

# RESEARCH MANUAL

**Canterbury**

District Health Board

Te Poari Hauora o Waitaha

*Revised version 1 July 2012*

All material referred to in this Manual is available at the Research Office, University of Otago, Christchurch at 36 Cashel Street, Christchurch.

Revisions and updates to this manual and any of the content to be proposed in writing to the research committee, submissions will be considered at the next scheduled meeting of the research committee and if approved by the committee will be referred to the author for updating who will gain authorization, arrange sign off and re issue of the manual.

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## 1. General Information

This Research Manual comes under the umbrella of the Clinical Research<sup>1</sup> Policy.

The major tertiary and secondary health care providers in Canterbury are the public hospitals of the Canterbury District Health Board (CDHB). The CDHB provides a comprehensive range of medical services for the population of greater Canterbury (427,086) and, in several areas, tertiary services for the South Island and the North Island south of Hamilton.

The principal hospitals serving the population of Canterbury include; Christchurch Hospital, Christchurch Women's Hospital, The Princess Margaret Hospital, Hillmorton Hospital, Burwood Hospital and Ashburton Hospital. In addition to the principal hospitals there are a number of rural hospitals, community and mental health services provided at a wide variety of other locations throughout Canterbury.

### **Canterbury District Health Board**

Ta Matou Matakite - Our Vision

Ki te whakapakari, whakamaanawa me te whakahaere i te hauora

Mo te orakapai o ka takata o te rohe o Waitaha

To promote, enhance and facilitate the health and well-being of the people of the Canterbury District

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<sup>1</sup> Clinical research is defined as “Research based on humans and designed to answer questions about health and disease. In addition to direct examination of individual patients and populations, it includes the study of biological samples and personal data. It also includes research on volunteers, or on populations of apparently healthy individuals and other studies where such study relates to a disease process being investigated.”

## **2. CDHB Research Committee**

The CDHB Research Committee is a Standing Committee within the Canterbury District Health Board, reporting to the Clinical Board.

The Committee develops policy and advises the Clinical Board and Executive Management Team regarding research conducted within the CDHB.

The primary function of the CDHB Research Committee is to provide governance and advice to the Clinical Board on matters related to clinical research activities within the CDHB. The Committee will consider all issues regarding research and will respond on behalf of groups or individuals within the CDHB and/or make recommendations to the Clinical Board.

The Research Committee Terms of Reference; Meeting dates and Minutes; Members of the Committee; and other information may be viewed on the CDHB intranet at: <http://intranet.cdhb.local/division/cm/rc/default.aspx>

### 3. The Research Office

The health research campus in Christchurch is served by a Research Office temporarily based at 36 Cashel Street, Christchurch. This is a shared facility funded by the University of Otago, Christchurch and the Canterbury District Health Board (CDHB). It provides open access service for anyone involved in health research working within these organisations. **For all staff, it is compulsory to submit grant applications through the Research Office.**

It is not intended that the Research Office should direct research in the DHB – that is the role of the principal investigator, *within the service context*, working with their Clinical Director and Divisional managers, in the first instance.

The Research office's proposed functions are to be complementary to existing research activity; providing assistance on request, ensuring that the clinical groups are adhering to the Policy procedure and that the organisational Research Register is current.

The Research Office should promote and support research activity for staff who do not already work within a research based environment, and for whom the research method is a novelty.

The Research Manager, Research Advisor and Administrative Assistant are available to provide advice on all aspects of the conduct of research in Canterbury. A major focus of the Research Office is the dissemination of research grant funding information and advice to applicants on eligibility criteria and budgeting. Provided grant applications are received by the advertised date, the Research Office will take responsibility for the processing, checking and photocopying of grant applications and ensuring that they are couriered to the appropriate destination in a timely fashion. These services are provided free of charge to staff.

Location: 36 Cashel Street, Christchurch

Telephone: 03 364 3630

Email: [research.uoc@otago.ac.nz](mailto:research.uoc@otago.ac.nz)

Website: [www.otago.ac.nz/christchurch/research/researchoffice/](http://www.otago.ac.nz/christchurch/research/researchoffice/)

### 3.1 Research Office – Services

**Information:**

- Upcoming funding opportunities
- Discussion Documents
- Research Related Policy & Procedures
- External scholarships and fellowships
- Summer studentships
- Ethics committee procedures
- Conferences and seminars

**Advice / Support:**

- Advice to new researchers on eligibility for grants and awards
- Support the development of applications/tenders etc to all funding sources
- Provide assistance and advice for commercial research budgets to ensure that, wherever possible, all costs are considered and covered by the sponsor
- Assistance with completing budget and application forms for contestable research grants
- Assistance in establishment of appropriate clauses in contracts (checking contractual obligations)
- Assistance with protection of Intellectual Property, Commercialisation and Technology Transfer Agreements
- Assistance with Material Transfer and Confidentiality Agreements
- Support for researchers - any queries or concerns are addressed promptly or referred on where appropriate

**Liaison:**

- With funding bodies
- With industry partners
- With collaborators

**Administration:**

- Process grant applications including, checking applications and budgets to ensure they meet Sponsor and Institutional requirements, obtain Host Institution signatures, photocopy required copies, courier to funding bodies before the deadline
- Ensure all necessary approvals are obtained before accounts are opened for research projects to begin – ethical consents etc.
- Records management – maintain copies of applications, contracts, sub-contracts and any correspondence relating to contracts
- Maintain a CDHB Database of all research for audit purposes

### 3.2 Standardised Indemnity and Compensation Agreement (sICA)

The CDHB supports the use of the Standardised Indemnity and Compensation Agreement (sICA), developed by the New Zealand Association of Clinical Research (NZACRes). The sICA is pre-approved for use in clinical trials that are sponsored by pharmaceutical and medical device companies and conducted in NZ public health organisations.

#### Background

1. Each clinical trial sponsored by a manufacturer of a pharmaceutical or medical device and conducted in NZ public health organisations must be covered by an Indemnity and Compensation Agreement between the site and the trial sponsor.
2. The intention is that this sICA can be used by all NZ DHBs without modification to speed the process of approval of clinical trials and remove the need for lengthy and difficult negotiation.
3. The sICA has been developed for use in all industry-sponsored clinical trials that take place in NZ DHBs.
4. The sICA does not cover clinical trials that are:
  - sponsored by collaborative clinical trial groups;
  - are investigator-initiated;

as compensation for injuries caused to participants as a result of their participation in these clinical trials is covered by NZ's statutory no-fault compensation scheme (*Injury Prevention, Rehabilitation, and Compensation Act 2001*).

#### Application

5. Wide consultation with DHBs and their legal representatives has taken place with regard to the sICA. It is envisaged that all DHBs, as well as some other health service providers in NZ, will use the sICA. However, its use remains at the discretion of individual organisations.
6. Where a pharmaceutical or medical device company uses the sICA without alteration the DHB or other health services should feel comfortable in accepting this agreement without further review.
7. Where a pharmaceutical or medical device company wishes to use their own Indemnity and Compensation Agreement, or makes non-trivial alterations to the sICA through the addition or deletion of clauses or through the addition of special conditions, the DHB or other health services provider should give such a request the same consideration it would give to any other contract negotiation.

The sICA (Version 2.0) can be used from **July 1, 2010** and may be downloaded from the web at: <http://www.nzacres.org.nz/>

### **3.3 Standardised Clinical Trial Research Agreement (sCTRA)**

The CDHB supports the use of the Standardised Clinical Trial Research Agreement (sCTRA) developed by the New Zealand Association of Clinical Research (NZACRes).

#### **Background**

The New Zealand Association of Clinical Research (NZACRes) has developed a standardised Clinical Trial Research Agreement (sCTRA) based on the Medicines Australia template that has successfully been used in Australia. The sCTRA Working Group has consulted widely with the New Zealand clinical research industry in New Zealand to produce the first New Zealand version of the standardised Clinical Trial Research Agreement.

This agreement has undergone an independent legal review and the sCTRA Working Group intends to conduct a six month post-release review (April 2012) to address any feedback received after publication.

#### **Objectives**

- to develop a standardised Clinical Trial Research Agreement for use in contract clinical trials in New Zealand, consistent with international practice;
- to save time, money and manpower in order to facilitate the approval process;
- to have a streamlined contract negotiation process in order to reduce clinical trial start-up times;
- to ensure that New Zealand remains an attractive location to conduct clinical research.

#### **Advantages**

- Single legal review required for main body of the contract when used for the first time.
- Contracting process is de-risked for all contracting parties by having consistent contract terms with all clinical trial Sponsors.
- Only Schedule 2 and Schedule 7 will need to be negotiated and reviewed, eliminating the need for a full review of contract, creating a streamlined contract negotiation process.

The sCTRA form and guidelines may be downloaded from the web at: <http://www.nzacres.org.nz/>

## 4. Ethical Approval for Research Projects

Research involving human participants requires approval of a New Zealand Health and Disability Ethics Committee. If unsure whether your project requires ethics approval, please refer to the Health and Disability Ethics Committee website at:

<http://www.ethics.health.govt.nz/>

From 1 July 2012 ethical approval for research projects is obtained via an online application form on the [HDEC website](#). Locality authorisation for Canterbury DHB is obtained via the Research Office. When researchers are completing their on-line ethics application form they will need to enter the following email address for locality authorisation from the CDHB: [research.uoc@otago.ac.nz](mailto:research.uoc@otago.ac.nz)

Researchers are asked to complete the [CDHB Locality Authorisation form](#) after they have submitted their on-line ethics application. For further information about locality authorisation from Canterbury DHB email [research.uoc@otago.ac.nz](mailto:research.uoc@otago.ac.nz) or phone the Research Office on 03 364-3630.

## **5. Approvals Required - HSNO and Other Regulatory Consents**

Any research requiring the development, importation or transport of a genetically modified organism requires special approval by the Environmental Risk Management Authority (ERMA). Research using hazardous substances and/or tracked substances also require a risk assessment and other procedures to be put in place before the research work commences. In other instances, approval is required by the Department of Conservation, the Ministry of Agriculture and Fisheries, or other regulatory authorities where the development, transport or importation of organisms and particular classes of substances is required.

For advice on whether research requires such approvals contact:

Quality Manager  
Canterbury Health Laboratories  
Telephone 364 0388

## **6. Research involving Maori**

### **6.1 Maori Consultation**

The Ethics Committees and the Health Research Council of New Zealand, as well as many other funding organisations, have particular requirements with regard to consultation with Maori.

#### **Canterbury District Health Board staff should contact:**

Te Komiti Whakarite  
c/- Catherine Grant  
Office Administrator  
Nga Ratonga Hauora Maori  
Maori Health Services  
245 Antigua Street  
Christchurch Hospital  
Tel +64 3 378 6160 (internal 86160)  
Email [catherine.grant@cdhb.govt.nz](mailto:catherine.grant@cdhb.govt.nz)

#### ***Te Komiti Whakarite***

One of the primary goals of Te Komiti Whakarite is to provide a Canterbury District Health Board (CDHB) response to the need for Maori consultation (as currently required under the New Zealand National Ethics Committee process for all health research conducted in Aotearoa New Zealand) on all research that is undertaken under the auspices and within the services provided by CDHB.

Part of this goal is to develop an assessment process that promotes practices which ensure that research effectively contributes to Maori health development whenever possible. Further information about Te Komiti Whakarite can be found on the CDHB Intranet at: <http://inraweb.cdhb.local/quality%2Dmaori/te%2Dkomiti/>

## 7. Recommendations regarding copyright and 'soft' IP

1. **CDHB logo.** This is readily available (i.e. through the intranet at: <http://intraweb.cdhb.local/manuals/pagetemplates.htm> and Medical Illustrations) to all CDHB employees. Employees may choose to use the logo on educational material such as slides, posters and documents, including educational course material that is produced whilst undertaking CDHB activities. The benefits of increasing employee accessibility to the CDHB logo far outweigh the risk of inappropriate use of the logo.
2. **Applying copyright and 'copyright' to written material and images, produced during the course of CDHB activities, which are likely to be distributed outside the organisation.** Copyright enables work to be attributed to the organisation/individual at no cost and may also offer a low level of IP (intellectual property) protection. Authors should consider placing all materials that might be used outside the CDHB and in which the author has invested much creative energy, under copyright. This could be written as: © Canterbury District Health Board, 2011. It is also possible to acknowledge individual authorship, for example: Mary Smith and John Bloggs, Department of Wonderful Ideas, © Canterbury District Health Board. In some instances, authors might choose to make materials such as powerpoint slides widely available on the internet, with the intention of sharing the slides, yet would like to have the graphics associated with the slides attributable to themselves, as CDHB employees. In this situation, it may be appropriate to share e-materials through Creative Commons or similar. There may be some instances when a considerable amount of work has gone into a piece of work, typically a standalone educational course or similar and this work may be considered to have commercialisable potential. In this situation, the authors may wish to discuss further options for IP protection with the Health Innovation Hub.
3. **“Locking” document content.** Some authors may consider it appropriate to ‘lock’ the CDHB logo and also the copyright markings into documents that are being shared electronically. Medical Illustrations will be able to advise, as required.
4. **Respecting copyright of other authors' materials.** CDHB employees should respect the copyright of others. There are occasions when it may be advisable to check source documentation for copyright, check whether permissions are required and also whether licensing fees apply. For example, it may be possible to download a copy of a questionnaire, typically a quality of life or psychometric questionnaire,

from a non-authorised internet site and find this copy has omitted details about copyright, permissions and licensing agreements.

Prepared by Helen Lunt, Clinical Director, Health Innovation Hub, 22.11.2011.

## **8. Insurance for Clinical Trials**

All trials involving human subjects that are not conducted for the benefit of a pharmaceutical company may be subject to cover as provided in the Accident Compensation Legislation. In this regard, a Declaration is required from the Principal Investigator at the time of submitting an Ethics Committee Application. This "No Fault" compensation scheme provides limited compensation for trial subjects who are in paid employment at the time of injury or untoward event pertaining to a clinical trial. This DOES NOT provide adequate compensation for those who are unemployed who will not be eligible for earnings related compensation.

For those research projects supported by the pharmaceutical industry, adequate cover is usually provided for participants in the study and the draft guidelines of the Researched Medicines Industry are generally adhered to. It should be noted, however, that this may not provide protection for researchers who may be subject to civil action, either directly or through their employer. For this reason both the indemnities contained in Clinical Trial contract documentation, and insurance cover, become relevant. Indemnity clauses in agreements need to be reviewed by the Research office, with appropriate legal advice as required.

For Canterbury DHB employees there is also insurance coverage (in addition to any the researcher may have in their personal capacity or through other employers). The Canterbury DHB's insurance policies are part of a national arrangement and may vary from year to year. Again the Research office can provide any necessary advice on the updated provisions.

### **8.1 Federalwide Assurance (FWA)**

Researchers conducting human research within CDHB with an overseas agency (e.g. pharmaceutical company) may be asked whether their institution has Federalwide Assurance for the protection of human subjects for international (Non-US) institutions.

The CDHB/Christchurch Hospital has been given Federalwide Assurance. Details may be obtained from the Research Office.

Any queries about Federalwide Assurance should be directed to the Chair of the CDHB Research Committee, Dr Mark Smith

## 9. Research Finances and Provision of Overheads

### A. Financial management of research monies

1. Research money will be held in research accounts (700s) managed by researchers. Research accounts will operate in a similar manner to Trust Funds accounts and any surplus will be carried forward and available for use in future years.
2. The research accounts currently held in a separate Division called Research and Development will be allocated to the appropriate clusters in the Hospital Divisions.
3. The research accounts will be available to CDs, Chief and Chairs on a monthly basis and will be incorporated in each GM's monthly results. Service Managers will ensure that the appropriate direct costs incurred by research will be charged to the research accounts.
4. To assist monitoring, it may be desirable to load the budget for each research project when the project is approved.
5. DHB Research Committee will receive quarterly reports on the overall research accounts financial performance with relevant supporting detail information.
6. At the completion of a research project, after all expenses are paid, **any surplus will remain in the research trust account** of the researcher or group for reinvestment in **approved** research, education, equipment and training.
7. In cases where there is uncertainty regarding the use of research profits these will be referred to the Research Committee for a decision.

### B. Research Overheads

1. Research is seen as a benefit for the CDHB.
2. The purpose of charging for research overheads is not to make a profit for the organisation but to;
  - a. Fund support for research activities in the DHB, and
  - b. To cover unidentifiable costs
3. Overheads transferred to research will be used to support the Research Office and fund other research support such as access to biostatistics advice and employment of research coordination.
4. Contribution to research and unidentifiable costs for commercially sponsored research is to be paid by way of an overhead charge of 20% of the project revenue (capped at \$50,000 per project per annum). 10% will go to the research office while the other 10% will go to the division to meet unidentifiable costs.
5. Surcharge reduction: If the research avoids costs for the DHB (e.g. through provision of free pharmaceuticals) then the surcharge may be reduced

accordingly. The amount must be able to be verified and any reduction will be approved on a case by case basis by the research committee. **The maximum amount of reduction approved will be 10% and will reduce the non-identifiable cost recovery.**

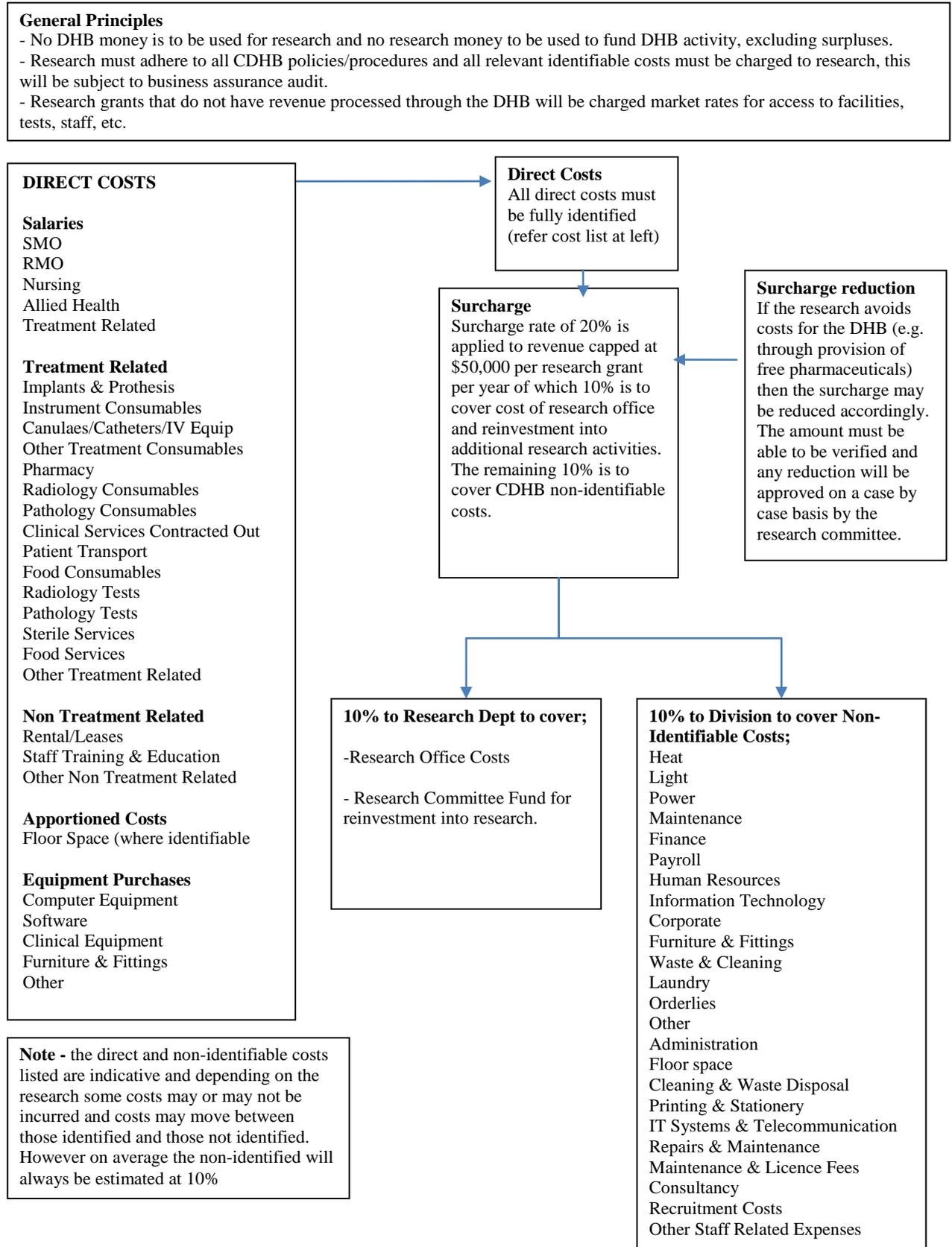
6. Collaborative/Charitable research funded by organisations such as CMRF that do not fund overheads will be exempt from overhead payments.
7. Overhead payments for research funded by HRC or other government agencies to be 65% of salary as currently in place.
8. An account called “Research Overheads” has been set up to monitor the research overhead funds collected and how these funds have been applied.
9. Refer to the following flowchart (7.1) that provides more detail around identifiable/non-identifiable costs and process.

**C. CDHB Research Grants - Application of Overheads**

<b>Grant signed Prior 1 July 2009</b>	<b>Grants signed Post 1 July 2009</b>
<b>Commercial</b>	
No overheads charged during original contract term.  If contract term is extended then overhead (20% of revenue) will be applied from the extension date (if the extension commencement date is post 1 July 2010). Note this does not include minor contract variations that may arise during a grants original term.	Overhead (20% of revenue) charged on commencement of study.
<b>HRC Contestable</b>	
Overhead (65% of personnel costs) charged after 1 July 2010 (as this is already built into the contract price).	Overhead (65% of personnel costs) charged on commencement of study.
<b>Collaborative</b>	
No overheads chargeable.	No overheads chargeable.

### 9.1 Commercial Research Cost Flowchart

**Note – this does not cover Charitable and Government funded agreements**



## **9.2 Definitions of Commercial and Non-Commercial Research**

“Commercially sponsored research” is defined as research being carried out principally for the benefit of a manufacturer or distributor of the drug or item in respect of which the research is taking place. The following factors may be considered in determining whether or not a trial is principally for a manufacturer’s or distributor’s benefit:

- (a) Who is initiating the proposed research study? That is, is the proposed research study investigator-initiated or the result of an approach to the investigator from a pharmaceutical company or any other company involved in health research?
- (b) Who is designing and planning the hypothesis to be tested and/or research questions to be asked in the proposed research?
- (c) Will the director of the proposed research study or other investigators involved in the study be receiving any direct financial remuneration either as an employee or as a consultant of the pharmaceutical company or any other company involved in the proposed research?
- (d) Is the pharmaceutical company or any other company involved in health research putting any restrictions or delay on the timely publication of the results of the study?
- (e) Is the pharmaceutical company or any other company involved providing any funding and/or materials for the proposed research?

Research that is not principally for the benefit of the manufacturer or distributor of the medicine or item being trialled is distinct from “commercially sponsored” research, and does not attract an overhead charge. Examples of this type of investigator-initiated research include projects managed by academic consortia such as the US-based Children’s Oncology Group and the Australasian Leukaemia-Lymphoma Group.

## **9.3 Joint Hosts**

When a project is hosted jointly among two or more institutions, a written Memorandum regarding the split of overhead payments is advised.

- **The Purchase and Disposal of Equipment**

Unless otherwise stated, all equipment and capital items become the property of the DHB from the commencement of the grant or research project. The purchase of equipment should be made through the usual DHB channels and appropriate delegations.

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## 10. Guidelines for Responsible Practice in Research and Procedures for Dealing with Allegations of Misconduct in Research

- Introduction
- Part 1: Code of Conduct for Responsible Practice in Research
- Part 2: Procedures for Dealing with Allegations of Misconduct in Research

### Scope

This policy applies to researchers, research staff and any other staff involved in research.

### Introduction

The mission statement of the Canterbury District Health Board (CDHB) is: "To improve, promote and protect the health of the people in the community and foster the well-being and independence of people with disabilities and reduce disparities".

Integrity in conduct of research by CDHB staff is pivotal to fulfilling this mission.

CDHB staff may work alone, with colleagues inside or outside the CDHB and with students and must at all times exhibit high ethical standards and ensure the validity and accuracy of data collected and reported.

This document is composed of two parts: (i) guidelines for conduct of research and (ii) procedures for dealing with allegations of misconduct in research.

This document draws heavily on The University of Otago's Code of Conduct for Responsible Practise in Research and Procedures for dealing with Allegations of Misconduct in Research. This is itself drawn from Research Guidelines on Fraud and Serious Misconduct in Research, Australian Vice-Chancellors Committee, Canberra, 1989, pp 1-7, and Guidelines for Responsible Practice in Research and Dealing with Problems of Research Misconduct, Australian Vice-Chancellors Committee, Canberra, 1990, pp 1-10.

### Part One: Code of Conduct for Responsible Practise in Research

#### *1. General Considerations*

(1) It is a basic assumption that researchers are committed to the highest standards of professional conduct in undertaking and supervising research. They have a duty to maintain the highest standards of probity in research applicable to their science or discipline, and to the good standing of the CDHB. These standards include rigorous opposition to all forms of fraud, including misrepresentation and falsification of results, the observance of the highest standards of safety in relation to themselves, co-workers and research participants, the maintenance of confidentiality and the full attribution and acknowledgment of authorship of all published material.

(2) Researchers and research workers should participate only in work which conforms to agreed ethical standards and which they are competent to perform.

(3) Institutions, researchers and research workers have a responsibility to ensure the safety of all those associated with research. Researchers should ensure the

implementation of the CDHB's policies relating to Health & Safety including; Hepatitis B Infection; HIV Infection and AIDS; Standard Laboratory Practices for Control of Infection Risks; and the Revised New Zealand Guidelines for Genetical Manipulation Research. Staff should ensure that all research workers and students under their supervision are aware of the relevant codes and policies.

(4) Research involving the use of humans or of personal information (including health records) must be approved by the appropriate Regional or Multi-Region Ethics Committee (or their successors).

Research involving animals must be approved by the University of Otago, Christchurch's Committee on Ethics in the Care and Use of Laboratory Animals.

(5) If data or material of a confidential nature are obtained by a CDHB staff member or student, full confidentiality must be observed. The data or material must not be used for any purpose other than the research, including personal commercial advantage or passed to a third party for that person's commercial advantage, except with the specific consent of the person or agency providing the data or material. In all research involving the collection or use of personal information the provisions of the Privacy Act 1993 and the Health Information Privacy Code 1994 must be fully observed.

(6) Research methods and results shall be open to scrutiny by the scientific community through publication in appropriate journals. Publication may be withheld for a short finite period if the results are commercially sensitive and/or when patent protection is being sought, but authority for such temporary withholding of publication must in all cases be obtained from the Clinical Board

(7) Ownership of intellectual property resulting from research is defined in the Canterbury District Health Board Policy for Intellectual Property Rights.

## ***2. Publication and Authorship***

(1) Original data of published material should be archived for five (5) years after publication for possible future scrutiny. The CDHB is responsible for providing data storage space and each Department should be responsible for deciding on an appropriate policy for the storage whether centrally or by an individual.

Individual research workers shall be entitled to hold copies of the data. Special provision must be made for security of data and access to it, if it includes information about individuals who may be identifiable, either directly or through a key to code numbers. Practices in this regard must conform to the principles of the Privacy Act 1993 and the Health Information Privacy Code 1994.

(2) It is neither desirable nor practical for the CDHB to supervise the creation of books, papers or articles. Researchers and students must be very careful in using material from other authors and ensure that it is properly acknowledged and permission obtained to reproduce copyright material in other publications.

(3) It is important that all authors listed on the publication shall have contributed in a significant way to the work. The principal author is responsible for the entire publication and should ensure that other authors accept, in writing, responsibility either for the entire paper or for that part of it with which they were concerned.

(4) It is important that authors of publications acknowledge any technical assistance and the source of any funding support.

(5) The submission to several journals of papers, articles or abstracts containing similar data or material must be properly declared to the authorities concerned.

### ***3. Research Centres and Units***

Wherever appropriate, the head of the Centre or unit or the director of the research should be personally involved in research supervision. Within such groupings, there should be wide discussion of the work of all individuals by their peers.

### ***4. Disclosure of Potential Conflict of Interest***

Disclosure of any potential conflict of interest is essential for the responsible conduct of research. Such disclosure must be made to the relevant authorities, which will include the funding or sponsoring agencies and the Clinical Director of the relevant department or research centre. (In the case of Clinical Directors of Department or Directors of Research Centres, disclosure should be made to the Chief Medical Officer.)

## **Part 2: Procedures for dealing with allegations of Misconduct in Research**

### **1. Misconduct in Research includes:**

(1) The fabrication of data by claiming results where none have been obtained.

(2) The falsification of data, by changing records or falsely claiming the use of techniques or methods or of levels of precision.

(3) Plagiarism, including the direct copying of handwritten, typed, printed or published text or notation, the use of other people's data without acknowledgement or permission where that was appropriate and the deliberate use of published or unpublished ideas from other people without adequate attribution.

(4) Misleading ascription of authorship, including listing of authors without their permission, attributing work to others who have not contributed to the research and failing to acknowledge work primarily produced by a research student, trainee or associate.

(5) Other practices that seriously deviate from those accepted within the research community for proposing, conducting or reporting research, such as intentional infringement of the CDHB's code of ethical behaviour as set out in the Human Resources Manual.

Misconduct does not include honest error or honest differences in the interpretation or judgment of data.

### **2. Procedures**

(1) Mechanism for lodging complaints:

Initially, the complaint or allegation should be discussed with the Chair of the Research Committee. If the complainant is not a member of the CDHB, preliminary discussion with the Chair of the Research Committee is still appropriate. Complainants must be

given a copy of the CDHB's procedures for dealing with misconduct in research. After the initial discussion, the complainant should decide whether or not to proceed.

(2) Should the complainant decide to proceed, the allegations must be submitted in writing to the Chief Medical Officer through the Clinical Board. The complainant should be informed that, in general, any materials which refer to another person will be "personal information" and can be requested by that person under the provisions of the Privacy Act 1993.

(3) Once the complainant has decided to proceed, the Chief Medical Officer will, after consultation as he or she deems fit, appoint the Chair of the Research Committee to conduct a Preliminary Inquiry and appropriate Committee Members. The Chief Medical Officer will determine the terms of reference for the preliminary inquiry.

(4) Once an allegation is made, the protection of all interested parties is essential.

Interested parties may include:

- The person bringing the allegation;
- The person or persons against whom a complaint is made;
- Research students and staff working with the person(s) concerned;
- The Department(s) in which the research was conducted;
- Publishers, actual or potential, of allegedly fraudulent work;
- Funding bodies which have contributed to the research;
- Human participants in on-going or past research;
- The public, in some cases - for example, if a drug is involved.

Adequate protection of those involved in the complaint and the Preliminary Inquiry demands confidentiality and reasonable speed in the early stages of the Preliminary Inquiry. Where protection of the interests of other parties involves some necessary disclosure, this should take place only after the response of the person(s) complained against has been considered. Such judgments should be made by the person(s) conducting the Preliminary Inquiry and communicated to the Chief Medical Officer.

(5) Consideration will need to be given as to whether or not the person(s) complained against should be suspended from research activity during the Preliminary Inquiry. The decision to suspend the person(s) complained against will be made by the Chief Medical Officer after consultation with the person(s) conducting the Preliminary Inquiry. If such action is contemplated, the person(s) complained against will be given an opportunity to comment in writing within fourteen (14) days before any action is taken. Any such suspension will be on full pay.

(6) The Preliminary Inquiry:

A Preliminary Inquiry means an assessment by the person(s) Chair of the Research Committee of the information provided by the complainant together with the response of the person(s) complained against to determine whether an allegation or apparent instance of research misconduct merits formal investigation.

(a) Immediately the complaint is lodged with the Chief Medical Officer, the person(s) complained against should be:

(i) informed in writing and given full details of the complaint, including the name of the complainant except in unusual circumstances, and informed that a Preliminary Inquiry is to proceed;

(ii) given not more than thirty (30) days in which to respond in writing; and

(iii) required to produce experimental data files or other material to be kept secure during the Preliminary Inquiry.

(b) The Preliminary Inquiry must be completed quickly, preferably within thirty (30) days, and confidentiality must be maintained.

(c) The Preliminary Inquiry should be limited to an assessment of the information supplied by the complainant and the response of the person(s) against whom the complaint has been made, in order to determine that the complaint is not trivial and that there is or is likely to be sufficient evidence to warrant holding a full Formal Investigation.

(d) Action on completion of the Preliminary Inquiry

(i) If no case is found to exist, the person(s) complained against and the complainant should be informed that there will be no further action taken. The conclusion must be recorded officially in a form satisfactory to the person(s) complained against. Provision should be made for the custody of the material supplied.

If the person(s) conducting the Preliminary Inquiry forms the view that the complaint has been vexatious or without any reasonable foundation, this finding shall be reported to the Chief Medical Officer. The Chief Medical Officer may then consider whether disciplinary or other action against the complainant is appropriate. If the complaint was reasonably brought but unsubstantiated, the case should cease. The Chief Medical Officer will need to exercise his or her judgment at this point to determine whether there are other individuals or organisations that need to be informed. This will depend upon the degree of confidentiality that has been achieved.

(ii) If the Preliminary Inquiry finds that there is a case to answer, the report to that effect will be referred to the person(s) complained against for comment before the finding is released to interested parties. A limited time will be allowed for these comments to be made and the final version of the report will include these comments. If there is a finding that serious misconduct may have occurred, formal procedures will be commenced.

### **3. Formal Investigation**

Formal investigation means a formal examination and evaluation of all relevant matters to determine whether serious misconduct in research has occurred. Formal grievance procedures as set out in the Human Resources Manual will be carefully followed.

(1) There are a number of procedural matters which need to be considered in setting up a Formal Investigation into alleged serious misconduct in research. The gravity of such a charge and its consequences, if proven, require that the procedure for the Formal Investigation follows the rules of natural justice. The person(s) complained against (and possibly other persons concerned) will be entitled to an oral hearing with legal representation and the right to cross-examine witnesses. All relevant evidence or other material before the investigators will need to be disclosed and open to questioning.

(a) Those charged with conducting the Formal Investigation must be unbiased and seen so to be, and should include someone who is a recognised authority in the discipline concerned, as well as an appropriately experienced lawyer.

(b) While confidentiality remains important during a Formal Investigation, other matters may take precedence. It is not possible in advance to state what should happen. The adjudicating body must determine what should be made public and when, bearing in mind the interests of all concerned.

It is important to protect the accused. If the charges are not proven, the accused will need to have a statement that "The charge was found to have no basis" placed on his or her record and, if suspended, to be reinstated. A charge of serious misconduct in research could damage a person's future prospects and a defamation action could result unless the procedures laid down are carefully followed. It is important to protect the complainant. In some cases, there could be subsequent victimisation which could seriously affect his or her career. There may be reason to inform the publishers of a paper that its production may have resulted from misconduct in research. Relevant funding agencies should be consulted and informed that an investigation is in progress.

(c) If allegations are made which appear to cast doubt on the validity of one or more research publications, it may be necessary to investigate past research as well as that covered by all allegations.

(d) If the person accused has been found guilty of misconduct, it is important that the position of past and present co-workers should be clarified.

#### (2) Powers of Investigation:

The Chief Medical Officer may require any members of the CDHB to give oral evidence before those conducting the Formal Investigation or to produce any material or other records in their possession relating to the matters at issue. The Chief Medical Officer may also require the person(s) complained against to repeat an experiment, where this is appropriate.

#### (3) Action following the Formal Investigation:

The decision of the Formal Investigation will take the form of a recommendation to the Chief Medical Officer. If the complaint is found to be established, the CDHB will take disciplinary action which is consistent with the current Disciplinary Codes relevant to the person(s) complained against. The person(s) complained against will be given the opportunity to make representation on the recommended penalty before such a penalty is imposed. In addition, relevant publishers, professional and academic organisations, sponsoring agencies and all other New Zealand Universities will be notified.

If the complaint is not sustained, action may be needed to redress any damage to the person(s) complained against, including the costs incurred in defending themselves. It will also be necessary to consider whether the initial allegations were made maliciously and, if so, what appropriate action should be taken.

#### (4) Action if the accused resigns:

It is part of the CDHB's procedures that, in the event of resignation or departure from the CDHB, a Formal Investigation will nevertheless be conducted to report on the status of the research and on any necessary remedial action needed to protect affected people (see section 2. (4)) and the public.

*In the event of the chairman of the Research Committee having a conflict of interest, another senior member of the Research Committee will take responsibility for co-ordinating the initial investigation.*

## 11. The Canterbury Medical Research Foundation

The Canterbury Medical Research Foundation is a charitable organisation established over forty years ago to advance the quality of health care by fostering the strength and excellence of health research in Canterbury. Funding is from the Canterbury community for Canterbury based research in all fields of health research.

The Foundation's priorities are to assist young researchers to get established, so that they can obtain larger funding amounts from the Health Research Council, Cancer Society etc. As well as project grants up to \$75,000, the Foundation also funds travel grants, grants-in-aid, Summer Studentships and PhD Fellowships. The CMRF Fellowship provides funding for a medical graduate to undertake full-time health research (3 year Fellowship). All research must be carried out in Canterbury hospitals or tertiary institutions.

The CMRF secretariat contact details are:

Guy Johnson, Director  
Level 1/230 Antigua Street  
Christchurch 8011

Telephone: 03 353 1240  
Fax: 03 374 2176  
E-mail: [health@cmrf.org.nz](mailto:health@cmrf.org.nz)  
Website: [www.cmrf.org.nz](http://www.cmrf.org.nz)

## 12. Canterbury Medical Library

Chief Librarian                      Ms Marg Walker

Administrative Assistant:        Mrs Elizabeth Hughes

Telephone:                            03 364 0500 (internal 80500)

The Canterbury Medical Library's mission is to support the educational, patient care and research activities of the staff and students of the University of Otago, Christchurch and the Canterbury District Health Board

Canterbury Medical Library is operating from alternative venues owing to earthquake damage to its main building. Information about the library, including hours of opening and any changes to the hours, is available from the library and from the library's web page -<http://www.otago.ac.nz/christchurch/library/>

### **13. Research Involving Students**

All researchers should be aware of the need to protect students in Canterbury from undue pressure relating to participation as subjects in clinical research. The general policy of the University of Otago, Christchurch is that medical students should not be recruited to research projects of any sort without the written approval of the Dean of the University of Otago, Christchurch. For other students, their academic head must be consulted.

### **14. Research Involving Animals**

All research involving animals is normally hosted by the University of Otago, Christchurch. Such activities are subject to the oversight of the Animal Ethics Committee.

All researchers planning research involving animals should in the first instance contact the Secretary of the Animal Ethics Committee via the Research Office.

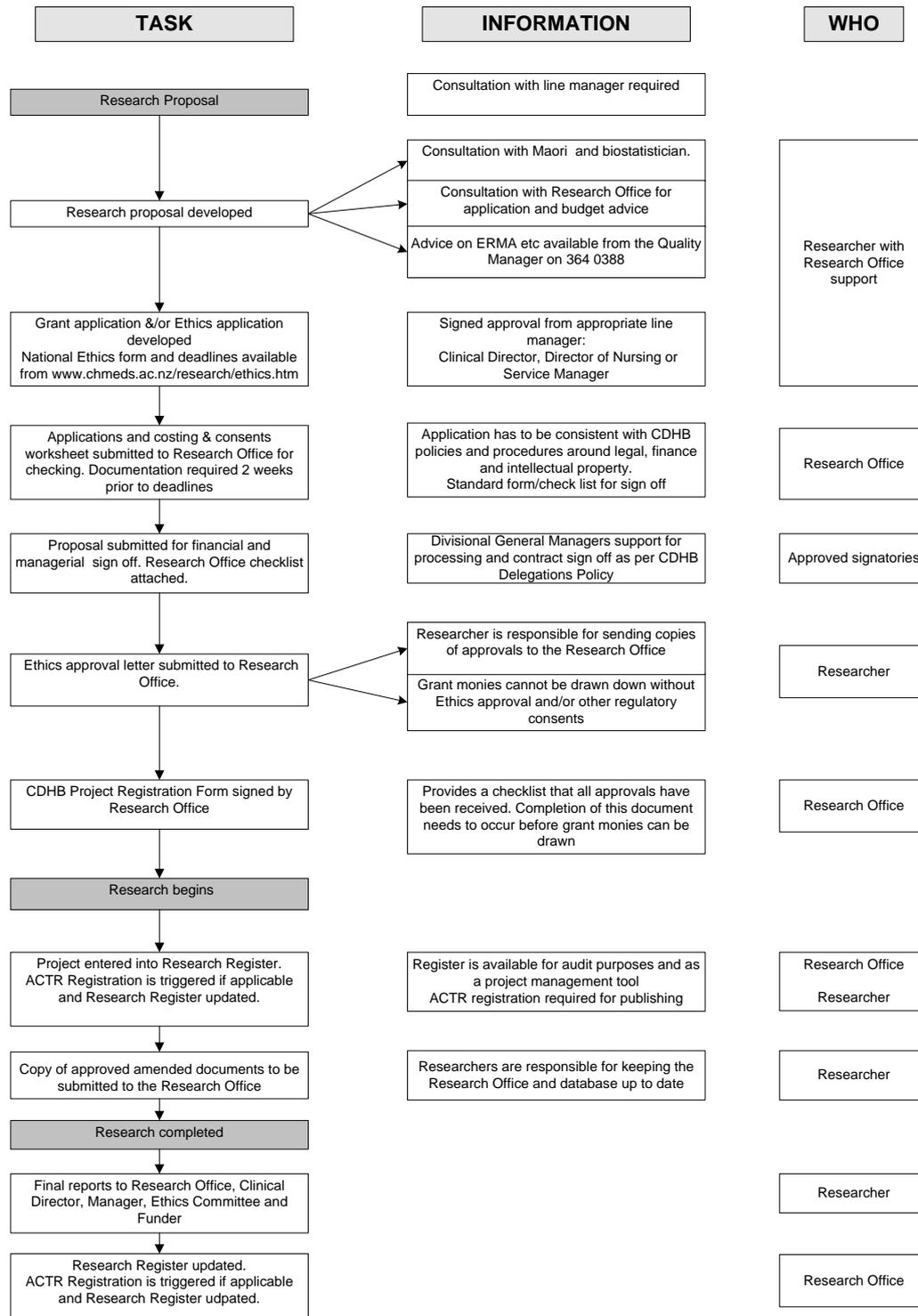
## **15. Research Procedures - CDHB**

For research carried out in Canterbury District Health Board institutions the following flowcharts outline the procedure.

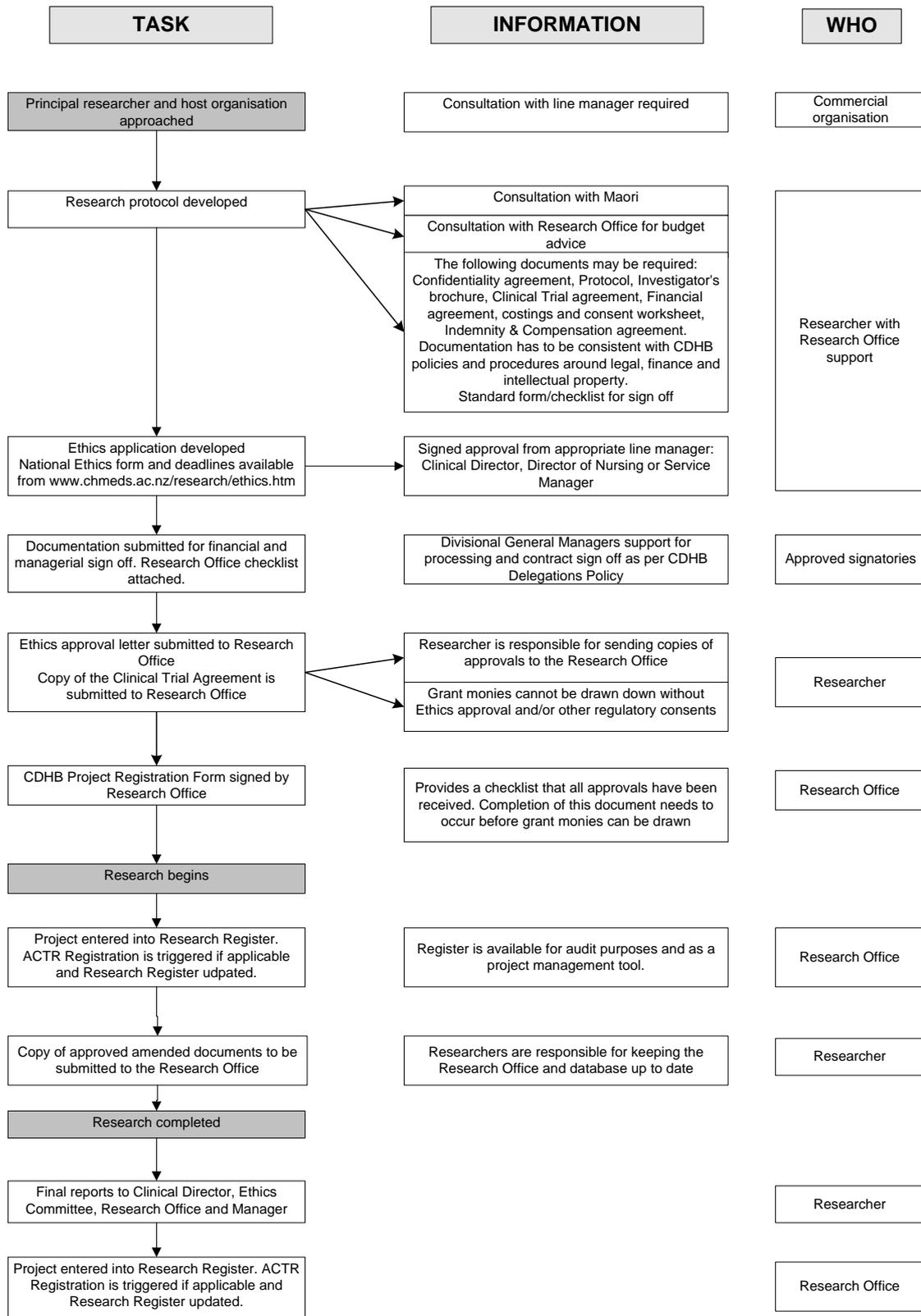
**Note:**

*Each Clinical Director will keep a written record of research protocols under way in the Department. The full protocol, Ethics Committee Approval and related documents will be held in a central file by the Clinical Director for a minimum of 15 years following the completion of the study.*

## 15.1 CDHB Grant Application &/or Ethics Application Flowchart



### 15.2 CDHB Commercially Sponsored Clinical Trial Application Flowchart



**14. Research documents and links are available on the web at:**

<http://www.otago.ac.nz/christchurch/research/researchoffice/downloads/>

## Appendix 1: Research Register

<http://researchregister/>

**New Research Projects will be entered by the Research Office.**

**A form will be sent to you requesting the following information:**

<b>Category:</b>	Select ONE category from the OECD Fields of Research.
<b>Short Title of Project:</b>	Short title of project – 50 characters maximum.
<b>Contact Organisation:</b>	This is the organisation that is the employer of the Principal Investigator and will usually be the host organisation for the research project (i.e. CDHB, UOC or External Organisation)
<b>Principal Investigator:</b>	Principal Investigator for the CDHB site.
<b>Funding:</b>	The name of the organisation that has provided the funding for the project.
<b>CDHB Study Account:</b>	Enter the number of the study account if the host institution is CDHB. <b>Do not enter study account numbers for other organisations.</b>
<b>Description of Project:</b>	200 words maximum in lay language. You may find the 'Lay description' section in your Ethics Application appropriate to “cut and paste” into this section. Do not include any commercially sensitive information.
<b>Names of Researcher(s):</b>	Please enter the names of other researchers involved with the project. This will enable other staff members to identify colleagues with particular research skills by searching the database.
<b>Division:</b>	Select a Division of the CDHB if the project is being undertaken by CDHB staff, including staff who have joint appointments with the University of Otago.
<b>Clinical Director:</b>	Select the name of the Clinical Director who approved the study at its inception, i.e. signed ethics Part 4 declaration or the CCW or emailed approval to the Research Office.
<b>Department:</b>	Select from the drop down list for CDHB departments.
<b>Start Date:</b>	Enter date the project started
<b>Expected end date:</b>	Enter the anticipated date of completion of the study.
<b>Completion date:</b>	Leave blank unless the study has completed.
<b>Status:</b>	Planning, underway, completed or withdrawn.

<b>Ethical consent required?</b>	If consent from a human or animal ethics committee is required answer <b>'Yes'</b> ; if not, answer <b>'No'</b> .
<b>Ethical Consent type:</b>	Human &/or animal. If you answered “no” to the above question, ‘type’ defaults to ‘not applicable’.
<b>Ethical Consent Approval No:</b>	Enter the approval number assigned to the project by the relevant ethics committee.
<b>Ethical Consent Expiry Date:</b>	Enter the date at which ethics approval expires. If an extension of approval is obtained this entry will need to be updated.
<b>Other Consent Required?</b>	This section is for recording whether other types of approval are required before the research can proceed e.g. SCOTT, MAF, ERMA, Department of Conservation.
<b>Other Consent Type:</b>	Enter the name of the approving body(s).
<b>Other Consent Approval No:</b>	Enter approval number(s) assigned by approving bodies
<b>Other Consent Expiry Date:</b>	Enter expiry date(s) for other approvals. If an extension of approval is obtained this entry will need to be updated.
<b>Sponsor Agreement/Contract?</b>	Some research projects will require an agreement to be signed between the researcher’s employer and the research sponsor e.g. pharmaceutical company, HRC. If this is the case enter <b>'Yes'</b> ; if not enter <b>'No'</b> .
<b>CDHB Signatory:</b>	Enter the name of the CDHB staff member who signed this agreement. This will usually be the CDHB Research Committee Chair or the CDHB CEO.
<b>Agreement Date:</b>	Enter the date that the agreement was signed.
<b>Other Manager Approval Needed?</b>	Where the research is likely to impact on other areas, for example, nursing, allied health, laboratory, radiology, pharmacy, medical records, the Clinical Director is required to obtain approval from the senior manager of that service. (See section 12.3 of the Research Manual) The Clinical Director should ensure that the appropriate <b>'Yes'</b> or <b>'No'</b> entry is made after consultation with potentially affected services.

## Appendix 2: Clinical Directors' Research Guidelines

Clinical Directors should:

1. Be aware of the Research Procedures for CDHB.
2. Be familiar with the principles contained in the *Guideline on the Regulation of Therapeutic Products in New Zealand* and/or the *International Conference on Harmonization Good Clinical Practice: consolidated guideline* (for clinical studies), and the *Declaration of Helsinki*.
3. Ensure that all staff under the Clinical Director's responsibility who are undertaking research have access to a copy and are familiar with the principles contained in the CDHB Research Manual, and the above guidelines. In particular ensure that all research staff under the Clinical Director's responsibility are aware of the correct research procedures that must be followed.
4. Carefully review each research proposal for appropriateness and sign off, when satisfied. Ensure that the investigator submits the research proposal through the Research Office as outlined in section 15.1 and 15.2.
5. Ensure that the Department retains a full copy of the research proposal, patient information sheet and approval, and all regulatory approvals for each project for a period of at least 15 years after the completion of the project.

