FTE to the Programme, must be employed by a New Zealand host institution and have citizenship or permanent residency status in New Zealand.

#### **4. Research Programme Qualifying Parameters**

It is recognised that awarding of Programme status in any funding round may be restricted on the basis of available funds. As such, the funding of a Programme will be based on its ability to deliver quality research outcomes. Applicants should therefore ensure that their proposal demonstrates that their research Programme has the ability to meet the following parameters:

- **Host Institution:** The group of researchers applying for a Programme should have strong support from their respective host institution(s).
- **Research Team:** It is the intent of the HRC to foster collaborative research efforts of multiple investigators. Evaluation of any Programme will consider the strength of each member of its team of researchers. Named Investigators should have an extensive track-record of achievement (including peer-reviewed research contracts and publications). The Programme Director must be resident in New Zealand at the time of application.
- **Qualifying Research:** Programmes should represent a substantive body of ongoing research, i.e., encompassed in a **minimum of three distinct objectives** addressing a common theme.
- **Strategic Nature** of the Proposed Research Programme: Priority will be given to the establishment of strategic research Programmes that demonstrate a collaborative approach to improvements in

health. Priority will also be given to Programmes which demonstrate well-developed links from basic/fundamental to applied health research, and which are likely to impact on the health of New Zealanders.

- **International Competitiveness** of the Research: Preference will be given to research which is at the forefront of international research efforts, i.e., research areas in which New Zealand is at a particular advantage or which are “leading edge” within their respective discipline.
- **Collaboration:** Interaction with other research groups, and if appropriate, connection with health services providers and the health policy development process are desirable.
- **Training:** Opportunities for young investigators should exist or be developed within the Programme.
- **Responsiveness to Māori:** The research group’s policies and general activities with respect to responsiveness to Māori as it relates to health and/or health research should be evident.

## 5. Negotiation of Contract Details

Following the approval by Council of a research Programme, the HRC will negotiate with the Director and the host institution to:

- confirm the research objectives to be supported;
- determine the final Programme budget; and
- establish any funding to be provided by other agencies in support of the Programme research objectives.

## 6. Overview of Assessment Process for HRC Research Programmes

Assessment of Programme applications shall be the responsibility of a disciplined-based science assessing committee (SAC) and the Programme Assessing Committee (PAC) with final approval by the Grant Approval Committee (GAC) and Council. Applications are assessed through several stages:

- The applications will be assessed by external reviewers and applicants will be able to comment on reviewer reports.
- The applications will be assessed and scored (maximum score, 28) by SAC on the following criteria: rationale for research, design and methods, research impact, expertise and track record of the research team; the score for “cohesiveness of research Programme” is also used but not included in the total score.
- PAC reserves the right to shortlist proposals prior to the PAC meeting informed by the prior SAC process and scores. Shortlisted applicants are interviewed by PAC.
- The applications will be assessed and scored (maximum score, 28) by the PAC on the following criteria: quality of health research, potential for outcomes, vision of Programme, research team collaboration and integration.
- The applications ranked by the aggregated SAC and PAC scores (maximum total score, 56) and considered Fundable, will be considered by GAC for recommendation to Council.
- The outcome of research Programme applications will be announced in June of the year following submission.

For further information with regard to scoring criteria, please refer to the *HRC Peer Review Manual* available from the HRC website.

## 7. HRC Research Programme Funding

In the 2017, the HRC received and assessed ten Programme applications and five new Programmes costing \$24.8 M were approved for funding. The 2018 round is expected to fund at a similar level.

## Part B: Rules for Submitting the PA218 Application Form

### 1. Use of PA218 Form

#### 1.1 When to use PA218 Form

The PA218 form must be used for Research Programme applications in any Research Investment Stream.

#### 1.2 Prior to submission of PA218 Form

The HRC only accepts applications online (HRC Gateway) (<https://gateway.hrc.govt.nz>). Prior to any submission, Named Investigators must have a Gateway account and register the application to receive an application reference number (HRC Ref ID #) to use on the application form. Key opening and due dates are in the 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.

The regularly updated reference documents and forms are on the HRC web site ([www.hrc.govt.nz](http://www.hrc.govt.nz)).

#### 1.3 New Host Organisations

This is the organisation that will administer the award contract for a successful application. If the desired organisation does not appear on the list, select “Health Research Council of New Zealand” until the list can be updated. New organisations are required to provide due diligence information.

### 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 (CV must be Arial 12-point type font\*)
- Use default margins
- Use single line spacing
- Not exceed any page limits.

*\*The CV is not an HRC document and has different formatting requirements.*

#### 2.2 Compliance

The HRC will not process any application that does not comply with stated page limits or font sizes.

#### 2.3 Additional Documents

Any additional documentation (including letters of commitment/supporting documents) must arrive at the HRC by the due date for applications, and must show the application reference number. Details of co-funding commitments or funding from other sources, such as another Fellowship award, that are offered or confirmed after the closing date must be provided to HRC and may be used by to the assessing committee.

### 3 Copies of Applications Required

#### 3.1 Paper Copies

Submit two stapled double-sided printed copies. Attach supporting documents.

#### 3.2 No Faxed Copies

The HRC will not accept faxed applications.

#### 3.3 Electronic copy

Upload the PA218 file using the HRC Gateway.

Submit the form as a .pdf file created by using the pdf function in MSWord or other pdf generator. Ensure that the pdf version meets page limits and that graphics and tables are satisfactorily presented.

Submit the budget information file in both xlsx and pdf formats. Use the HRC file as it contains special features used for HRC processes. Do not input anything in the coloured cells.

The HRC Gateway will allocate file names.

#### Important

The application is submitted to the host Research Office when the applicant uploads the files through the 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.

#### 3.4 Do not Send Files

Do not send these files directly to the HRC. Independent researchers and smaller research providers requiring assistance should contact the relevant HRC Project Manager for information if they have difficulty.

#### 3.5 Returned Applications

No part or parts of an application can be returned to the applicant.

### 4. Closing Dates

#### 4.1 Registration and Submission of Application Online

There is no separate closing date for registration of applications, but this step is still required and must be signed off by the applicant's Research Office before the HRC Ref ID # is issued so that the full application can be completed.

The closing date for applications is **1 pm on 11 October 2017**. No applications will be accepted **after 1 pm** on the closing date unless **written** authorisation has been received from the HRC at least one week prior to the closing date.

Applications are released to the HRC only after approval by the applicant host Research Office or equivalent. Applicants should complete online submission of the application several days before the HRC closing date to allow for host Research Office processing.

#### 4.2 Submission of Paper Copies

The closing date for paper copies of the Full Application to reach HRC is **5 pm on 13 October 2017**.

#### 4.3 Incomplete Applications

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

### 5. Privacy Provisions

#### Statistical Purposes

The information requested in an application will be used for the purpose of assessing that application and, in a non-identifiable form; some information will be used for HRC statistical purposes. The HRC

undertakes to store all applications in a secure place and to destroy declined applications after due process to preserve confidentiality, unless applications are required to be kept by the National Archives.

### **Peer Review**

Personal information contained in the application may be made available to members of the HRC Committees relevant to the review of the application. This includes electronic and paper copies of the application.

### **Media Release**

In the event that an application is successful, the HRC reserves the right to release First Named Investigators' names, details of the host institution, contact details (work phone or email), contract title, lay summaries and funding and overheads awarded for public interest purposes and to meet the statutory requirements of the Health Research Council Act 1990.

### **Official Information Act**

Should the HRC receive requests for information in an application via the Official Information Act then we will consult with the host institution in handling the request. Where appropriate, or in certain circumstances the request may be transferred by the HRC to the host institution.

## **6. Mailing Address**

The application should be sent to the HRC office address:

**Mailing Address:**

Research Investments & Contracts Group  
Health Research Council of New Zealand  
P O Box 5541  
Wellesley Street, AUCKLAND 1141

**Physical/ Courier Address:**

Research Investments & Contracts  
Health Research Council of New Zealand  
3<sup>rd</sup> Floor, ProCare Building  
110 Stanley Street, AUCKLAND 1010

The HRC Gateway will show the status of any proposal. Do not contact the HRC for application status.

## **7. Enquiries**

All enquiries related to HRC applications should 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 enquires relating to applications, contact the HRC:

Dr Vernon Choy	Telephone: (09) 303 – 5206	Email: vchoy@hrc.govt.nz
Melanie Duncan	Telephone: (09) 303 – 5215	Email: mduncan@hrc.govt.nz
Stacey Pene	Telephone: (09) 303 – 5225	Email: spene@hrc.govt.nz
Lucy Pomeroy	Telephone: (09) 303 – 5223	Email: lpomeroy@hrc.govt.nz

## Part C: Guidelines for Completion of the PA218 Application Form

Module 1 of the application must be completed on the HRC Gateway to register the application and receive an HRC Ref ID#. This form contains a Coversheet, Modules 2, Module 3 and Sections 4A-4D of Module 4. The contract information and/or budget 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.

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

### 1. Use of PA218 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:

- a) Enter information only at the indicated form fields.
- b) Do not reformat Module and Section headings.
- c) Do not delete spreadsheet columns/shaded rows, but you may insert more unshaded rows.
- d) 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.
- e) Input HRC Ref ID# and NI surname on the coversheet.

### 2. Module 1: General Information

Module 1 is wholly online and is not part of the form.

#### Research Investment Stream

Choose the appropriate application type and investment stream from the funding round list on the HRC Gateway.

#### Research Title

The research title should be succinct and clearly describe the proposed project. The title must not exceed 80 characters, including spaces and punctuation.

#### Host Organisation

The host organisation will be responsible for administering any awarded contract. For example, for those applicants at Wellington School of Medicine, Dunedin School of Medicine or Christchurch School of Medicine, the host institution is the University of Otago.

#### Research Location(s)

This is the specific **department(s)** and **organisation** where the majority of research or data analysis will be undertaken. For example, "Department of Community Health, Christchurch School of Medicine" is an example of a research location. Another way of looking at this is, "which group should be credited in any HRC publication of successful applications?" This is usually where the First Named Investigator is based.

#### Research Staff Costs, Overhead, Research Working Expenses and Total Cost of Research

Enter Total Cost of Research on the registration page.

### **Commencement Date and Term**

Enter the proposed commencement date and the term (months). Please note that contracts cannot be activated until 1 July 2018 at the earliest.

### **First Named Investigator (Director)**

The Director will be considered the first point of contact during the application and assessment process, and will be understood to be acting for, and in concurrence with, the other Named Investigators. All correspondence for the application will be addressed to this person. Only the Director will be cited by the HRC in its press release on the successful applications. Please ensure that the details are consistent between the HRC Gateway profile and CV.

Information on ethnic identity, gender and whether the researcher is a clinician (and practising) is used for HRC evaluation purposes only. The ethnic identity and gender information is optional. A **clinician** is defined as a health professional involved in the clinical practice of medicine, psychology, dentistry, physiotherapy/occupational therapy or pharmacy. This includes all qualified doctors, nurses, midwives, dentists, pharmacists, physiotherapists, occupational therapists, dieticians and psychologists. Dieticians and psychologists are only considered clinicians if they have been involved in clinical practice (evidence of this must be provided in the CV). Dental nurses and physiotherapy assistants are not considered to be clinicians. A **practising** clinician is an individual who is contractually obligated to treat patients or clients, and does not engage with patients only for the purposes of research.

### **Email Address**

Provided in HRC Gateway profile.

### **Lay Summary of Research**

The lay summary should be a statement of not more than 150 words suitable for dissemination to, and understanding by, a lay audience, e.g., in a media release. Include:

- a) Research objectives
- b) Principal methodologies, e.g., RCT (to allow assessment in this category)
- c) Potential health outcomes or impact.

Also ensure the content has been reviewed and is in a final form ready for publication if needed. Note that if Programme objectives are modified, the NI will be asked to submit a revised lay summary.

### **Discipline**

Make a choice from the scrollable dropdown list.

### **List of Named Investigators**

NIs are defined as those researchers duly responsible for the conduct of the proposed research (this may include subcontractors who are NIs). Typically, these persons would be those doing the research. "Role" covers position or skills in the project including FTE, e.g., data manager, 0.1 FTE; synthetic chemist with unique scaffolding technology essential to objective 1, 0.05 FTE; statistician with broad epidemiology experience, 0.13 FTE; Unit Director with management overview, 0.03FTE.

Please ensure that the details of NIs are consistent between their HRC Gateway profile and CV.

## **3. Module 2: Research**

### **3.1 Section 2A: Summary of Research Programme (one page only)**

The summary should clearly describe goals and objectives, research plan (including outline of methods) and significance and/or relevance of the research Programme. The summary should be a maximum of one page. A clear and succinct summary including all the important points of the proposal can help reviewers get an overview of the proposal, and is useful as a quick reference for assessing committees. Use the suggested headings and add others if required.

### 3.2 Section 2B: List of Proposed Research Objectives

List the proposed research objectives/project within the Programme and the NI leading that objective/project.

### 3.3 Section 2C: Description of Proposed Research Programme (15 page maximum)

This section is for the applicants to provide an overall description of their research Programme. The following should serve as headings and as a guide for completion of this section. Throughout this description, remember that readers include not only discipline-specific assessors (reviewers and science assessing committees), but also the more **broadly** experienced Programme Assessing Committee. Usage of the terms “objectives” and “projects” are not tightly defined and in some contexts may be interchangeable. The following areas should be considered; it is easier to read the application when the headings and questions are not deleted:

1. Describe the research objectives - How do they form a cohesive theme of research (use diagrams as appropriate)? For each objective, the rationale, design and methods, impact on Investment Signal goal(s) and research team track record should be covered as these are the scoring criteria assessed by the Science Assessing Committee. In addition the SAC considers “Cohesiveness of Research Programme” and the Programme Assessing Committee will score “Quality of Health Research” and “Potential for Outcomes”.
2. The long-term research goals of the group as they relate to the government’s goals for health and the HRC’s Research Investment Streams and Signal goals. A Programme may fit more than one Research Investment Stream, but it is advisable to indicate the principal Stream that is being addressed for this proposal. “Vision of Programme” is a scoring criterion assessed by the Programme Assessing Committee.
3. Collaboration with other research groups and connection with health services providers and the health policy development process.
4. The staffing, management and organisation of the research Programme, including leadership and communication, administrative mechanisms, resource and financial management. “Research Team Collaboration and Integration” is a scoring criterion assessed by the Programme Assessing Committee.
5. The training opportunities for young investigators that exist or will be developed within the Programme. The leadership opportunities for mid-career researchers. The consideration of gender balance throughout the research team.
6. The level of support and facilities provided by the host organisation.
7. The research group’s productivity and likely impact on improving human health. “Potential for Outcomes” is a scoring criterion assessed by the Programme Assessing Committee.
8. The group’s policies and practices for the dissemination of research results. Include plans for stakeholder engagement and how research results will be communicated to ensure knowledge transfer and achieve change.
9. The research group’s policies and general activities with respect to responsiveness to Māori as it relates to health and/or health research. “Potential for Outcomes” is a scoring criterion assessed by the Programme Assessing Committee.

See Appendix for applications with clinical trials objectives.

## 4. Module 3: References

Ensure this section is 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.

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.

Section 4E – entered online

Sections 4F – 4I are to be completed on the separate Excel file (HRC218budget.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 for whom CVs have been provided. 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. Un-named postdoctoral fellows should be justified here, but it is recommended that named postdoctoral fellows provide a CV. Science Assessing Committees may consider not awarding funds for roles that are not fully justified or are simply described as a “training opportunity”. 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 on 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).

#### 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 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 Science Assessing Committee will clearly understand why the requested materials, travel, or research tools are necessary for the successful completion of the research. Ensure any significant one-line items are justified adequately enough for the Science Assessing Committee to understand the appropriateness. Clearly justify the roles of students (must be named) and casual staff so that the Science Assessing Committee can appreciate how these persons are important and necessary for the proposed research to be completed. 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 Institution during the term of the contract. The HRC encourages the inclusion of allowable costs associated with knowledge transfer activities.

List all supporting budget documents in Section 4D (Letters of Collaboration/Supporting Documents Index) and attach to the end of the printed paper copies of the application (not required on uploaded application).

### 5.2 Section 4B: Previous/Current Contracts and Awards

#### List Contracts awarded within the past 5 years

Using the table provided, outline current and previous support from any agency that has been received by the research team. Only include support for any NI, who was First Named investigator on those grants and whose FTE contribution is 10% or more on the current application. Copy the table and repeat for each received grant as required. This section is intended to provide the HRC reviewers and committee reviewers with an overall summary of the applicants’ 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.

**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 Final End of Grant Report(s)

Final Reports for recently completed HRC contracts are made available to the Science Assessing Committees. Please ensure that HRC Final Reports (for the **First Named Investigator** only) for contracts awarded in the last 5 years are included with the application by uploading the pdf version of the report to

the online submission system. Do not upload full deliverable reports from HRC Research Partnerships contracts; only upload the **executive summary** of deliverable report. Submission of annual reports are an HRC contract requirement. Delayed submission without justification will result not only in contract suspension but also in disqualification of new research applications.

### 5.3 Section 4C: Other Support

#### Other Research Applications Awaiting Decision

List in this section the applicant's research applications pending with other agencies. If applicable, indicate in the spaces provided any overlap of resources and personnel that the listed application might have with this application submitted to the HRC. Please append to this section the coversheet and abstract of potentially **overlapping** contracts submitted to other funding agencies.

If the applicant, or any NI believes that disclosure of a significant relationship to companies would be valuable (e.g. contribution to project costs, staff joint appointments or equipment), provide details. 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. This statement has been presented to HRC reviewers and members of Science Assessing Committees.

#### Co-Funding

Please indicate and provide details if the applicant has approached other agencies for joint funding of this research. If applicable, detail the support and 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 potential 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

Use this section to **list** any subcontracts/MOU, letters of collaboration, appendices and any other supporting documents. The documents themselves should be attached to the end of the printed paper copy of the application, not attached to the uploaded form.

The subcontract/MOU should be included with the original application and any copies. Attach subcontracts/MOU to the end of the printed paper copy of this application.

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. Letters of collaboration and any other supporting documents should be attached to the end of the printed paper copy of the application and include the HRC Ref ID#.

### 5.5 Section 4E: Milestones and Objectives

This information is entered on the HRC Gateway. milestones and objectives are assessed along with budget requests, included in an awarded research contract and are used for contract reporting.

#### Objectives

Briefly describe the intended deliverables of this research application. Objectives should be **clear** and **measurable**, as your research performance will be evaluated against these objectives in an awarded contract.

Note that 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. Please note there is no limit to the number of objectives and milestones online.

### Timeline for completion of milestones for Objectives

Provide key milestones that you aim to achieve. Each milestone must relate to one or more of the objectives listed above, e.g.:

Year	Milestone	Objective(s)
1	Recruit 200 patients for clinical 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.

If objectives and milestones are of insufficient detail the HRC reserves the right to not process the application and/or request further details at contracting stage.

### 5.6 Section 4F: Research Proposal Budget

The budget spreadsheet in Section 4F can be used for different types of applications. Select from the dropdown list the application type you wish to submit.

The guidelines below should be considered only a summary of the HRC funding rules. For more information refer to the *HRC Rules* which are available on the HRC website.

#### 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 4F. 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.

**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, [ethics@hrc.govt.nz](mailto:ethics@hrc.govt.nz)

#### Salary

Only enter **Contract 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. The monetary value (\$) should be the **actual** salary amount that the named staff member is expected to receive for the research proposed during that period, not annual salary. The budget does not accept FTE less than 3%. The HRC and Science Assessing Committees do not favour listing numerous investigators with a very low FTE and salary requests only when there is a 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 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 4G. The total GST-exclusive dollar figure for the subcontract/MOU should be all-

inclusive, including overhead calculations. 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 (\$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 '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 '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 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, can be claimed).
- Conference allowance: The maximum allowance for conference attendance is \$1,000 per annum per NI if **fully supported** by the grant and must be fully justified. The allowance cannot be distributed proportionately between grants. This allowance is intended to contribute to the cost of attending a conference, meeting or seminar. Fares and allowances should be calculated in accordance with the regulations and scales of the host institution.

The following are considered to be expenses included in the overhead rate and may not be claimed as direct costs against contract funding; contributions to property costs or laboratory space, cost of staff

appointments, utility charges such as lighting, heating and water, telephone installation and connection fees and line charges, laboratory "bench fees", capital costs, (with the exception of minor equipment), equipment charges (includes computer hardware and office based software), contributions to any central or group service or utility, and all library charges. Such institutional costs are included in the overhead costs paid on an HRC Contract.

### **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 should appear in a detailed subcontract/MOU between the host institution and non-host institution. A MOU should also include overhead calculations for salaries. (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 4G (MOU Budget). Attach a copy of the subcontract/MOU at the end of the printed paper copy of the application. MOUs should also be provided for time only subcontracted staff not employed by the host.

### **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.

### **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.

## **5.7 Section 4G: 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 4G to provide budget details for all MOU requesting more than \$50,000; add a copy Section G 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. The total dollar amount for each year should then be entered under 'Working expenses - Subcontracts' and a copy of the subcontract/MOU should be attached to the end of the printed paper copy of the application.

A CV should be provided in Module 5 for all NIs on MOU 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. If you require any further advice contact one of the HRC Project Managers.

All subcontracts/MOU should be listed in Section 4D (Letters of Collaboration/Supporting Documents Index). If there are no subcontracts/MOU for this application, or none requesting more than \$50,000 you may delete or ignore Section 4G.

## **5.8 Section 4H: 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 (eg, 3.5%) 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 4F and 4G). Heads of Department will be required to agree to provide workload relief for research staff working on HRC contracts (Principles of Full Cost Funding). Provide Ethnicity for all personnel if this information is relevant to the proposed research.

## 5.9 Section 4I: 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.

## 6. Module 5: NZ Standard CV

Upload a CV for all staff (include those on MOU), that will contribute to this research.

Use the original CV formatting including the default font and 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 in Module 1. For example, title and contact details may need updating in the CV before submission.

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

## 7. Module 6: Research Classification

Module 6 is for HRC evaluation purposes only. The information is not used in allocating funding.

### 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.

### 7.2 Section 6C Category and Health Issue

#### Portfolio Mapping Category

Enter the requested information on the 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	✓
<b>Biomedical</b>		
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, <i>etc.</i> ).	
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).	
<b>Clinical</b>		
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.	
<b>Health Services</b>		
Health Economics	Research into the cost-effectiveness of treatments/services <i>etc.</i>	
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.	
<b>Public Health</b>		
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 <i>etc.</i> 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, <i>etc.</i> Includes research using diagnostics in a particular group.	
Community services	Research around community-run services and community groups, e.g. Marae-based healthcare services.	

### Health Issue

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

## **Appendix 1: Improving the Rigour and Completeness of Clinical Trial Proposals.**

The Clinical Trials Assessing Committee (CTAC) has been active since the 2013 Annual Funding Round and 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 rigor 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 clinical trial protocols. Research proposals for clinical trial funding from the HRC should reflect clinical trial 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 are encouraged to consider the broad expertise of their audience (CTAC) when describing their clinical 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.

## **Appendix 2: Presentation and Interview of Shortlisted Applicants at PAC**

After SAC assessment, applications will be shortlisted for PAC assessment using ranked scores. This process will be completed about two weeks prior to the PAC meeting and the selected applicants will be notified to choose a time slot in the PAC schedule in the first week of May 2017. Applicants may contact the HRC to tentatively choose an appointment time subject to final confirmation. The proposed Director may bring to the meeting senior members of the research team (generally leads of the objectives/projects named in Section 2B of the application).

The following points should be noted by applicants invited to PAC:

1. PAC chair is responsible for meeting processes and does not score or take part in discussion.
2. PAC is **multidisciplinary** with New Zealand and Australian members with experience in managing research involving teams of investigators. The applicant must be prepared to address the broad expertise of the committee.
3. SAC assesses health research criteria (as defined in the Peer Review Manual), but PAC may follow up some questions/issues raised by SAC and will score overall “quality of health research”.
4. Applicants spend an hour with PAC, beginning with a 30-minute presentation. The presentation should:
  - a. Give an overview of each objective or project - how each contributes to the overall Programme, track record of senior investigators leading each project.
  - b. Indicate the strategic direction for the Programme.
  - c. Cover the potential for health impact.
  - d. Detail the organisation and planning for the team, training opportunities – track record with details.
  - e. How the Programme addresses Responsiveness to Māori – investigators, career development, community engagement.
  - f. Address the assessment criteria used by PAC to score applications (potential for outcomes, vision of programme, team collaboration and integration, quality of the health research) – the Peer Review Manual describe assessment criteria.
5. A 30-minute interview follows the presentation with an opportunity for **other** members of the applicant’s team to contribute to discussion and answer questions. PAC may ask questions raised by the SAC, seek further information related to the PAC score criteria and also seek clarification about any other issues, e.g., research team capabilities.