Guidelines for completing the Application Form for Approval of a Research Project at ADHB (form for the Standard Approval Pathway) v3

All research at the ADHB requires Institutional Approval. The standard approval pathway is via the Research Review Committee (RRC) and the Māori Advisor for Research. The RRC and the Māori Advisor for Research generally review all research requiring the approval of a Health and Disability Ethics Committee (HDEC), all research requiring a budget, and some lower risk studies not requiring HDEC approval, but where the research affects the normal care of patients. If your research project has none of these features (e.g. is an audit or related activity) it may be appropriate for the ADHB low risk study review process (use below link for more information).
http://www.adhb.govt.nz/ResearchOffice/Research-Approval/Expedited/expedited.htm

The ADHB standard research approval pathway generally runs in tandem with the HDEC approval.

1. The RRC review

The RRC will review all research projects involving ADHB for scientific merit and rigor, to ensure that research does not negatively affect ADHB core functions and resources, and to ensure research is financially viable. Decisions to support applications need, at a minimum, to demonstrate the following characteristics:

- Evidence of scientific rigor
- Consistent with ADHB policies, goals and objectives
- Complies with all current regulations, standards, guidelines and ethical approval processes

2. The Māori locality review

The purpose of the Māori locality assessment is to increase Māori participation in research occurring at ADHB with the end goal of improving health outcomes for Māori and other populations.

The focus of the Māori locality assessment is to ensure that research projects meet the requirements of the Treaty of Waitangi and Tikanga Best Practice.

3. Applying for ADHB Approval

2.1 General

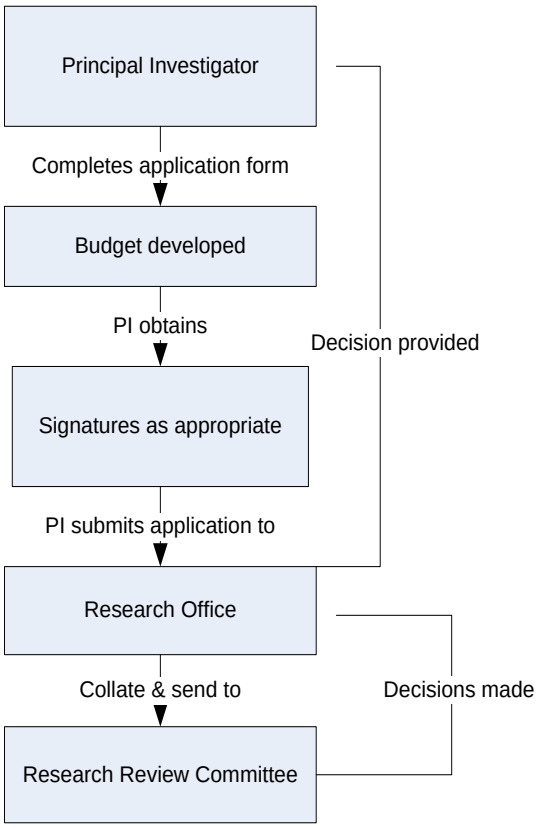
Use the **Application Form for Approval of a Research Project at ADHB** to make a request for approval to undertake research within the ADHB.

The timetable for RRC meetings to consider applications is on the Research Office (RO) Web site.

1. The form must have signatures indicating approval at a minimum from the Service Clinical Directors of all ADHB departments or service areas having significant involvement in the project.

2. The completed application and associated documents are forwarded to the RO. The RO submits final documents to the RRC and the Māori Advisor for Research.

3. The RRC and the Māori Advisor for Research will review the application and convey the response to the RO. The RO will communicate with the principal investigator / designate conveying the decision.



2.2 Application Form Guide

Section A: General Summary

Please complete the general information requested.

- Provide the name, role, address and contact details for the Principal Investigator/Co-ordinating Investigator[1] who should either be the Principal Investigator/Co-ordinating Investigator according to the ethics application, or the lead named investigator at the ADHB site.

- Provide the names and addresses of all other ADHB staff that will have the status of investigator on the research project.

- All applicants must declare whether the research project is a clinical trial/interventional study.

[1] Note that the use of the terminology of Co-ordinating Investigator (as per New Zealand Health and Disability Ethics Committee's SoPs) and Principal Investigator are used interchangeably in this document.

- If the research project will have a designated study co-ordinator, provide their name and contact details.

- For non –ADHB researchers an ADHB Contact is necessary when the research study does not include an ADHB investigator directly. This person agrees to be the link for the project within the ADHB. They are responsible for ensuring that the external researchers are aware of any relevant ADHB processes and policies. They need to ensure that confidentiality agreements are signed and that, if appropriate, ID badges are obtained. This person must sign on the application form to confirm this agreement.

- Scientific Review –Has this project been scientifically assessed? Please describe and provide copies of the reviews (i.e. HRC or AMRF review comments).

- Conflict of Interest, please refer to the ADHB policy on Conflict of Interest and briefly describe the conflict here i.e. partner in development, shareholder. It is essential that any conflict issues are mentioned in your ethics application.

Section B: Document checklist

This section describes other documentation required for the RRC review of the application, in addition to the fully signed application form[2].

- All applications must be accompanied by a detailed protocol.

- All interventional studies and most research directly involving patients that is more than minimal risk will need an associated Health and Disability Ethics Committee (HDEC) application. If you are a student or staff member of a University your project may require your University's ethics committee's approval even if the project does not require HDEC approval. Provide the institutional ethics committee application form if so.

- The research will not be required to have prior ethical approval for RRC to review, but if you have received approval (full or provisional) from an ethics committee, submit with your application.

- All Participant Information Sheets (PIS) and Informed Consent forms (ICF) to be used in the research must be provided. Provide age-appropriate and

[2] Legal review (where required, e.g. when there will be a research contract with an external organisation) is conducted separately to the RRC review but also coordinated by the Research Office. However, it is recommended for the sake of timeliness that draft legal documents are submitted to the Research Office in a parallel time frame with the RRC review. Go to the below link for more information about ADHB legal review of research document http://www.adhb.govt.nz/ResearchOffice/Pre-Registration/Legal/legal_review.htm

culturally-appropriate versions if children, young adults or specific populations are being targeted for the study. When participants will be recruited from Auckland or Waitemata DHBs you must include the below Māori cultural and research support contact details in the PIS or ICF.

(If you require Māori cultural support, talk to your whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324
If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext 3204)

- All commercial studies and all studies with either independent funding or involving use of ADHB resource (or both) need to be accompanied by a fully signed ADHB budget form.

- If the research involved the non-standard (i.e. not required for normal care of the participants) collection, transportation, storage or disposal of human tissue the application should be accompanied by a letter from the central laboratory detailing how these procedures will be undertaken.

- Questionnaires are vital if the research involves evaluation (e.g. validity, reliability) of a questionnaire or when a questionnaire has been specifically developed or updated to collect the study data. You do not need to submit questionnaires with your application if they are standardised instruments.

- Provide evidence of any consultation with Māori that has been undertaken for the research. This is required for research that is Māori – focussed or using Kaupapa Māori methodology. For other research consultation is recommended but not required. You can also provide evidence of Māori Tikanga/cultural best practice and safety training that the investigators and research staff have undertaken. Māori research review is undertaken by the Māori Advisor for Research (or designate), but coordinated by the Research Office. It will be organised automatically when the documents for RRC are submitted.

- If you have made an application to a funding body (e.g. A+ Trust, Green Lane Research and Education Trust, HRC) to cover the costs of the research, include with the RRC application. The Research Office will not issue final approval for the study until funding is confirmed.

Section C: Proposed Research

The RRC will review this section for their scientific assessment. Although two assigned reviewers will look at the full set of documents submitted, most of the RRC members will look at only the application form and budget so it is important that all

information relevant to the scientific conduct of the study is described (don't just refer to the study protocol).

Research design (or research proposal) should be organised under the below headings:

- Background/Justification - Why is it important to do this research project; is there equipoise around the study question?; is there a reason for targeting a specific group/ demographic of patients?

- Aims/Hypotheses – what is it you are intending to discover? Have you got predictions about the outcomes based on the literature/background?

- Research Design – what type of study design will you use to address the study question (e.g. retrospective/prospective, interventional/observational, between groups/repeated measures etc.)?; describe the study population including inclusion and exclusion factors; how/when/where/by whom will participants be screened for inclusion and recruited?; what is the sample size and how has this been determined (e.g. with a power analysis); what data will you collect or what instruments will be used?; describe any risks and moderators for minimizing risks including a stopping plan where relevant.

- Endpoints/Analyses – how will you evaluate the data/information collected for the research to answer the study questions? What is the statistical analysis plan? How will the outcomes be represented? How will the outcomes be translated to inform practice?

Throughout, it is important that the research proposal is very clear about how, where, when and by whom study activities will take place, as this will inform the RRC about required involvement of ADHB staff, equipment and premises. RRC need to ensure that the conduct of the study will not disrupt the normal care of patients (for instance, could extra procedures carried out for the research affect access to care for patients not involved with the study?). External researchers recruiting patients from ADHB should be clear about how patients will be identified and approached, in what setting, and how/whether ADHB staff assisted in this process.

Clinical safety: These questions are about research procedures carried out by personnel of other ADHB departments or servicer areas (not the principal investigator's). Their purpose is to remind researchers to consider if there are any risks that study procedures might not be carried out as per the protocol when performed outside their department. Researchers should explain the steps that will be taken to ensure all personnel involved with the study will follow the protocol and know who to contact if they have questions.

Timeline: Include a time line illustrating how the research will be staged over the anticipated study duration, i.e. participant recruitment the subsequent visits etc,

anticipated final visits and final report dates. Be realistic about the start date– the project can't possibly begin until the ADHB (and ethics in most cases) review processes have been completed and the study is fully approved, so factor this in. You should have well developed assumptions about the time it will take to recruit the required number of eligible patients (based, for instance, on prior audit of the study population and complications/co-morbidities, plus factors that might affect recruitment such as burden of participation).

Section D: Responsiveness to Māori

This section of the application form is read by the Māori Advisor for Research as part of the Māori locality assessment. The relevant information is now required in the application form whereas previously it was obtained from the application for ethical approval and related documents. This change has been made for the sake of consistency of process, as since 2012 institutional ethics committees as well as HDECs review health and disability research, and the different committees have different requirements for Maori responsiveness. Some of the questions have been taken directly from sections p.4 and f.1 of the HDEC Main (application) Form and applicants can cut and paste from this form if appropriate.

Section E: Financial

Read this section even if you think it won't apply to you. All applicants must provide some information in this section even if there will be no budget required at ADHB.

Budget attached? Your application will require a budget if a) it is a commercial study, b) there will be income/funding coming to ADHB for the research, c) there will be use of ADHB consumables for the research, d) equipment will have to be purchased by ADHB, e) ADHB will have to employ new staff or pay a contractor or sub-contractor, f) there will be extra tests or procedures with known costs performed at ADHB, g) the study will require a new admission or longer hospital stay for patients, h) the study will require FTE of research-only staff or any staff named on a research contract, i) there will be costs of participation for patients (e.g. travel, parking), j) access will be required to archived or paper clinical records.

Justify why no budget attached: If you are not submitting a budget with this application please explain why a budget is not required (i.e. none of the above apply). Some funded research projects will not require a budget if none of the costs sit with ADHB, for instance if all study personnel are employed by another organisation.

Research with commercial funder: These questions are to enable the RRC to determine if commercial fees and overheads ought to apply when a study is presented as investigator initiated but funded by a commercial entity. If the research is not in this category then these questions can be skipped. If RRC deem that the funder will be the principal beneficiary of the research, or otherwise have a

substantial interest in the research for potential commercial advantage, the RRC may require the budget to be resubmitted with commercial fees and overheads.

Standard care, extra procedures for research and resource impact: If the research will involve ADHB patients, describe the normal care pathway for these patients for the time period they will be participants.

Describe any extra procedures, tests or activities participants will undergo that are carried out for the research and are not part of standard care. Extra procedures that will incur costs for ADHB (e.g. x-rays, blood draw, physiology lab, cath lab, admission or extra overnight stay) will need to be covered in the budget. Even if you don't think there will be any costs for the extra to standard procedures in your study, describe these anyway. Note that extra to standard procedures will not need to be budgeted if they are not being carried out at ADHB or by ADHB staff.

Please describe the impact of you study has on specific resource use and potential impact on access to these services for normal patient care. If your study utilises resources that are under pressure (e.g. radiology, echocardiography), you must describe the arrangements that illustrate how your project will have no impact on the use of these services for standard patient care (i.e. for patients who will not be participants in the study) or report that these services will be undertaken privately by another organisation.

Breakdown of budget: If there will be income to or costs for ADHB you will need to submit a budget with your application form and complete this section. Work with your research or service accountant to develop your budget identifying all costs (direct and indirect) and revenue sources (see template on RO website).

Breakdown the budget according to the categories provided in the application form. For the categories relating to participant-related costs (e.g. laboratories, radiology, pharmacy (dispensing), travel vouchers, CRF completion and study visits), work out the costs per procedure for one patient, the combined costs in that category per patient, and the total for the predicted number of patients to be recruited. The dollar amounts given in the breakdown must be consistent with those in the budget.

Documents to accompany the budget are (where relevant) all agreed quotes and service delivery agreements i.e. pharmacy, lab, and radiology quotes for services required for this study.

In addition to the budget details you must also provide a timeline of anticipated costs and income (as per template tab 4 "Timing") for the duration of the study (this should reflect the contract or funders financial agreement). This is to enable the *Trust Accountant* to notify *billing* when to invoice and also know when *revenue* is expected. Regular reports of actuals and forecast can then be generated (at appropriate timelines).

Sources of funding: If your study is funded please indicate all of the funding sources even if the study requires no budget at ADHB. It is important that you correctly indicate the **origin** of the funding e.g. if a foreign university will be providing the funding to ADHB but the funds originated from that institutions government (NHMRC, MRC, NIH) then tick "Foreign government agency". If your funding is from a Charity or grant fund please attach the letter of confirmation of your funding success or the contract from the sponsor/funding body. If you have applied for funding but do not know the result, please enter the date when you expect to hear the result. RRC approval is dependent on successfully securing all funding required to complete the study.

Trust Funding Support Requested: If you are asking for funding support from the A+ Trust please use the appropriate form (links provided).

Savings: The RRC welcomes information on the financial benefits of research conducted at ADHB. If your project has identified true savings clearly illustrate this in your budget.

Operational Budget: If operational budget is being utilised, please tick and ensure you have obtained the appropriate signature for this in section H.

Capex: If your project involves the purchase of equipment Capex, please refer to the ADHB Capital Approval & Acquisition Policy (*Updated May 2004)* and if possible include your approval with this application. If you are unable to include your approval, please ensure that you send a copy to the RO once obtained. No funds can be allocated/spent on Capex goods without this approval documentation. Please note that Capital purchases for research projects where funds are provided externally from ADHB are subject to the same rules as all other capital spending.

Section F: Contracts and Legal

This section is for applications for studies which will require a contract with an external organisation and / or other legal review by ADHB (mandatory for industry sponsored clinical trials). Use this section as your check list for documents that need to be submitted before or with your application. The RO can create a file and hold your documents until finalised for submission to RRC.

All legal documents (Confidentiality agreements, Head Agreements, Contract, Indemnity and Compensation and Insurance Certificate etc.) must be submitted to the RO and be approved by ADHB legal Council. It is recommended that the final versions are ready at the time of the RRC meeting. An ADHB approval letter will not be provided until these documents are complete and signed.

Section G: Departmental Approval

Please obtain the signature illustrating support of your project from the Service Clinical Director of the ADHB department within which the research will take place. If

your project crosses two services i.e. Paediatric and Adult Neurology then both Service Clinical Directors are required to sign. If an Investigator in the study is also the departmental Clinical Director then the form should be signed by the Director of the ADHB healthcare Directorate instead. You are not able to authorise your own studies.

Section H: Financial Approval

The required signature for financial approval depends on the amount of income for the study, For budgets where the income will be $10,000 or less the RC manager of the service area where the costs will be incurred will sign. For budgets with income between $10,000 and $50,000 the service clinical director will sign. For budgets with income greater than $50,000 the level 2 manager will sign. If you are requesting operational support as part of your budget you must also get the Chief Financial Officer signatures of approval.

NB: Agreement by any of these persons can have a qualification i.e. for studies seeking support funding, rather than delay applications, the signee can agree in principle but ask for fund confirmation before the project can start.

Section I: Clinical Trial Registration

In September 2004, the members of the International Committee of Medical Journal Editors (ICMJE) published a joint editorial aimed at promoting registration of all clinical trials. They stated that they will consider a trial for publication only if it has been registered before the enrolment of the first patient.

It is essential that your register your study if it is a clinical trial to ensure ability to publish. Enter the number and site that the study is registered.

It is important to note that it is the SPONSOR who is responsible for registering the trial. This includes responsibility for accuracy and for completeness. They are also responsible for keeping the information up to date. However the SPONSOR can delegate this authority. If there is no sponsor (i.e. Investigator initiated despite funding coming from HRC etc) then it is the Principal Investigator's responsibility to register the trial. Check www.actr.org.au for further information.

All new trials will need to demonstrate registration or indicate that registration is under way, as part of the criteria for management approval.

2.3 Administration

The Research Office (RO) acts as the conduit to the RRC and Māori Advisor for Research. The RO will create a file with all your documents, and once complete, will submit the project to the next RRC meeting and Māori review list. The RO may be able to offer advice and suggestions and as such the earlier they are aware of the project the more they can assist.

It is essential that you send the legal documents as soon as possible as the review process can take some time to complete especially if negotiations are required. To facilitate a timely response it is recommended that your approved legal documents are present at the time of submission to the RRC. A delay in approving these documents will result in a delay in both signing of contracts and management approval.

Documents Required for review

See 2.2 Section B of this document. It is recommended that you send the documents as you complete or receive them. A file will be created in the RO with a unique identifier (i.e. your project registration "A+" number (see registering your research project in the research manual or on the web site). Once all documents are received the study will be submitted to the Māori Advisor for Research and the RRC for their next available agenda.

If your study requires ethical approval please submit a copy of your ethics approval letter as soon as you receive it as final RRC approval is dependent on the RO receiving and confirming you have ethics approval.

Legal documents

Although the ADHB will remain the organisation to deliver the research the organisation which will be contractually named on all legal contracts will be the **Auckland DHB Charitable Trust.** All cheques will need to be made out to this name and NOT the ADHB. If the financial arrangements are that income is in the form of an electronic transfer the account name, Bank and address and number are as below:

Bank:	WESTPAC
Account number:	03-1509-0022063-00
Address:	P O Box 26417 Epsom 1051
GST Number:	66-934-136

2.4 Deadlines

The RRC usually meets on the 4th Monday of the month from 1300-1500 although this can vary. The deadline for submission is the Monday two weeks before the meeting, at 5pm. The dates for the RRC meetings and deadlines are published on the RO website. Late submissions will be considered on a case by case basis.

2.5 Response

Decisions will be made at the RRC meeting and the RO will convey this decision to the principal investigator (or designate) via email, usually within the next two working days. Studies approved at the RRC meeting will only be granted full ADHB institutional approval when all other review processes (e.g. Maori, ethics, legal, funding, anti-microbial, Medsafe) have been satisfactorily completed. You may **not start** your research until you have received the formal ADHB approval letter.

If the project is not approved outright at the RRC meeting, the RO will send an email stipulating the reasons why clarification is required and what steps to take to progress the project to acceptance and therefore ADHB approval. Investigators (or designates) should submit their response to the RO which will forward it on to the RRC subcommittee for review and acceptance. This process normally does not require the response to be presented to the next RRC meeting, but occasionally applications for approval are declined at the RRC meeting and then the way forward is to submit a revised application, addressing the RRC's concerns, for the next available agenda.

2.6 Appeals

If the research proposal in its current form is not approved and the principal investigator does not agree with the provisions requested to progress to acceptance or to the reason that it was rejected outright (i.e. deemed not suitable to undertake within the ADHB), the investigator can request reconsideration. To submit for reconsideration, the investigator must draft a letter explaining why either the changes suggested are not possible or why reconsideration (if declined) is necessary. Please attach a copy of the original declining letter with your response.

If the result of the appeal to the RRC is still not satisfactory to the researcher, the project and correspondence will be submitted to the Research Governance Committee for their review and opinion. The Research Governance Committee will reverse the original decision only where it is satisfied that the original decision contained errors of judgement of a sufficiently serious nature to warrant the reversal.

The Research Governance Committee will in all cases either affirm or reverse the original decision.