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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?**

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| --- | --- | --- |
| 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)

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|  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**) for details of the study documentation to be submitted for locality authorisation.*  [↑](#endnote-ref-1)