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LOCALITY AUTHORISATION Form

(HEALTH NEW ZEALAND | Te whatu ORa - SOUTHERN)

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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 HRS Code of Conduct***)**

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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, Phone & Email:* |
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* 1. **Is this project subject to a confidentiality disclosure agreement?** [ ] Yes[ ] No

***If Yes****, all recipients are warned that some information relating to this clinical trial, including the protocol, is confidential and has been disclosed to Health NZ Southern or the University of Otago under the terms of a Confidential Disclosure Agreement (CDA). Please keep this information confidential.*

* 1. **Intended source of financial support for this project** (*please tick* 🗹  *all sources*)

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| Commercial contract |[ ]
| Other 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. **Name of insurer(s)**

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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 attach 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. **Which Health NZ Southern (or other) support services are required? (***please 🗹 as many as necessary****)***

 [ ]  Radiology [ ]  Pharmacy [ ]  None

 [ ]  Awanui Labs [ ]  Other

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(*Please complete and attach the relevant Research Resource Request Form(s))*

* 1. **Name of Health NZ Southern Directorate(s) and Service(s) responsible for this research**

|  |  |
| --- | --- |
|  *Directorate(s):* | *Service(s):*  |
|  |  |

* 1. **How will eligible Health NZ Southern patients be identified and recruited?**[ ]  No patients will be recruited [ ]  Participants will be recruited from the community (e.g. via advertising)

Potential Health NZ Southern patients will be identified by:

 [ ]  screening clinical records or clinic lists

 [ ]  by treating clinician/therapist

Potential Health NZ Southern patients invited to participate:

 [ ]  via letter/email from the clinician involved in their care

[ ]  asked to participate by their clinician

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| Other: |  |

*List all Health NZ - Southern clinics & services to be involved with recruitment:*

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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:**

*Patient safety and clinical impact have 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 Head of Department/Academic Leader. 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 General Manager approval:**

*Health NZ Southern financial and resource requirements have been reviewed and approved by the General Manager. This includes confirmation of the availability and cost of Health NZ Southern resources external to the Directorate e.g. Pathology, Radiology, Pharmacy.*

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| *General Manager Name:* | *General Manager Signature:*  | *Date:* |
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**Section 3: Ethic & Regulatory requirements**

* 1. **Ethics Approval (please 🗹 one *)*** [ ]  HDEC Full [ ]  HDEC Expedited [ ]  UoO EC

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| --- | --- |
|  Name of Ethics Committee |  |
|  Reference No: |  | Date Approved: |  |

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

 Has SCOTT/Peer Review been initiated? [ ]  Yes [ ]  No

 Has SCOTT/Peer Review been obtained? [ ]  Yes [ ]  No

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

 Has consultation with Māori been initiated? [ ]  Yes [ ]  No

* 1. **Trial Registration (please 🗹 one for each question*)***

 Is this a clinical trial? [ ]  Yes [ ]  No

 Are you the initiator of this trial? [ ]  Yes [ ]  No [ ]  N/A

 Has/will this trial be registered? [ ]  Yes [ ]  No [ ]  N/A

* 1. **Section 30, Medicines Act 1981 (please 🗹 one)**

 If this a clinical trial of a new medicine (as defined by the [Medicines Act 1981](http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM53790.html)), does it have Medsafe approval?

 [ ]  Yes [ ]  No [ ]  N/A

* 1. **Health NZ Southern Patient Alerts (please 🗹 one*)***

Does this research involve medical/surgical/treatment intervention(s) over and above the standard medical procedures the patients receive?

 [ ]  Yes [ ]  No

**If yes,** please attach a sample of a National Medical Warnings Request form. (*It is the investigator’s obligation to flag this research involvement in SI PICS as a Medical Warning for each participant as a patient safety requirement*.) A sample of an alert sheet for inclusion in the patient’s paper notes is optional.

* 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. **Data Management Plan** **(please 🗹 one*)***

Has a data management plan been prepared and submitted for ethics review? [ ]  Yes [ ]  No

***If No****, please 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

4. Indemnity covered by:

 🞎 ACC (*Declaration A marked for your information*.)

🞎 Company (*Contracts reviewed and recommended for signing by Health NZ - Southern*.)

🞎 University (*The research is a student project or is externally funded research and*

 *University policies will apply.*)

 🞎 Other …………………………………………

**Health Research South Manager signature:**

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|  | *HRS Manager Signature:*  | *Date:* |
| *Dr Mette Goodin* |  |  |
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**Dunedin School of Medicine Dean approval:**

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| ***“I have reviewed this application and approve of this research commencing subject to ethical approval.”*** |

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| --- | --- | --- |
|  | *DSM Dean Signature:*  | *Date:* |
| *Professor Jo Baxter**Dean, Dunedin School of Medicine* |  |  |

**Health NZ Southern Leadership Team approval:**

***“I have reviewed this application and approve of this research commencing subject to ethical approval.”***

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| --- | --- | --- |
|  | *Health NZ – Southern Authorised Signature:*  | *Date:* |
| *Hamish Brown**Group Director of Operations Southern*  |  |  |

 🞎 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: \_\_\_\_\_\_\_\_\_\_\_\_\_* |

**HDEC online locality authorisation given:** 🞎 Yes 🞎 No 🞎 N/A

**Comments if application is declined:**

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**Staff to be informed/consulted**

Must include the Service Manager of all involved services (e.g. if patients are recruited from their service)

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.*