MidCentral District Health Board
Te Pae Hauora o Ruahine o Tararua

GUIDELINE

COMPLETING AN APPLICATION FOR THE LOW RISK RESEARCH ACTIVITY FORM	
Applicable to: **MidCentral District Health Board Staff**	Issued by: **Chief Medical Officer**
	Contact: **Research Support Officer**

1. PURPOSE

Research approval means that the researcher (applicant) has advised MidCentral DHB (MDHB) of their purpose or intent for research and has information of either their own research design or on behalf of an existing national /international research to submit for assessment and locality approval. An assessment reviews the methodology, research safety, cultural considerations, equity and ethics as well as legal and that this meets the goals of MidCentral and the overarching New Zealand Health Research Strategy 2017-2027.

All research facilitated at MDHB requires locality approval. It is also a national requirement for any research involving humans or any there part of – for example: Blood and or tissue require New Zealand Health and Disability Committees (HDEC) approval.
All research at MDHB that will be published also requires approval.

This guideline is intended as a supporting document to complete the Low risk research activity approval form. This is done section by section, question by question.

Often a low risk research study, does not require a formal review by HDEC, however, ethical considerations is still considered and reflected for participant and researcher safety. This is covered in section 3 of the form.

Along with this application, cultural considerations and Te Tiri O Waitangi and its articles are the foundations for deliberate and strengthening unity and therefore incorporated of all health research (New Zealand Health Research Strategy 2017-2027, MOH & MDHB Strategy 2021). This accountability is for honest commitment and understanding inequity. All researchers who wish to do research at MDHB are also required to complete the Maori Review Research Form (MDHB-7660) along with the Low risk research activity form (MDHB-7661).

The low risk activity approval form is intended to encourage good quality ethical studies.

2. SCOPE

Low risk research activity is one which the nature of the harm is minimal (harm being physical harm, psychological harm, disrespect or harm to dignity, social or cultural harm, privacy harm, economic harm, legal harm, autonomy harm). Low risk or minimal risk is the probability and magnitude of harm in research is not greater than the probability of harms ordinarily encountered in daily life (NEAC, 2019).

Low risk research may or may not require HDEC approval; however, the application does require MDHB locality approval by the Chief Medical Officer (CMO) and or the Clinical Board.

The Maori Review Research form is required and is reviewed by MDHB Cultural Advisories and appraised for Tikanga best practice and the Treaty of Waitangi principles.

3. ROLES & RESPONSIBILITIES

The applicant/researcher:
An applicant is a health professional person (usually doing post graduate studies) or a partnership with a concept/thesis for research or is the applicant of an existing clinical trial or research that is national/international – both applications need to enquire for locality (MCH) approval via the research office.
For additional information about research at MidCentral Health, forms and to other links, visit the following hyperlink
http://www.midcentraldhb.govt.nz/WorkingMDHB/Pages/Research.aspx#
It's the applicant's responsibility to complete the application forms and the RSO is available to support this process.

Research Support Officer (RSO):
Provides support, advice, assistance in completing forms, and any other queries please contact the Research Support Officer, via email research@midcentraldhb.govt.nz and ext. 8036. Also welcomes meetings to introduce or discuss your research further or if you wish to discuss research concepts etc.

Normal business hours - Monday to Friday.

Maori Research Review Advisory Panel
MDHB cultural lead and advisories appraise research applications for Tikanga best practice and the Treaty of Waitangi and for the principles of partnership, protection and participation.

Chief Medical Officer (CMO)
The CMO has oversight of the overall research process and represents research to the various governance committees.

4. GUIDELINE

Overview

It is suggested to complete both the low risk research activity form and the Maori research review form at the same time and gather your accompanying information. You are welcome to meet with the RSO to introduce/discuss your research before you submit if you wish, please make this arrangement.

Approval form for Low Risk Research Activity Form
The completed form along with all the supporting documentation is sent to the research support officer via email at research@midcentraldhb.govt.nz

The review process assesses the application for research feasibility, study design, and ethical considerations, along with current regulations, standards, legislations, MDHB policies, procedures, guidelines and local considerations. If there are any queries, we may ring you and or meet with you to discuss further.

Approval for Māori Review of Research form
The form supports Maori consultation and Treaty of Waitangi principles ie. Reviews the level of Maori participation that range from no expected involvement, significant involvement, participant involvement, Maori equity for health development, and cultural respect, safety and relationships. The focus of the process is to ensure that research projects meet the requirements of the Treaty of Waitangi and Tikanga Best Practice.

The completed form is also submitted together with the low risk research activity form or this may have been sent separately as an adjunct to an existing application. Once completed, the form is sent to the research support officer via email research@midcentraldhb.govt.nz
This application is reviewed by the RSO and the MCH Maori Health team Cultural advisories. An email will be sent to acknowledge the receipt of the application and periodically to advise of updates.

Low risk research activity form

Section 1 - The two forms
This is a general section that includes the name of your research/project and general identification and contact details.

→ For non –MDHB researchers/applicants: you require a MDHB employed senior/peer contact person (who will remain employed until the conclusion of your research) that does not include an MDHB investigator directly involved in the study. The contact person and contact number agrees to be identified on your application and to be the contact person for the research on behalf of the MDHB and necessitates signing the application form to confirm this agreement. Your contact person is responsible for ensuring the external research parties are aware of relevant MDHB processes, contacts and policies. Your contact person is overall responsible for ensuring that appropriate procedures are followed to assist the study team with their research. The contact person may contact the research office for advice or support.
*Note that it is the applicants' responsibility to identify and recruit an MDHB contact person.

→ For undergraduate/post graduate students: (non MDHB applicants and MDHB staff who are students also) you require a MDHB employed clinical supervisor, who will remain employed within MDHB until the conclusion of your research. The clinical supervisor and contact number agrees to be identified on your application and necessitates signing the application form to confirm this agreement. It is the clinical supervisor's responsibility to ensure the student is appropriately advised on clinical safety, ongoing ethics and correct processes of the participants involved in the research, and to protect the interests of MDHB and to adhere to MDHB policies. The supervisor may contact the research office for advice or support.
*Note that it is the applicants' responsibility to identify and recruit an MDHB contact person.

Section 2: Proposal
This section is to show the study has been well thought out and has a strong foundation with potential for high quality results that will impact our organisation in a positive way.

→ **Indicate the study type:** The choice of study type mainly depends on the research question being asked particularly when your study is not a clinical trial. Therefore by referring to the Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (July 2012). Authored by National Ethics Advisory Committee's (NEAC) may help you. Click on the hyperlink -

https://www.moh.govt.nz/notebook/nbbooks.nsf/0/F21C6588D45EBA67CC257A600009C6C7/$file/ethical-guidelines-for-observational-studies-2012.pdf

→ **What is the principal study question?** Basically, what is your hypothesis? Your research is designed to answer a question or set of questions. Describe the question/s your research project is designed to answer, providing a background or rationale as to why you are interested in this question (e.g. relevance to current or future clinical practice), and hypotheses if relevant. Your hypotheses or study question must be testable, measurable, be clear and understandable, what you expect might happen and may have an independent or dependent variable in the question, it's a starting point for investigation for example "*This study is designed to assess the hypothesis that sleep-deprived people will perform worse on a test than individuals who are not sleep-deprived."*

→ **What is involved for participants in this study?** If the study involves participants, describe what taking part in the study will entail for the participants. Provides details in a participation information sheet about where, when, by whom and for how long the research procedures will take. If participation will involve the disclosure of health information by individuals describe how this will be undertaken that ensures privacy and how the information is held and destroyed. The information sheet is also part of the informed consent procedure process with your participant that is demonstrated as part of ethics approval. Is there is a consent form? Describe how the participant withdraw from the study?. How does the participant make a complaint if they wish to?

The information provided with the application is: the participant information sheet, consent form.

→ **Description of study methods:** Briefly describe the research method and or research design you are going to undertake.

i) The **research design** is a framework for planning your research and answering your research question/s. Discuss your research design having made decisions regarding the following:
- The type of data you need
- The location and timeframe of the research
- The participants and sources
- The variables and hypotheses (if relevant)
- The methods for collecting and analysing data

The research design sets the parameters of your project: it determines exactly what will and will not be included. It also defines the criteria by which you will evaluate your results and draw your conclusions. The reliability and validity of your study depends on how you collect the information, measure, analyze, and interpret your data.

ii) **Research methods** are specific procedures for collecting and analyzing data. Developing your research methods is an integral part of your research design. When planning your methods, there are two key decisions you will make.

First, decide how you will collect data. Your methods depend on what type of data you need to answer your research question:

- Qualitative vs. quantitative: Will your data take the form of words or numbers?
- Primary vs. secondary: Will you collect original data yourself, or will you use data that has already been collected by someone else?

- Descriptive vs. experimental: Will you take measurements of something as it is, or will you perform an experiment?
- Second, decide how you will analyze the data.
- For quantitative data, you can use statistical analysis methods to test relationships between variables.
- For qualitative data, you can use methods such as thematic analysis to interpret patterns and meanings in the data.

→ **Describe any impact on MDHB resources:** is there any involvement of MDHB staff, equipment, consumables, facilities and premises? External researchers recruiting patients from MDHB should be clear about how/whether MDHB staff will assist in this process.

→ **Final reporting Mechanism:** Discuss how will the outcomes be represented? How will the outcomes be translated to inform practice?

Section 3: Ethics

It is recommended you refer to the - National Ethics Advisory Committee, December 2019 document (NEAC)
https://neac.health.govt.nz/publications-and-resources/neac-publications/national-ethical-standards-health-and-disability

Low risk research activity can inform and have an impact on service delivery but does not necessarily require Health & Disability Ethics Committee Approval (HDEC). As an organisation we pride ourselves to provide excellence to our patients and a safe environment for our patients and our staff. To translate this into any research activity, we need to have confidence when a study is presented that ethical considerations have been reviewed. Therefore, the questions in section 3 are designed so the applicant and the reviewer have certainty ethical considerations have been made.

Note You are NOT required to complete this section, when a HDEC process is required,* ***OR*** *when a HDEC Form has been completed and has been submitted and awaiting the outcome,* ***OR*** *HDEC has been approved.*

→ **Benefits of the study?** Explain what the benefits are, the research will provide.

→ **What risks do you expect the study will pose?** Acknowledge what the actual and potential risks of the study are, no matter how minor, moderate the risks are. All research has risks associated and acknowledging risks helps you and the reviewers to understand the risks, and how better able to manage the risks effectively.

→ **What steps will you take to minimise the risks?** Discuss how you will manage the risks.

→ **Will you be collecting information directly from individuals?** Explain how you will be collecting information – often in low risk study's there is some secondary use of health information without consent and therefore carries some risk to loss of privacy and confidentiality, it is important to acknowledge these risks and explain how will you minimise the risks to the use of this information? How will you store the information and destroy the information?

If you are collecting information directly from individuals - describe how you will:

- Identify the participants
- Approach to recruit the participants
- Include the Informed Consent and participant information sheet
- Need to consider a confidentiality agreement maybe required if you are not a MDHB employee and your MDHB contact person/clinical supervisor will need to be involved

→ **Collecting information from a third party?** If you intend to collect information about individuals from a third party, please discuss this as per questions in this section. It's advisable to read the NEAC guidelines that have information about collecting health information from third parties.

Q6 to Q11 pertains to accessing, using, obtaining patient information at MDHB. This aspect is taken very seriously and the Privacy Act 2020 and MDHB polices for confidentiality applies.

→ **Informed Consent for access to health/patient records?**
→ **If informed consent will not be obtained in these circumstances an ethics committee approval is required**.

→ **External Study Databases or Registries**: For research involving patient information being entered into an external study database or patient registries, informed consent and / or an ethical approval is be obtained if identifiable health information will be shared with researchers from other organisations.

If the identifiable patient information secured and available only to the MDHB, or available to other researchers only in an unidentified form, it is recommended you permit patients the option to opt out of having their information entered into database or registry.

Describe the reasonable steps you will take to provide information to patients on how their information will be used, stored, who gets to see the information and how the patient gets the choice to opt out of this participation.

It is <u>not acceptable</u> to include patient information in a database or registry when known to be contrary to the patient's wishes, and this is unethical.

→ **Justification for not obtaining informed consent for research purposes:** If you are not seeking informed consent for use of patient identifiable information <u>you must justify why.</u>
It is considered appropriate for employees to access health information without consent when undertaking for the purposes of auditing or related activity. There may also be scientific reasons to use a 'case' for a health condition in order to obtain the true clinical picture and / or to not exclude any groups of participants for which gaining informed consent might be challenging. Please refer to the <u>NEAC guidelines 6.43-6.47</u> for more detailed information

<u>Section 4: Administration, Declarations and Transparency</u>
All applicants must notify MDHB research office intermittently of their study progress. This is done via the research email address; it will also be the research office responsibility to remain in contact with you also requesting an update. This is so ongoing support can be provided and the research database is updated and the results from the studies are applied are appropriately to MDHB clinical applications and that we gain knowledge from study

outcomes. It would also be expected to share your study during the promotional week of research week. This gives you an opportunity to showcase your research; this can be done via poster, or presentations.

Supporting documents required – as relevant to the research design and approach undertaken:

a. A protocol and or a study plan: The NEAC guidelines document provides information on what is included in a protocol.
b. Ethics: You are NOT required to complete the ethics section of this form, when a HDEC process is required, OR when a HDEC form has been completed and submitted and you are awaiting the outcome, OR HDEC has been approved, please submit the documentation. If you have acquired institutional support from another organisation, submit this documentation.
c. Participant Information Sheets (PIS) and Informed Consent forms (ICF): to be used in the research are to be submitted. Provide age-appropriate and culturally-appropriate versions i.e. if children, young adults or for specific populations for the study.
d. Copies of Questionnaire/s, surveys etc
e. Provide documentation evidence of any consultation with Māori that has been undertaken for the research. Māori research review is undertaken by the MDHB Research Review Committee and is coordinated by the Research Support Officer.
f. Any other information that is relevant to the study.

Section 5: Respective Management Endorsement

Relevant management endorsements is very important and key as this is an understanding between yourself and manager/s in the use of the clinical area/s, consumables, access to patient information's, databases, your professional boundaries, if there is any altered fte considerations, arrangements and rostering's to accommodate doing your research, and other such considerations, understandings and agreements. There is also professional respect to uphold between services if your research bridges into other services.

If you are an external research applicant (non MDHB employee) and you are applying for study on MDHB premises or internally ie. Phone interviews, questionnaires, surveys etc, please apply for permission/endorsement from the respective department manager AND from the clinical executive/medical lead OR from the respective manager in charge of the service and provide evidence of this with your application. The RSO will help you with the contact details via email upon request.

MDHB staff: Department/Ward/unit/Service Support: Charge Nurse/Clinical Nurse Manager/Department Manager/ADON

You must discuss your intentions and application for research with your manager. This may be a low risk research activity; however, this still involves your time to do this. You may need to consider discussing with you manager your working hours and fte to support your time and wellbeing during this interim. Please also discuss with you manager what the study involves. If your study bridges across two services i.e. Paediatric and adult medical then both ward charge nurses/department managers are required to endorse the study.

Non MDHB applicants for research support in a department: It's important to gain departmental permission. Complete the forms as discussed in this guideline and the RSO can support you with advice regarding contacts of the departments via email or phone.

Operations Executive OR Clinical Executive Endorsement to Proceed
The operations executive or the clinical executive respectively are to that the study to review the integrity, resource and cost implications of the study as well as endorse the study in terms of the ethical and professional requirements, and that the application clearly demonstrates potential clinical, professional and/or strategic benefit to the organisation.

Clinical Board Acknowledgement of Registration
MDHB Clinical Board approval is required in addition to any HDEC, Educational Institute ethical review or other approvals. At MDHB the Chief medical officer approves the application on behalf of the MDHB clinical Board.

5. REFERENCES

National Ethics Advisory Committee, December 2019, Ministry of Health.
Ethical Guidelines for Observational Studies: Observational Research, Audits and Related Activities (July 2012). National Ethics Advisory Committee

6. RELATED MDHB DOCUMENTS

MDHB-7660: Maori Research Review Form
MDHB-1997: Health Research Policy

7. FURTHER INFORMATION / ASSISTANCE

Discussed in the document

8. KEYWORDS

Research, health research, Maori research, low risk