

# RESEARCH APPROVAL GUIDELINES

## 1. AIM OF THE ADHB RESEARCH REVIEW COMMITTEE (RRC)

The aims of the RRC are

- To provide scientific review, advice and approval of all ethics approved research which involves the ADHB.
- To provide peer oversight and expert advice to enable the organisation to achieve ADHB goals of supporting and promoting high quality research. The Committee will have an advisory role on ways of encouraging more research activity in the organisation.
- To identify areas of potential growth in high quality research and to promote mechanisms to stimulate appropriate research programmes in such areas.
- To oversee and promote the development and implementation of the ADHB research strategy.
- To provide a conduit for the accountability of researchers via the Clinical Board, CEO and the Board.

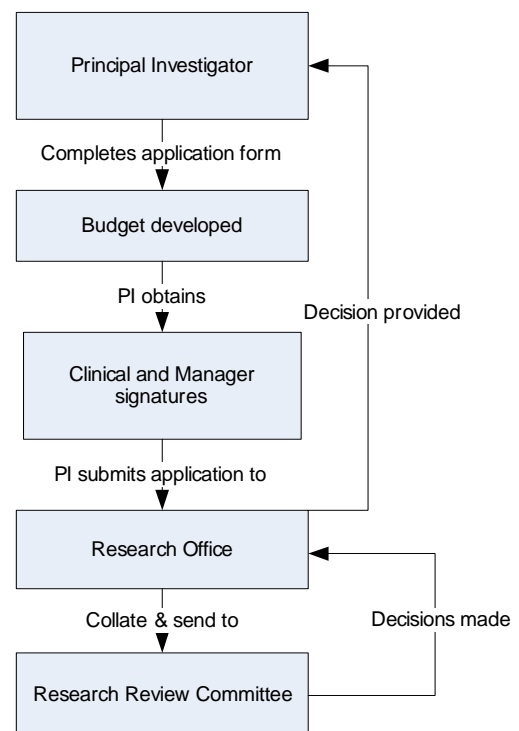
## 2. APPLICATION FOR RRC APPROVAL

### 2.1 General

Use the [RRC Application form](#) to make a request for approval to undertake research within the ADHB.

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

- 2.1.1 The form must have signatures indicating approval from the Clinical Director and Service Manager. If Principal Investigator is also the Clinical Director, then the Clinical Leader or Medical Director signature is required instead.
- 2.1.2 The completed application and associated documents are forwarded to the RO. The RO submits final documents to the RRC.
- 2.1.3 The RRC will review the application and convey the response to the RO. The RO will send a letter to the principal investigator/designate conveying the decision.



## 2.2 Application Form Guide

---

### **Section A: General Summary**

Please complete the general information requested.

Please include physical location of Principal Investigator and if relevant, the name and physical contact details of the research coordinator.

- **For non –ADHB researchers, an ADHB Contact** is necessary when the research study does not include an ADHB person 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) if available. If it has not been reviewed by an external body please describe any internal or peer review process undertaken.
- **Conflict of Interest** - Please refer to the ADHB policy on Conflict of Interest and briefly describe the conflict here i.e. partner in product development, shareholder. It is essential that any conflict issues are mentioned in your ethics application.

### **Section B: Proposed Research**

The following section requests information on the proposed study.

The Abstract should be written in plain English avoiding abbreviations where possible.

The Research design (or research proposal) should include your study hypothesis or aims, brief background, methodology, sample size calculations (if relevant), statistical analyses and significance. (See Box 1 below for some heading guides)

#### Box 1: Guide for writing your proposal/ developing your study design

- 1 Hypothesis or aims specific Aims (what do you intend to do?)
- 2 Background and Significance (why is the work important?)
- 3 Research Design and Methods (what will you do?) Include information on the following
  - a. Study population and recruitment processes
  - b. Instruments
  - c. Data Collection
- 4 Sample size and power analysis
- 5 Statistical Analysis plan
- 6 Risks and moderators for minimizing risks including a stopping plan
- 7 Risk-benefit ratio
- 8 Data Safety Monitoring Plan (Discussion of how risks/adverse events will be identified and managed. Include data safety monitoring board (DSMB) information, if such exists). DSMB information requirements are as follows: Members of the committee and their qualifications.

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. This can either be documented in the box provided or attached as a separate sheet.

### **Section C: Financial**

Ensure you have read the ADHB Research Financial Policy (on intranet under ADHB Policies) before drafting your budget. All research income is to be paid directly into the Auckland DHB Charitable Trust Account, not the Research RC.

**Note:** *No projects will be approved by the RRC or the Grants Committee without a budget and supporting documentation or explanation of why a budget is not attached.*

- **Budget:** Work with your service accountant to develop your budget identifying all costs (direct and indirect) and revenue sources that pertain to the ADHB. A template and guide for budget development is on the RO website). If part of the research is undertaken by another organisation then please note what that organisation will undertake and if there are any arrangements with ADHB services i.e. an agreement to take bloods and store by LabPlus and whether these are billed direct to the sponsor or are part of the income for the study and hence will be part of your budget costs. For a simple example see box 2 below.

Please enter all the names of the Sponsor, organisation or other source of the funding in the income lines so the RRC can see who is funding the project.

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 example on RO website budget template) for the duration of the study (this should reflect the sponsor or funder's 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 (according to appropriate timelines). It is understood that this baseline budget is an estimate only and that details change depending on recruitment numbers etc. The purpose of projecting out the timeline from the baseline budget is to get an indication of anticipated costs and income. This budget can be adjusted as knowledge of real costs and income are established.

- **Describe reasons if budget not attached:** It is acknowledged that some studies do not incur any costs i.e. small student project, involves only Doctor time as per CME agreement, uses minimal ADHB time (i.e. giving of an information sheet whereby the potential participant contacts the researcher direct), or the only service used is LabPlus and this has been arranged directly with them, with invoicing organised directly between sponsor and LabPlus. If you believe your study fits within this category please ensure that you explain this clearly, to enable the RRC to ascertain that a budget was not needed.
- **Describe ADHB resource impact:** Please describe the impact your study has on specific ADHB resources and if relevant the potential impact on access to these services for normal patient care.

If your study utilises ADHB resources that are currently under pressure i.e. Echocardiology, you must describe arrangements that illustrate how your project will have no impact on the use of these services for standard patient care or report that these services will be undertaken privately by XXX organisation (include quote/agreement). If discussions with the manager of the service or similar person have taken place and an agreement has been arranged please

include their name and the contact details or attach their support letter acknowledging that the service is able to cater this research project.

If you say there is no impact but describe a service use outside normal clinic hours please indicate whether this has been agreed with the department manager and service manager and that it does not require staff to remain after hours or work overtime.

- **Describe what care is standard and what is extra for the proposed Research:** When a study uses some standard care and additional research related interventions or tests plus staff, it is important that you describe the standard and the extra so that the committee can easily review your financial documentation accurately. If there is confusion further clarification will be requested and this is likely to delay your study being approved. A simplified example of standard and extra research activities is below:

Box 2: Example of Standard and Extra Research Activities

<b>Study:</b> A double blind, placebo controlled, randomised study examining the safety and efficacy of XXX in patients with Fuzzy Hoop Syndrome	
Clearly describe what care is standard and what is extra for Research	
Study Assessments / Visits:	<b>Standard care</b> <ul style="list-style-type: none"> <li>▪ Standard 1 visit per year.</li> <li>▪ Patients normally have one x-ray per year.</li> <li>▪ Full set bloods taken once a year incl. LFT GTT, Cardiac enzymes</li> <li>▪ Staff nurses undertake normal patient care.</li> </ul>
	<b>Non-standard care</b> <ul style="list-style-type: none"> <li>▪ 1 extra x-ray, 1 MRI, 3 additional sets of bloods, PCR test.</li> </ul>
	<b>Resource impact (e.g. clinic space, access to facilities, potential savings)</b> <ul style="list-style-type: none"> <li>▪ Use of hospital radiology and laboratory</li> </ul>
Breakdown / Explanation of Budget	
Working Expenses	<b>Laboratories:</b> PCR test, plus 1 extra set of bloods x1 (\$xx), 2 extra sets x2 pts (\$xx/pt) – see Labplus quote
	<b>Pharmacy:</b> Awaiting quote from pharmacy for randomisation and dispensing
	<b>Radiology :</b> 1 extra x-ray/pt – see radiology quote 1 MRI/pt done privately and directly billed to the sponsor (so not in ADHB budget)
Researcher/Co-Ordinator Time:	<b>Study preparation, ethics and ADHB approval:</b>
	<b>Study assessments/visits and CRF completion:</b> collects study data and completes CRFs; follows up records, and appointments
	<b>Monitoring:</b> Arranges monitoring, answers data queries
	<b>Other costs:</b>
Miscellaneous Costs:	<b>Travel / taxi vouchers:</b> Each post-discharge visit will reimburse participants at \$100/visit
	<b>Refreshments:</b> Staff valuations @ \$100/pt
	<b>Stationery:</b>
	<b>Archiving:</b>
	<b>Other miscellaneous costs :</b>

- **Funding Support / Success Letters:** If your funding is from a Charity (NHF) or grant fund (AMRF) please attach the letter of confirmation of your funding success. 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 funding. A copy of the funding letter confirming success of funding e.g. NHF or AMRF letters or the contract from the sponsor/funding body must be submitted to the Research Office before approval can be granted.

If your study does not have a formal contract but funds are being provided by a Charity or other funding body, you still must provide a letter confirming the funding and include detail of the income and the anticipated timing of outgoings i.e. quarterly or 6 monthly as appropriate.

**Note:** *It is recommended that you ask the accountant to sign a copy of the budget as acknowledged (See the budget guide).*

For ADHB Internal Staff Only

- a. Use of Department Research Surpluses for research projects – these surpluses may be used to support the financing of a project where there is a funding shortfall. This should be discussed and agreed to by the department Clinical Director/Leader, and Service Manager.
- b. The budget is prepared as per the guidelines – enter in the revenue section the A+ Trust account number and the amount is spread across the timeline as appropriate.
- c. Complete the A+ Trust application form (*this is necessary as the Trust is a separate entity to ADHB and require it for audit purposes*) and obtain appropriate approval signatures.  
<http://adhbintranet/CorpFinance/docs/A+%20Trust%20Application%20Form%202008.xls>
- d. Submit the completed and signed form to the A+ Trust (A+ Trust Accountant, Finance, Level One, Building 10, GCC) and provide a copy of it along with your RRC application.

- **Funding Support Requested:** NB: this is currently under development and as such is not available to access.
- **Savings:** If your project has identified true savings for the service (i.e. free drug supplied when this would normally have been purchased) clearly illustrate this in your budget. The distribution of savings will be managed according to the ADHB Research Financial Policy: Savings (on the Internet under ADHB Policies). **Note: There is no ADHB Savings Policy as yet.**

**If you require use of savings.** All approvals for Savings use must be discussed and approved by your Clinical Director, Service Manager and final sign off by the CFO, **PRIOR** to submitting it for the Research Review Committee. It is recommended that you include a cover note to describe why the study is not fully funded, the importance of the research to the service/area/field, and the amount of savings required. Currently each application will be on a case by case basis and that the request is to cover the actual deficit rather than develop a budget which identifies a surplus due to savings. Please note that savings are generally dependent on your recruitment numbers and therefore the amount if approved, actually used to support the study will reflect the true saving versus baseline budget projection.

- **Operational Budget:** If operational budget is being utilised, please tick and ensure you have obtained the appropriate signatures for this in section E. This must be obtained **PRIOR** to submitting it for the RRC. It is recommended that you include a cover note to describe why the study is not fully funded, the importance of the research to the service/area/ field, and the amount of savings required.

Please refer to the ADHB Research Financial Policy: Operational Support for further information and guidance and criteria for accessing operational budget approval.

- **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 from your funds 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 D: Contracts and Legal**

- **Contract:** Please indicate here if a contract, Memorandum, Service Agreement, or other formal agreement used to convey service purchase and delivery is required.

Please indicate if it has been reviewed and approved by the legal department (via the Research Office) and if it accompanies this application for sign off.

**Contract will be finalised by:** If it does not accompany the application please enter an estimated date for when the contracts will arrive for signing. Final approval cannot be given until the Contracts and other legal material have been approved and signed.

- **ACC:** Please tick here if your project has been certified as ACC.
- **Non-ACC:** Please tick here if your project has been certified as being for the benefit of the manufacturer or sponsor and as such not covered by ACC.
- **Indemnity and Compensation and Insurance Certificate:** If your study is certified as non-ACC please indicate that the Indemnity and Compensation Agreement has been signed and that a current Insurance Certificate has been provided. Please note here the expiry date.

#### **Section E: Approval Signatures**

It is up to the researcher or designates to obtain the appropriate signatures illustrating support by the department and service of your project. At a minimum signatures of the Clinical Director (or similar position) and Service Manager signature are required.

If your project crosses two services i.e. Paediatric and Adult Neurology then both sets of Managers, Clinical Directors are required to sign.

If the Principal Investigator in the study is also the Clinical Director then the Clinical Leader or Medical Director signature is required instead. A Clinical Director is not able to approve his/her own studies.

If operational support is requested please provide the necessary detail and obtain the Chief Financial Officer signature of approval.

**NB:** Do not expect that these people are available to sign your forms without due consideration. It is recommended that you find out when the person is available and how much time they wish to have in order to review and sign. It is essential you set enough time aside for signing in order to meet the RRC agenda. Your study will not be accepted on the agenda without signatures and lack of planning will not be accepted as an exceptional circumstance for placing on the Agenda.

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

### **Section F: 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<sup>1</sup>. 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 you 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<sup>2</sup> 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](http://www.actr.org.au) for further information.

If appropriate, all new clinical 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. The RO will create a file with all your documents, and once complete, will submit the project to the next RRC meeting.

It is essential that you send the legal documents as soon as possible as their review 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. If the project is approved, these documents will be signed at the Grants Committee (meets immediately after RRC meeting) on behalf of the Auckland DHB Charitable Trust. A delay in approving these documents will result in a delay in both signing of contracts and management approval.

---

<sup>1</sup> Clinical Trial is defined as “Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.”

<sup>2</sup> Sponsor is defined as “an individual, company or institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial”.

## CHECKLIST - documents required to submit research study to the ADHB Research Review Committee (RRC)

Documents	Comments	Essential to submit for RRC agenda	ASAP / before ADHB approval can be given
<b>ESSENTIAL DOCUMENTATION FOR STANDARD APPLICATION</b>			
RRC application form	1x signed original + 1x single-sided hard copy + electronic	✓	
Final Ethics application, Participant Information Sheet & Consent Form	1x hard copy + electronic ( <i>If any change made after registration with RO, then 1x hard copy + e-copy</i> )	✓	
<b>IF COSTS TO ADHB – submit above essential documents plus:</b>			
Budget (including quotes)	2x hard copies, signed by accountant + electronic	✓	
<b>IF CLINICAL TRIAL – submit above essential documents plus</b>			
Protocol	1x hard copy + electronic	✓	
Investigator’s Brochure	1x hard copy or electronic if available	✓	
Contract / Agreements	3x final approved, with PI signature, for sign-off		✓
Indemnity and Compensation	3x final approved for signature		✓
Current Insurance Certificate	1x hard copy or electronic if available		✓
<b>IF OTHER FUNDING – submit above relevant essential documents plus:</b>			
Funding approval letter	1x hard copy or electronic if available		✓
Funding application	1x hard copy + electronic		✓
<b>IF APPLICABLE</b>			
Scientific Review Support comments	1x hard copy or electronic if available		✓
Other documents (list) e.g. Memorandum of Understanding	1x hard copy or electronic if available		✓
<b>FINAL APPROVAL</b>			
Ethics Approval Letter	1x hard copy or electronic if available		✓

**IMPORTANT NOTE:** Study cannot proceed until final institutional approval letter received from the Research Office.

## The Research Office

The RO continues to offer advice and suggestions and as such the earlier they are aware of the project and can review your documents, the more they can assist. It is therefore recommended that you send at minimum the ethics application and patient information sheet and consent forms as soon as you are able. A file will be created in the RO with a unique identifier (i.e. your project registration number. See registering your research project on the web site <http://www.adhb.govt.nz/rdo/>).

When all documents are received for the study (including signed originals), it will be submitted to the RRC for their next meeting. Final ADHB institutional approval for research is dependent on the RO receiving and confirming you have ethics approval. No research can start without both ADHB institutional approval and Ethics Committee approval.

## Contractual Documents

Although the ADHB will remain the organisation to deliver the research the organisation which will be contractually named on all legal documents 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. However we recommend that you ask for cheques to be sent as these are easier to manage within the current financial system.

*Bank:* ASB  
*Account number:* 12-3113-0000668-00  
*Address:* P O Box 26417  
Epsom 1051  
*GST Number:* 66-934-136

## Indemnity and Compensation Documents

It is recommended that the ADHB standard Indemnity and Compensation Agreement is used when a study is Non-ACC. This agreement can be found on the RO website under the Research Process : Pre – registration -> Legal Review. Please note that despite the contractual relationship changing to the Auckland DHB Charitable Trust, the ADHB remains as the institute or party indemnified under the Indemnity and Compensation Agreement.

## 2.4 Deadlines

---

Research Review Committee meets monthly on the 4th Monday of every month – between 1300 and 1500. The Research Office requests that all documentation required for the RRC is received at the office by 5pm on the Monday two weeks before the meeting (i.e. 14 days before the meeting date). Please check the website for any changes to these times particularly when the meeting day falls on a public holiday.

Late submissions will generally not be considered however if your study is pressured by a short recruitment period and the documents may not be ready in time to meet a review, allowances may be able to be made on a case by case basis. However, it is essential that you discuss the potential with the Research Office early and not the day that the agenda closes.

## 2.5 Response

---

Final decisions will be made at the RRC meeting and this will be conveyed to researchers (and/or designate) within the next two working days. If approved, the response will be in the form of 1) an ADHB acknowledgement email/letter and if relevant, the signed contracts for your research master file and for the sponsor will be enclosed, or 2) an e-mail saying that approval was given but a formal letter will not be forthcoming until ethics approval has been received and/or legal requirements completed.

You **may not start** your research until you have received the formal ADHB institutional approval letter.

If a project is approved subject to further clarification, an e-mail will be sent to the Principal Investigator and relevant other contact asking for further information. Please send your responses to the RO who will send it on to the two primary reviewers for comment. A response will take between two to three days. Once confirmed as satisfactory, an approval letter will be sent, pending ethics approval and if appropriate, any outstanding legal requirements.

If a project is declined, a letter will be sent stipulating the reasons and what is required to progress it to approval. Responses should be sent to the RO. The RO will forward them on to the primary reviewers or a subcommittee for review and acceptance. A turn around time of 3-4 working days from receipt of amended documents or clarification letter is anticipated. If deemed necessary, it may be decided by the reviewers that the project needs to go back to the full committee. You will be informed of this decision and be included on the next Agenda.

## 2.6 Appeals

---

If the research proposal in its current form is declined and the principal investigator does not agree with the provisions requested by the RRC, to progress to acceptance or to the reason that it was declined (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 is necessary and forward to the RO for distribution to the committee. A decision can be made under the delegated authority of the Chair however the Chair may refer the matter back to a full committee meeting. The researcher will be informed of this process.

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 Clinical Board for their review and opinion. The Clinical Board 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 Clinical Board will in all cases either affirm or reverse the original decision.