Research

Policy Responsibilities and Authorisation

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Target Audience	All persons (internal and external to Waikato DHB) undertaking research on Waikato DHB patients and/or staff.
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Policy Review History

Version	Updated by	Date Updated	Summary of Changes
6	Sarah Brodnax	20/08/2018	Transfer to new template and major update

Research

Contents

1. Introduction

1.1 Purpose

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.

All research activities undertaken by, or on behalf of, the Waikato DHB must meet ethical and legal standards for research and meet internal requirements.

This policy applies to all persons employed by Waikato DHB, all staff with honorary appointments to Waikato DHB and to any person undertaking research involving care of patients at Waikato DHB, involving staff of Waikato DHB and/or other resources.

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 allocation and utilisation.

Further detail on the process of registering research at Waikato DHB can be found on our website https://www.waikatodhb.health.nz/learning-and-research/research/

1.2 Background

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. Waikato DHB has included as a strategic imperative the aim of being "a centre of excellence in learning, training, research and innovation". This includes priorities of cultivating a culture of innovation, research, learning and training across the organisation and fostering a research environment that is responsive to the needs of our population.

Research and the Treaty of Waitangi

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. In line with Partnership, Participation and Protection Waikato DHB has made a strong commitment to support and promote diverse research and to support the individuals who undertake the research. Research is essential to the organisation to support improvement in health gain for Māori and to meet the Waikato DHB priority of eliminating inequity in healthcare.

Health Information Standards Organisation

DHBs are established under the New Zealand Public Health and Disability Act (NZPHD Act). As Crown entities, DHBs also fall within the scope of the Crown Entities Act 2004 (CE Act). Through both the DHB is legislatively obligated to adhere to the Operational Policy Framework (OPF). The Operational Policy Framework (OPF) is a set of business rules, policy and guideline principles that outline the operating functions of DHBs. Sec 11.2.3 c sets the obligation for the DHB to adhere to all published HISO standards.

Two specific HISO standards with implications for research include:

- HISO 10029 – Health Information Security Framework: Sets the expectations on how health information is created, displayed, processed, transported, stored, & disposed of in a way that maintains the information's confidentiality, integrity, & availability. The standard includes specific cloud obligations, which are specifically relevant for research noting the definition of cloud is any storage or processing of information completed outside of the DHB.
- HISO 10064 - Health Information Governance Guideline: Sets the expectations when utilising health information to ensure compliance with the Privacy Act and the Health Information Privacy Code.

1.3 Scope

All persons, both internal and external researchers, involved in research activity undertaken in the Waikato DHB.

This policy relates to research by Waikato DHB staff or others, relating to staff, patients or population of the Waikato DHB area, specifically relating to health and health services.

All research conducted in the Waikato DHB must be conducted with the knowledge of Waikato DHB and must meet the requirements of the ethics committees from which approval has been obtained (where applicable).

1.4 Exclusions

Audit and related activity and quality improvement - please see the Clinical Audit Policy (under development)

National Ethics Advisory Committee (NEAC) standards note the following activities, in line with international guidance, are considered non-research. Some activities may start as a non-research activity, but then develop a research component. In such cases those involved in the activity must reconsider whether further ethical oversight is warranted.

- Public health investigations explore possible risks to public health, are often immediate or urgent and are often required by legislation. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions.
- Public health surveillance involves monitoring risks to health by methods that include systematically collecting, analysing and communicating information about disease rates.
- Pharmacovigilance (post-marketing surveillance) involves monitoring the adverse effects of pharmaceuticals after their introduction into the general population. Its methods include spontaneously reporting adverse events and monitoring all adverse events for a restricted group of medicines (prescription event monitoring).
- Resource utilisation reviews evaluate the use of resources in a particular health or disability service activity. For example, they might review health records to

determine health care inputs such as chest X-rays for patients with a particular diagnosis.

- Programme evaluation focuses on a whole programme, rather than specific interventions, where the sole purpose of the exercise is to refine and improve the programme or monitoring.
- Audit and quality assurance activities involve investigating whether an activity meets explicit standards, as defined in an auditing document, for the purpose of checking and improving the activity audited. An audit generates knowledge for the situation in which it was collected rather than generalisable knowledge. It should provide feedback primarily to the service, although it may also involve a more general publication or presentation of its findings. Access to confidential medical and personal information the service holds should be restricted to those individuals the service provider employs or contracts, the funder of the service, or an agency responsible for overseeing the safety and quality of the service. Such information should be used solely for the purpose of auditing a service.
- Quality improvement involves cycles of interventions that are linked to measurable assessment with the goal of improving the process, outcome and efficiency of health care. For an activity to be considered quality improvement, it must not be conducted to generate evidence to support an intervention's efficacy, but it can involve evaluating and changing practice.

2. Definitions

Audit (Clinical Audit)	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 of current practice. It should be noted that some clinical audits may require ethical approval if the audit reaches a threshold of more than minimal risk. For further information see the Standard Operating Procedures for Health And Disability Ethics Committees (Section 8.2).
Co-ordinating Investigator (CI) or Principal Investigator (PI)	The CI/PI for a study must be professionally based, in whole or in part, in New Zealand. In the case of international studies, a local investigator should be nominated as the CI/PI for the New Zealand arm of the study. The CI/PI has the overall responsibly for the conduct of the trial in New Zealand and is the person authorised by the sponsor (if applicable) and Waikato DHB to lead the research project within the Waikato DHB
Conflict of Interest	A situation where there is a divergence between the individual interests of a person and their professional responsibilities such that an independent observer might reasonably conclude that the professional actions of that person are unduly influenced by their own interests.
Ethics Committees	The Ministry of Health-funded Health and Disability Ethics Committees (HDEC) are accredited by the Health Research Council of New Zealand. They are independent of District Health Boards. Tertiary institutions also have ethics committees (Institutional Ethics Committee – IEC), which are independent of District Health Boards.

Director	Level 4 Manager as per Delegations of Authority Manual
Executive Director	Level 3 Manager as per Delegations of Authority Manual
Participant	Person who takes part in research whether directly or indirectly (e.g through the use of their information or stored tissue samples). In some research this may include wider whanau or collective
Patient/Consumer	Patient / consumer / client / tāngata whiaora Person who has received care from the Waikato DHB. May also include authorised patient representatives / primary care-givers for research involving patients not able to independently represent themselves.
Representative of Waikato DHB	All Waikato DHB employees, contractors, external personnel and students on placement within Waikato DHB.
Research	Research conducted within the Waikato DHB is defined as the systematic investigation and study designed to establish facts and new conclusions. Human research is conducted with or about people or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through: taking part in surveys, interviews or focus groups; undergoing psychological, physiological or medical testing or treatment; being observed by researchers; researchers having access to their personal documents or other materials; the collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, and head, bones, tumour and other biopsy specimens) or their exhaled breath; access to their identifiable information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database *(ref: The Royal Melbourne Hospital).* 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.
Research requiring ethical approval	Research requiring Health and Disability Ethics Committee approval, excluding audit, (as defined by the Ministry of Health Guidelines for the Ethical Approval of Research) may include: a) Prospective clinical/interventional trials b) Observational studies involving some extra potentially dangerous intervention. c) Observational studies that do not involve extra intervention, but do have issues of privacy, sample disposal, information and/or consent. d) Where the principal investigator requires ethical approval for funding, academic or publication requirements. e) Any amendments to the protocol of an existing approved research project. Research may require ethical approval by an Institutional Ethics Committee rather than HDEC.

Types of Research	
Observational Research	The researcher does not influence the assignment of any variable in an observational study. Instead, the researcher observes and analyses natural relationships between variables and outcomes and records them. Observational studies include case control studies, cohort studies, cross-sectional studies, case reports, case series and descriptive studies. The prospective collection of data – such as from blood samples, imaging or questionnaires – does not change a study from observational to interventional. Observational studies are not automatically of minimal risk; indeed, they may involve invasive or high-risk means of collecting data from participants.
Interventional Research	A study in which the researcher controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). The term 'intervention study' is often used interchangeably with 'experimental study. Many interventional studies are clinical trials. May evaluate: a preventative, diagnostic or therapeutic intervention, a new intervention, an intervention established in practice but not adequately substantiated by scientific evidence, an established intervention being used for a new purpose, withholding or altered administration of an established intervention, a change in the method of delivering care.
Epidemiological and public health research studies	These studies often involve use of different study methods and tools on a large number of research participants in single or multiple settings. Many include features of observational studies (such as cross-sectional studies), case control studies, cohort studies, case reports, case series and other descriptive studies, as well as features of intervention studies (such as field trials and cluster randomised controlled trials, stepped-wedge and quasi-experimental study designs involving groups, geographic areas, institutions or systems collectively rather than individually Normally carried out locally for local quality improvement. In cases where it is part of a national programme these may be registered with the DHB to reflect our participation. Ethics may be required for some of these activities. Also see Section 1.4 Exclusions
Audit or Related Activities	
Waikato Health Trust	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. To do this, contact the Waikato DHB Finance Department.

3. Policy Statements

The Waikato DHB policy for research is that all research undertaken at Waikato DHB or involving Waikato DHB staff, patients or resources must:

- be registered with the Research Office
- include completion of the Waikato DHB locality approval process
- comply with all relevant legislation, regulations, codes and guidelines as applicable.

4. Policy Processes

4.1 Roles and 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 Ki Te Taumata o Pae Ora - 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, privacy, data security and legal standards of research.

All Staff

All staff involved in research at Waikato DHB must adhere to this policy and ensure that research protocols are followed.

Clinicians

All clinicians involved in research at Waikato DHB must adhere to this policy and ensure that research protocols are followed. Clinicians approving research are indicating their support of the research project being conducted in their department and that there are suitable and adequate facilities and resources for the research project to be conducted at this site. See further detail in Appendix A.

Managers (Directors/Executive Directors)

Managers approving research are indicating their support of the research project being conducted in their service and that there are suitable and adequate facilities and resources for the research project to be conducted at this site.

They are also indicating that the research meets service and organisational strategic goals. See further detail in Appendix A.

Contractors / External Researchers and Persons of Interest

Those external researchers who have been given access to information from Waikato DHB will have signed an access to information form, completed the required Research Office processes and will adhere to the Research Policy.

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 Director/Manager of the service.

4.2 Registration of Research

All research must be registered with the research office. The process for registering research is outlined in Appendix A. This includes those studies which are sponsored by pharmaceutical companies, investigator led studies and research conducted for attainment of a qualification.

Researchers are responsible for obtaining ethics approval as required and Māori Research Review Committee endorsement. They are also responsible for obtaining financial/budget and procurement approval (if required) and a legal review of any agreements pertaining to the study.

4.3 Māori Consultation at Waikato DHB

Te Puna Oranga (Māori Health Service), Waikato DHB is responsible for providing Māori consultation for researchers and leads the Māori Research Review Committee (MRRC). In alignment with the Waikato DHB Strategy which has an increased emphasis on health equity for high need populations, the MRRC encourages researchers to consider how they can maximise the potential for Māori health gain from their research. This includes oversampling of Māori participants if possible to get equal or adequate explanatory power. The MRCC seeks to ensure that ethnicity is collected and recorded appropriately for all clinical trials and stipulates that the census ethnicity question is used correctly. Guidance on research questions and analyses is provided on an as required basis. Waikato DHB Research Advisory Group has endorsed Te Mana Raraunga – Māori Data Sovereignty Network Charter.

4.4 Ethical Standards

All health and disability research must comply with established ethical standards. The Health and Disability Ethics Committees (HDECs) check that proposed health and disability research meets or exceeds established ethical standards determined by the National Ethics Advisory Committee (NEAC). These ethical standards are contained in:

- Ethical Guidelines for Observational Studies
- Ethical Guidelines for Intervention Studies.

(These are available on the NEAC website https://neac.health.govt.nz/publications)

These standards apply to all health and disability research, regardless of whether HDEC review is required for that research.

Not all health and disability research requires HDEC review. The complete definition of the scope of HDEC review is contained at section 3 of the Standard Operating Procedures for HDECs, available at https://ethics.health.govt.nz/

Where research is considered by HDEC to be Out of Scope, ethical consideration will be given to ensure the study meets the DHB requirements for confidentiality, informed consent and safety and security.

4.5 Other Processes

4.5.1 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.

Identification of any risks related to a specific research contract is an essential component of the approval process. A current insurance certificate for the trial is required; furthermore 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 Waikato DHB Legal Service (see also Insurance for Clinical Trials, later in this document). 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. The Research Office will give the final approval for the organisation.

4.5.2 Third party research

Third parties (for example trusts, independent companies or individual researchers) specifically approved for this purpose by Waikato DHB, 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 Director/Executive Director:

- To ensure that all research undertaken by the third party is completed to at least the same standard of research as that undertaken by the Waikato DHB including Waikato DHB sign-off and locality approval;
- To ensure the research protocol has undergone scientific review from an HDEC approved source
- To ensure that the funding provided by the third party appropriately reflects the use made of the Waikato DHB services, staff and equipment (including clinic time).
- To ensure these parties to sign an Access to Information form.

4.5.3 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 Waikato DHB Conflict of Interest policy).

A conflict of interest, in the context of research, exists where the interest or responsibilities of an individual or an institution have the potential to influence the way they carry out their institutional role or professional obligations in research. A conflict may relate to financial interests and/or private, professional or institutional benefits that depend significantly on the research outcome. In addition to affecting the integrity of a researcher, a conflict of interest may compromise the research process itself, as well as the institutional governance of research.

For research this includes clarifying whether

- any investigator or direct members of their families have any commercial interest in the intervention(s) being studied, or any financial relationship to the study sponsor or funder(s) that may inappropriately influence his or her conduct in the study;
- any investigator will be remunerated for their involvement in the study in a way that may inappropriately influence his or her conduct in the study (for instance bonuses for favourable results or high recruitment rates)
- any investigator will also be the usual health or disability support service provider for one or more of the participants in the study

and how these potential conflicts of interest will be minimised and managed.

4.5.4 Contentious Issues

Contentious issues that arise regarding any research project shall firstly be discussed within the relevant service; and if unable to be resolved by the service (Clinical Director, Clinical Nurse Director, Operations Director group) then the issue will be raised to the Executive Director responsible for the service. If the issue is unable to be resolved, the issue will be raised with the Director – Quality & Patient Safety; and if necessary taken to the Research Advisory Group.

Contentious issues may include not following Waikato DHB process; questions regarding the research project and whether to sign-off or not; and serious issues such as misconduct in research.

Misconduct in research is fabrication, falsification, plagiarism, negligence, abuse of confidentiality or access, or other practices that deviate from those that are commonly accepted within the scholarly and scientific community for proposing, conducting or reporting research. Misconduct does not include honest error or honest differences in interpretation or judgments of data but does include undertaking research without prior approval of the DHB and Health and Disability Ethics Committees (HDEC). Occurrences of misconduct should be registered through the Datix system (either complaint or incident) and with the Internal Audit unit and be reviewed through those channels. Any reports on misconduct issues will be monitored by the Research Advisory Group.

4.5.5 Research and use of Patient Information

Patient information may be used for research purposes and the following requirements must be met:

- Justification for the use of data must meet with Health Information Privacy Code and Code of Rights requirements.
- Where research involves the use of health information, the information provider will require the researcher to present the Waikato DHB Approval of Research form to validate access to the information (for example Clinical Records staff to provide access to clinical records; Operational Performance & Support staff before providing patient lists).
- Reasonable steps must be taken to protect health information against loss, unauthorised access, use, modification, disclosure or other misuse, for example
    - by ensuring the information is stored in a physically secure environment
    - by removing names or other identifying information from any copies of records where practicable,
    - by using an identifier to ensure that identification of individuals is only possible by reference to a master index which is stored securely
    - by password protecting any information on a spreadsheet, and making it available only available to the research staff.
    - by ensuring identifiable patient information is not be sent to an external email (such as Hotmail, gmail).

- by ensuring data collection does not happen in the cloud (for example google forms, dropbox, personal laptops) unless approved by IS.

- 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, Disclosure of Health Information Policy, Informed Consent policy and any contractual requirements.
- Where informed consent is required for the research, written informed consent must be obtained and comply with the Waikato DHB Policy on Informed Consent. Where the study is required to have HDEC approval, the information and consent form is required to be approved by HDEC.
- Researchers wishing to keep health information longer than required for the original research project must obtain the approval of the HDEC.
- 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 limited to that required to carry out the research proposed (Obligation for ensuring this rests with the researcher).

Where clinical services hold databases with patients' clinical information in them for the purpose of research:

- the information in these databases shall be held securely to ensure patient privacy standards are met, including having a governance process relating to accessing data
- the patient should be informed that the information is being held, and the purpose for which it is held.
- If consent is not evident, ethical approval may be needed in order for the data base to be used for research purposes. Ethical approval is not required if the information is to be used for purposes such as service evaluation, outcome analysis.

The Information Privacy Policy (Ref.1976) states: The primary purpose for which information should be collected is to provide assessment and treatment to patients of the Waikato DHB. Waikato DHB also has a range of other related purposes including planning, administrative functions, education, research, quality improvement and reporting requirements.

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

4.5.6 Research on our own staff

Requests to conduct research activities involving Waikato DHB staff (such as surveys or interviews for example) must be registered through the Research Office process. Waikato DHB has an absolute right to know what will become of the information obtained from Waikato DHB staff and its intended use and application. Waikato DHB staff have a right to remain anonymous. The decision by Waikato DHB staff of whether to participate or not in research will not affect their employment at Waikato DHB.

4.5.7 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.

4.5.8 The use of stored body parts and bodily substances for research

It is the responsibility of the researcher to obtain informed consent prior to the collection of any tissue, body parts or bodily substances 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, and HDEC application form (as defined by section 7 of the Human Tissue Act 2008).

For studies where this tissue, body parts or bodily substances is being kept beyond the completion of the trial (biobanking), or where genetic analysis is occurring, participants should be asked to re-sign the consent for this at the end of the clinical trial.

4.5.9 New Medicines

Where the study involves the administration of a new medicine to participants, these sites must be registered with Medsafe's Clinical Trial Site Self-Certification scheme http://www.medsafe.govt.nz/medicines/clinical-trials.asp

4.5.10 Publication

Employees of the Waikato Clinical Campus and any other education providers who also perform clinical duties at Waikato DHB should consider whether any proposed publication will be a Waikato DHB publication. In general, any publication with direct application to their clinical practice and made available to colleagues and patients, a Waikato DHB publication.

Employees of the DHB who submit clinical and academic work for publication must ensure this meets Waikato DHB Media & Communication policy requirements. This includes joint authorship with education providers and other organisations. In these circumstances, follow the policy without prejudice to the ownership of intellectual property as governed by other policies and agreements.

Research undertaken by Waikato DHB investigators should cite and credit Waikato DHB.

4.5.11 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. Research must also reflect the principles of Good Clinical Practice (GCP) available at http://ichgcp.net and the Medsafe Guideline on the Regulation of Therapeutic Product s in new Zealand-Part 11: Clinical trials –regulatory approval and good clinical practice requirements available at: http://www.medsafe.govt.nz/medicines/clinical-trials.asp
- Any contractual relationships with external companies/contractors or institutions must be conducted with the Waikato DHB (or in cases approved by the Legal Service, by an approved trust) and not with individual employees of Waikato DHB. All contractual and related documents for research must be authorised by the Legal Service. All contractual requirements must be complied with in full.
- 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 they will have adequate time to oversee the project, have overall responsibility for it, and that they will be personally involved in the project.

4.5.12 Reporting

On completion of the study the researcher will advise the research office, and will also provide a report on completion of the analysis of the results.

4.5.13 Retention of Data

Retention of data will be dictated by either the formal contract for the research study or by the General Disposal Authority (the disposal schedule authorised by the chief archivist which defines the (minimum) retention periods and consequent disposal actions for classes of records held by District Health Boards).

4.6 Clinical Trial Specific Processes

Clinical Trials

All clinical trials/research involving medication must comply with the Waikato DHB Medicine Management Clinical Trial protocol.

All staff covered by the scope of this policy will adhere to the principles of GCP http://ichgcp.net. This applies regardless of whether approval under the Medicines Act is required for the trial.

All staff have timely access to correct protocols, manuals, equipment and procedures for the appropriate management of any research.

Please also refer to Appendix B of this document.

All patients on a clinical trial will have this fact noted in their clinical record.

All patients participating in a clinical trial have details entered on the clinical research trials/audit section of the Alerts and Warnings form (134726) in the front of the clinical record and on the Alert/Medical Warning section of the iPM (patient management) system. Contact details of the trial coordinator and/or investigators must be available. For further detail please refer to the Medicines Management Policy and Medicines Management – Clinical Trials Protocol.

Serious Adverse Event Management

The Serious Adverse Event (SAE) definition in relation to Clinical Trials may not meet the Incident Reporting guidelines as defined in the Waikato DHB Incident Management Policy. However if the SAE is, in the opinion of the Principal investigator, Co-Investigator or Sub-Investigator, related to any trial related procedures or medication then staff are required to follow the Waikato DHB Incident Management policy.

Any SAE identified in an incident report (in line with 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 Director/Executive Director and the Waikato DHB Director Quality & Patient Safety using the Waikato DHB Datix system and policy process.
- The external entity that has contracted with Waikato DHB, where relevant, will submit a copy of this SAE to the Director/Executive Director and Director Quality & Patient Safety

If as a result of a SAE un-blinding is necessary, it is a requirement that the Sponsor is notified within 24 hours, and HDEC, Medsafe and SCOTT (Standing Committee on Therapeutic Trials) be notified within seven calendar days of the Principal Investigator being informed of the SAE.

All other SAE that do not involve 'breaking a code' and are not study end points have to meet reporting guidelines to HDEC prior to reporting.

5. Financial management of research projects

Financial Management of Research Projects

The Director/Executive Director 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 Director/Executive Director.

Accounting Procedures

Funds received by Waikato DHB from external parties for research will be held in an approved Waikato DHB balance sheet account and Responsibility Centre (RC) during the life of the research. During the research and at completion of the research, surplus funds may be transferred to the Waikato HealthTrust or other third parties (e.g. other than Waikato Health Trust) approved by the Chief Executive.

Budgeting and financial monitoring of Funded Research Projects

All anticipated costs incurred by the Waikato DHB Unit/Service in regards to the research project are to be included in an approved budget. A budget for all new research projects

needs to be prepared detailing the source of funding, all anticipated revenue and expenses, as well as clearly indicating whether a surplus or a loss is anticipated for the research project. All income and expenditure related to the research project is to be accounted for in the accounting system and the Finance Manager is to ensure financial reports are made available to the relevant research departments. The budget must be approved by the Finance Manager and the Director/Executive Director as part of the standard research approval/authorisation process.

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.

New Devices

Any new device to be used in a research project whether provided by the sponsor or not must be approved by procurement as part of the Waikato DHB locality approval process.

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 new equipment used either as the focus of research or in carrying out research must be approved through the Procurement process, and as part of that process be checked by biomedical engineering and infection prevention and control.

Transfer of funds to/from external organisations (other than Waikato Health Trust)

Other than the Waikato Health Trust, no other organisation may receive Waikato DHB funds generated through research activity without the organisation being approved by the Chief Executive for this purpose.

Where the result of a research project is a loss, efforts should be made to recover the loss made from the funding party of the research project (Waikato Health Trust or external organisation).

6. Audit

6.1 Indicators

- All research projects undertaken at Waikato DHB are registered with the Research Office
- All research projects within Waikato DHB are authorised in a timely manner and meet the requirements of this policy.
- Researchers supply a report or executive summary to the Research Office once their study has finished.

7. Legislative Requirements

7.1 Legislation

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 Practitioners Competence Assurance Act 2003
- Human Tissue Act 2008
- The Accident Compensation Act 2001
- New Zealand Bill of Rights Act 1990
- Public Records Act 2005
- Radiation Safety Act 2016
- The Medicines Act 1981 and
- The Medicines (database of medical devices) Regulations 2003
- Medsafe NZ http://www.medsafe.govt.nz/medicines/clinical-trials.asp

7.2 External Standards

- Ethical Guidelines for Intervention Studies (2012)
- Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (2012)
- Te Ara Tika - Guidelines for Maori research ethics (Health Research Council of New Zealand, 2010)
- Pacific Health Research Guidelines (Health Research Council of New Zealand (2014)

8. Associated Documents

8.1 Associated Waikato DHB Documents

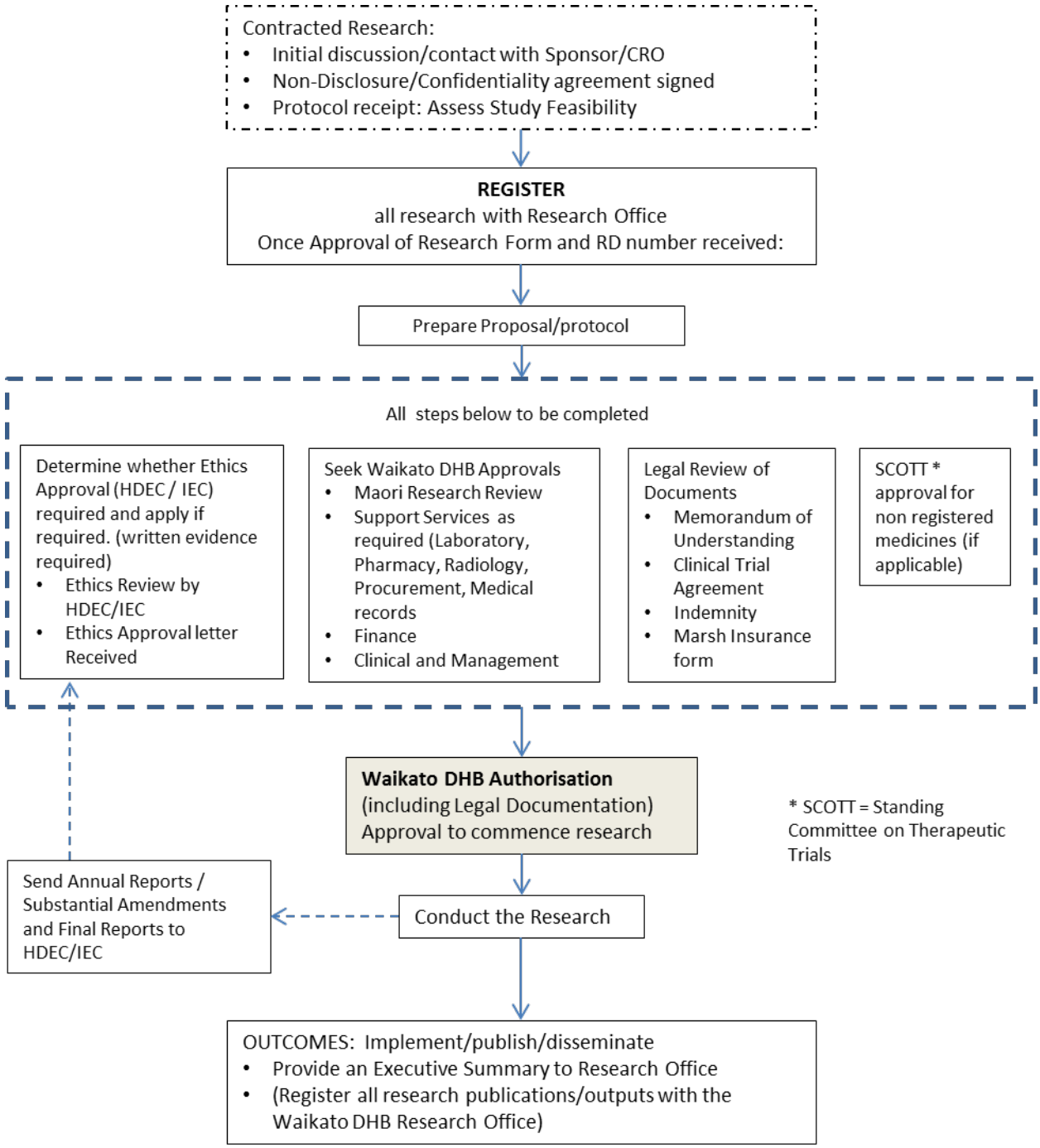
- Waikato DHB Medicines Management Policy (Ref. 0138)
- Waikato DHB Clinical Trial Medicine Management protocol (Ref. 5274)
- Waikato DHB Conflict of Interest Policy (Ref. 0006)
- Waikato DHB Delegations of Authority Policy (Ref. 2175)
- Waikato DHB Disclosure of Health Information (Ref. 1365)
- Waikato DHB Incident Management Policy (Ref. 0104)
- Waikato DHB Information Privacy (Ref. 1976)
- Waikato DHB Information Security Policy (Ref. 3153)
- Waikato DHB Information and Data Management Protocol (Ref. 5858)
- Waikato DHB Informed Consent policy (Ref. 1969)
- Waikato DHB Intellectual Property policy (Ref. 1036)
- Waikato DHB Sponsorship Policy (Ref. 0122)
- Waikato DHB Tikanga Recommended Best Practice Guidelines (Ref. 2118)
- Waikato DHB Towards Māori Health Gain Framework
- Waikato DHB Access to Information Declaration

8.2 Other Documents

- Health and Disability Ethics Committees https://ethics.health.govt.nz/
- National Ethics Advisory Committee (NEAC) Ethical Standards for Health and Disability Research
- Ministry of Health Guidelines for Research with Māori
- ICH GCP : International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice guidelines
- NZACRes standard clinical trial agreement and indemnities
- World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects https://www.wma.net/what-we-do/education/medical-ethics-manual/
- General Disposal Authority
- Te Mana Rauranga – Māori Data Sovereignty Network Charter

Appendix A - Research Approval Process at Waikato DHB

Explanations of the steps in this flowchart are outlined on the following page.



Flow Chart Explanations

Sponsored research

The Confidentiality Agreement (CDA) or Non-Disclosure Agreement (NDA) is sent to researchers by the sponsor or the Contract Research Organisation (CRO). The potential PI does not have delegated authority to sign CDA/NDA and is required to follow process – send the CDA/NDA to the Legal Service, who will approve document and send to the Research Office for signing and return to the researcher. On receipt of this signed CDA/NDA the sponsor or CRO will forward the study protocol to the researchers. When it has been agreed that the researchers will conduct the study, the researcher will send the NZ DHB Standard Indemnity and the NZ Standard Clinical Trial Agreement to the sponsor/CRO. Once agreement is reached the Legal Service approves the agreements and forwards to the Research Office to arrange final approval.

Register your Research: Waikato DHB Approval of Research form

All research to be undertaken at Waikato DHB must be registered. This is done by completing the Register Your Research form online at the Waikato DHB website https://www.waikatodhb.health.nz/learning-and-research/research/research-approval-process/

The form must be signed by all relevant parties and presented as detailed below. All the steps below must be completed prior to seeking final sign-off of the project. Final sign-off will be provided by Director Quality & Patient Safety.

Approvals external to Waikato DHB

It is the responsibility of the researcher to obtain external approvals prior to sign-off by Waikato DHB.

- Ethics approval – either HDEC or IEC – must be obtained prior to sign-off by Waikato DHB.
- Researchers requiring HDEC approval must complete the ethics application on line and note Waikato DHB as a local site (including requesting locality approval through the HDEC on-line form) in conjunction with the Health Research Council (HRC) Guidelines for researchers. (Note: These guidelines are available on the internet http://ethics.health.govt.nz
- Specific approvals may be required depending on the nature of the research. These may include (but are not limited to):
    - National Radiation Laboratory (NRL) approval for radiation used in research. http://www.health.govt.nz/our-work/radiation-safety
    - SCOTT (Standing Committee on Therapeutic Trials) http://www.hrc.govt.nz/about-us/committees/standing-committee-therapeutic-trials-scott approval for unregistered medicines or formulations to be used in a trial.

Ethics application - HDEC

Where required, health research conducted in New Zealand must be submitted to the central HDEC, based in Wellington, using their online forms. The central HDEC will then allocate the application to a local HDEC with capacity to deal with it. Relevant approvals must be sought from external agencies such as SCOTT and NRL prior to submission.

The locality assessment is signed by the Research Office once all the relevant documents and regulatory approval are received by the institution.

Ethics application - Institutional Ethics (IEC)

Health research conducted in New Zealand for the attainment of a qualification must be submitted to the relevant institutional ethics committee for approval. A copy of this approval is to be provided to the research office.

Approvals within Waikato DHB

Māori consultation

Research requiring ethical approval in the Waikato DHB must also include consultation with the Māori Research Review Committee. The requirements for this are outlined on the Waikato DHB Internet Research Approval site. Non-sponsored and internal research should consult with Māori prior to finalisation of the proposal/protocol. With sponsored studies, where the protocol is finalised prior to consultation with Te Puna Oranga, consultation on the research process is still required.

Support Services

Sign-off is required by any support services within Waikato DHB that will be used by the research study – pharmacy, laboratory, radiology, clinical records for example.

Finance and Procurement

Finance will review the budget for all clinical trial research, and other research projects that involve use of Waikato DHB resources such as clinic time, consumables, and extra staffing. Research studies being undertaken by a sole researcher, in their own time, and not using Waikato DHB resources may not require formal financial review.

Waikato DHB Procurement approval is required for any new device to be used in the research project, whether provided by the sponsor or not. If the device or consumable is already being used by the DHB for another purpose, procurement approval is not required.

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. The Ethics Committee will decide whether the trial is covered by ACC or not. 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 Legal team.

For Waikato DHB employees there is also insurance coverage (in addition to any the researcher may have in their personal capacity or through other employers). The Waikato DHB's insurance policies are part of a national arrangement and may vary from year to year. The Research Office can provide any necessary advice on the updated provisions. Our Insurer has prepared a Clinical Trials Checklist for insurance that must be completed and sent to Legal with the Contracts for review. A copy of the Clinical Trials Insurance Checklist is also to be forwarded to the Financial Accountant responsible for insurance.

Clinical / Management Approvals

The researcher is expected to discuss their proposed research project with the Clinical Director of the relevant service prior to commencing the registration process.

It is the responsibility of the Clinical Director / Clinical Unit leader to ensure that:

- they have discussed this research project and the resource implications for this department with the Principal Investigator, and that the Principal Investigator has discussed these resource implications with any affected services/staff members.
- all researchers/students from the department involved in the research project have the skills, training and experience necessary to undertake their role.
- their signature indicates their support the research project being conducted in their department and that there are suitable and adequate facilities and resources for the research project to be conducted at this site.

It is the responsibility of the relevant Director / Executive Director 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. This includes the need/costs for additional clinic appointments or longer admission beyond normal standard of care.
- Research is not commenced until all required approvals have been obtained and the proposed research has final authorisation to proceed from the Director Quality & Patient Safety.
- All income and expenditure related to the research project is accounted for and any deficit or surplus of resources is managed appropriately.

It is the responsibility of the Director of Quality & Patient Safety to ensure that the research approval process has been followed, that required internal and external approvals are evident and that the research project fits within the strategic direction of Waikato DHB.

Legal Review of Documents

Any documents to be signed by the organisation relating to research will be reviewed by the Waikato DHB legal team, and are to be signed by the Principal Investigator as read and acknowledged (where applicable). The documents will then be signed on behalf of Waikato DHB by the Director Quality & Patient Safety.

Final Authorisation

Once the Approval of Research form has been signed off by all relevant parties, final locality authorisation for the research project to proceed is given by the Director Quality & Patient Safety. The Research Office will then return a fully signed copy of the Approval of Research and complete the locality authorisation online for HDEC. The research can then commence.

Appendix B - Clinical Trials

Research Registration and Document Checklist

- Research projects are required to be registered with the Research Office
- This research registration form and the relevant checklist forms are available from the Waikato DHB internet site.
- Once registered the researcher will receive a Waikato DHB Approval of Research document which shows the required Management and relevant Clinical Support Service approval signatures
- Copy of Completed electronic Ethics Application
- Participant Information Sheet/Leaflet and Consent Form
- Completed Request for Clinical Trial Agreement Approval from Legal services This accompanies the research related legal agreements (all of which are to be signed by Director Quality & Patient Safety on behalf of Waikato DHB)
    - Clinical Trial Agreement
    - Indemnity (where relevant)
    - Memorandum of Understanding (where relevant)
    - Data Sharing Agreement (where relevant)
    - Any future amendments to these documents are also to be signed by Director of Quality & Patient Safety.
- Evidence of cultural consultation
- Evidence of Procurement approval for any new devices to be used in the research
- Waikato DHB 'Access to Information' form for external researchers
- Letter of approval from external Institution
- HDEC final approval
- SCOTT approval if relevant
- NRL approval if relevant
- The approved budget for the research project in the form of a memo from unit accountant (where relevant).
- Approval from the service for any additional clinic appointments or longer admission beyond normal standard of care
- If a trial is discontinued prematurely, the relevant regulatory authorities will be notified by the lead site, and researchers will notify the research office.
- The research office will be notified of trial completion; in addition, a copy of the final ethics report will be forwarded to the research office along with a summary of the results of the research project.