Guidelines

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

New Zealand Government New Zealand Government

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Programme Application Guidelines

(PA215)

New Zealand Government

www.hrc.govt.nz

Table of Contents

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.

The HRC reserves the right to allocate funds from the contestable funding pool to Programmes and Projects in an appropriate strategic mix. This may occur, for example, should the Research Committees recommend that more new research Programmes be established than was otherwise available. The HRC also reserves the right to transfer any unallocated Programme funds to the contestable Project funding pool.

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** currently 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 after reviewing the Investment Signals, the General Guidelines and the Frequently Asked Questions (FAQ) documents. 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 which RIS to submit to, as the final decision is that of the investigator. Applicants may change this at any time until final submission. Only proposals that have been admitted to an incorrect stream due to administrative error can be reassigned after the closing date.

3. Programme Director Requirements

A Named Investigator may be a Director of only one HRC Programme at a time (except see point 1 below), but may be funded as a Named Investigator on other HRC research contracts.

A proposed Director must meet one of the following requirements **at the due date of application**:

1) Director on an HRC Programme with no more than one year to run, ie, Director of a Programme contract that will expire on or before October 2015;
2) Director of an HRC Programme in the last five years, ie, Director of a Programme contract that expired after October 2009;
3) First Named Investigator on at least two investigator-initiated HRC, or equivalent agency, Project contracts begun in the last four years, ie, started at least two Project contracts on or after October 2010;
4) First Named Investigator on one investigator-initiated HRC Project, begun in the last two years, and leading a team of at least two other First Named Investigators of investigator-initiated Project grants from the HRC or equivalent agency in the last four years, eg, proposed Director started a Project contract on November 2012, 2nd NI started a Project contract on October 2010, 3rd NI started a Marsden grant on December 2011.

In this context, equivalent means a Project of similar value and tenure to an HRC Project from an agency that allocates funds using internationally accepted contestable processes and peer review, eg, Marsden fund, NHMRC, NIH, Wellcome Trust and MRC. The start and expiry dates of a grant are stated in HRC research contracts.

An HRC Programme Director must assign at least 20% FTE to the Programme, must be employed by a New Zealand host institution and reside 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[1].
- **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.

[1] This residency requirement does not apply to project applicants, who are required to have New Zealand as their principal domicile at the time of taking up the contract (see HRC Rule 1.3.5).

- **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

Review of all Programme applications shall be the responsibility of a disciplined-based science assessing committee (SAC) and the Programme Assessing Committee (PAC) with final discussion and approval by the Grant Approval Committee (GAC) and Council. Members of the individual HRC Research Committees are represented on PAC and GAC. 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 reviewed 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. Only applications considered Fundable by SAC will proceed to PAC.
- PAC reserves the right to shortlist proposals prior to the PAC meeting informed by the prior SAC process and scores.
- The applications will be reviewed and scored (maximum score, 21) by the PAC on the following criteria: potential for outcomes, vision of Programme, research team collaboration and integration.
- The applications ranked by the aggregated SAC and PAC scores (total score, 49) will be considered by GAC for recommendation to Council.
- The outcome of research Programme applications will be announced at the same time as research projects from the funding round, i.e. 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

The HRC currently funds twenty-eight Programmes consisting of eight 6-year contracts (no longer available; six biomedical, two public health) and twenty 5-year contracts (thirteen biomedical, one Maori health and six public health). In the 2014 funding round, four new Programmes were funded. The 2015 round is expected to fund six new Programmes.

Part B: Rules for Submitting the PA215 Application Form

1. Use of PA215 Form

1.1 When to use PA215 Form

The PA215 form must be used for Research Programme applications in any Research Investment Stream.

1.2 Prior to submission of PA215 Form

Before submitting this application form, applicants should:

- Confirm their eligibility;
- Register the application on the HRC Gateway;
- Read Research Investment Stream signals, the General Guidelines and the Frequently Asked Questions documents;;
- Read Guidelines on Ethics in Health Research;
- Read Guidelines for Researchers on Health Research Involving Māori,
- Read Guidelines for Pacific Health Research.

Applicants should also familiarise themselves with the relevant sections of the current *HRC Peer Review Manual*.

All documents are available on the HRC web site (www.hrc.govt.nz).

1.3 New Host Organisations

New host organisations (e.g. Independent Hosts), that have not previously been funded by the HRC or applied for HRC funding, will be required to start the "due diligence" process before their application is processed. Please contact the HRC for further 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 original form as it contains special features.

Applicants must:

- Use Arial type font no smaller than 10-point. (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/styles.

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. Co-funding commitments from other sources that are confirmed after the closing date must be provided as they become known and may be useful to the committee.

3 Copies of Applications Required

3.1 Paper Copies

Submit two stapled double-sided printed copies.

3.2 No Faxed Copies

The HRC will not accept faxed applications.

3.3 Electronic copy

Upload the PA215 file using the HRC Gateway.

Submit the form as a .pdf file created by using pdf function in MSWord or other pdf generator. The conversion to pdf format prior to uploading allows applicants quicker access to the final compiled application, containing all Sections, so that inspection of graphics can be completed.

HRC Gateway will allocate file names.

Submit the HRC215budget.xlsx 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.

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 approval. Always allow sufficient time near the closing date for these steps.

3.4 Do not Send Files

Do not send digital files directly to the HRC. Independent researchers and 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 Submission of Application Online

The closing date for applications to be submitted online to HRC is **12 noon on 15 October 2014**. Full Applications are released to the HRC only after approval by the applicant host Research Office or equivalent, which will require access to the application several days before the HRC closing date.

4.2 Submission of Paper Copies

The closing date for paper copies of the Full Application to reach HRC is **5 pm on 17 October 2014**.

4.3 Incomplete Applications

Incomplete applications will be deleted from the HRC Gateway.

5. Privacy Provisions

5.1 Statistical Purposes

The information requested in an application will be used for the purpose of assessing that application and, in a non-identifiable format; 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.

5.2 Peer Review

Personal information contained in the application may be made available to external reviewers and members of the HRC Committees relevant to the review of the application. This includes electronic and paper copies of the application. The HRC may seek reports from reviewers, where appropriate, to assess the scientific merit, health importance and cultural appropriateness of the application.

5.3 Media Release

In the event that an application is successful, the HRC reserves the right to release applicants' 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 of New Zealand Act 1990.

5.4 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:
Attention: Investment Processes Group
Health Research Council of New Zealand
P O Box 5541
Wellesley Street, AUCKLAND 1141

Physical/Courier Address:
Attention: Investment Processes Group
Health Research Council of New Zealand
3rd 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:

Rachel Brown	Telephone:	(09) 303 – 5084	Email: rbrown@hrc.govt.nz
Dr Vernon Choy	Telephone:	(09) 303 – 5206	Email: vchoy@hrc.govt.nz
Melanie Duncan	Telephone:	(09) 303 – 5215	Email: mduncan@hrc.govt.nz
Dr Katie Evans	Telephone:	(09) 303 – 5223	Email: kevans@hrc.govt.nz
Dr Deming Gong	Telephone:	(09) 303 – 5228	Email: dgong@hrc.govt.nz
Lucy Pomeroy	Telephone:	(09) 303 – 5223	Email: lpomeroy@hrc.govt.nz
Jaylene Wehipeihana	Telephone:	(09) 303 – 5207	Email: jwehipeihana@hrc.govt.nz

For HRC Gateway assistance, contact:

Vivien Lovell	Telephone:	(09) 303 – 5210	Email: vlovell@hrc.govt.nz

Part C: Guidelines for Completion of the PA215 Application Form

Module 1 of the application must be completed on the HRC Gateway. This is the registration section with several additional fields to complete. The form contains a coversheet and Modules 2-7 of the application. The form can be downloaded and completed before being uploaded to the HRC Gateway as a pdf file. The completed application will be compiled by the HRC Gateway; it can then be accessed for downloading and printing.

1. Use of PA215 Form

Please use the original PA215 form and HRC215budget spreadsheet as these contain special features.

The form is compatible with Windows PC and MAC computers. Some Modules of the form have restricted editing enabled so that formatting 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 fonts for Module/Section headings.
c) Do not merge tables.
d) Do not delete spreadsheet columns/shaded rows, but you may insert more unshaded rows.
e) Use the original documents. Do not copy and paste into a new document as this can drastically change fonts and remove other features required for HRC processes.
f) Input HRC REF ID # and NI surname on the coversheet.
g) Module 2 must begin on a new page.

2. Module 1: General Information

Module 1 is wholly online and is no longer part of the form. All or most information will have been completed at registration and some fields may be editable or updated until final submission of the application.

Research Investment Stream
Complete the HRC reference ID# and Research Investment Stream box on the Coversheet.

The Research Investment Stream is selected on registration of the application.

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

First Named Investigator (Director)
The title (e.g. Associate Professor, Dr), first name(s), and surname of the Director should be entered in this table. 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 names of NIs 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.

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.

Total Cost of Research
Enter amount from the budget spreadsheet.

Commencement Date and Term
Enter the proposed commencement date and the term (months). Contracts for this round cannot be activated before 1 July 2015.

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, eg, in a media release. Include:

a) Research objectives
b) Principal methodologies, eg, 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.

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, eg, 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.

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.

Please ensure that the names 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 to 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 "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. "Research Team Collaboration and Integration" is a scoring criterion assessed by the Programme Assessing Committee.
4. The staffing, management and organisation of the research Programme, including administrative mechanisms, resource and financial management.
5. The training opportunities for young investigators that exist or will be developed within the Programme.
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

References for Module 2 should be listed in Module 3.

Ensure this section starts on a new page, to avoid it being included in page limits: there is no limit to the number of reference pages.

Citations for key references in the text in Module 2 should be supplied. Details must include author(s), title of article, journal, year, volume and page numbers. Asterisks are to be placed beside applicant's publications.

Applicants wishing to upload their references into Module 3 from **EndNote** should first paste the references into a blank document, and then copy and paste these into the form.

5. Module 4: Contract Information and Budget

Sections 4A – 4D are to be completed on the separate Excel file (HRC214budget.xls). Sections 4E – 4H are part of the PA215 form.

a) Enter the HRC REF ID number at the top of Section 4A.
b) The budget spreadsheet in Section 4B can be used for any of the funding round applications. Select from the dropdown list, which application type to submit.
c) Attach printouts of the Excel spreadsheet sections, in the correct order, in the relevant part of the original application form and the copies. If the application DOES NOT request funds for Subcontracts/Memoranda of Understanding (MOU) OR funds requested for Subcontract/MOU are less than $50,000, do not include a printout of Section 4C. For all sheets of the Excel file, page orientation may be in Portrait (preferred) or Landscape. Try to have page breaks at logical points.
d) The Contract Information and Budget spreadsheet must be submitted as a separate Excel file using the online system.

5.1 Section 4A: Contract Information

Please note, that should the application be funded, these tables will form the basis of the contract objectives and may be amended prior to commencement.

Objectives - Briefly describe the intended deliverables of this research application as numbered points within the table provided. Research reports will be evaluated against these objectives.

Timeline for completion of milestones for Objectives - For each year of the proposed study**,** provide key milestones that are to be achieved. Each milestone must relate to one or more of the Objectives. Expand the table by adding a row for each milestone if required, e.g.:

Year	Milestone	Objective(s)
1	Recruit patients for clinical study	Objective 2
2	Complete data entry (lab study)	Objective 1
2	Complete data entry (clinical study)	Objective 2
3	Dissemination of findings at Hui	All Objectives

5.2 Section 4B: Research Proposal Budget

The guidelines below should be considered only a summary of the HRC funding rules. For more complete information refer to the *Health Research Council of New Zealand Rules* which are available on the HRC website. It is useful to indicate with headings the distribution of budget items across the individual objectives/projects.

1. Budget calculations and spreadsheet

All calculations should be GST exclusive and be in whole dollar amounts i.e. no cents or decimals. Page orientation may be in Portrait (preferred) or Landscape. Try to have page breaks at logical points.

The "Salary," "Working Expenses" and "Total Cost of This Research" are components of Section 4B. The spreadsheet contains formulae to automatically sum each year of costs. To insert more rows into a table, select a cell on the row above, go to Insert on the Menu bar and choose Insert row (or right click and insert). This will not affect the formulae.

The 'Total Cost of Research" shaded table automatically calculates all of the figures in this box.

Do not enter any details into any shaded areas. Shaded areas contain either column/row labels or formulae.

Note: If you are intending to ask the HRC's Data Monitoring Committee (DMC) to monitor this study, there is no cost involved in using the HRC's DMC. However, if the DMC 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

2. 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. 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 (i.e., the product of their **Annual Salary X %FTE** devoted to this research application). Salaries for years 2 to 5 can be increased by 3% per annum from year 1, or by more if specific details of expected promotion are provided.

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, Masters and PhD Students on studentships/allowances 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 (see point 3. – Working Expenses, for details). 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'.
b) If funding to provide a studentship/allowance for a **named PhD or Masters Student** is requested, the allowance should not be entered into the Staff section of the budget. Please enter Masters and PhD studentships/allowances into 'Working expenses – Materials and Research Expenses'.
c) **Casual Staff** (those persons without an ongoing role or commitment to the research, but providing one-off services to the research on a part-time, hourly or *per diem* basis, e.g. interviewers) should also be requested under 'Working expenses - Materials and Research Expenses'.

3. Working Expenses

Working expenses include 'direct costs' only. The only exception is in the case of subcontracts, as described above. HRC Rules do not allow for significant expenditure on equipment or buildings other than that provided in the overhead rate. Budgeting information is mostly useful when it can be distributed across research objectives/projects. 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).
- For clinical trials with oversight by a Data Monitoring Committee (DMC) include costs related to report production and travel to DMC meetings. (Note: the DMC may be internal to the trial or independent, such as the HRC DMC. For further information see the website or contact the Administrator or Chair of the HRC DMC)
- Minor research equipment (to a total of $5000).

- 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).
- 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.
- 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.
- Studentships/allowances for named Masters or PhD students can be claimed if a description of the student's research project is provided in Section 4E. Funds will be conditional upon the institution arranging a tax-free allowance 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 and must be fully justified. The allowance cannot be distributed proportionately between grants. This allowance is intended to contribute to the cost of relevant domestic travel to attend one conference, meeting or seminar annually. Domestic travel is considered to include Australia, excluding Northern Territory and Western Australia. 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, room hire, 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 (including FTEs) 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 4C (MOU Budget). Include a copy of the subcontract/MOU after Section 4C. If the subcontract/MOU is less than $50,000 include the copy of the subcontract/MOU after Section 4B and exclude Section 4C from the application.

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.

4. Total Cost of Research
Enter the appropriate overhead rate (OHR) in the spreadsheet. 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, this table will automatically calculate the total cost of the research. The applicant should enter that figure in the registration field "Likely Cost of Research".

5.3 Section 4C: MOU Budget

When a substantial proportion of the total budget of a research proposal is contained in a subcontract/MOU, having the expenditure itemised in the same way as the overall research proposal budget (see above) will greatly assist the Science Assessing Committee in their evaluation of the proposal. Use the tables in Section 4C to provide budget details for all MOU requesting more than $50,000. 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 of the subcontract/MOU should then be entered under 'Working expenses – Subcontracts' and a copy of the subcontract/MOU should be included at the end of Section 4C with all copies of the application. For subcontract/MOU to a value of less than $50,000, insert copies after Section 4B.

A CV should be included in Module 5 for all Named Investigators 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. If you require any further advice contact one of the HRC Project Managers.

All subcontract/MOU should be listed in Section 4H (Letters of Collaboration/Supporting Documents Index).

5.4 Section 4D: FTE Summary

List the time involvement of ALL personnel (including those on subcontract/MOU) in terms of Full Time Equivalents (%FTE). Give all names (for un-named positions, indicate as "Technician", "Research Nurse", "Postdoctoral Fellow" etc). State FTE as a percentage and not a decimal proportion, e.g., "10%" instead of "0.1". Half percentages (e.g. 2.5%) are not allowed. Indicate when Named Investigators are "Time Only" (i.e. NOT receiving salary for their involvement in the project). All investigators on subcontract/MOU should be identified as "Time Only". Identify all Postgraduate students by "Masters" or "PhD" as well as by their name. Ensure the FTE figures are the same as those in the budget and MOU budget sections (Sections 4B and 4C). Heads of Department will be required to agree in writing 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.

5.5 Section 4E: Justification of Expenses

Justification of Research Staff
Use this section to justify the role and %FTE of the Named Investigators and any other research staff for whom CVs have been provided. Also explain the role of ALL OTHER personnel (named or un-named) 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 in Module 5. Science Assessing Committees may consider not awarding funds for roles that are not fully justified or are simply described as a "training opportunity". 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 named students and casual staff should be justified in the following section.

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 named students and casual staff so that the Science Assessing Committee can appreciate how they 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.

Insert all supporting budget documents at the end of Module 4, and list these documents in Section 4H (see below).

5.6 Section 4F: Listing of Previous/Current Contracts

Outline of current and previous support from all agencies
Using the tables provided, outline current and previous support from any agency that has been received by the research team. Only include support for any NIs whose FTE contribution is 10% or more on the current application. Copy the table and repeat 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.

Final Reports for recently completed HRC contracts are made available to the Science Assessing Committees. Please ensure that all HRC Final Reports funded via the Annual Funding Round and Research Partnership awards (for the First Named Investigator only) from the past 5 years are included with the application by uploading the pdf version of the report to the online submission system. Please contact your Research Office in the first instance if you do not have a copy.

5.7 Section 4G: Other Support

Other Research Applications Awaiting Decision
If any Project application related to this Programme application has been submitted to the HRC in the same Funding Round, applicants must agree to withdraw the Project if the Programme is funded when the research is substantially the same.

List the research applications the team has pending with other funding agencies. If applicable, indicate in the spaces provided any overlap of resources and personnel that the listed research application might have with this application submitted to the HRC. This information is especially important where there may be overlaps between Projects and Programmes. Applicants must advise the HRC through their Research Office of the outcome of these applications.

If any Named Investigator 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 required.

Co-funding
Please indicate and provide details if the research group has approached other agencies for joint funding of this research. If applicable, detail the support and joint funding arrangements for this research.

If the proposed research is part of a larger study then please provide details of all funding sources contributing to the larger study. For example, if the proposed research is the New Zealand arm of a multicentre clinical trial then provide details of all funding sources for the multicentre trial.

Financial Interest(s)
For the purposes of HRC funding applications, a financial interest is anything of economic value, 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.

A financial conflict of interest is a situation in which an individual's financial relationships 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 interests in a

funding application, the applicant should also outline the specific details of their proposed conflict management strategy.

5.8 Section 4H: Letters of Collaboration/Supporting Documents Index

Use this section to **list** any subcontracts/MOU, letters of collaboration, appendices and any other supporting documents. These documents are not required to be submitted electronically with the online application. The documents themselves should be attached to the original hard copy of the application as per the instructions below.

Any subcontract/MOU should be included with the original application after Section 4B (<$50K) or 4C (>$50K), and include the HRC Reference ID#.

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 should be paper-clipped separately after Section 4H with the original application and include the HRC Reference ID#.

If Appendices need to be attached (e.g. example of a questionnaire) then please contact the HRC for approval although this is rarely exercised.

Other supporting documents, for example documents supporting budget items, should be paper-clipped separately after Section 4H with the original application and include the HRC Reference ID#.

Collaborators (National and International)
Complete the Collaborators table by providing the collaborators' full names, organisations, and countries (the location where the organisation is based and the collaborators undertake their research).

For **collaboration purpose,** select one of the following options:

- Research
- Commercialisation
- Knowledge transfer

For **Support,** indicate the value of any funding for this research provided by the collaborator in New Zealand dollars or list any in-kind support.

6. Module 5: NZ Standard CV

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

Copy and paste the NZ Standard CV into this section of the form. Part 2b-2d of the CV are not required. Take care to use the original CV formatting including the default font (Arial 12) and 5-page limit. The HRC will not accept any other form of CV.

The information provided in the CV **must be the same** as that provided in Section 1 (online). For example, title and contact details may need updating in the CV before submission.

7. Module 6: Administration

Module 6 is only required for successful applicants and will be completed during contracting. It is here **for reference** only. The complete administrative agreement can be downloaded from the HRC website.

7.1 Section 6A: Ethical and Regulatory Approval

All areas must be fully and accurately completed for this section to be accepted. Indicate if the application requires human or animal ethical approval. If ethical approval is not required, reasons must be given. List any regulatory consents required from other bodies that must be gained before the research can commence.

Note:

1) The ethical agreement page is a contract stating that you will obtain appropriate ethical approval and regulatory consents, if required, before research commences.
2) The importance of adherence to the Council's Guidelines on Ethics in Health Research is emphasised. Especially where research involves human or animal subjects, human or animal materials, or personal information, you must signify that the research application has been submitted to, and given ethical approval by a properly constituted ethics committee approved for this purpose by the HRC.
3) Once applications have been received by the HRC, major procedural changes to your research protocol resulting from decisions of an Ethics Committee will require withdrawal of the application and resubmission to a later funding round. It is therefore suggested that you apply for ethical approval before submitting your application to the HRC to avoid unnecessary delays in contract commencement.
4) No contract funds will be released by the HRC until all ethical and administrative agreements, as detailed in this form, are fully met.
5) If appropriate, more than one Ethics Committee approval may be necessary, for example, if the research geographically covers an area serviced by more than one committee or if human and animal studies will be undertaken. Details are available from the HRC or the Ministry of Health.
6) Ethics Committees accredited to review research applications to the HRC are listed in the "*Guidelines on Ethics in Health Research*", contained on the HRC website. Also refer to the "*National Application Form for Ethical Approval of a Research Projects*" (form EA0502) also available on the HRC website.
7) If the proposed research is a clinical trial, a community intervention study or an innovative treatment then you must indicate what independent data monitoring arrangements are in place.

7.2 Section 6B: Administrative Agreement

The administrative agreement should be signed by **authorised officers** of the New Zealand host institution that will administer the contract. **The host institution must be clearly and unambiguously identified**.

8. Module 7: Research Classification

This module is for use by the Secretariat for evaluation and reporting.

8.1 Section 7A: ANZSRC

You are **required** to categorise your research using ANZSRC codes for the Fields of Research (FOR) and Socioeconomic Objective (SEO) classifications found on the HRC web link (http://classifications.hrc.govt.nz). Find the appropriate code(s) (6-digits) and description and insert in the table. The entries must include the 6-digit code AND description. Add a percentage (nearest 10%) for each category with a total of 100%. Only use 3 codes for each of FOR and SEO.

8.2 Section 7B: Economic Benefits

Provide a brief description of any potential economic benefits that may arise from the research. If no 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.

Appendix: 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.