**Locality Approval - Low Risk Research Form**

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| **Definition:** Research activities classified as low risk are characterized by a minimal potential for harm. This harm may encompass various forms, including physical, psychological, disrespect or harm to dignity, social or cultural, privacy, economic, legal, and autonomy-related harm. The designation of low risk or minimal risk indicates that the likelihood and severity of harm in the research context do not exceed the risks typically faced in everyday life (NEAC, 2019). |
|  **Use this form if your application is for:** |
| This form is intended for research studies that are classified as minimal or low risk, which have received ethics approval from the Health and Disability Ethics Committee (HDEC) or a University Institution, or that fall outside the scope of HDEC screening. This application is specifically requesting locality approval. |
|  **Office use only** |
|  | Your application has locality approval |
|  | Your application has not attained locality approval. |
| Signed by the Research Support Office: Date Kind regards |

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| **Research ID**  |  |
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| **Section 1: General Information: Complete relevant sectors**  |
| Title of the study: |  |
| Principle Investigator (PI) Or contact person at Palmerston North hospital |  |
| Department of the contact person at Palmerston North Hospital |  |
| External Facility i.e. University/provider/other hospital |  |
| Email Address |  |
| Research coordinator of this application if different to PI. |  |
| Email address |  |
| **Post Graduate Student to complete**  |
| University Supervisor  |  |
| University Facility |  |
| Phone Number |  |
| Email address |  |
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| **Section 2: DOCUMENTS CHECKLIST** |
| Submit the documents relevant to the project:* + Low Risk Research form
	+ Māori Review of Research (Rangahau) form
	+ Evidence of Māori consultation
	+ HDEC Ethics online application form
	+ Ethics approval letter from either HDEC or Education Faculty **OR** out of scope letter from HDEC
	+ Protocol (encouraged to submit)
	+ Participant Information Sheets and Informed Consent Forms
	+ Informed consent/s for human tissue collection
	+ Copy of any Questionnaires / Survey
	+ Data Management Plan
	+ Medsafe letter
	+ HRC funding letter or other funding letter
	+ Other - state:
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| **Mandatory to complete:** What is the source of funding for your research? Various sources of funding include HRC funding, private sponsorship, commercial sponsorship, self-funding, and hospital contributions etc.*type or paste text here* |
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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 [ ]  Study initiated from outside NZ[ ]  Clinical trial [ ]  Nation-wide (within NZ)[ ]  Descriptive Research [ ]  Qualitative Research[ ]  Survey [ ]  Cross sectional research [ ]  Other, *type or paste text here* |
|  What is the research question, hypothesis, or aim of the study/audit? |
| *type or paste text here* |
| Please provide a detailed description of the study protocol, including the methodology, procedures, and any relevant timelines.*type or paste text here* |
| Describe how the participants will be engaged in the study/audit? Please describe the methods used to engage participants, such as recruitment strategies, informed consent procedures, and data collection techniques (e.g., surveys, interviews, observations). *type or paste text here* [ ]  NA  |
| Does the study, audit, or project encompass the recruitment of individuals or the gathering of information from Māori and or other ethnic backgrounds? [ ]  Yes, please specify the ethnicities involved (e.g., Māori, Pacific Peoples, Asian, etc.)[ ]  NA |
| Will the study, audit, or project collect and analyse data based on ethnicity?  [ ]  Yes [ ]  NA |
| Has consultation with the Māori community been conducted regarding the recruitment of Māori participants or the collection of information from Māori?  [ ]  Yes [ ]  No [ ]  NA   |
| Does the study, audit, or project include the recruitment of individuals with disabilities? (Promoting research that includes individuals with disabilities).[ ]  Yes [ ]  No [ ]  NA |
| Does the study, audit, or project require access to patient information or participation from private hospitals?If yes, please specify the facilities involved, how the information will be accessed, and the process for obtaining patient consent. |
| [ ]  Yes, *type or paste text here*[ ]  NA |
| Identify the specific resources from MidCentral that will be utilized or needed, such as a statistician, data extraction capabilities, access to clinical records, allocation of staff time, IT devices and support, as well as consumables. [ ]  NA Please state:  |
| *type or paste text here* |
| Is this project/audit/research study for publication?  |
| [ ]  Yes [ ]  No Is this project/audit/research study for conference, poster, presentation? [ ]  Yes [ ]  No  |
| **Human Tissue Collection and Care:** Does the research methodology involve the collection of tissue samples  [x]  No. **Proceed to Section 3** [ ]  YesP**lease provide the following details regarding the tissue samples:**1. **Type of Tissue Samples**:Specify the type(s) of tissue being collected (e.g., blood, skin, biopsy samples, etc.).
2. **Quantity of Tissue Samples**:Indicate the estimated or exact quantity of tissue to be collected for the study.
3. **Preservation Methods**:Describe the methods used to preserve the tissue samples (e.g., refrigeration, freezing, chemical preservation, etc.).
4. **Overseas Transportation Procedures**:Outline the procedures for transporting tissue samples internationally, including any regulatory compliance, packaging, and safety measures in place.
5. **Storage Duration**:Specify the expected duration for which the tissue samples will be stored (e.g., short-term, long-term, indefinitely).
6. **Disposal Methods**:Detail the methods that will be used for the proper disposal of tissue samples once they are no longer required for the study (e.g., incineration, biological waste disposal, etc.)
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| **Human Tissue Protection:** **Is the option to return collected tissue offered to Māori participants?**  [ ]  No.  [ ]  Yes, please describe the process and any cultural considerations taken into account when offering the return of tissue to Māori participants.**Are there participant consent forms for the storage of samples for future unspecified use?** [ ]  Yes [ ]  NAyes, please provide details on the consent process, including how participants are informed about the potential future use of their samples.**Are there participant consent forms for the use of samples in genetic analysis?** [ ]  Yes [ ]  NA If yes, please describe the consent process and how participants are informed about the use of their samples for genetic research.  |
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| **Section 3: Ethical Considerations** |
| For research activities assessed as low risk, it is not necessary for all studies to undergo HDEC ethics review. Please complete the HDEC screening tool and submit the letter indicating 'out of scope' as proof that this consideration has been made. Find out if your study requires HDEC review via the Health & Disability Ethics website |
| **Ethics status: Which option represents the current status for ethics?**  [ ]  HDEC Ethics approval  [ ]  University Ethics approval gained [ ]  Have applied for ethics via HDEC  [ ]  Ethics approval not required: please state why *type or paste text here*  |
| **What benefits are expected to arise from the study or audit, and how will this enhance patient outcomes?**Please describe the expected benefits of the study or audit and how these benefits will contribute to improving patient care or outcomes. |
| *type or paste text here* |
| **What potential risks are associated with the study or audit, and what measures are in place to mitigate these risks?**Outline the potential risks to participants or the data collection process and the strategies or measures in place to minimize or manage these risks. |
| *type or paste text here* |
| **Is the project or audit gathering information from health records and/or patient clinical records?** If yes, please specify the type of health or clinical records being used. | [ ]  Yes [ ]  No  |
| **Is the project or audit using identifiable patient information or is the data de-identified?**☐ Identifiable data☐ De-identified data | [ ]  Yes [ ]  No  |
| **Will participants have an ‘opt-out’ option as part of the informed consent process?**If yes, please explain how participants can opt-out and what the implications are for their participation in the study. | [ ]  Yes [ ]  No [x]  NA |
| **Is there a potential for commercial interest arising from this study?**If yes, please describe any potential commercial interests or partnerships related to the study | [ ]  Yes [ ]  No  |
| **How is the data retained, what is the duration of its retention, and who will have access to it?**Please specify the methods of data storage, the length of time the data will be retained, and the individuals or organizations who will have access to the data. Additionally, describe the procedures for data disposal after retention. |
| *type or paste text here* |
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| **Section 4: Administration and Declaration** |
| **Declaration:** Upon the completion of the study, I will inform the research office. Additionally, I will provide a copy of the report to the research office OR I will notify the research office regarding the reference or supply a copy of the publication for records. | Date: Name and contact details:  |  |
| **Administration: Application and supporting documents are emailed to the:** research@midcentraldhb.govt.nz Research Support OfficeOffice of the Chief Medical Officer. Phone: 06 3508036. Extn: 8036 |
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| **Professional Approval/Clinical Executive Endorsement** |
| Name |  |
| Job Title |  |
| Date |  |
| Signature |  |
| Comment: |
|  |
| **Operations Executive Endorsement**  |
| Name |  |
| Job Title |  |
| Date |  |
| Comment: |
|  |  |
| **Clinical Board Acknowledgment of Endorsement from CMO**  |
| Name |  |
| Date |  |
| Signature |  |
| Comment: |