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Minimal Risk

LOCALITY AUTHORISATION Form

(HEALTH NEW ZEALAND | Te WHATU ORA - SOUTHERN)

TO BE USED WITH University of Otago MINIMAL RISK OR CATEGORY b eTHICS APPLICATION/APPROVAL ONLY

NOT to be used FOR STUDIES REVIEWED BY HDEC

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| --- | --- |
| **Project ID**  (*HRS to complete)* |  |

**Section 1: Overview of intended research** - *(Please send a copy of this section to Health Research South)*

# Research Project Short Title (*include protocol number, if applicable*):

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* 1. **Principal Investigator (***for Health NZ Southern, please see guidelines***)**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| *Title & Name* |  | | | *Email* |  | | | | | |
| *Position* |  | | | | | | | | | |
| *Location (incl Dept)* |  | | | | | *Phone* | |  | | |
| *Employer percentage:* | |  | **% Health NZ Southern** | | | |  | | % **U of O** |  |

* 1. **Associated Investigators**  (*including* ***external/study PI*** *and Research Nurses*)

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| --- | --- | --- |
| *Title & Name:* | *Role in research team* | *Location & Email, Phone:* |
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* 1. **Intended source of financial support for this project** (*please tick* 🗹  *all sources*)

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| Contract *(non-commercial/investigator led e.g. HRC, collaborative/network trials)* |  |
| Research grant – other *(without a contract including UoO/DSM grants, bequests etc)* |  |
| Internal DSM Department funds |  |
| Other *(This includes non-DSM Departments)* |  |
| No funding |  |

* 1. **Name of funder(s)** (*commercial sponsor, funding agency, DSM department, etc.*)

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* 1. **If funding is from external source, where will research account be held?**

|  |  |  |  |
| --- | --- | --- | --- |
| Health NZ Research Account |  | A/C Number |  |
| DSM University Research Account |  | A/C Code |  |
| Not Applicable |  |  |  |

* 1. **Is there student involvement?**  Yes No

Student Name & Sponsorship: (*i.e. sponsor/funder and/or supervisor, e.g. Summer Studentship, Masters, PhD*)

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| **EXPECTED STARTING DATE:** |  | **EXPECTED FINISHING DATE:** |  |
|  |  |  |  |
| **DATE RECEIVED:** |  | **DATE REGISTERED:** |  |

**Section 2: Financial and Resource Implications**

* 1. **Full costs of this research have been identified?** (*please 🗹 one)* Yes  N/A

***If Yes****, please complete and attach an appropriate Health NZ - Southern or University of Otago costing template, or other budget layout.* ***(Costs to the Health NZ -Southern must be clearly identified in your budget)***

***If N/A****, please provide explanation.*

* 1. **Will resources of the Health NZ - Southern be used for this project?**  Yes  No
  2. **How will the costs of Health NZ - Southern resources be paid?***(please see Guidelines****)***

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* 1. **Total amount awarded or contracted: $\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  2. **total amount budgeted: $ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
  3. **Name of Health NZ - Southern Directorate(s) and Service(s) responsible for this research**

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| --- | --- |
| *Directorate(s):* | *Service(s):* |
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**Section 2A: Departmental / Group approval to conduct research**

*The following are the official signatories for approval processes, but* ***researchers should ensure liaison occurs with potentially affected managers.***

**Health NZ Southern Clinical Leader approval:**

*Clinical impact has been reviewed and approved by the Health NZ Southern Clinical Leader.*

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| *Clinical Leader Name:* | *Clinical Leader Signature:* | *Date:* |
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**Dunedin School Of Medicine Academic Leader approval:**

*DSM financial and resource issues have been reviewed and approved by the DSM Academic Leader[[1]](#endnote-1).*

*This includes confirmation of the availability and cost of DSM resources external to the department.*

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| *Academic Leader Name:* | *Academic Leader Signature:* | *Date:* |
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**Health NZ – Southern Service Manager approval:**

*Health NZ - Southern financial and resource requirements have been reviewed and approved by the Service Manager.*

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| *Service Manager Name:* | *Service Manager Signature:* | *Date:* |
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**Section 3: Ethical & Regulatory requirements**

* 1. **Project type (please 🗹 one *)***

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| Retrospective data analysis of patient medical records  Staff survey  Evaluation of teaching curriculum | |
| Other |  | |

* 1. **Ethics Approval (please 🗹 one *)***

UoO Human Ethics Committee Health – Minimal Risk Health Research

UoO Human Ethics Committee – Category B (NB: only projects not considered health research)

|  |  |  |  |
| --- | --- | --- | --- |
| Reference No: |  | Date Approved: |  |

* 1. **Peer Review (please 🗹 one for each question*****)***

Has Peer Review been initiated?  Yes  No

Has Peer Review been obtained?  Yes  No

* 1. **Māori Consultation (please 🗹 one*****)***

Has consultation with Māori been initiated?  Yes  No

* 1. **Good Clinical Research Practice** **(please 🗹 one*****)***

*GCP training for Principal Investigators is an HRS locality requirement.*

Do you have up to date certification in Good Clinical Practice (GCP)?  Yes  No

*(See “Guideline on the Regulation of Therapeutic Products in New Zealand Part 11: Clinical trials – regulatory approval and good clinical practice requirements.” Please contact HRS for further details if you are unfamiliar with GCP)*

* 1. **How will Health NZ Southern patients’ clinical information be accessed?**

Paper records already on the ward/unit (i.e. current patients)

Paper records requested via the Clinical Records department

Electronic data extract already within the department

Electronic data extract requested via the Health Information Group (list of NHIs or full data set)

via Clinical Portal

Other (specify):

No patient clinical information will be accessed

* 1. **Describe how any collected data will be kept safe and who will be responsible for ensuring policies and ethical standards are met for access, transfer, storage & disposal of data (paper/electronic files/video/audio):**

**Section 3A: Researcher Declaration -** *(When Locality Authorisation has been granted the HRS will notify you in writing that the research has approval to commence).*

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| ***“As the site Principal Investigator, I am declaring that to the best of my knowledge, all information provided in Sections 1-3 is correct.”*** | |
| *Signature of Principal Investigator:* | *Date:* |
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**HRS Comments –** *(Please include Section and Subsection number as reference)*

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**HRS Comments for Board –** *(include external PI details AND budget comments, if $ amount not known)*

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**Section 4: Organisational approval to conduct research and final approval to commence research**

***Health Research South to complete Section 4***

1. Directorate / Department approval has been given by the appropriate individuals:

🞎 Yes 🞎 No

2. Subject to verification of final ethics approval, all required documentation is complete

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🞎 Yes 🞎 No Date:

3. Where appropriate, University of Otago research process has been completed

🞎 Yes 🞎 No 🞎 N/A

**Health Research South Manager signature :**

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| --- | --- | --- |
|  | *HRS Manager Signature:* | *Date:* |
| *Dr Mette Goodin* |  |  |
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🞎 Ethics approval requirements have been completed

🞎 Written approval to commence research sent to the Principal Investigator

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| *Initialled (Research Advisor): [\_\_\_\_\_\_\_\_\_\_\_\_]* | | *Letter Sent on: [\_\_\_\_\_ /\_\_\_\_\_/20 \_\_\_\_]* |

1. **Comments if application is declined:**

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   **Staff to be informed/consulted**

   Must include the Service Manager of all affected services

   Please note signatures are not mandatory but some sort of evidence of this liaison should be provided

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   *Please see the Health Research South website (*[*www.otago.ac.nz/hrs*](http://www.otago.ac.nz/hrs)*) or contact a Research Advisor (*[*hrs@otago.ac.nz*](mailto:hrs@otago.ac.nz)*) for details of the study documentation to be submitted for locality authorisation.*  [↑](#endnote-ref-1)