PARTNERSHIP
APPLICATION GUIDELINES

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

July 2020

2020 NATIONAL BREAST CANCER REGISTER REQUEST FOR PROPOSALS (RFP)

APPLICATION GUIDELINES

To use with form:

2020 National Breast Cancer Register Application Form

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Part A: Introduction

Please note that these guidelines have been specifically tailored for the Request for Proposals entitled **2020 National Breast Cancer Register**.

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 to continue in the process.

Applicants are first required to submit a Registration before the submission of a full 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.

All forms are available on HRC Gateway.

Event	Description	Date Due
Registration	Complete and submit online form on HRC Gateway	**1pm, 2 September 2020**
Full Application	Complete online sections and upload to HRC Gateway: - 2020 National Breast Cancer Register Application Form - 2020 National Breast Cancer Register Budget Form - CVs for Named Investigators	**1pm, 16 September 2020**
Peer Review	HRC coordinates the external peer review of all full applications	
Applicant Response (Rebuttal)	Research team to complete and submit rebuttal template via HRC Gateway	**1pm, 4 December 2020**
HRC Assessment	Independent assessing committee undertakes assessment	
Results	Applicants notified of outcome	**February 2021**

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 an Application

1. Use of Application Form

1.1 When to use the Application Form

The **2020 National Breast Cancer Register Application Form** must be used when submitting a full application.

1.2 Prior to submission

The HRC only accepts applications on HRC Gateway. Prior to any submission, Named Investigators must have a current Gateway account, that must be updated annually.

Before submitting this application form, applicants should read (in addition to the Request for Proposals):

- This document for information on submitting an application and specific instructions
- The accompanying HRC External Peer Review Guidance document to understand application assessment
- Guidelines on Ethics in Health Research
- Guidelines for Researchers on Health Research Involving Māori
- Guidelines for Pacific Health Research.

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

1.3 New host organisation

New host organisations that have not previously been funded by the HRC will be required to provide due diligence information before a contract can be offered. Please contact the HRC for further information. The host organisation is the organisation that will be responsible for administering a contract awarded.

Host organisations are also responsible for ensuring that New Zealand is the principal domicile[1] and principal place of employment for the First Named Investigator. By submitting an application, the host is satisfied that this criterion has been met.

2. Format

2.1 General formatting

Proposals must be written in a clear, concise manner with sufficient detail to enable the reviewers to understand the scope and implications of the proposal.

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

Use the correct HRC form as it contains special features.

Applicants must:

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

[1] Principal Domicile means the holding of New Zealand citizenship, or a residence class visa under the *Immigration Act 2009*, and either be domiciled or residing in New Zealand with the intention of residing here indefinitely, having done so for the immediately preceding 12 months. According to Section 4 of the *Immigration Act*, “residence class visa” means a permanent resident visa or a resident visa.

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 not required

Applications must be submitted through HRC Gateway and, for this round, printed copies of the applications are not required.

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.

HRC Gateway will allocate file names.

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

3.3 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.

4. Closing dates for Full Application

4.1 Submission of Full Application online

Upload the **2020 National Breast Cancer Register 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 is **1pm, 16 September 2020** via HRC Gateway. 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. No applications will be accepted after the closing date and time unless written authorisation has been received from the HRC at least one week prior to the closing date.

4.2 Paper copies not required

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. However, for this round, paper copies are not required.

4.3 Incomplete applications

Incomplete applications will be regarded as withdrawn.

5. Privacy provisions

5.1 Statistical and reporting purposes

The information provided in an application will be used for assessing that application and, in a non-identifiable form, some information will be used for HRC statistical and reporting purposes. The HRC undertakes to store all applications in a secure place, which may include the New Zealand Research Information System (NZRIS) 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, and to external reviewers relevant to the review of the application.

5.3 Media release

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

5.4 Official Information Act

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

6. Enquiries

All enquiries related to HRC applications are 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:

Lea Narciso	Research Investment Manager, Research Partnerships, HRC	Email: lnarciso@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.

Registrations are due by **1pm, 2 September 2020**.

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 does not 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.

Incomplete or late Registrations will not be accepted.

Completing the registration

This Module must be completed in HRC Gateway. Start the application process by clicking on the 'Apply now' button on the **2020 National Breast Cancer Register** information page. The 'Apply now' button will only appear when the application submission period is open. Clicking on the 'Apply now' button will open a dialogue form where the following information will be required.

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.

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.

If the host organisation has a research office with more than one staff member, please select the contact in the research office who will most likely be handling the application, or who will be the principal contact.

If the host organisation has more than one research office, please select which research office will be handling the application.

2nd Step

First Named Investigator

Some of this information will be automatically populated from the First Named Investigator's (NI) profile in Gateway (e.g., Organisation and department). If the profile is not current, details must 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. Once an application is created, the First NI cannot be changed.

3rd Step

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

Named Investigators

All NIs must be registered users of HRC Gateway before they can be added to the application. User profiles must be updated by each NI before submitting an application so that the current details are in the application. Click on the "Update" button to enter additional information as requested. All NIs on successful applications may be cited by the HRC in its various communication channels.

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.

Note: Ethnicity, iwi, clinician, or practising clinician are not required to be entered as these details will automatically populate from the individual person profiles. Each Named Investigator will need to sign-in to HRC Gateway and check and update their details before applications are submitted.

You may wish to designate a hapū, iwi 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.

FTE for each Named Investigator 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. **The FTE value should be the value for the first year of that investigator's involvement (from the budget spreadsheet)**.

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).

Type of research

Select from the drop-down list what you consider the most appropriate term for broadly describing the research proposal for assessment purposes.

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

The lay summary should summarise the intent of the research, planned methodologies, as well as the potential health benefits or outcomes that could arise as a result of HRC supporting this application. This information will be used to inform the Council in the final approval process if the application is recommended for funding. The lay summary will also be publicised through the HRC's communication channels (e.g. website) and should be written to be readily understood by members of the public (150-word limit).

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 Application 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 **2020 National Breast Cancer Register Application Form** contains a Coversheet, Module 2, Module 3 and Sections 4A-4D of Module 4. Supporting documents (as listed in Section 4D) are now required to be uploaded separately in HRC Gateway. The contract information and/or budget Excel file for Module 4 must be uploaded separately. Module 5 contains NI CVs that are uploaded separately. Module 6 is the research classification of the research that must be completed online.

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

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

1. Use of Application Form

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

The form is compatible with Windows PC and MAC computers. The form has default formatting that conforms to HRC requirements. Figures and tables are best pasted in from a draft document instead of created directly in the form.

Remember:

- Input HRC reference ID# and First Named Investigator surname on the coversheet.
- 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.
- Enter information only at the indicated form fields.
- Do not reformat Module and Section headings.
- Do not delete spreadsheet columns/shaded rows, but you may insert more unshaded rows.

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.

FTE for Named Investigators (NI)

A defined FTE value will need to be entered for each named investigator (and for the First Named Investigator). The FTE value should be the value for the first year of that investigator's involvement (from the budget spreadsheet).

Objectives and milestones

Objectives and milestones are **assessed** along with budget requests, included in awarded research contracts, and used for contract reporting templates. This section is now inserted immediately after the list of Named Investigators in the final system-generated PDF.

Poorly described milestones and objectives can affect application scoring, or result in delayed processing of an application or requests for further information at contracting.

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

Milestones

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

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

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

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

3. Module 2: Proposal

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

This section should clearly summarise the research proposal. A clear and succinct summary including all important points of the application provides a good overview and is useful as a quick reference for assessing committee members. Use the headings and add subheadings if required.

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

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

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

The HRC Data Monitoring Core 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 DMCC in particular see (https://www.hrc.govt.nz/resources/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

Consideration should be given to how the research will contribute to the health needs of Māori, recognising that the most appropriate approach to advancing Māori health will vary by the type of research and consideration should be context-specific, as determined by the nature and scope of the research. For example, 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. Are you partnering or engaging with Māori, or have you sought advice for the study from a Māori researcher/representative? Does the research team have the required skills and expertise, and builds capability and capacity of the Māori health research workforce?

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 into 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 4E) 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.

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

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

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

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

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

See Appendix 1 for 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. There is no limit to the number of reference pages. Reference to Māori terms in the application with brief translation should be included here. Asterisks are to be placed beside applicants' publications. Endnote lists must be copied into a plain text editor before pasting in here. Details must include a **full list of all author(s)**, title of article, journal, year, volume and page numbers; however, if references are multi-authored, there is discretion to limit the author list to a more convenient number to fit any space limitations.

5. Module 4: Contract information and budget

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

Sections 4E – 4H are to be completed on the separate Excel file (**2020 National Breast Cancer Register Budget Form**).

5.1 Section 4A: Justification of expenses

Justification of research staff

Use this section to justify the role and FTE of the Named Investigators and any other research staff listed in section 4E. Also explain the role of ALL OTHER personnel (named or un-named, funded or not funded by the proposal), who will actively contribute to this research. These may be research assistants, technicians, medical staff, interviewers and support staff or similar, whose names or position titles are listed in the budget under "Research Staff" and who have specific FTE involvements. Un-named postdoctoral fellows should be justified but it is recommended that named postdoctoral fellows should be included as Named Investigators and should provide a CV. Assessing committees may decline funds for roles that are not fully justified or are simply described as a "training opportunity". Provide evidence that biostatisticians, data managers, and health economists are integrated into the team as appropriate, e.g. sufficient FTE is allocated for each year of the contract. It is the responsibility of the applicants to ensure that no personnel 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". Any promotion of staff or increase in salaries over the term of the contract (beyond 3 percent annually) **must be clearly justified** in Section 4A.

Note: The HRC does not consider annual scale increments or across-the-board wage increases as promotions.

Justification of working expenses and casual staff

All items listed under Materials and Research Expenses in the budget should be justified, with costs broken down per item, and full costs for number of units requested. The application review process will consider the appropriateness of the budget and working expenses. If there are exceptional requests for working expenses, ensure that the 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 via HRC Gateway.

5.2 Section 4B: Previous/current contracts and awards

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

Using the table provided, outline current and previous support from any agency that has been received by **the First Named Investigator as principal investigator**. Copy the table and repeat for each received grant as required. This section is intended to provide the HRC reviewers and committee members with an overall summary of the First Named Investigator's abilities to secure research funding for this type of research.

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

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

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

Previous HRC 'end of contract reports'

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

- Ensure that reports are for the **First Named Investigator** of this application, when they were also the **Principal Investigator for a previously funded contract**, awarded in the last **5 years**.
- **Programme** contract reports for the **senior Named Investigators** who were the **Principal Investigator** can also be included, for contracts awarded in the last **6 years**.
- Do not upload full deliverable reports from HRC **Research Partnerships** contracts; only upload the **executive summary** of deliverable reports.

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

5.3 Section 4C: Other support

Other research applications awaiting decision and co-funding

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

Co-Funding

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

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

Financial or Other Interest(s)

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

A conflict of interest is a situation in which an individual's financial relationships or interests may compromise, or have the appearance of compromising, the individual's professional judgment in conducting or reporting research. **In the event that an applicant has identified financial or other**

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

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

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

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

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

5.5 Section 4E: Research proposal budget

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

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

Budget calculations and spreadsheet

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

The "Salary", "Working Expenses" and "Total Cost of This Research" are components of Section 4E. The spreadsheet automatically calculates totals for each year of costs. Insert more rows into the table if required.

The "Total Cost of Research" shaded section automatically calculates all 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 each year**, or by more if specific details of expected promotion are provided and **fully justified** in Section 4A. Note: the HRC does not consider annual scale increments or across-the-board wage increases as promotions.

The budget form does not accept FTE less than 3%. The HRC and 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 4F. The total GST-exclusive dollar figure for the subcontract/MOU should be all-inclusive, including overhead calculations. **Note:** The HRC does not cover overheads for overseas-based organisations. The subcontract/MOU total should then be entered under 'Working Expenses - Subcontracts' for each year.

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

c) Casual Staff (those persons without an on-going role or commitment to the research, but providing one-off services to the research on a part-time, hourly or per diem basis, e.g. interviewers) should also be requested under 'Working expenses - Materials and Research Expenses'.

Working Expenses

Working expenses include 'direct costs' only. The only exception is in the case of subcontracts, as described above. Estimates of costs should be expressed in current prices **exclusive of GST**.

Materials and Research Expenses

The direct costs of the research include all the disbursements that can be identified, justified and charged to a contract and may include the following:

- Research consumables (these should be itemised at current cost per unit and full cost for number required).
- Other costs **directly** related to the research – telephone calls/communications, mail and freight.
- Computer-related license fees for research-specific software; access to High Performance Computing infrastructure (NeSI).
- Minor research equipment (to a total of $5,000).
- A proportionate part of new specialised equipment (equipment to be acquired) may be included and **fully** justified on research applications (upload budgetary supportive documents separately via HRC Gateway and list in Section 4D).
- Depreciation on specialised equipment: depreciation and capital costs on existing equipment are included in the overhead rate. If an institution's auditors have certified that specific items of equipment have been excluded from the Research Rate, then depreciation on the excluded equipment can be included in research applications and justified in the same manner as other direct costs.
- Expenses of research participants.
- Costs associated with knowledge transfer activities.
- Travel costs **directly** related to the conduct of the research. Contract funds may be used to provide assistance with overseas travel provided the HRC is satisfied that such travel is directly relevant to the conduct of the research and that alternative sources of funding are not available. This is not intended to relieve the applicant's host institution of its obligation to assist with the costs of overseas travel by its employees.
- Costs for Masters ($20,000 pa) or PhD ($30,000 pa) named students only can be claimed if a description of the student's research project is provided in Section 4A. Funds will be conditional upon the institution arranging a tax-free stipend that satisfies the Inland Revenue and host institution's rules. Ensure that PhD students requested are supported for three years of PhD study, either entirely or partly through this project. **Note: Students' fees and thesis costs cannot be claimed**.
- Dissemination of research results (fair and reasonable charges associated with the approved publication of the results of HRC sponsored research in journals, reports, monographs or books may be paid from contract funds. Also, costs incurred from other forms of dissemination, such as meeting with community groups, or conference dissemination can be claimed if reasonable and justified).
- Conference allowance: The maximum allowance for conference attendance is $1,000 per annum per Named Investigator **if fully supported at 100% FTE** by the grant and must be fully justified. The allowance cannot be distributed proportionately between grants. This allowance is distinct from the cost to disseminate findings from this proposed research; this cost must also be fully justified. Fares and allowances should be calculated in accordance with the regulations and scales of the host institution.
- **Note:** If you are intending to ask the HRC's Data Monitoring Core Committee (DMCC) to monitor this study, there is no cost involved in using the HRC's DMCC. However, if the DMCC agrees to monitor the trial, costs for members of the study team (including the study

statistician) to attend the meetings (and preparation of biannual statistical reports) will need to be included in the budget for the application. If you have any questions please contact the Secretary to the DMCC, info@hrc.govt.nz.

Subcontracts/Memorandum of Understanding (MOU)

Subcontract staff are not employees of the host institution. The salaries for these staff and all other expenses (e.g. working expenses) requested for the subcontract must appear in a detailed subcontract/MOU between the host institution and non-host institution. A MOU should also include overhead calculations for salaries.

Note: The HRC does not cover overheads for overseas-based organisations. If a subcontract/MOU is greater than $50,000, all expenses requested should be broken down into the appropriate categories in Section 4F (MOU Budget). Upload the MOUs separately via HRC Gateway (see Section 4D above).

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

Salary-associated costs

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

International expenses

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

Total cost of research

Enter the appropriate overhead rate (OHR) in the budget. Researchers should seek advice from their host institution Research Office on the costing of their research applications and the overhead rate negotiated with the HRC.

After entering the appropriate overhead rate, the total cost of the research will be automatically calculated. Enter this amount in the online section of the research application.

Note: For the 2020 National Breast Cancer Register 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 50% share of the funds provided by the non-government partner). The application budget form has 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.

5.6 Section 4F: MOU Budget

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

Note: The HRC does not cover overheads for overseas-based organisations.

The total dollar amount for each year should then be entered under 'Working Expenses – Subcontracts' and a copy of the subcontract/MOU should be uploaded separately in HRC Gateway.

A CV must be provided in Module 5 for all NIs on MOUs to enable the Science Assessing Committees to determine whether the investigator's expertise is appropriate and/or necessary.

Without this information the Science Assessing Committees may decide not to support the budget for the MOU. CVs are not necessary for employees of commercial enterprises providing service for fees.

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

5.7 Section 4G: FTE summary

List the time involvement of ALL personnel (including those on a subcontract/MOUs) in terms of Full Time Equivalents, e.g. 10% FTE. Give all names (for un-named positions, indicate as “Technician”, “Research Nurse” and “Postdoctoral Fellow”, etc.). Half percentages (e.g. 4.5%) are not allowed. Indicate when NIs are “Time Only” (i.e., **not** receiving salary for their involvement in the research project). Identify all Postgraduate students by “Master’s” or “PhD” as well as by their names. Ensure the FTE figures are the same as those in the budget and MOU budget sections (Sections 4E and 4F), as well as in Module 1. Heads of Department will be required to agree to provide workload relief for research staff working on HRC contracts (Principles of Full Cost Funding).

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

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

For **Collaboration Purpose** select one of the following options: Research; Commercialisation; Knowledge transfer.

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

6. Module 5: NZ standard CV

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

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

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

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

7. Module 6: Research classification

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

7.1 Section 6A: ANZSRC and keywords

Categorise the proposed research using the ANZSRC codes for the Fields of Research (FOR) and Socioeconomic Objective (SEO). Enter the percentage to the nearest 10% for each category to a total of 100%.

Enter keywords that categorise the research.

7.2 Section 6B: Economic benefits

Please provide a brief description of any potential economic benefits you consider may arise from your research. If no direct economic benefits are anticipated, please state this rather than leaving the field blank. The HRC’s interpretation of economic benefits is broad and includes:

- Contributing to maintaining a healthy and productive population;
- Contributing to an efficient and cost-effective health system; and
- Value generated from IP and innovation.

7.3 Section 6C: Health issues and mapping category

Health issues

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

Mapping category

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

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

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

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

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

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

Applicants are encouraged to consider the broad expertise of their audience (CTAC) when describing their trial protocol. For example, when describing sample size (SPIRIT item 14) in Section 2B/Design and Methods of the 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

Applications assessed and scored by external peer reviewers and Assessing Committee members will utilise the following criteria and anchor point descriptors. The best possible score for any specific application is 28.

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.