Guidelines

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

January 2019

2019 Breast Cancer Research in NZ RFP
Project Application Guidelines

JV219P

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Part A: Introduction

Please note that these guidelines have been specifically tailored for the Request for Proposals entitled **2019 Breast Cancer Research in NZ RFP**.

This Request for Proposals is a component of the HRC's Partnership Programme, through which the HRC forms strategic partnerships with funders and stakeholders to target resources towards developing the evidence-base in key areas of need and to strengthen the links between policy and practice.

Applicants should note that Partnership Programme Requests for Proposals focus on key priority areas and are intended to support targeted, outcome-focused research.

1. Outline of the Application Process

The table outlines the process for submitting a project application. Applicants must meet each of the deadlines below in order to continue in the process.

Applicants are first required to submit a Registration before the submission of a project application. The Registration is completed online via HRC Gateway (Online Submission System).

The full application is due subsequently and should be uploaded via HRC Gateway and hard copies sent to the HRC.

All forms are available on HRC Gateway.

Event	Description	Date Due
Registration	Complete & submit online form on HRC Gateway	**1pm, 27 February 2019**
Full Application	Complete online sections & upload to HRC Gateway: - 2019 BC Research RFP Project Application Form - 2019 BC Research RFP Project Budget Form - CVs for Named Investigators	**1pm, 13 March 2019**
	Submit hard copies of complete Full Application	**5pm, 15 March 2019**
Peer Review	HRC coordinates the external peer review of all full applications	**April 2019**
Applicant Rebuttal	Research team to complete & submit rebuttal template via HRC Gateway	**1pm, 29 May 2019**
HRC Assessment	Independent assessing committee undertakes assessment	**June 2019**
Results	Outcome notification	**September 2019**

2. Creating an HRC Gateway User Account

If they do not already have one, applicants will need to create a new account on HRC Gateway, which can be accessed via the following URL: https://gateway.hrc.govt.nz/

Please note that all named investigators must have an HRC Gateway user account so that their details can be included in the online form.

Part B: General Rules for Submitting the JV219P Application Form

1. Use of JV219P Form

1.1 When to Use JV219P Form

The 2019 BC Research RFP Project Application Form (JV219P) must be used when submitting a project full application.

1.2 Prior to Submission

The HRC only accepts applications online (HRC Gateway) (https://gateway.hrc.govt.nz). Prior to any submission, Named Investigators must have a current Gateway account, that must be updated annually. Key opening and due dates are in the section below.

Before submitting this application form, applicants should read:

- This document for eligibility and specific instructions
- Guidelines on Ethics in Health Research
- Guidelines for Researchers on Health Research Involving Māori
- Guidelines for Pacific Health Research.

The regularly updated reference documents are on the HRC website (www.hrc.govt.nz).

1.3 New Host Organisation

New host organisations (e.g. Independent Hosts), that have not previously been funded by the HRC, will be required to provide due diligence information before a contract can be offered and preferably before an application is submitted to avoid unnecessary work. Please contact the HRC for further information.

2. Format

2.1 General Formatting

Proposals must have sufficient detail so that the reviewers can understand the scope and implications of the proposal.

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

Use the correct HRC form as it contains special features.

Applicants must:

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

2.2 Compliance

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

3. Copies of Applications Required

3.1 Paper Copy

Applications must be submitted on the HRC Gateway and two printed copies sent to the HRC.

The two complete printed applications must be double-sided and stapled.

3.2 Electronic Copy

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

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

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.

3.3 Do not Send Files

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

3.4 Returned Applications

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

4. Closing Dates for Full Application

4.1 Submission of Full Application Online

Upload the application form using 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. HRC Gateway will allocate file names.

The closing date for full applications to be submitted online to HRC is **1pm, 13 March 2019**. Full applications are released to the HRC only after approval by the applicant host Research Office or equivalent, which will require access to the full application several days before the HRC closing date.

4.2 Submission of Paper Copies

The online system creates a single PDF document of the complete application by merging the uploaded application form with the online Registration details for processing and printing. Send two copies of the system-generated version to the HRC by **5pm, 15 March 2019**.

4.3 Incomplete Applications

Incomplete applications will be deleted from the HRC Gateway.

5. Privacy Provisions

5.1 Statistical Purposes

The information provided in an application will be used for assessing that application and, in a non-identifiable form, some information will be used for HRC statistical and reporting purposes. The HRC undertakes to store all applications in a secure place, which may include storing the information in the National Research Information System (NRIS) curated by MBIE with details provided by funders of the science sector.

5.2 Personal Information

Personal information contained in the application will available to members of the HRC Committees relevant to the review of the application.

5.3 Media Release

The HRC publishes details of research contracts including First Named Investigators' host institution, contact details (work phone or email), research title, lay summaries and funding awarded for public interest purposes and to meet the statutory requirements of the Health Research Council Act 1990.

5.4 Official Information Act

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

6. 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
3rd Floor, ProCare Building
110 Stanley Street, AUCKLAND 1010

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 enquiries relating to applications, contact the HRC:

Isabella Cheung Telephone: (09) 280 – 3860 Email: icheung@hrc.govt.nz

Part C: Completing a Registration (via HRC Gateway)

Applicants are first required to submit a Registration. The Registration involves completing a simple, web-based form that is submitted electronically via HRC Gateway. Hard copies of the Registration are not required.

Submitting a Registration signals the intention of the applicant to submit a full application. Submitting a Registration also generates an HRC reference number to use on the full application form. The information entered as part of the Registration will form the majority of Module 1 of the full application.

Once submitted, the Registration is forwarded (in HRC Gateway) to the host Research Office. The Research Office will then need to approve the Registration and then forward to the HRC. Always allow sufficient time near the Registration closing date for these steps. If the host institution doesn't have a research office, the Registration will be automatically forwarded to the HRC.

First named investigators and all other named investigators must have an HRC Gateway account, to be able to be included in an application. Named investigators will be able to be added after a Registration has been submitted and before the full application is submitted.

Registrations are due by **1pm, 27 February 2019**.

Incomplete or late Registrations will not be accepted.

Completing the Registration

1st Step

The applicant will first be required to enter a research title and select a host organisation (there will also be options to select a specific research office and research office contact if applicable).

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 (e.g. 'growth factors' contains 14 characters). Do not use all uppercase type.

Host Organisation

The host organisation is the institution or organisation that will be responsible for administering any contract awarded. 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

Select the relevant 'Host organisation' from the drop-down list (this shows host organisations currently recognised by the HRC). If applicable, a specific research office and research office contact will be able to be selected.

Please note: If your host organisation does not appear in the drop-down list, please tick the check box 'My host organisation is not in the list'. A field 'Host organisation details' will appear in the next section and the name of the host organisation should be entered here.

2nd Step

First Named Investigator

Some of this information will be automatically populated from the First Named Investigator's profile in Gateway (e.g., Organisation and department). Please note that the FTE of the First NI will default to 1 – this will need to be updated. If the profile is not current details will need to be updated. The details listed on the application will be automatically refreshed after the profile is updated. Click on the 'Update' button to enter and update the information requested.

The First NI 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 NIs. All correspondence for the application will be addressed to this person and the host. Only the First NI

will be cited by the HRC in its press release on successful applications. Once an application is created, the first named investigator cannot be changed.

3rd Step

Click on the 'Update' button to enter details for the following fields.

Note: if a field does not need to be completed until the full application stage, there will be a blank space next to that field – information will only be able to be entered at the full application stage.

Named Investigators

All NIs must be registered users of the HRC Gateway before they can be added to the application. User profiles must be updated before starting an application so that the current details are in the application. Click on the "Update" button to enter information as requested.

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

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

FTE for each NI is also required, as the assessing committee needs to know the level of commitment or responsibility of each team member. It is particularly important to identify more junior investigators who may undertake key components for the proposed research.

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

Research Location(s)

This is the specific department(s) and organisation where the majority of research or data analysis will be undertaken.

Discipline

Select from the drop-down box.

Duration

Enter the proposed term of the research (months).

Commencement Date

Enter the proposed commencement date. **Note**: please carefully consider the start date, as depending on the specific requirements of the relevant partnership initiative, applicants will be held to their proposed start date.

Lay Summary

Provide a summary of the research (150-word limit). Include research objectives, principal methodologies (especially for randomised controlled trials and population interventions) and potential health outcomes or impact.

Nominated Impartial Peer Reviewers

Nominated peer reviewers are not references to support the application. External peer reviewers will be utilised by the HRC to carry out peer review of full applications. They should not be people that may be compromised in their assessment of applications due to a conflict of interest such as having a professional, working, collegial or personal relationship with an applicant. Ideally the nominated peer reviewers should not be at the same institution as the named investigators. Applicants may nominate up to two.

Peer Reviewers Unacceptable to Applicant

Name an individual or research group that would be unacceptable as a peer reviewer. An individual or research group may be unacceptable as a reviewer because: 1) they are competitors, 2) there is a conflict of interest, 3) there are commercially sensitivity issues.

Part D: Submitting a Full Application – Completion of the JV219P Form

Module 1 is now completed entirely online and is no longer part of the form. This module incorporates the Registration information, with some additional fields required at the full application stage. Some fields may be editable or updated from Registration. The 2019 BC Research RFP Project Application Form contains a Coversheet, Modules 2, Module 3 and Module 4 (Sections 4A-4D) of Module 4. Module 4E is the Milestones and Objectives and is entered in HRC Gateway. The contract information and/or budget file for Module 4F-4I must be uploaded separately (2019 BC Research RFP Project Budget Form). Module 5 contains NI CVs that are uploaded separately. Module 6 is the research classification of the research that must be completed on the HRC Gateway.

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.

Note: an applicant checklist has been added to the start of application form. Every point must be checked off to acknowledge compliance with application guidelines. Completion of the checklist by applicants indicates that the submitted application complies with all requirements as the HRC will no longer undertake this compliance check.

1. Use of JV219P Form

Use the original form and budget 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.
a) Do not reformat Module and Section headings.
b) Do not delete spreadsheet columns/shaded rows, but you may insert more unshaded rows.
c) 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.
d) Input HRC Ref ID# and NI surname on the coversheet.

2. Module 1: General Information

Module 1 is now completed entirely online and is no longer part of the form. This module incorporates the Registration information, with some additional fields required at the full application stage. Some fields may be editable or updated from Registration.

Research Costs

Enter in the relevant totals for Staff Costs, Overhead, Working Expenses and Total Cost of Research (from the excel budget spreadsheet).

Named Investigators (NI)

All NI must be registered users of the HRC Gateway with a current profile, that must be updated annually.

3. Module 2: Proposed Research

3.1 Section 2A Summary of Proposed Research (one page only)

This section should clearly summarise the research proposal. The summary should be a maximum of **one page**. A clear and succinct summary including all the important points of the application can help reviewers get an overview of the proposal and is useful as a quick reference for assessing committee members. Use the suggested headings and add subheadings if required.

3.2 Section 2B Description of Proposed Research (10-page limit, excluding references)

The section headings provided should be used. Throughout your discussion, remember that your audience includes not only your discipline-specific peer reviewers, but also a more broadly experienced assessing committee. It is in your best interest to structure your discussion in a clear and logical fashion. Ideally, seek feedback from a colleague outside your immediate research area.

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

Rationale for Research

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

Fit with RFP

The relevance and contributions of this research application to the aims and objectives of the RFP must be clearly expressed. For example, what is the significance and contribution of the research to this research field; where relevant, how could the research impact upon health policy and/or the provision of health services? Rather than wasting valuable space with large amounts of background information on the general health problem, focus on how your research will address the problem and/or develop new knowledge.

Design and Methods

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

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

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

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

Responsiveness to Māori

How might your research contribute to the health needs of Māori? What is the health significance and context of this research to Māori? Discuss the incidence or prevalence in Māori, or indicate if not known to be significantly different from the general population. Have you sought advice for the study from a Māori researcher/representative?

Dissemination of Results and Knowledge Transfer

Provide full details of your proposed dissemination strategy. As all partnership initiatives are designed to contribute to an evidence base in key areas of need, and strengthen the links between policy and practice, this should include how the research results will be appropriately disseminated to the following end-users:

- Policy-makers, professional colleagues, health service funders and providers, the general public, study participants, iwi and other important groups.

As well as peer reviewed publications, dissemination examples include leaflets, reports, workshops, participant newsletters, guidelines, hui and public meetings, conference presentations and mass media items as appropriate. Processes for ensuring that all information is tailored to the needs of the intended audience, so that research findings can be of maximum utility, should be fully detailed.

Describe how knowledge transfer activities have been integrated in to the research plan. Specify who is responsible for any key knowledge transfer activities. **Expenses associated with certain dissemination activities may be included in your budget (see section 4F) but must be included in the budget justification section.**

Expertise and Track Record of the Research Team

Provide evidence that the team has the qualifications, experience and knowledge in the proposed research area; right mix of expertise, and appropriate networks and collaborations; history of productivity and delivery; and the right research environment/infrastructure to deliver the research and disseminate results.

Declare any career disruptions that may be relevant to your career history. A career disruption is defined as a prolonged interruption to an applicant's capacity to work due to pregnancy, major illness/injury and/or carer responsibilities.

The expertise and track record of each member of the team, (i.e., NIs), must be described. Committees consider the FTE of senior investigators on each proposal and weight their scoring on the expertise and track record of the research team accordingly, i.e., high scores should not be allocated on the basis of a senior NI who has a small percentage FTE involvement in the research. Include a brief description of the team's track record related to the proposal area, to demonstrate the ability to deliver proposed study outcomes. Highlight important skills, expertise and previous collaborations in the team that would support delivery of the proposed research. Justification for staff roles should be provided.

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

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

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

See Appendix 1 for clinical trial applications.

4. Module 3: References

Ensure this section starts on a new page.

Citations for key references in the text in Module 2 should be supplied. Details must include a **full list of all author(s),** title of article, journal, year, volume and page numbers. Asterisks are to be placed beside applicant's publications. If references are multi-authored, there is discretion to limit the author list to a more convenient number to fit any space limitations.

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

5. Module 4: Contract Information and Budget

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

Section 4E – entered online (Milestones & Objectives)

Sections 4F – 4I are to be completed on the separate Excel file (2019 BC Research RFP Project Budget Form).

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 actively contribute to this research. These may be research assistants, technicians, medical staff, interviewers and support staff or similar, whose names or position titles are listed in the budget under "Research Staff" and who have specific FTE involvements. Un-named postdoctoral fellows should be justified but it is recommended that named postdoctoral fellows should be included as NIs and should provide a CV. Assessing committees may decline funds for roles that are not fully justified or are simply described as a "training opportunity". Provide evidence that biostatisticians, data managers and health economists are integrated into the team as appropriate, e.g., sufficient FTE is allocated for each year of the contract. It is the responsibility of the applicants to ensure that no personnel in this section will exceed 100% FTE of their combined commitments during the term of the contract. The roles of students and casual staff should be justified under 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, and full costs for number of units requested. The application review process will consider the appropriateness of the budget and working expenses. If there are exceptional requests for working expenses, ensure that the assessing committee will clearly understand why the requested materials, travel, research tools and significant one-line items are necessary for the successful completion of the research. Clearly justify the role of students (must be named) and casual staff so that the assessing committee can appreciate how these persons are necessary for the proposed research. It is the responsibility of the applicants to ensure that no students in this section will exceed 100% FTE on their combined commitments with the Host Institution during the term of the contract. The HRC encourages the inclusion of allowable costs associated with knowledge transfer activities.

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

List all supporting budget documents in Section 4D (Letters of Collaboration/Supporting Documents Index) and upload separately into Gateway.

5.2 Section 4B Previous/Current Contracts and Awards

List Contracts awarded to the First Named Investigator within the past 5 years

Using the table provided, outline current and previous support from any agency that has been received by the First Named Investigator. Copy the table and repeat for each received grant as

required. This section is intended to provide the HRC reviewers and committee members with an overall summary of the first named investigator's abilities to secure research funding for this type of research.

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

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

Previous HRC End of Contract Reports

End of Contract or Final reports for recently completed HRC contracts are part of this application. Ensure that reports for the **First Named Investigator** of this application for contracts awarded in the last 6 years are uploaded with other application files to the online submission system. Do not upload full deliverable reports from HRC **Research Partnerships** contracts; only upload the **executive summary** of deliverable reports.

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

5.3 Section 4C Other Support

Other Research Applications Awaiting Decision and Co-Funding

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

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

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

Financial or Other Interest(s)

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

A conflict of interest is a situation in which an individual's financial relationships or interests may compromise, or have the appearance of compromising, the individual's professional judgment in conducting or reporting research. In the event that an applicant has identified financial or other interests in a funding application, the applicant should also outline the specific details of their proposed conflict management strategy.

5.4 Section 4D Letters of Collaboration/Supporting Documents List

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

The documents themselves should be uploaded separately into Gateway.

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

letter of collaboration recognises their intended commitment to the conduct of the proposed research and timeline of their involvement.

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 used for contract reporting templates.

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

Objectives

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

Note that the HRC suggests a minimum of 3 objectives, with sufficient standalone operational detail and scientific information included to be able to inform progress assessment in subsequent years. There is no limit to the number of objectives and milestones.

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.

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

5.6 Section 4F Research Proposal Budget

Further instructions are contained in the Notes tab of the file.

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 are GST exclusive are 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.

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; time only permissible. The monetary value ($) should be the **actual** salary amount that the named staff member is expected to receive for the research proposed. Salaries for year 2 may be increased by a maximum of 3% per annum or by more if specific details of expected promotion are provided and fully justified in Section 4A.

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

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

Do not enter **Salary associated costs** (i.e. amounts requested for employer's contribution to approved superannuation schemes and accident compensation levies) for Research Staff in this Salary section – instead enter them in the **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 (**note:** the HRC doesn't cover overheads for overseas based organisations). The subcontract/MOU total should then be entered under 'Working expenses - Subcontracts' for each year.

a) 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'.

b) 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 **fully** 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, or conference dissemination can be claimed if reasonable and justified).
- Conference allowance: The maximum allowance for conference attendance is $1,000 per annum per Named Investigator if **fully supported at 100% FTE** by the grant and must be fully justified. The allowance cannot be distributed proportionately between grants. This allowance is distinct from the cost to disseminate findings from this proposed research; this cost must also be fully justified. Fares and allowances should be calculated in accordance with the regulations and scales of the host institution.
- **Note**: If you are intending to ask the HRC's Data Monitoring Core Committee (DMCC) to monitor this study, there is no cost involved in using the HRC's DMCC. However, if the DMCC agrees to monitor the trial, costs for members of the study team (including the study statistician) to attend the meetings (and preparation of biannual statistical reports) will need to be included in the budget for the application. If you have any questions please contact the Secretary to the DMCC, ethics@hrc.govt.nz.

Subcontracts/Memorandum of Understanding (MOU)

Subcontract staff are not employees of the host institution. The salaries for these staff and all other expenses (e.g. working expenses) requested for the subcontract should appear in a detailed MOU between the host institution and non-host institution. A MOU should also include overhead calculations for salaries (**note:** the HRC doesn't cover overheads for overseas based organisations). A *pro forma* MOU is available upon request from the HRC. If a MOU is greater than $50,000, all expenses requested should be broken down into the appropriate categories in Section 4G (MOU Budget). Upload the MOU with this form. 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. The amounts for each year should be entered separately in the budget form and the percentage rates for both ACC and super should be noted (and justified where required).

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.

Note: For this RFP, overhead costs can only be claimed for the share of the total funding pool that is derived from government funds (i.e. no overhead costs can be claimed for the share of the funds provided by non-government organisations). The application budget form been configured to automatically provide the correct total research costs once the appropriate overhead rate for the host institution has been entered in the spreadsheet.

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 of Section 4G for each subcontractor. The overhead rate used should be that for the Host Institution of the subcontracted staff, not that of the main Host Institution of the applicant (**note**: the HRC doesn't cover overheads for overseas based organisations). The total dollar amount for each year should then be entered under 'Working expenses - Subcontracts' and a copy of the subcontract/MOU should be uploaded separately in HRC Gateway.

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

All subcontracts/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 (e.g., 4.5%) are not allowed. Indicate when NIs are "Time Only" (i.e., **not** receiving salary for their involvement in the project). Identify all Postgraduate students by "Masters" or "PhD" as well as by their names. Ensure the FTE figures are the same as those in the budget and MOU budget sections (Sections 4F and 4G), as well as in Module 1. Heads of Department will be required to agree to provide workload relief for research staff working on HRC contracts (Principles of Full Cost Funding).

5.9 Section 4I List of Collaborators (National and International)

Please complete the Collaborators section (not Named Investigators) by providing full name, organisation, and country (the location where the organisation is based and the collaborators undertake their research).

For **collaboration purpose** select one of the following options: Research; Commercialisation; Knowledge transfer.

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

6. Module 5: NZ Standard CV Template

Upload a CV for all Named Investigators (include those on MOU).

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

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

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

7. Module 6: Research Classification

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.

7.3 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	✓
Biomedical		
Gene	Research into the genetic basis of disease, identification of genes involved. Linkage analysis falls here and not under clinical studies.	
Cell Biology	Analysis of molecular-level interactions. This includes protein-protein interactions, determination of the function of genes involved in diseases, and whole cell studies (e.g. immunological studies, transfections, *etc*).	
Physiology	This includes all physiology and anatomy. Animal models of disease are included in this category, and studies on host-pathogen interactions.	
Diagnostics	This includes innovations, and the development/refinement of new or existing diagnostic tools.	
Pharmaceuticals /Treatments	This includes the development of new pharmaceuticals (drug design and development), as well as new treatments for diseases (e.g. vaccines, other therapies).	
Clinical		
Clinical Studies	Research involving human subjects. This excludes research in which samples from human subjects are used for fundamental biomedical research, such as genetic linkage analyses.	
Clinical Trials	Randomised clinical trials, usually randomised controlled clinical trials.	
Health Services		
Health Economics	Research into the cost-effectiveness of treatments/services etc.	
Clinical Services	This includes primary and secondary care services. Access to and appropriateness of services are also included, and safety of services and compensation. Macro-level analysis of health system changes falls into this area.	
Public Health		
Knowledge Resources	This includes all epidemiology, underpinning social science (qualitative and quantitative), development of tools and new methodologies, and development of indicators.	
Risk Factors	Research linking life experiences, behaviours, exposures *etc.* with health outcomes.	
Interventions	Research that includes the design and evaluation of interventions.	
At-Risk Populations	Includes research on specific population groups. These groups may be based on age, ethnicity, occupation, *etc*. Includes research using diagnostics in a particular group.	
Community services	Research around community-run services and community groups, e.g. Marae-based healthcare services.	

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

Issues with methodological quality and poor demonstration of knowledge of clinical trial conduct are generic weaknesses that have been highlighted by CTAC. In order to improve the 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 trial protocols and applications to the HRC should reflect protocols that conform to the SPIRIT 2013 guidelines.

With regard to the content of HRC applications, consideration should be given to all 33 items on the SPIRIT checklist, with particular attention to the items listed in the Methods section (items 9 – 23). Addressing these items is likely to improve methodological quality and enhance the demonstration of knowledge of clinical trial conduct. Furthermore, applicants should give consideration to designing phase III trials with 90% power to detect well justified minimum important differences. Exceptions would include, a research question of particular importance to New Zealanders that can only be addressed in New Zealand, and the trial size is limited by the pool of patients and the pressure for a timely answer.

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

It has also been noted that a significant number of clinical trial research proposals are requests for funding for the New Zealand arm of an international study. Clear administrative information relating to Funding (SPIRIT item 4) is required in Section 4C/Co-Funding of the application form, including the status of all sources of funding and whether the proposal is dependent on international funding. Roles and responsibilities (SPIRIT item 5) should be stated explicitly in Section 2B/Expertise and track record of the research team, including the specific role of the 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), 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: Assessment Criteria

A. Fit with the Request for Proposals (RFP)

7 = The applicants have convincingly demonstrated that the proposed research fully aligns with all of the objectives and requirements as stated in the RFP. The proposal clearly conveys a thorough understanding of the objectives and requirements and has outlined how the components of the RFP will be addressed.

4 = The applicants have attempted to align the proposed research with the objectives and requirements as stated in the RFP. The proposal does not address all of the objectives and requirements, or does not sufficiently address all of the objectives and requirements to provide the desired outcomes of the RFP. The proposal conveys an understanding of the requirements and has attempted to outline how the components of the RFP will be addressed.

1 = The applicants have not aligned the proposed research with the objectives and requirements to provide the desired outcomes of the RFP. The proposal conveys no understanding of the objectives and requirements of the RFP.

B. Scientific Merit

7 = The rationale for the proposed research is extremely well made. The aims and (where appropriate) hypotheses are excellent. The proposed research may represent a highly original and innovative approach to addressing the health question. Original findings are highly likely to result.

4 = The rationale for the study is well made. The aims and (where appropriate) hypotheses are acceptable. Original findings may result.

1 = The rationale, aims and hypotheses for the study are poor or absent. Original findings are unlikely to result.

C. Design and Methods

7 = The proposed study design is excellent. The methods and proposed analyses are very comprehensive and clearly appropriate. The applicants demonstrate full awareness of the relevant technical issues. The statistical power (where appropriate) is sufficient to ensure a definitive outcome and the statistical analyses are well-developed. It is difficult to suggest improvements.

4 = The study design is adequate. There may be either insufficient detail for parts of the method and proposed analyses, or the study would benefit significantly by improvements in a one or more of these areas.

1 = The study design is unacceptable as proposed. Either the design is inappropriate, or there is no (or very little) detail on the methodology and proposed analyses.

D. Expertise of the Research Team

7 = The research team collectively have outstanding academic qualifications, as well as excellent topic based knowledge and experience to undertake the proposed research. They have an outstanding publication track record in major peer reviewed scientific journals as well as other professional publications, and/or substantial experience in disseminating research results.

4 = The research team collectively have the academic qualifications, topic based knowledge, and experience to undertake the proposed research. They have a track record of publication in peer reviewed scientific journals and other professional publications, and/or experience in disseminating research results. There are some areas, however, where this has not been fully demonstrated.

1 = The research team collectively have inadequate and/or inappropriate academic qualifications or research backgrounds to undertake the proposed research. They collectively have a weak publication record and there are serious doubts as to whether the research will be completed and disseminated appropriately.