**MDHB Locality Application for Low Risk Research Activity**

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| 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. |
| **Use this form if your application is for:** |
| * A cost-neutral study, or if cost to MCH, explain how this cost is covered.
 |
| * This form is used for minimal or low risk research study that has gained ethics approval from HDEC or from a University Institution or no ethics required, and this application is seeking locality approval.
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| * A low risk research by a non-MCH/external facility and has ethic approval / or no ethics approval and this application is seeking locality approval.
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| * A low risk research activity by an external facility seeking locality approval, as the research is within MCH region or on hospital site
 |
| **Office use only** |
|  | Your application has locality approval |
|  | Your application not achieved locality approval. |
| Signed by the Research Support Office: Date:Ngā mihi maiohaKind regards |

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| **Research ID** (RSO to complete) |  |
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| **Section 1: General Information: Complete relevant sectors**  |
| Title |  |
| Principle Investigator |  |
| External Facility ie University/DHB  |  |
| Email Address |  |
| Research coordinator of this application |  |
| Email address |  |
| MidCentral Health Lead Investigator/Research Lead | Clinical Lead must know and have agreed to this arrangement. |
| MCH Directorate or Service |  |
| Phone number |  |
| Email address |  |
|  | **For Clinical Audits** |
| MidCentral Health: Sponsor  | Clinical sponsor must know and have agreed to support the audit. |
| MCH Directorate or Service |  |
| Phone number |  |
| Email address |  |
|  | **Post Graduate Student to complete**  |
| University Supervisor/s  |  |
| University Facility |  |
| Phone Number |  |
| Email address |  |
| MidCentral Health Clinical supervisor  | Clinical supervisor must know and have agreed to this arrangement. |
| MCH Directorate or Service |  |
| Phone Number |  |
| Email Address |  |
|  | **For external institutions/hospitals, if the contact person is different to any of the above sections** |
| MidCentral Health contact name | Contact person must know and have agreed to this arrangement. |
| MCH Directorate or Service |  |
| Phone number |  |
| Email Address |  |
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| **Section 2: DOCUMENTS CHECKLIST** |
| Submit the documents relevant to the project:* + MCH Research Activity form OR MCH Low Risk Activity form
	+ MCH Maori Review of Research (Rangahau) form
	+ Ethics online application form
	+ Ethics approval letter
	+ Protocol (encouraged to submit)
	+ Participant Information Sheets and Informed Consent Forms
	+ Informed consent/s for human tissue collection
	+ Questionnaires / Surveys
	+ Evidence of Māori consultation external to MidCentral Health

Other supporting documentation relevant to the application: please state:  |
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| **Section2: Proposal and Participation** |
| **Research design: What type of research, study, project or trial design is your study? Multi-selection as applicable. *For definitions, refer to the : Standard Operating Procedures for Health and Disability Ethics Committees, version 1.0 2012 http://ethics.health.govt.nz/operating-procedures*** |
|  [ ]  Observational study [ ]  Quality Improvement [ ]  Interventional study [ ]  A clinical audit  [ ]  Post Graduate research [ ]  Multi-national study initiated outside NZ [ ]  Clinical trial [ ]  Nation-wide (within NZ)[ ]  Survey  [ ]  Other, *type or paste text here* |
|  What is the principal study question, hypothesis or objective of the study/audit? |
| *type or paste text here* |
| Describe how will the participants be involved in the study/audit? If this is an audit of public sector information, participants may not be directly involved, and consent not required.*type or paste text here*  |
| Does this involve private patient participation and or access to private patient information? If so, state the facilities to be involved and how you are going to access the information and the consent gained for this. |
| *type or paste text here* |
| State what/who MidCentral Health resources will be used/required: ie. statistician, data extraction, access to clinical records, use of staff time, IT devices/support, consumables). |
| *type or paste text here* |
| Is this project/audit/research study for publication?  |
| *type or paste text here* |
| How and who to - is the study/audit going to be reported? Ie presentation, conference, poster, report to be disseminated*type or paste text here*  |
| Have you sought Maori/Iwi consultation external to MCH? YES / NO  |
| Is the project/audit collecting and analysing by ethnicity? YES / NO NO: Explain this option: *type or paste text here*  |
| **Our process is for MCH Maori review and endorsement and therefore the Maori Review for Research is to be completed and sent with this application. Maori health outcomes and equity for health is fundamental in our MCH health strategies.**  |
| **Human Tissue collection:** Does this study involve the collection of tissue samples? [ ]  No. **Proceed to Section 3** [ ]  Yes. Please provide all details of the nature and number of the samples, how is the tissue stored and the transport of, overseas transport, and how long is the samples stored for and the method of disposal? *type or paste text here* Is the tissue collected - offered back to Maori participants as an option?[ ]  No. please explain this option: *type or paste text here*  [ ]  Yes, and is part of the patient information and informed consent process.Are there participant consent forms for storage of samples for future unspecified use? [ ]  Not applicable [ ]  Yes Are there participant consent forms for use of samples for genetic analysis? [ ]  Not applicable [ ]  Yes  |
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| **Section 3: Ethical considerations** |
| **Ethics status: Which option represents the current status for ethics? If you are not sure whether the research requires ethics, please contact HDEC 0800 819 6877 or the University you are with for their advice.** [ ]  HDEC Ethics approval gained [ ]  University Ethics approval gained: state with whom *type or paste text here* [ ]  Have applied for ethics via HDEC [ ]  Ethics approval not required: please state why *type or paste text here*  |
| What are the benefits expected from the study/audit?  |
| *type or paste text here* |
| What are the risks anticipated from the study/audit and how are these risk/s mitigated?  |
| *type or paste text here* |
| What steps will you take to minimise expected risk? |
| *type or paste text here* |
| Does this project/audit involve collecting information directly from participants? YES: explain the recruitment method.  | YES / NO |
| *type or paste text here* |
| Does this project/audit involve collecting information from a third-party about the participants? YES: State the third-party relationship to the participants, and State why is it appropriate to gain the information from the third-party. | YES / NO |
| *type or paste text here* |
| Does the project/audit collect data from health records and or patient clinical records?  | YES / NO |
| Does the project/audit information you are collecting from participants or a clinical audit - identifiable or potentially be identifiable?YES: will you obtain informed consent from the participants? If NO: state, the reason for not obtaining informed consent from the participants.*type or paste text here* | YES / NOYES / NO/ NA |
| Will the participants have an ‘opt out’ option as part of the informed consent?  | YES / NO/ NA |
| Explain all measures taken to preserve the confidentiality of the patient information. How is the information stored and how long is the information stored for before destruction?Who will have access to the data? |
| *type or paste text here* |
| **IMPORTANT (1):** If you are not obtaining informed consent to use identified patient information, and with the combination of any one of the following, please discuss with or apply for HDEC or via your University. * You are not employed by or contracted to MDHB,
* You are retaining unique identifiers (e.g. NHI) in your dataset that could link to other databases/registries
* You are obtaining health information from other health care organisations in addition to MDHB.
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| **IMPORTANT (2): Storage of information is to comply with MidCentral Health Policy:**No personal devices are used to store patient information outside of the Citrix environment ie: non encrypted personal device hard drives or person storage systems. All staff who require to store patient data must do so on an encrypted and secure hard drive such as a DHB device for their research or clinical audit activities (August 2020). |

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| **Section 4: Administration and Declaration** |
| Proposed study start date:  |
| Proposed completion date:  |
| **Declaration:** I will notify MCH research office when study is complete I will submit a copy of the report to MCH research office.I will notify MCH research office of the reference or supply a copy of the publication. | Date: Signature or type/write your name:  |  |
| **SUBMISSION: Application and supporting documents are emailed to the:** research@midcentraldhb.govt.nz Annette CarseResearch SupportChief Medical Office. |
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| **MDHB Professional Approval/Clinical Executive Endorsement** |
| Clinical Exec / Professional Lead / Clinical Lead/ ADON / DON/M/ Nursing Leader  |
| Name |  |
| Job Title |  |
| Date |  |
| Signature |  |
| Comment: |
|  |
| **Operations Executive Endorsement to Proceed** |
|  |
| Name |  |
| Job Title |  |
| Date |  |
| Comment: |
|  |  |
| **Clinical Board Acknowledgment of Registration (CMO)** |
|  |
| Name |  |
| Date |  |
| Signature |  |
| Comment: |