**MDHB Locality Application for: Research - Rangahau Activity**

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| **Use this form if your application is for:** | |
| * Frequently involves the following elements: Confidentiality agreement, budget & cost implications, contract agreement, or MOU | |
| * This form is used for Research activities on MCH site, and has ethical approval from HDEC or from a University i.e. clinical trials, randomisation research activity | |
| * This form is for internal services/departments or external institutions, facilities to apply for locality approval | |
| * Research that involves human participants and human tissue collection | |
| **Office use only** | |
|  | Your application has been endorsed |
|  | Your application is not yet endorsed. Details of further requirements are provided below. |
| Signed by the Research Support Office:    Date:  Ngā mihi maioha Kind 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 | MCH lead must know and have agreed to this arrangement. | | |
| MCH Directorate or Service |  | | |
| Phone number |  | | |
| Email address |  | | |
|  | **Post Graduate Student to complete** | | |
| University Supervisor |  | | |
| 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 |  | | |
|  | **GCP certified (Good Clinical Practice) Please add their names** | | |
| Name/s |  | | |
| Name/s |  | | |
| Name/s |  | | |
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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   + Participant Information Sheets and Informed Consent Forms   + Informed consent/s for human tissue collection   + Questionnaires / Surveys   + Evidence of Māori consultation external to MidCentral Health   + Funding application /letter   + For research involving new medicines, Medsafe approval is to be decided as per Section 30 [Medicines Act 1981](http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html)   + Medsafe Letter   **Other supporting documentation and processes completed: (tick)**   * + Confidentiality Disclosure Agreement Contract (Reviewed by MCH, approved and signed by MCH and Research company)   + Contract: CTRA agreement (Reviewed by MCH, approved and signed by MCH and Research company)   + MOU (Reviewed by MCH, approved and signed by MCH and Research company)   + Is this research grant funded?   + Research funded by the company or other?   + No funding involved. | | | |
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| **Section 3: 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  Experimental Study  Interventional study  Clinical trial  Post Graduate research  Multi-national study initiated outside NZ  Nation-wide (within NZ)  Other, *type or paste text here* | | | |
| What is the principal study question, hypothesis or objective, study design, analyses of the research? | | | |
| *type or paste text here* | | | |
| State what/who MidCentral Health resources will be used/required: ie. statistician, data extraction, access to clinical records, access to wards/services, use of staff time, IT devices/support, consumables). | | | |
| *type or paste text here* | | | |
| Is this research study for publication? | | | |
| *type or paste text here* | | | |
| Will participants receive a koha (gift), payment, or reimbursement of costs for participating in the study?  No  Yes: state how  ⓘ [NEAC Reimbursements, koha and incentives for participants](https://neac.health.govt.nz/assets/Uploads/NEAC/publications/national-ethical-standards-health-disability-research-quality-improvement-2019.pdf) – See page 147 | | | |
| 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 research collected and analyzed 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 form 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 and waiting for reply  Ethics approval not required: please state why *type or paste text here* | | | |
| **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.   * **I have read this important notice** | | | |

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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](mailto:research@midcentraldhb.govt.nz)  Research Support  Chief Medical Office.  Phone: extn 8036, 06 3508036 | | | |
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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: | | | |
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| **Operations Executive Endorsement to Proceed** | | | |
|  | | | |
| Name |  | | |
| Job Title |  | | |
| Date |  | | |
| Comment: | | | |
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| **Clinical Board Acknowledgment of Registration (CMO)** | | | |
|  | | | |
| Name |  | | |
| Date |  | | |
| Signature |  | | |
| Comment: | | | |

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| **ⓘ Research Resource Documents** | |
| MidCentral District Health Board | * [Research Policy](http://www.midcentraldhb.govt.nz/WorkingMDHB/Documents/MDHB%20Research%20Policy.pdf) * [Achieving Health Equity Think Piece 2018](http://www.midcentraldhb.govt.nz/AboutMDHB/BoardandCommittees/Documents/Electronic%20agenda%20Part%201%20Equity%20Attachments%20Pg%20223-370.pdf) |
| National Ethics Advisory Committee | * [National Ethical Standards – Health and Disability Research and Quality Improvement](https://neac.health.govt.nz/assets/Uploads/NEAC/publications/national-ethical-standards-health-disability-research-quality-improvement-2019.pdf) * [Māori Research Ethics: An overview](https://neac.health.govt.nz/assets/Uploads/NEAC/publications/neac-maori-research-ethics-an-overview-2012.pdf) |
| Health Research Council of New Zealand | * [Health Research Council](https://www.hrc.govt.nz/resources/te-ara-tika-guidelines-maori-research-ethics-0) * [Te Ara Tika Guidelines for Maori Research Ethics](https://www.hrc.govt.nz/resources/te-ara-tika-guidelines-maori-research-ethics-0) |
| Heath and Disability Ethics Committees | * [Standard Operating Procedures](https://ethics.health.govt.nz/operating-procedures) * [Guides, Templates & Forms](https://ethics.health.govt.nz/guides-templates-and-forms/) |
| Ministry of Health | * [New Zealand Health Research Strategy](https://www.health.govt.nz/system/files/documents/publications/nz-health-research-strategy-jun17.pdf) * [NZ health statistics](https://www.health.govt.nz/nz-health-statistics) |
| Stats NZ | * [Stats NZ Infoshare](http://archive.stats.govt.nz/infoshare/Default.aspx) |