POLICY

HEALTH RESEARCH

Applicable to: **Te Pae Hauora o Ruahine o Tararua | MidCentral**	Issued by: **CMO Office**
	Contact: **Research Support**

1. BACKGROUND/PURPOSE

Te Pae Hauora o Ruahine o Tararua | MidCentral commitment to health research is for 'Better health outcomes, better health care for all, through research based informed healthcare'. The purpose of this document is to provide guidance to the locality framework which supports an effective process, for low risk acitivties and for clinical trial research. It includes research activities in partnership with the applicant to ensure ethical, legal and professional standards are met. The research clearly needs to demonstrate clinical, professional and/or strategic benefit to the organisation. The full cycle of research includes research findings are communicated effectively within and to the relevant health services once completed.

Relevant documents or considerations include:

1. **Te Tiriti o Waitangi** will overarch our engagement and commitment: Te Whatu Ora MidCentral acknowledges the significance of Te Tiriti o Waitangi as a foundational document for public policy. Te Tiriti guides MidCentral in how it governs and conducts itself, how true partnership with iwi is demonstrated, how beliefs, values and tikanga are cherished and how excellence, in all its definitions, is attained.
2. **Wai 2575 Māori Health Trends Report:** The Health Services and Outcomes Kaupapa Inquiry (Wai 2575) was initiated by the Waitangi Tribunal in 2016. The Wai 2575 Māori Health Trends Report, that was produced to inform the Wai 2575, provides data that clearly demonstrates the need for an equity focus within the New Zealand health sector. Such a commitment to equity extends to the focus of our health research. To achieve equitable health outcomes, there needs to be a focus within our health research that address issues Māori consider important and is led by Māori health researchers.
3. That new understanding and knowledge gained creates and translates into improving services and health outcomes – local value add
4. For measuring Māori health outcomes by Māori and for Māori with early consultation
5. Promote and maintain appropriate partnerships, networks and collaborations for local research. Examples include University/educational institutions.
6. Promote research opportunities to strengthen community collaboration
7. Facilitate research that meets equity outcomes, organisational, professional, and legal requirements and expectations.
8. To appraise the ethical standards within the application, and to advise accordingly to apply via formal ethics process with HDEC or the Scoping of ethics via Health and Disability Ethics committee (HDEC) OR the University/educational institute approval. It is important to note MidCentral research process is not an ethics committee and does not replace the formalities of ethical approval via HDEC or universities.

9. To promote and grow public confidence to a realisation of improved health outcomes through research.
10. ICH GCP: the International conference on harmonisation good clinical practice, its encouraged staff complete this online training. The principle of this certification ensures good conduct of the research undertaken.
11. Confidentiality/Privacy of patient information (deidentified data)
12. Tissue/Blood samples – adhere to MidCentral policies and legislation
13. Data Handling and records and retention.
14. Publication and conference presentations.

PURPOSE

The purpose of this document is to understand the research process at MidCentral and to inform the applicants of the process and what underpins research activity and endorsement at MidCentral.

- Encourage external agencies to have undertaken Māori/Iwi consultation within their locality.
- Protects the rights and wellbeing of people subject to research activities
- Ensure research meets relevant statutory requirements (including requirements relating to clinical trials under the Medicines Act 1981)
- Database of research is maintained
- A process that supports publications and conferences
- Strong collaboration with our Pae Ora Māori Research Review committee at the heart of our activity and locality approval. (meet monthly, no hui in January of each year, unless stated otherwise)
- A process of approval via the research office
- That internal and external health research opportunities that involves our patients, and our people, our information is via the research office. This includes external groups seeking to gain consent within our directorates individualistically from the research office. Internal directorates are to refer to the research office if an agency is seeking consent from an authority within the directorate.

The research policy aims to strengthen current and future research efforts from health sector participation. MidCentral locality is working to build vibrancy for research & innovation into services for improved health outcomes with an organisational culture to support research.

Our culture for research-informed healthcare delivers better care because:

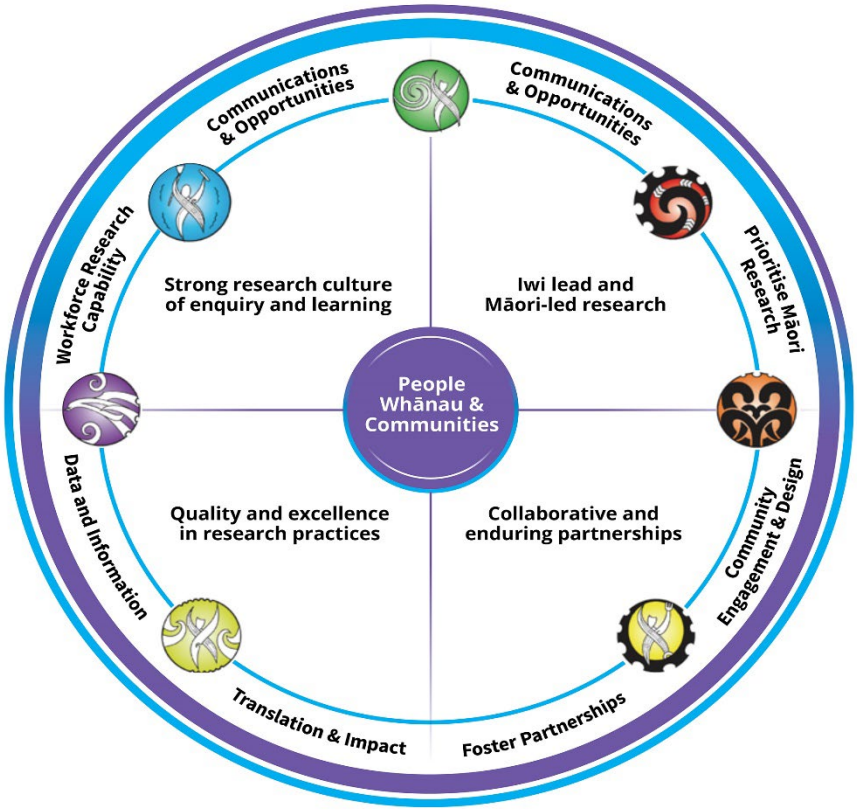
- new understanding and knowledge creates and translates into improving services and health outcomes
- it will recognize and progress equity to access, equity of experience and equity of outcomes
- research supports vibrancy and enhances a culture of enquiry and innovation in clinical practice
- research opportunities strengthen community collaboration
- Te Tiriti o Waitangi will underpin engagement and commitment to benefit all New Zealand Māori for healthier outcomes.

2. INTRODUCTION

Locality research framework (2022) encompasses the work completed by workshops in 2022 and reflects from within our MCH strategy. This framework underpins our purpose for

BETTER HEALTH OUTCOMES, BETTER HEALTH CARE FOR ALL, THROUGH RESEACH-INFORMED HEALTHCARE .

- **Ka Ao, Ka Awatea**: The Ka Ao, Ka Awatea Refresh 2020-2022 (MCH) is the guiding strategy for the health sector to plan and deliver health and disability services that lead to better health outcomes for Māori. It seeks to progress a cohesive and integrated strategy for Māori health and wellbeing across the district. Within Ka Ao, Ka Awatea, a series of principles are defined. These same principles are included within our research framework below



Our Locality research framework is underpinned by the following values:

Compassionate, Courageous, Respectful, Accountable, & Trus

3. SCOPE

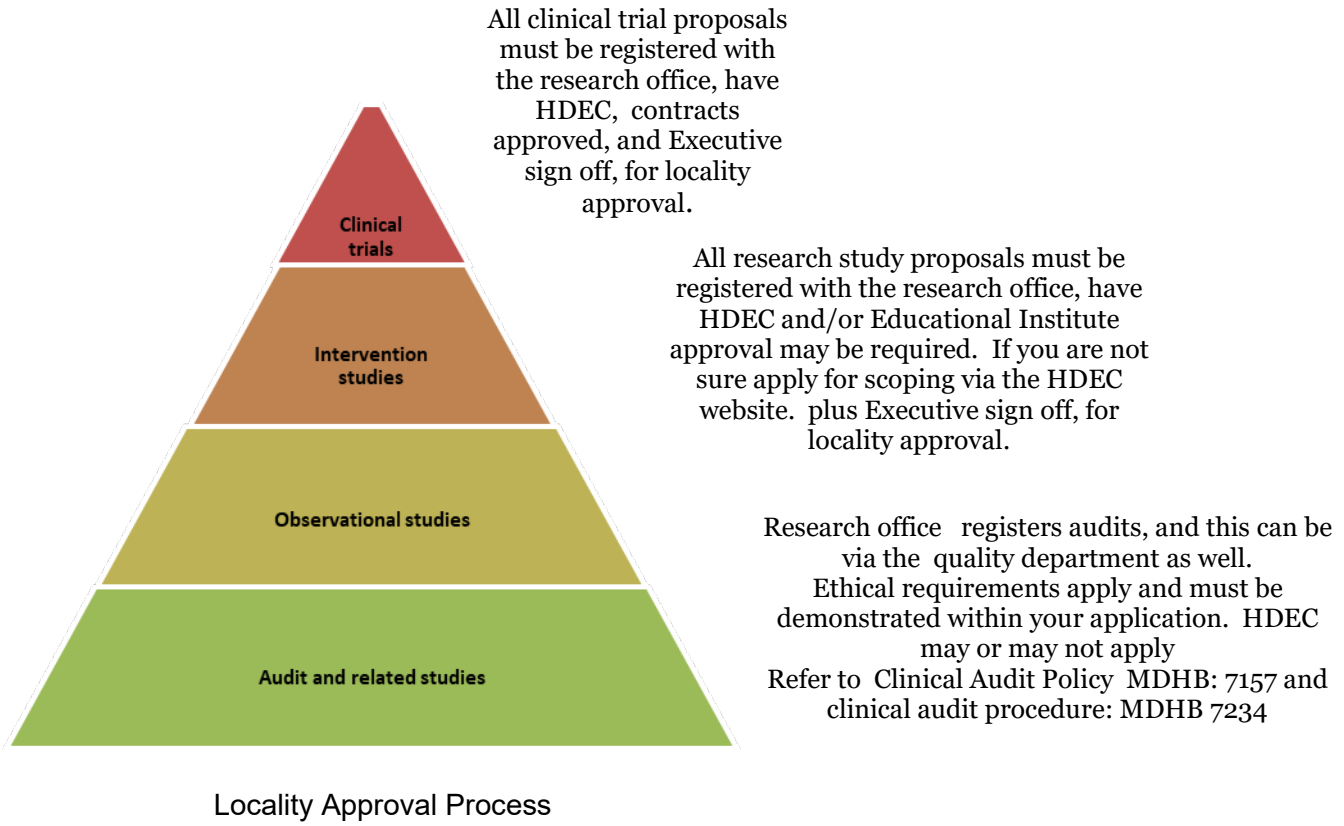
This Policy applies to all:

- Employees and health professions, honorary, students, sub-contractors, consultants and agents involved in health and disability research activities. Often related to within scope competencies with or without publishing.
- Authorised persons accessing our premises, records or patients for the purposes of undertaking health and disability research activities

With the varied study activities and methodologies, importance is placed on all activities being conducted within the ethical framework, identifying the risks within the study AND to have

considered the inclusion of Māori health outcomes. This aligns with Te Whatu Ora by incorporating an equity led by design in alignment with Te Tiriti that delivers for Maori and other priority populations and groups. If Maori health outcomes are not by design within your research design, its important to explain this.

Audit and quality improvement related studies are low risk activities that may or may not require ethical approval, whereas clinical trials and interventional studies require significant oversight and ethical approval. Accordingly low risk versus research of RCTs, and interventional have its own set of considerations and approval requirements. The diagram below guides the general approach and for whether ethics approval is required, along with strong emphasis for Maori consultation when relavant. All internal applications are submitted to our Maori Health Research review committee.



Locality Approval Process

Definitions:

- **Research:** is designed to derive generalisable NEW knowledge designed to test a hypothesis, has clearly defined questions, aims and or objectives. Study design may involve patient groups, patient involvement and normally ethics is required.
- **Audit:** designed and conducted to produce information to inform delivery of best care, i.e., designed to answer 'does this service or practice reach the predetermined standard? Audits measure against a standard, there is no allocation to interventions, does not involve patient contact and does not typically require ethics.
- **Quality Improvement:** Quality improvement is an umbrella term that refers to a range of activities that involve cycles of change that re linked to measurable assessment with the goal of improving the experience, process, safety and efficiency of health care. It must not be conducted generate evidence to support an intervention efficacy but can involve evaluating and changing practice. This is about system functioning not the individual. (NEAC, 2019). Refer to NEAC 2019 under quality improvement for applied ethics.

- **Evaluation:** is designed and conducted to define or judge current care. Designed to answer, what standard does this service achieve?', this measures without reference to a standard, there is no allocation to intervention and does not require ethics.

4. PRINCIPAL INVESTIGATOR'S/APPLICANT RESPONSIBILITIES

The principal investigator is responsible for the oversight of the study and for determining and obtaining the appropriate level of review and approval required for the study :

- The ethical standards investigators must meet or exceed in conducting **intervention studies** are contained in the ***HDEC Ethical Guidelines for Intervention Studies*****.**
- The ethical standards investigators must meet or exceed in conducting **observational studies** are contained in the ***HDEC Ethical Guidelines for Observational Studies*****.**

The principal investigator has the overall responsibility for ensuring the study meets or exceeds the ethical standards contained in the relevant HDEC guideline – please refer to the HDEC website. This conduct and accountability applies whether HDEC approval was given or out of scope, along with any other ethics committee from an educational institute.

The principal investigator must have prepared a research study that discusses and includes methodology and a protocol for all types of research activity.

All investigators conducting or involved in a study are responsible for ensuring their activities meet ethical standards within the application and whilst conducting the study.

All investigators and staff involved in the study must complete the good Clinical practice certification (GCP) via websites that support the training.

For clinical trials and other applicable studies , the confidentiality disclosure agreement (CDA), study contract (CTA) budget, indemnity and insurance are manged by the research office. This excludes the clinical trials department from RCTS directorate.

Publication of your work:

If the research is for publication, a registration number will be required. This can be obtained from either the research office or from quality department if it is an audit. Prior to publication, it is the Principal Investigators responsibility to check with the publisher or conference conveners as to the requirements for publication.

5. Locality Approval

All research activity applications must be completed using MidCentral forms:

- Current forms may be found either by emailing the reaserch office, or on the Te Whatu Ora Midcentral Intranet hyperlink below

  Research at MidCentral DHB

- *Medical leads, executives etc are to refer to the research office for locality approval process. Consent forms from external agencies that want access and permission to conduct their study on MidCentral premises, access to our people and data is **NOT** locality approval.

Types of forms used for an application

- Advertising form: is for applicants wanting to advertise their study on MidCentral premises
- Low risk form: for low risk studies ie for audits, quality improvement, observational, retrospective, prospective,
- Research form: interventional study, clinical trials,
- Maori research review form for endorsement

Supporting Documentation

- Ethics – one of the following as relevant
  - HDEC –the relevant Ethics approval letter OR the out-of-scope letter from HDEC – if this applies to your study design. *You may need to submit a Scope of Review determining whether the study requires and ethics approval process. Find out if your study requires HDEC review | Health and Disability Ethics Committees* Submitting an HDEC application is an online process on the HDEC website. refer to the HDEC website for more information *http://www.ethics.health.govt.nz*
  - Educational Institute Ethics - Where a study is being undertaken from within an education facility i.e., university, or polytechnic, the relevant Institutional Ethics Committee for approval letter is provided
- Study Protcol/Proposal – It is encouraged to write up your s study with a protocol, that discusses the design of the study, describes the objectives, methodology, and the overall aspects of the research to be carried out.
- Participant Information Sheets and Informed Consent Forms – where relevant. Templates may be found on the NZ HDEC website.
- A copy of the Questionnaires / Surveys – Where relevant
- Evidence of Maori consultation (external applications) – for external applications it is encouraged that applicants seek their own locality Maori consultation (outside of MidCentral review process) and provide the letter as supporting evidence.
- Any other supporting documentation relavant to the application

Locality Authorisation:

This will be completed by a staff member in the research office. Once all of the above has been completed and received by the research office. The request for locality authorisation is to the medical leads and executives of the directorate for sign off and then to the CMO for the final sign off. Once this is achieved the locality letter is completed and sent to the applicant.

Māori Research Review Group at MidCentral

MidCentral Māori Research Review Group is part of the process for obtaining the overall locality approval that is undertaken. This group meets monthly except for January of each year. The hui reviews each application for Te tiriti o Waitangi, Māori identity – to maintain or enhance mana Māori, tikanga practices are observed and Māori health and wellbeing outcomes including equity. This group is NOT an ethics approval committee. The group may contact you for further information as required via the research office, however, most of the time, endorsement letter is provided that may provide advice.

For MidCentral staff to have completed the culturally responsive course, cultural competency course and Te Tiriti o Waitangi.

Study design must consider how Māori are involved, the impact on Māori health, how Māori will be involved and how Māori can be involved in the study team.

6. Other approvals relevant for some study designs: i.e., drug trials.

In addition to approvals and forms in section 6, other relevant and specific approvals may also be required depending on the nature of the study, i.e.:

CLINICAL TRIALS CHECKLIST

- Completion of the Clinical Trials Checklist
- National Radiation Laboratory approval for radiation used in research
- SCOTT (Standing Committee on Therapeutic Trials) recommendations to Medsafe for approval for unregistered medicines or formulations to be used in a trial, or other new medicines
- approval under other legislation such as the Hazardous Substances and New Organisms Act 1996.

7. Contracts with third parties: this involves MidCentral being best represented and protected.

Where a third party is involved in a study, the principal investigator at MidCentral ensures a consultation with Te Pae Hauora o Ruahine o Tararua | MidCentral. The facilitation is via the research office, excluding the clinical trials department in RCTS (Regional Cancer Treatment Service).

The Contracts Department at MidCentral seeks legal advice and reviews and approves the contract that includes confidentiality and disclosure agreements, budget contracts etc

- the role and responsibilities of the third party (e.g., as a funder or providing other resources or contributions to the study);
- the terms and conditions upon which Te Pae Hauora o Ruahine o Tararua | MidCentral has approved the study; and health and safety plus indemnity is assured.
- Te Pae Hauora o Ruahine o Tararua | MidCentral contribution and responsibilities about the study;
- any additional conditions by HDEC.
- the agreed performance measures for quality assurance.
- the principal investigator's obligations to provide timely written feedback on the project outcomes and recommendations back to the research office
- the process and approvals required if any change or increase to the likely cost of the study occurs.
- suitable protection of Te Pae Hauora o Ruahine o Tararua | MidCentral and other parties' respective intellectual property rights.
- that the principal investigator will acknowledge Te Pae Hauora o Ruahine o Tararua | MidCentral in any publication or publicity arising out of the study, unless agreed otherwise by the Clinical Board (e.g., in cases where inappropriate identification of participants may result).

8. Indemnity and compensation agreements for clinical trials

RCTS clinical trials department facilitate and manage their own contracts.
All clinical trials must use the Standardised Indemnity and Compensation Agreement (sICA).
The sICA can be downloaded from *http://www.nzacres.org.nz*

9. Review by insurers, this is managed via MidCentral contracts department

The following studies must be referred to insurers for a review and directive before they commence:

- studies that are not subject to New Zealand Law and jurisdiction
- studies in respect of which MDHB is not the investigator, but the sponsor.

The principal investigator must consult with the MidCentral Contracts Department on all studies. The MidCentral Contracts Department will determine whether the study needs to be referred MidCentral insurers for review.

10. Information privacy and access to clinical records

Please do not use your own personal computer to store patient information outside of the Citrix environment. e.g. non encrypted personal device, hard drives or other personal storage systems.

You can store patient data for clinical audit purposes on an encrypted secure hard or external drive (i.e. pen drives/USB stick) and use your own computer to open the data, just don't make a copy on your personal device.

MDHB-1943 Information Technology Systems Security And Access

MDHB 5367 Mobile Computing, Portable Storage Devices And Wireless Acceptable Use

Where a study involves collecting, collating, using, storing and disclosing health and personnel information, you must comply with the following:

1. Health Information Privacy Code 2020 Office of the Privacy Commissioner | Health Information Privacy Code 2020

2. MDHB-8154 : National Privacy Policy (this is found on the Controlled Documents site via the intranet)

11. Informed consent: Health and Disability Services Consumer rights (Right 6), Right 7(4)

Investigators must obtain the prior informed consent of study participants (unless an exception applies) and must comply with the following

1. MDHB 1998: Informed Consent policy
2. MDHB 5560: Informed consent in clinical trials – guideline
3. MDHB 6295: Clinical imaging of patient – usage, consent and storage Policy

12. ASSISTANCE

The Research Office is part of the CMO office and is the principal contact for research

Contact the Research support on extn 8036, direct dial: 06 3508036 or via email research@midcentral.govt.nz

For statistician assistance contact the research office, and you will be advised accordingly of who to contact.

13. PROCESS, ROLES AND RESPONSIBILITIES

Activity / process steps	Roles and responsibilities:			
	Principal Investigator	**Research office**	**Directorate Executive / Leads**	**Contracts Department**
Consult on methodology design	Obtain advice and agreement from parties and stakeholders involved including (as relevant): • Pharmacy for drug trials[1] • Pae Ora • Data Quality & Health Information • Clinical Coding (Planning & Support Unit) for data, • Patient Safety & Clinical Effectiveness • Allied health. Write a protocol to support your study whether this is low risk or RCTs etc.	Advice Consult with Contracts Department on behalf of the applicants	Consult regarding study resource requirements or potential to impact on hospital operations (e.g., for large studies).	Determine whether the study needs to be referred insurers or for legal advice for review. Advise on the form and negotiation of a suitable contract for studies involving third parties. Review and provide advice on liability under research contracts Where legal advice is required a further 7 days Negotiate with the study sponsor regarding costs of legal advice. Liaise with legal advisors where necessary.
ETHICS	• Consult with HDEC online submission OR submit a Scope of review application • Educational Institute ethics committee i.e. University you are working for or a student of • Māori consultation in your	Discuss with applicants whether ethical approval is sought Sign locality authorisation for HDEC applications		

[1] refer MDHB – 994, Investigator Procedure for the Initiation of Drug Trials

Activity / process steps	Roles and responsibilities:			
	Principal Investigator	**Research office**	**Directorate Executive / Leads**	**Contracts Department**
	local area. • Submit ethical letters and out of scope letters with your application			
Obtain locality approval	Ensure the study design complies with NEAC Ethical Guidelines for intervention or observational studies Apply for and obtain professional review and endorsement (if applicable) Complete, relevant research forms	Facilitate indemnity requirements, CDA and CTRA contracts with the contracts department (excluding RCTS clinical trials department) • non-MDHB employees undertaking studies • studies undertaken on behalf of another agency (e.g., a pharmaceutical company). Forward study proposal for approval to Clinical Board including: • external ethical approval obtained (where required) – HDEC or Institutional Ethics Committee • all other external approvals are obtained as required (see section 6). Apply for and obtain professional review and endorsement- this is via the executive sign off at the end of	Respond to the application within ten working days of receipt of the proposal. Finalise and agree budget (where applicable) – record agreed budget or other support in MoU with principal investigator. Endorse study for approval.	

Activity / process steps	Roles and responsibilities:			
	Principal Investigator	**Research office**	**Directorate Executive / Leads**	**Contracts Department**
		the process.		

Register the research study	To submit a copy of the report, conference report and publications to the research office	Maintain the research registry Register approved studies and note any conditions on approval.		
Research Study Contract Required for studies involving third parties	Prepare the contract for the research study and send to the research office for legal review and negotiation	CMO signs approved research contracts on behalf of MCH and third parties		Consult on the development and finalisation of the research contract. Approve the final research contract. Enter research contract into Contract Management System and assign contract reference number. Prepare two original research contracts (once approval) and arrange signing by CEO or Chief Medical Officer. Hold originals of all contract documents.
Undertake the research study	Ensure locality approval has been obtained prior to commencing any study activity. Comply with local policies, guidelines and procedures, HDEC (or other ethical approvals) and legislative requirements and contracts / MoU. Submit annual reports to HDEC (if the study is subject to HDEC approval).	Provide advice and support where required Monitor the study's progress. .	Raise invoices for third party contributions (if any). Monitor the study's progress. ***Medical leads, executives etc are to refer to the research office for locality approval process. Consent forms from external agencies is <u>NOT</u> locality approval.**	Provide advice on managing contractual issues (i.e., third party performance) that may arise in relation to study implementation.

Notify and manage adverse events / issues	Notify and consult with the CMO on issues that arise. Report all adverse events via the incident reporting process, to the CMO Operations Director, and Contracts Department (as required) in a timely manner., This may include Medsafe, HDEC or a study sponsor being notified.	Notify issues that arise regarding any study to the CMO Provide advice and support where required. Liaise with Contracts Department regarding implications for insurers.	Receive and review adverse event reports. Provide advice on remedial action.	Notify MCH insurer of any claim or circumstances that may give rise to a claim associated with a study. Manage related contract issues.
Seek approval for changes to the research study	Submit any change to the initial application for further review to CMO. Complete any further HDEC approval process required because of the change.	Review changes and refer to Clinical Board for approval. Record approved changes in the Register.	Review and endorse any change to the initial application.	Notify MDHB's insurer of any changes as required. Attend to preparation and signing of contract variations (if required).
Close the research study	Notify study close as set out in the research study proposal to CMO and Contacts Department. Notify study close to HDEC (if the study is subject to HDEC approval).	Record the study as 'closed' in the Register.		Notify insurers that the study has closed (if required).
Report on the research study	Submit a final report to the: • Research office and CMO • the Clinical Library. Undertake further consultation with stakeholders / Māori as required. Disseminate the study findings in accordance with the study proposal (including to HDEC if required).	Receive final study reports and forward to the CMO Store in the research database Provide an annual report on research activities to the CMO (update of all studies approved and completed) including for annual report to the Hospital Advisory Committee.		Ensure contract reporting as required is closed Attend to the expiry dates of contracts

14. DEFINITIONS

Audits and related studies	Audits or related studies are studies that do not have any impact on the intervention or service levels received by participants and are often undertaken retrospectively. Examples of audits or related studies are:[2] **Audits** systematically evaluating aspects of health or disability support service delivery by considering measurable indicators of performance and/or quality. Clinical Audits are required to comply with MDHB's Clinical Audit Policy. **Evaluation studies** evaluating the relevance, effectiveness and impact of activities in the light of their objectives. Several types of evaluation are distinguished, including evaluation of the structure, process and outcome of an activity. **Programme evaluation** evaluating a whole programme, rather than specific interventions. **Quality assurance** assessing the adequacy of existing practice against a standard to improve health and disability support services. **Quality Improvement** Quality improvement (QI) is an umbrella term that refers to a range of activities. Quality improvement activities involve cycles of change that are linked to measurable assessment, with the goal of improving the experience, process, safety 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. **Outcome analyses** assessing health and disability support service quality by reviewing health care information to evaluate outcomes without comparing them against a standard. For example, clinicians may retrospectively examine health care notes and perform descriptive analyses to determine the outcome of medical treatment or course of a particular illness. **Benchmarking** comparing two or more health and disability support services to improve practice. **Public health investigations** exploring risks to public health. Examples are investigations into outbreaks or clusters of disease, analyses of vaccine safety and effectiveness, and contact tracing of communicable conditions. **Public health surveillance** monitoring risks to health, including by systematically collecting, analysing and disseminating information about disease rates. **Pharmacovigilance** (post-marketing surveillance) monitoring the adverse effects of pharmaceuticals after their introduction

[2] National Ethics Advisory Committee. 2012. *Ethical Guidelines for Observational Studies: Observational research, audits and related activities. Revised edition*. Wellington: Ministry of Health, pp 4-5.

	into the general population, by such methods as the spontaneous reporting of adverse events and the monitoring of all adverse events for a restricted group of medicines (prescription event monitoring). **Resource utilisation reviews** evaluating the use of resources in a particular health or disability service activity, for example, by reviewing health records to determine health care inputs such as chest X-rays for patients with a particular diagnosis.
Clinical Trial	A research study using human subjects in which an investigator controls and studies the interventions which are provided to participants for the purpose of adding to the knowledge of health (or other) effects of the intervention.
Ethical Review/Approval	A review and approval provided by: • the New Zealand Health and Disability Ethics Committees; or • the ethics committee of the relevant academic institution (i.e., for Health Research undertaken for an academic qualification).
Funder	A person or organisation that provides funding for the study (e.g. HRC, Marsden Fund).
Intervention study	A study in which the investigator controls and studies the intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). (For further definition of 'intervention study' see the HDEC Ethical Guidelines for Intervention Studies.)
HDEC	The New Zealand Health and Disability Ethics Committee.
Locality authorisation	Refers to MDHB's responsibility for governance issues arising from the conduct of research within its locality (Standing Operating Procedures for Health and Disability Ethics Committees, chapter 10, Locality Authorisation. Version 1 May 2012 *http://ethics.health.govt.nz/operating-procedures*). The locality authorisation ensures that the host organisation is aware of the proposed research and has assessed whether (considering staff, resources and other governance matters) it is safe and appropriate for the study to be conducted.
Observational study	All health and disability research that is not an intervention study is an 'observational study'. Like intervention studies, observational studies may involve looking at the health effects of interventions provided to human participants. However, researchers in such an observational study do not control these interventions, which would have been provided regardless of participation in the study. (For further definition of 'observational study' see the HDEC Ethical Guidelines for Observational Studies.) There are two types of observational studies: observational research, and audits and related studies.
Principal investigator	Means the lead investigator or researcher in relation to a study.
Professional advisors	Senior MDHB personnel who provide professional direction and strategic advice for the relevant discipline across the organisation.

sICA	Standardised Indemnity and Compensation Agreement developed by the New Zealand Association of Clinical Research (NZACRes) available as a download from *http://www.nzacres.org.nz*.
Sponsor	A person (or entity) who controls the design, running, and funding of a study (e.g. an industry-funded clinical drug trial).
Study	Research that aims to generate knowledge for the purpose of improving health and independence outcomes, and includes clinical trials, other intervention studies, observational studies and audit and related studies.

10. REFERENCES

- Towards Clinical Excellence – An Introduction to Clinical Audit, Peer Review and Other Clinical Practice Improvement Activities, Ministry of Health, April 2002
- Guidelines for Completion of the National Application for Ethical Approval of a Research Project (NAF-2005 v1), Health Research Council, January 2005
- Health Research Council Act 1990
- Health and Disability Commissioner Act 1994
- Code of Health and Disability Services Consumer Rights
- Medicines Act 1981, section 30
- Privacy Act 1993
- Health Information Privacy Code 2020

11. FURTHER ASSISTANCE

- Patient Safety & Clinical Effectiveness
- Quality and Clinical Risk
- Contracts Department
- Health Research Council of New Zealand (National Ethical Research forms are available)
- Ethic Committees: *http://www.ethicscommittees.health.govt.nz/*
- Guidelines for Researchers on Health Research Involving Māori, (2010), Health Research Council, *http://www.hrc.govt.nz/news-and-publications/publications/maori*
- Refer to references for detailed information relating to research and innovative ethical review.

12. RELATED MDHB DOCUMENTS

MDHB-1998	Policy	Informed Consent
MDHB-2010	Policy	Responsibilities for All Persons Who Access MidCentral District Health Board's Health Care Services
MDHB-2024	Policy	Intellectual Property
MDHB-1893	Policy	Appointment of Honorary Staff
MDHB-2005	Policy	Privacy Statement for all Persons Who Access MidCentral District Health Board's Care Services
MDHB-7157	Policy	Clinical Audit

MDHB-2031	Policy	Te Tiriti o Waitangi
MDHB-5560	Guideline	Informed consent in clinical trials
MDHB-6295	Policy	Clinical imaging of patient – usage, consent and storage
MDHB-1943	Policy	Information Technology systems security and access

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13. KEYWORDS

Ethical approval, Ethics, Research, Clinical Trial, Observational study, Intervention study, low risk