		Type: <b>Policy</b>	Document reference: <b>0142</b>	Manual Classification: <b>Administration and Clinical</b>
Title: <b>Research</b>			Effective date: <b>10 September 2009</b>	
Facilitator <small>sign/date</small>	Process authorised <small>sign/date</small>	Sponsor authorised <small>sign/date</small>	Version: <b>04</b>	Page: <b>1 of 13</b>
Mary La Pine/Suzie Gardner <b>Research Coordinator</b>	<i>Alfredo Bernal</i> <b>Manager Quality and Risk</b>	<i>Tom Watson</i> <b>Chief Medical Advisor</b>	Document expiry date: <b>10 September 2012</b>	

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## 1. Purpose and Scope

The purpose of this policy is to set out Waikato District Health Board's (DHB) requirements relating to undertaking and/or participating in research projects at Waikato DHB.


It is the intention of Waikato DHB to develop and maintain a role in health research within the Waikato. The Waikato DHB recognises the Treaty of Waitangi as the founding document of New Zealand and acknowledges the special relationship between Māori and the Crown under the Treaty. One of the key factors in meeting this objective will be a strong commitment by the organisation to support and promote diverse research and the individuals who undertake the research. Waikato DHB acknowledges the contribution research makes to health promotion and clinical treatment options. It supports research as a normal part of its operation within the parameters set out in this policy and where consistent with the organisation's strategic goals.

## 2. Policy

**All research activities undertaken by, or on behalf, of the Waikato DHB must meet ethical and legal standards for research and meet internal requirements.**  
**The primary focus of Waikato DHB clinical services is the delivery of care to patients. This primary function will take precedence over all other activities, including research, at all times and in relation to all resource utilisation.**

## 3. Authorisation


As signed above on behalf of the Chief Executive.

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Policy Processes and Associated Information

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## Appendix A

### 1. Standards and responsibilities

#### 1.1. Key responsibilities

The key responsibilities of Waikato DHB and its researchers are:

- Patient/consumer well being
- Protection of patient/consumer rights
- To work in accordance and acknowledge the principles of the Waikato DHB He Huarahi Oranga (Māori Health) Strategic Plan
- The safety of all individuals on Waikato DHB premises
- Prudent and transparent use of available time, funds and resources
- Meeting ethical and legal standards of research.

#### 1.2. Research approval

Waikato DHB approval from the Chief Operating Officer (COO) is required before any research may begin that involves the staff, patients and consumers of Waikato DHB or that is conducted on Waikato DHB premises.

Consultation and approval is required from the Waikato DHB Kaumatua Kaunihera Research Sub-committee and other relevant cultural groups.

##### 1.2.1. Approvals within Waikato DHB


- It is the responsibility of the relevant Group Manager to ensure that:
  - All costs incurred by the Waikato DHB Unit/Service in regard to the research project are included in an approved research budget (including those costs which will be incurred by contributing units e.g. laboratory) prior to recommending final approval.
  - Research is not commenced until all required approvals have been obtained and the proposed research has final authorisation to proceed from the COO.
  - All income and expenditure related to the research project is accounted for and any deficit or surplus of resources is managed appropriately.

##### 1.2.2. Approvals external Waikato DHB

- Relevant external approvals must be obtained prior to the commencement of research within Waikato DHB.
- Ethical approval of the research project must be obtained from the relevant Ethics Committee prior to the commencement of any research within Waikato DHB. Researchers must complete the National Application for Ethical Approval of a Research Project in conjunction with the Health Research Council (HRC) Guidelines for researchers. *(Note: These guidelines are available on the intranet research site, the internet [www.ethicscommittees.health.govt.nz/](http://www.ethicscommittees.health.govt.nz/) and in the Waikato DHB Library).*
- Specific approvals may be required depending on the nature of the research. These may include (but are not limited to):
  - National Radiation laboratory approval for radiation used in research.
  - SCOTT (Standing Committee on Therapeutic Trials) approval for unregistered medicines or formulations to be used in a trial.
  - Approval from the ethics committee of the relevant academic institution.

##### 1.2.3. Contract research

- Waikato DHB will conduct research for outside agencies when it is satisfied that the project is an appropriate Waikato DHB activity, conditions and resources are adequate, and staff are available, competent and interested in undertaking the work.

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- Identification of any risks related to a specific research contract is an essential component of the approval process. A Deed of Indemnity for Clinical Trials must be completed for every research project where patient injury is not covered by ACC and otherwise as required by the Legal Service. Site agreements and other contractual documentation must also be approved by the Legal Service.
- All applications for external support, financial or otherwise, of Waikato DHB research must be made in accordance with the Waikato DHB Sponsorship Policy. Prior approval must be obtained, as appropriate, from the relevant Clinical Unit Leader(s) / Clinical Director(s) and Business/Service Manager(s). This includes applications to the Health Research Council of New Zealand (HRC), other private funders or commercial sponsors.

#### 1.2.4. Third party research

Third parties (for example trusts or individual researchers) specifically approved for this purpose by the Chief Executive, may initiate research that involves staff, patients and consumers of the Waikato DHB or that is conducted in the Waikato DHB premises. In such cases funding will be provided by the third party for all costs involved in this research and surplus funds will be held by the third party. It is the responsibility of the relevant Group Manager:

- to ensure that all research undertaken by the third party achieves at least the same standard of research as of that undertaken by the Waikato DHB; and
- to ensure that the funding provided by the third party appropriately reflects the use made of the WaikatoDHB services, staff and equipment.


#### 1.3. Research authorisation checklist and database form

This checklist/database form is available from the Waikato DHB intranet. All proposals forwarded for final authorisation must include the Research Checklist/database form with the following attachments:

- The approved budget for the research project
- A copy of the completed Ethics Application Form
- The letter of approval from the relevant Ethics Committee
- The Waikato DHB Deed of Indemnity (signed by the external sponsor, COO and Principal Investigator) if required
- Approved site agreements and/or other contractual documentation if required
- Memorandum from the Legal Service outlining the legal risks associated with the contract documents if the research is contract research.

#### 1.3.1 Recording of research


- The office of the Chair, Board of Clinical Governance (BCG) must be notified of all clinical research and trials so that a single repository of this information exists within the organisation. Research of which the BCG has not been advised will be treated as not approved. Reports will be produced on a regular basis by the BCG office setting out the research being undertaken, the approximate cost, the surplus funds generated (whether for third party or Waikato DHB) and any other information considered relevant for management purposes.
- Prior to final approval, the checklist/database form must be presented to the office of the Chair, BCG and be assigned a database number.
- A copy of the final ethics report is to forwarded to the Chair, BCG.

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- 1.4. Final authorisation**
- Once the database number is assigned, final authorisation for the research project to proceed is given by the Chief Operating Officer.
- 1.5. Risk management**
- Research conducted by or on behalf of Waikato DHB must be compatible with the clinical needs of Waikato DHB patients/consumers and/or with Waikato DHB's goals as a funder and provider of services, and reflect principles of good research practice.
  - Any contractual relationships with external companies/contractors or institutions must be concluded with the Waikato DHB (or in cases approved by the Legal Service, by an approved trust –see 1.2.4) and not with individual employees of Waikato DHB. All contractual and related documents for research must be authorised by the Legal and Risk service. Any contract requirements must be fully complied with.
  - All individuals who are representatives of Waikato DHB must comply with Waikato DHB requirements and policies (including those detailed in this policy) regarding financial, liability and legislative aspects of research.
  - An essential function of the individual who is the Principal Investigator for a research project is that she or he will personally participate in the project to a significant degree.
- 1.6. Conflict of interest**
- Waikato DHB staff must not engage in any activity that gives rise or may give rise to a conflict of interest between their Waikato DHB activities and any other interests or obligations without appropriate disclosure and approval (see Conflict of Interest policy).
- 1.7. Acknowledgement of Waikato DHB**
- If required by the Group Manager the Waikato District Health Board should be acknowledged in any publication arising from the research.
- 1.8. Intellectual property**
- The ownership of Intellectual Property arising from research by or on behalf of Waikato DHB must be indicated in the relevant contracts or as set out in the Waikato DHB Intellectual Property policy.
- 1.9. Animal research**
- Proposals that include animal research will be considered, however there are additional requirements (e.g legislative) and/or potential issues (e.g public concern) that impact on Waikato DHB which need to be considered.
- 1.10. The use of stored body parts and bodily substances for research purposes**
- It is the responsibility of the researcher to obtain informed consent and to do so in a manner which is appropriate to the patient's needs and which meets legal requirements. This process must comply with the Waikato DHB policies on Informed Consent, Return or Disposal of Body Parts Tissue Prosthetic Devices, Waikato DHB Tikanga Best Practice guideline and Part 5 of the Ethics National Application form.
- 1.11. Clinical trials**
- All clinical trials/research involving medication must comply with the Waikato DHB Clinical Trial Medicine Management protocol.

## **2. Financial management of research projects**

The Group Manager must approve funds used for or generated by research. Rules concerning the application of such funds must be drawn up by the service concerned and approved by the Group Manager.

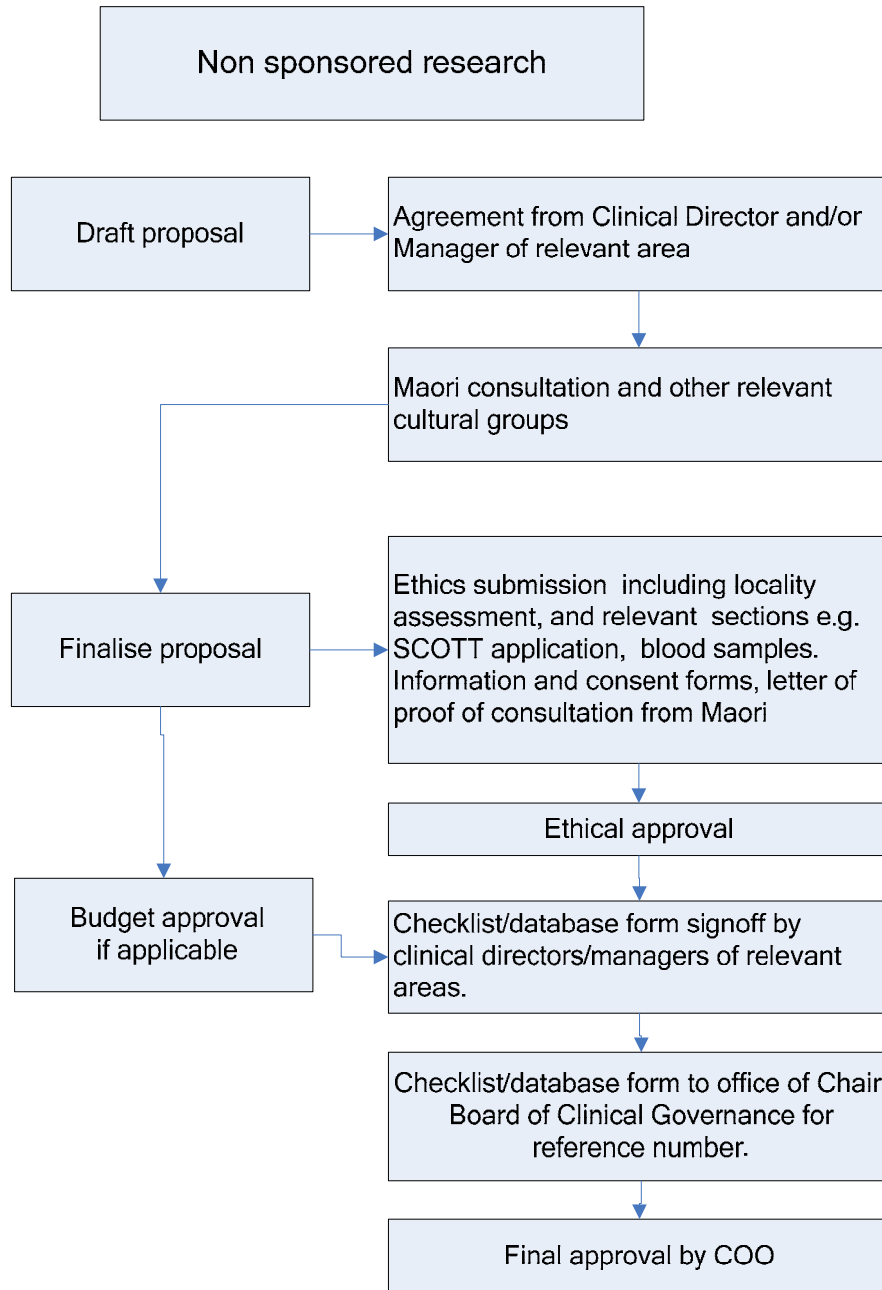
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- 2.1. Accounting procedures** Funds received by Waikato DHB from external parties for research will be held in an approved Waikato DHB responsibility centre (RC) during the life of the research. At the completion of the research surplus funds must be transferred to the Waikato HealthTrust or other third parties (e.g. trusts) approved by the Chief Executive (see 1.2.4).
- 2.2. Staff involvement** People employed by the Waikato DHB to work on research or clinical trials must have a position description that reflects the research component of their role, or a contract that is specific to the research/trial, or must be seconded from their permanent position on their existing contract terms and their time recharged to the project. Such employment must be undertaken by recruitment in accordance with the relevant Human Resources policies and must be approved by the relevant Group Manager.
- 2.3. Purchase of goods and services** The same delegated authorities and procedures for the approval and purchase of goods and services, including capital expenditure, must apply to research as for any other Waikato DHB expenditure. The relevant Group Manager must approve the rules which pertain to the use of surplus funds arising from research at the point that they are transferred to the Waikato Health Trust.
- 2.4. Asset management** Equipment used in research should be treated in the same way as any Waikato DHB equipment unless it is supplied under contract with a third party in which case the terms of the contract or agreement will prevail. Any electronic equipment used must be checked prior to use by biomedical electronics
- 2.5. End of year financial review** At the end of each financial year, and at the completion of a project, a review will be undertaken of all research projects to determine the status of residual funds. Under accounting standards no residual profits are to remain in the balance sheet of a service unit.
- 2.6. Surplus funds** No other trust or entity may be used for this purpose without express authority of the Chief Executive.

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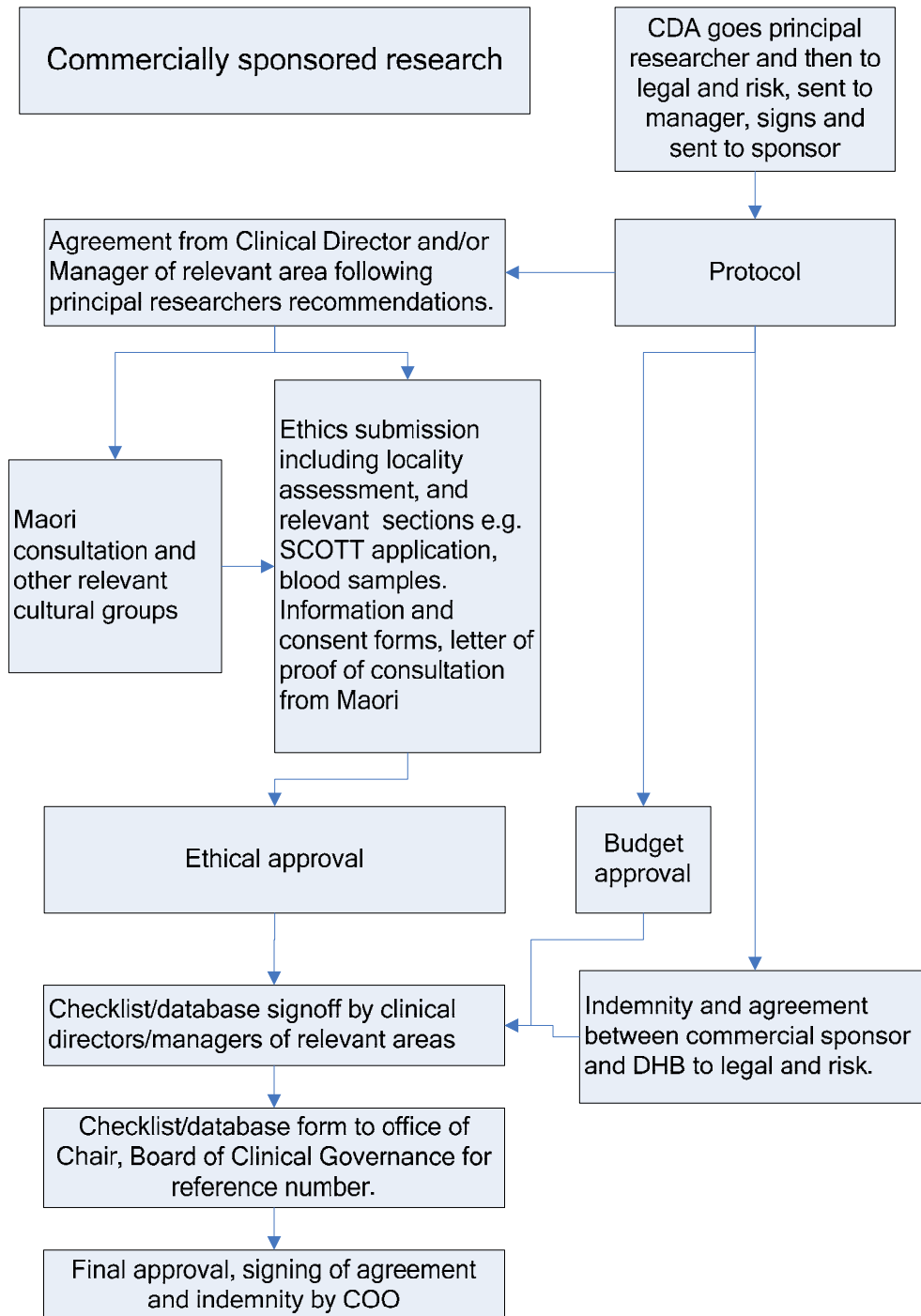
### 3. Research flowchart and explanatory information

#### 3.1. Non sponsored research



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### 3.2. Sponsored research




### 3.3. Flow chart explanations

All documents may be sourced via the Waikato DHB Intranet Research Information Site under Quickfind on the intranet home page.

#### Maori consultation

Research requiring ethical approval in the Waikato District Health Board must also include consultation with the Kaumatua Kaunihera Research Sub-committee. The requirements for this are outlined on the Waikato DHB Intranet Research Information site. Once approval has been given the researcher forwards the letter of approval and recommendations to

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the Ethics Committee. Non sponsored and internal research should consult with Maori prior to finalisation of the proposal/protocol. With sponsored studies where the protocol is set prior to consultation with Maori consultation on the research process is still required.

### **Sponsored research**

The confidentiality agreement (CDA) is sent to researchers by the sponsor or the contract research organisation (CRO). This must be sent to the Legal Service who will approve document and send to the relevant Manager for signing. However, if it is 'Deed' of confidentiality agreement it must be signed by the Chief Operating Officer (COO). On receipt of this the sponsor or CRO will forward the study protocol to the researchers. When it has been agreed the researchers will conduct the study, they will send the Waikato DHB Clinical Trial Agreement and appropriate indemnity to the sponsor/CRO. Once agreement is reached by both parties' lawyers they are sent to the COO for final approval and signatures.

### **Ethics Application**

Health research conducted in the upper North Island may be submitted to either the Northern X (Auckland) or Northern Y (Waikato) Regional Ethics Committees. Research conducted internationally or in multiple sites throughout New Zealand will submit to the Multi Region Ethics Committee based in Wellington. Relevant approvals must be sought from external agencies such as Standing Committee for Therapeutics Trials (SCOTT) and National Radiation Laboratory prior to submission.

Part 4 of the Ethics Application is signed by the researcher and Head of Department permitting the study to be conducted in the area. The locality assessment is signed by the COO agreeing to the research being conducted in the institution. Form A or B Is completed stating the research is covered by ACC or by Sponsors insurance. Include a Insurance certificate in Ethics Application for Form B trials. For applicable studies, Part 5 (Use of Human Tissue covered under Human Tissue Act of 2008), Part 6 (Genetic Research), Part 7 (Participants who are unable to give informed consent to participate), and/or Part 8 (Xenotransplantation) must be completed. Incomplete EA will result in delay of application been heard by Ethics Committees.

The following documents are permitted to be pending


- Locality assessment by organisation
- Response letter from group providing Maori consultation
- SCOTT or NRL approval

### **Research Authorisation checklist /database form**

The checklist must be signed by all relevant parties and presented with ethics and other approvals to the COO for final authorisation for the study before the study can be commenced. Prior to final COO approval a copy of the form must be lodged with the office of the Chair, Board of Clinical Governance and a database reference assigned. Final approval will not be given unless a reference has been assigned.

### **Expedited ethics review**

For some studies an expedited ethics review may be appropriate. These studies do not require full ethics review but the researcher must be

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complete an authorisation checklist/database form.


#### 4. Serious adverse event management

Any serious adverse event applicable to the requirements of the Waikato DHB Incident / Accident / Near Miss Policy arising from the research project, or which may be related to the research project, must be immediately notified to

- the Group Manager and the Waikato DHB Quality and Risk Manager. using the Waikato DHB Incident / Accident / Near Miss Notification form and policy process.
- where relevant the external entity that has contracted with Waikato DHB. A copy of this SAE form may be submitted to the Group Manager and Quality and Risk Manager attached to a blank Waikato DHB Incident / Accident / Near Miss Notification form
- Any patient participating in a clinical trial which results in breaking code of medication in case of blinding, then it is a requirement that the Director General of Health be notified within 3 working days of being informed of the Adverse Event
- All other SAE that do not involve 'breaking a code' and are not study end points are to be reported to ethics committees as part of regular reporting

#### 5. Research and use of patient information

- Patient information may be used for research purposes and the following requirements must be met:
- Where research involves the use of health information, the repository staff (e.g. Medical Records Department, Waikato Hospital) will require the researcher to present the research authorisation checklist/database form to validate access to the clinical records.
- If the information is going to be published or presented in a way which identifies (or may be used to identify) the patient, their consent, or that of their representative, must comply with the Waikato DHB information Privacy policy, Consent policy and any contractual requirements.
- Written informed consent must be obtained and comply with the Waikato DHB Policy on Informed Consent.
- Reasonable steps must be taken to protect health information against loss, unauthorised access, use, modification, disclosure or other misuse e.g.
  - by ensuring the information is stored in a physically secure environment
  - by removing names or other identifying information from any copies of records
  - by using an identifier to ensure that identification of individuals is only possible by reference to a master index which is stored securely.
  - Researchers wishing to keep health information longer than required for the original research project must obtain the approval of the Ethics Committee.
- Reasonable steps must be taken to ensure that the information is accurate, up to date, complete, relevant and not misleading. The extent of the health information required for the research must be


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limited to that required to carry out the research proposed.  
(Obligation for ensuring this rests with the researcher).

- Once the research has been completed the use of the health information relied upon must comply with the Waikato DHB Information Privacy policy and any contractual requirements.

## 6. Success indicators


- That all research projects within Waikato DHB are authorised in a timely manner and meet the requirements of this policy.

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## Appendix B

### 1. Definitions

<b>Audit</b>	Audit conducted within the Waikato DHB is defined as the systematic collection and review of objective evidence against accepted standards, to identify risks and opportunities for improvement and to provide quality assurance. Audits are fact finding and assessment exercises aimed at providing reliable, accurate information. It should be noted that some audits may require ethical approval if the audit reaches a threshold of more than minimal risk. For further information see the National Ethics Advisory Committee documented referenced above.
<b>Ethics committees</b>	The Ministry of Health-funded Ethics Committee are accredited by the Health Research Council of New Zealand. They are independent of the District Health Boards.
<b>Group manager</b>	Level 4 Manager as per Delegations of Authority Manual
<b>Patient</b>	Patient / client / consumer / tangata whiaora
<b>Principal investigator</b>	The designer of the research proposal or the person authorised by Waikato DHB to lead the research project.
<b>Representative of Waikato DHB</b>	All Waikato DHB employees, contractors, external personnel and students on placement within Waikato DHB.
<b>Research</b>	<p>Research conducted within the Waikato DHB is defined as the systematic investigation and study designed to establish facts and new conclusions. This includes clinical trials to test new drugs and other clinical procedures or equipment. These may be sponsored, under contract to third parties or conducted on behalf of the Waikato DHB</p> <p>For further information and discussion regarding audit or research refer to the following document: Operational Standards for Ethics Committees  <b>Web site <a href="http://www.newhealth.govt.nz">www.newhealth.govt.nz</a></b></p>
<b>Research requiring ethical approval</b>	<p>Research requiring ethical approval, excluding audit, (as defined by the Ministry of Health Guidelines for the Ethical Approval of Research) may include:</p> <ol style="list-style-type: none"> <li>Prospective clinical trials</li> <li>Observational studies involving some extra potentially dangerous intervention.</li> <li>Observational studies that do not involve extra intervention, but do have issues of privacy, sample disposal, information and/or consent.</li> <li>Where the principal investigator requires ethical approval for funding, academic or publication requirements.</li> </ol> <p>Any amendments to the protocol of an existing approved research project.</p>
<b>Service manager</b>	Level 5 Manager as per Delegations of Authority Manual
<b>Waikato Health Trust</b>	A charitable trust that administers donated funds under a trust deed for the benefit of health in the Waikato region. The trust is a separate legal entity from the Waikato DHB. Sub accounts may be set up with specific rules to suit individual research needs. Contact the Waikato DHB Finance Department.

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## 2. Legislative Requirements

Waikato DHB must comply with the following legislation (this list is not exclusive):

- Charitable Trusts Act 1957
- Code of Health and Disability Services Consumers' Rights 1996
- Health and Disability Commissioner Act 1994
- Health Information Privacy Code 1994
- Health Relevant Professional Regulation – e.g. Medical Practitioners Act 1995
- Health Practitioners Competence Assurance Act 2003
- Human Rights Act 1993
- Human Tissue Act 2004
- Injury Prevention Rehabilitation and Compensation Act 2001
- New Zealand Bill of Rights Act 1990
- Privacy Act 1993
- Convention on Rights of The Child 1993
- Health Act 1956
- Official Information Act 1982
- Public Records Bill 2004 (replaces the Archives Act 1957)
- Radiation Protection Act 1982

## 3. Associated Documents

- Health Research Council Guidelines
- Waikato Health Trust Deed
- Ministry of Health Guidelines for Research with Māori
- Operational Standard for Ethics Committees (Ministry of Health) – Section 3 (“Matters requiring ethical review”) and Section 4 (“Matters for which ethical advice may be sought”)
- Statement on Responsibilities in Clinical Research in Institutions (Medical Council of New Zealand) 1992.
- The Principles of the Treaty of Waitangi
- Consent in Child and Youth Health: Information for Practitioners MOH 1998
- Waikato DHB Intellectual Property policy
- Waikato DHB Clinical Trial Medicine Management protocol
- Waikato DHB Deed of Indemnity for Clinical Trials
- Waikato DHB Delegations of Authority Manual Schedule K
- Waikato DHB Informed Consent policy
- Waikato DHB Towards Māori Health Gain Framework
- Waikato DHB Tikanga Recommended Best Practice Guidelines-Cultural Competencies
- Research authorisation checklist/database form.