Pathway: Our People/ Service Delivery/ Clinical / Research Policy and Procedure

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POLICY STATEMENT:

Hospice South supports and encourages research that advances palliative care knowledge and improves outcomes for patients and whanau.
All research must:

- Protect the rights, safety, and dignity of participants
- Demonstrate cultural safety, with particular emphasis on Maori health equity and partnership
- Be scientifically and methodologically sound
- Comply with all applicable ethical, legal, and organisational requirements
- Be appropriately governed, resourced and monitored

PURPOSE:

To ensure that all research undertaken at Hospice South is ethical, safe and legally compliant. Is of clinical relevance, evidence -informed and of high quality. All research undertaken aligns with New Zealand health research standards, including any Health and Disability Ethics Committee (HDEC) requirements.
All research undertaken must uphold the principles of:

- Research excellence
- Transparency and accountability
- Partnership with Maori in accordance with Te Tiriti o Waitangi and
- Collaboration to maximise impact and knowledge translation

SCOPE:

This policy applies to:

- All Hospice South employees
- External researchers engaging with Hospice South
- All research stages including planning, approval, conduct and dissemination of research findings

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DEFINITIONS:

Research

A systematic investigation designed to develop or contribute to generalisable knowledge, including clinical, service, quality improvement, and evaluation studies where applicable.

Principal Investigator (PI)

The individual with primary responsibility for the design, conduct, and reporting of the research

Sponsor

The organisation or individual responsible for initiating, managing, and / or funding the study

Designated Research Governance Lead

Hospice South will nominate a senior manager to serve as the Research Governance Lead. The appointee may come from

- Medical leadership (e.g. Medical Director, Palliative Care Specialist)

- Nursing leadership (e.g. Nursing Director)
- Support services

The selection will be based on the projects nature and the level of involvement required.

PROCEDURE

Research Application and Approval

1. All research proposals must be submitted in writing to designated research governance lead prior to commencement of any research activity.

2. Applications must include
    - Study protocol
    - Ethical approval status (or the plan to obtain approval)
    - Risk assessment
    - Resource and impact assessment (staff time, systems, patient burden)

3. All proposals will undergo organisational review to assess
    - Alignment with Hospice Souths strategic priorities
    - Clinical relevance and the potential benefits to patients and whānau
    - Feasibility within existing services and the ability to facilitate the research within required timelines
    - Risk to patients, staff and Hospice services and overall operation
    - Cultural safety and alignment to Te Tiriti o Waitangi principles

4. Final approval will be granted at a level appropriate to the study's risk and scope and may include:
    - Clinical Director approval
    - Clinical Governance endorsement
    - CEO or Board approval where required.

5. Research may not commence until all internal and external approvals are confirmed in writing.

Ethical and Legal Compliance

Where required research must obtain approval from the Health and Disability Ethics Committee (HDEC) .
Research must comply with the Health Information Privacy Code 2020 and the Privacy Act 2020.
All research must meet Good Clinical Practice standards and align with Te Tiriti o Waitangi principles including partnership, participation and protection.
All research projects must ensure appropriate cultural consultation has occurred where required.

Informed Consent

Written informed consent must be obtained prior to any participation in the research.
Consent must be informed, voluntary and documented.

- A copy of the signed consent form must be retained in the patient record or within the research documents (where applicable)
- Research participants must be clearly informed of;

- The purpose of the study or research
- The risks and benefits
- Confidentiality and data use
- Their right to decline or withdraw at any time without impact on care

Research Governance and Oversight

- Each study must have a clearly identified Principal Investigator responsible for conduct and compliance
- Hospice South will provide internal oversight through the Designated Research Governance Lead or nominee, proportionate to the study's level of risk and complexity.
- Researchers must:
- Provide regular progress updates as agreed during approval
- Promptly report protocol deviations, adverse events, or emerging risks
- Comply with audit or review requests as required

Hospice South reserves the right to suspend or terminate any research if participant safety, ethical compliance, or organisational integrity are compromised.

Adverse Events and Safety reporting

All serious adverse events must be reported immediately to the:

- Patient's clinical care team
- The Clinical Director
- Designated research governance lead

Reporting must also comply with HDEC and sponsor requirements

Appropriate clinical and organisational responses must be enacted without delay

Where safety concerns arise Hospice South may suspend or terminate the research project

Risk Management

To ensure participant and organisational safety:

- Risks must be identified, assessed, and mitigated prior to the research commencement
- Participant wellbeing must take precedence over research objectives
- Research involvement must be clearly documented in patient systems for example alerts in PalCare.
- Key study information including investigator contact details must be readily available
- Risk assessments should be reviewed at regular intervals throughout the project lifecycle

Data Management and Privacy

Data must be collected, stored , and managed securely
Patient confidentiality must be strictly maintained
Access to identifiable data must be limited to authorised personnel
Data storage must comply with legal, ethical, and organisational requirements

Data retention and disposal must follow approved schedules and agreements as outlined in the research proposal plan

Intellectual Property

Intellectual property generated by Hospice South employees in the course of their work remains the property of Hospice South

- Any alternative arrangement must be agreed in writing prior to the research commencement

Collaborative agreements must clearly define ownership, use , and publication rights

Publications and Dissemination

Hospice South supports the release and dissemination of research findings to improve palliative care practice.

All publications and presentations must:

- Acknowledge Hospice South appropriately
- Maintain patient or participant confidentiality

Use of Hospice South branding, logos, or public statements must be approved in advance

Researchers are encouraged to share findings with Hospice South staff and stakeholders

Accountability and Financial Management

- Research must operate within approved budgets, contracts, and funding agreements
- All financial activity must comply with Hospice South financial policies and controls
- Resource use (staff time, facilities, systems) must be agreed in advance as part of the written project plan
- Any conflicts of interest must be declared and managed appropriately

See Appendic 1 for Research project flow chart

Related Documents	
Documents	Patient Consent and Patient Rights
Reference	Health and Disability Standard NZS 8134:2021 Health and Disability Commissioner Code of Health and Disability Services Consumers' Rights Health Information Privacy Code 2020 Privacy Act 2020

Appendix 1 **Research Project Flow chart**

Step 1: Initial scoping (Discuss with clinical / service lead)

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Step 2: Prepare Documentation (Protocol, consent, ethics status, risk and resource assessment)

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Step 3: Submit research proposal to the Designated Research Governance Lead

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Step 4: Organisational Review (Clinical relevance, risk, cultural safety, feasibility)

→ Revisions required?

- Yes → Return to Researcher → Update Documents → Resubmit
- No

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Step 5: Ethics Approval (HDEC if required)

→ Ethics approved?

- No → Address Ethics feedback → Resubmit to HDEC
- Yes

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Step 6: Organisational Approval (Clinical Director / CEO / Board as appropriate)

→ Approved

- No → Decline or Request changes
- Yes

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Step 7: Study Set up (System registration, staff briefing, agreements finalised)

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Step 8: Study Commences

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Step 9: Monitoring and Reporting (Progress reports, adverse events, audits if required)

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Step 10: Study completion (Final report, data management, close out)

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Step 11: Dissemination (Publication, acknowledgement of Hospice South)

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END