

RESEARCH POLICY

PERFORMANCE STANDARD

All research undertaken at Mary Potter Hospice involving Mary Potter Hospice clients, staff, or resources will be scientifically meritorious, clinically relevant, ethical, and legal.

The organisation's research programme develops the body of knowledge, protects staff and consumers/ patients and has processes to appropriately manage the organisation risk associated with research. (EQulP 5 standard 2.5.1)

Research is conducted in collaboration with other specialist care and primary care service providers and academic units. (HNZ standard 12.7)

RATIONALE

Research is the prerequisite for evidence based clinical practice that gives the speciality of palliative care a scientific base. Yet, participating in research can potentially bring physical, psychosocial, or financial harm to study participants. This potential for harm is particularly important to consider when researching patients with terminal illness and their families/whānau/caregivers (Ethical guidelines for intervention studies, Rev. ed. 2012, pp 55-57). Also, those who conduct research can be accused of harming others (e.g. by inappropriately sharing participant private information, by falsifying or misinterpreting data). Likewise, Mary Potter Hospice as an institution can potentially be harmed when it supports an ill-conceived or mismanaged study (e.g. tarnished reputation, financial drain and stressed staff if data collection is added to their work).

Thus, a policy that seeks to minimise harm from research is essential.

PURPOSE

To ensure Mary Potter Hospice research is sound, relevant, ethical and legal, this policy offers mechanisms for assessing and monitoring research, making the process more transparent, diminishing the possibilities for harm to research participants, researchers, and Mary Potter Hospice.

SCOPE

This policy applies to anyone who undertakes research involving human subjects at Mary Potter Hospice, whether a Mary Potter Hospice employee or a student, faculty, or staff member from a university and other external institution.

This policy applies to all empirical research endeavours and to audits that have significant potential to cause harm or require collecting additional personal information otherwise unnecessary for clinical care. (See National Ethics Advisory Committee, 2012, [pp. 25-26] for audit or related activity that requires Ethics Committee review.)

DEFINITIONS

- Research - systematic inquiry pursued to solve problems, answer questions, and generate new knowledge. (Criteria for research requiring Ethics Committee approval are listed in the *Standard Operating Procedures for Health and Disability Ethics Committees, 2012* and available from the New Zealand Health and Disabilities Ethics Committees [NZHDEC] website.)
- Audit - systematic evaluation of aspects of service delivery by considering measurable indicators of performance and/or quality; usually a peer review process involving continuous improvement of care (refer Mary Potter Hospice Audit Policy).
- The National Ethics Advisory Committee (NEAC) - is a committee set up under legislation to advise the Minister of Health on ethical issues in health services and research. It sets our guidelines which must be followed by researchers, but does not itself review projects. The full name is the National Advisory Committee on Health and Disability Support Services Ethics.
- Health and Disability Ethics Committees (HDECs) are responsible for reviewing projects, Mary Potter Hospice comes under Central HDEC. This is an independent body funded by the Ministry of Health which reviews research proposals for their adherence to ethical principles and scientific soundness.
- Locality authorisation is a standard condition of HDEC approval for the conduct of a study at a given locality. If the research is to occur in more than one locality, separate authorisation is required from each of those localities. Ministry of Health (2012). *Standard Operating Procedures for Health and Disability Ethics Committees*, [pp 38-40].

Also see <http://www.ethics.health.govt.nz/> for more information.

- Principal Investigator (PI) - the researcher who will assume full responsibility for the proposed investigation; this researcher must be qualified for the study proposed, play a significant role in the completion of the study, and be the point of contact for the Mary Potter Hospice Research Fellow.
- Adverse event - when research-related activity causes more than minimal harm to a Mary Potter Hospice client (e.g. severe emotional or physical distress).

PROCEDURE

Application submission

The Principal Investigator (PI) for a research investigation must submit an application to the Mary Potter Hospice Research Fellow. The PI may use the Mary Potter Hospice application form in Appendix 1 - Part A, or use the NZHDEC (ethics committee) application. Regardless of which format, these applications will be submitted with the Mary Potter Hospice Application Form - Part B and the pertinent supporting documents specified for each application.

If using the Mary Potter Hospice application, the PI is advised to first discuss the application with the Research Fellow as to ascertain how detailed the proposal should be. (High risk studies will require detailed attention to all aspects of the

proposal, whereas a low risk study may require comparatively minimal information.) The intent of the application is *not* to provide a barrier to research at Mary Potter Hospice. The Research Fellow will especially support Mary Potter Hospice staff wishing to conduct research to complete this application.

Application review

Once the “Application to Conduct Research at Mary Potter Hospice” (or NZHDEC application plus Part B of the Mary Potter Hospice application) is received, the Mary Potter Hospice Research Fellow will convene a peer review panel to evaluate the proposal. Each application’s peer review panel will be determined by:

- **Degree of potential harm** - High risk studies (e.g., clinical drug trial) will be reviewed by a panel of at least three qualified persons; low risk studies (e.g., surveys or interviews about mild-moderately sensitive topics) will be reviewed by at least one qualified reviewer and/or the PERQI team and/ or the Professional Advisory Group.
- **Topic and/or method of study** - Review panel members with content or methodological expertise that informs the proposal will be selected. Applicants may suggest unbiased experts for the review of their proposal.

All studies will be reviewed by the Mary Potter Hospice Research Fellow. Once a majority of the reviewers recommend the research proceed, the Research Fellow will discuss the study’s potential impact on Mary Potter Hospice with pertinent parties (e.g., Mary Potter Hospice administrators, clinical managers). Reviewed applications that raise significant concern will be brought to the Professional Advisory Group (PAG) for discussion. Every effort will be made to complete this review process within one month from the time of the application submission.

Feedback from the review panel and Mary Potter Hospice staff will be submitted in writing to the PI. Mary Potter Hospice holds the right to refuse any research requests. Rationale for such a refusal will be given. However, given Mary Potter Hospice commitment to support research, if a proposal is initially rejected, it is likely that Mary Potter Hospice will make recommendations to the PI for how to make the proposed study possible at Mary Potter Hospice. Once a proposal is approved, the PI can expect the support of the Mary Potter Hospice Research Fellow in gaining entry to Mary Potter Hospice to commence the study.

Investigator reporting mechanisms

The PI will submit a Final Report to the Mary Potter Hospice Research Fellow at the completion of the study (or when the study is aborted). If the research project continues for more than one year, the PI will be required to annually submit a Progress Report. The PI may use the NZHDEC or Mary Potter Hospice Progress and/or Final Report forms. Additionally, the PI is required to complete the Self-Audit form alongside any annual report.

Researchers must be responsible for keeping the original copies of all signed consents, and making these available for audit to the Mary Potter Hospice Research Fellow. Depending on the nature of the study, researchers may also be asked to document in the Patient Record (chart) a Mary Potter Hospice patient’s participation.

Adverse events

If a serious adverse event occurs because of the research, the research team member involved must immediately report this event verbally to the Mary Potter Hospice staff directly caring for this person, and in consultation with Mary Potter Hospice staff, initiate the therapeutic plan identified in the research proposal, if appropriate. As soon as possible thereafter, the PI must then submit an Adverse Event Report to either the Mary Potter Hospice Research Fellow or Director of Palliative Care. Mary Potter Hospice reserves the right to terminate a research project if it proves to be unexpectedly harmful to participants or Mary Potter Hospice.

Ethics committee approval

If a study meets the criteria set forth by NEAC for requiring Ethics Committee approval, then this approval is mandatory prior to commencing any data collection. The documentation of Ethics Committee approval may be submitted to Mary Potter Hospice with the application. Those applications which Mary Potter Hospice reviews and supports prior to the PI obtaining Ethics Committee approval will be approved pending ethics approval.

Mary Potter Hospice monitoring and governance

The Mary Potter Hospice Research Fellow will maintain a file for each research project. This file will include the PI's proposal, adverse event reports, and progress or final report/s, as well as other necessary documentation (e.g. proof of insurance or indemnification, Ethics Committee approval).

The Director of Palliative Care is responsible for informing the Board of Trustees of research projects/activities at Mary Potter Hospice.

The Mary Potter Hospice Research Fellow will monitor research studies by reviewing adverse event and annual reports (including the Self-Audit), auditing to ensure the informed consent process is completed prior to enrolling study participants, receiving observations or complaints from Mary Potter Hospice staff regarding study procedures or researchers.

If a problem is identified, the Research Fellow will discuss it with the appropriate persons (e.g. PI, Director of Palliative Care, PERQI team, management team). If any allegations of research misconduct are received, the Mary Potter Hospice Research Fellow and/or the Director of Palliative Care will take prompt and vigorous action to investigate and address these allegations. If an independent audit is required, the PI shall be responsible for its expense. If the allegation cannot be resolved, Mary Potter Hospice will void its approval for the study.

Responsibilities: cost, intellectual property, ethical conduct

When a research study requires considerable commitment from Mary Potter Hospice (e.g. for advice, supervision), reimbursement to the hospice may be negotiated between the PI and Mary Potter Hospice management.

Intellectual property generated as part of an employee's work for Mary Potter Hospice will remain the property of Mary Potter Hospice, unless otherwise negotiated and documented in writing prior to commencement of the research.

All members of a research team involved at Mary Potter Hospice must demonstrate they possess knowledge about the ethical and responsible conduct of research. This can be done by presenting a certificate of completion from an online tutorial (e.g., “Protecting Human Research Participants: NIH Office of Extramural Research” available from <http://phrp.hihtraining.com/users/login.php>) or evidence of other similar training (consult the resources listed under References).

APPENDICES

- Appendix 1 - Application to Conduct Research at Mary Potter Hospice
- Appendix 2 - Mary Potter Hospice Review
- Appendix 3 - Final Report
- Appendix 4 - Progress Report
- Appendix 5 - Serious Adverse Event Report
- Appendix 6 - Self Audit

RELATED MARY POTTER HOSPICE DOCUMENTS

- Audit policy
- Informed Consent policy
- Confidentiality Agreement
- Consumer Advisory Group Guidelines [pending approval]

REFERENCES AND RELEVANT LEGISLATION/ STANDARDS

1. EQUIP5 2.5.1
2. HNZ Standard 12.7
3. Ministry of Health. (2012). *Standard Operating Procedures for Health and Disability Ethics Committees*. Wellington: Author
<http://www.ethics.health.govt.nz>.
4. National Ethics Advisory Committee. (2012). *Ethical guidelines for observational studies: Observational research, audits and related activities* (Rev. ed.). Wellington, NZ: Ministry of Health.
5. Office of the Privacy Commissioner (1994). Health Information Privacy Code. Available from: <http://www.privacy.org.nz/assets/Files/Codes-of-Practice-materials/Health-Information-Privacy-Code-1994-including-Amendments.pdf>.
6. Health (Retention of Health Information) Regulations 1996 [administered by MOH].
7. Online resources about responsible conduct of research:
 - Monash University Department of Epidemiology and Preventive Medicine. (2003). *A guide to good research practice*. Melbourne, Australia: Monash University. Available from: <http://www.med.monash.edu.au/epidemiology/publications/grpg2003.pdf>.
 - National Institutes of Health. (n.d.). Bioethics resources on the web: tutorials and case studies. Available from: <http://bioethics.od.nih.gov/casestudies.html#research>.

- Office of Research Integrity, University of Pittsburgh. (2007). Guidelines for responsible conduct of research. Pittsburgh, PA: Author. Available from: <http://www.pitt.edu/~provost/ethresearch.html>.
- Health Research Council (2010). *Guidelines for researchers on health research involving Maori*. Wellington: Health Research Council. www.hrc.govt.nz
- Health Research Council of New Zealand (nd). *Te Ara Tika Guidelines for Maori research ethics: A framework for researchers and ethics committee members*. Wellington: Health Research Council. www.hrc.govt.nz

Acknowledgements

Mary Potter Hospice is grateful to Arohanui Hospice and Capital & Coast DHB for sharing their research policies. These documents have influenced the development of this policy. Likewise, the Self Audit tool is an adaptation of one developed by the Monash University Department of Epidemiology and Preventive Medicine.

Application to Conduct Research at Mary Potter Hospice	
Part A	
A.1 - Title of Research Project	
A.2 - Principal Investigator	
Title/Position	
Employer	
Address	
Work Telephone	
Work Email	
Faculty Mentor (if student research)	
Title/Position	
Employer	
Address	
Work Telephone	
Work Email	
A.3 - Other research team members (please state name, qualification, role in research team)	
Title/Position	
A.4 - Source of funding	
A.5 - Research proposal	
Aim/ Purpose	
Significance/ Background	
Design/ Methods (sampling framework, procedure, tools, data management & analysis)	
Ethical considerations (consent process, strategies for securing data)	
Cultural considerations (e.g. how you will handle the data collected in a culturally respectful manner)	

<p>What are the possible risks to participants and Mary Potter Hospice that this study could incur? What will you do to manage the risk?</p>		
<p>A.6 - PI Profile (What training or experience do you have that qualifies you to conduct this research study?)</p>		
<p>Part B B.1 - What resources and support do you think you will require from Mary Potter Hospice?</p>		
<p>B.2 - Do you agree to the following? (Please check box to indicate yes or no):</p>		
	Yes	No
<p>I agree to acknowledge “Mary Potter Hospice of Wellington, New Zealand” every time I present the findings of this research (in oral or written formats).</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>I agree to share the findings of my research with Mary Potter Hospice staff.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>I agree to make available for audit each participant’s consent to the Research Fellow.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>I agree to report (or have a member of my research team report) any adverse event this study may cause immediately to the Mary Potter Hospice clinician providing direct care for this patient, and then submit a completed Adverse Event Report form for each event to the Research Fellow or Director of Palliative Care.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>[If appropriate] I agree to ensure that the therapeutic plan identified in my research proposal for managing an adverse event is instituted, if agreed upon by Mary Potter Hospice staff involved in this study participant’s care. [If appropriate] I agree that my research funds will cover the cost for this therapeutic intervention.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>I agree to submit a completed Final Report at the end of the study, and Annual Reports as necessary.</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>I agree to securely maintain the data for an appropriate period of time after the study is completed (at least ten years).</p>	<input type="checkbox"/>	<input type="checkbox"/>

I agree to allow an independent auditor access to my data, if requested.	<input type="checkbox"/>	<input type="checkbox"/>
I agree that Mary Potter Hospice accepts no financial liability for this research project.	<input type="checkbox"/>	<input type="checkbox"/>
I agree to be responsible for (including to insure, if appropriate) the research property that I bring on the Mary Potter Hospice premises.	<input type="checkbox"/>	<input type="checkbox"/>
I agree that all members of my research team will wear name tags when on Mary Potter Hospice premises and behave in accordance with Mary Potter Hospice polices and philosophy.	<input type="checkbox"/>	<input type="checkbox"/>
I agree that if there is any change to the study protocol, that I will obtain Ethics Committee approval for that change prior to recommencing data collection at Mary Potter Hospice.	<input type="checkbox"/>	<input type="checkbox"/>
Sign off:		
Full Name (please print)		
Date:		
Signature:		
<p>When submitting this application, please also provide the following documentation:</p> <ul style="list-style-type: none"> • Ethics Committee approval (if necessary). • For non-Mary Potter Hospice researchers, documentation of financial indemnity or proof of public liability insurance. • Please provide a copy of study instruments, consent form, recruitment materials, and information sheet, as appropriate. • Mary Potter Hospice Confidentiality Agreement with your signature. 		

Mary Potter Hospice Research Review Form

Name/Title of reviewer:	_____	
Email:	_____	
Preferred telephone:	_____	
Title of Research Proposal:	_____	
<p>Please tick either Yes or No in response to each question. If you tick No for any question, please briefly explain in the Comments section below. Thank you.</p>		
Aims/Purpose: Are goals or research questions clear, well-defined?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Significance/Background: Is this study going to benefit society? Or, is it worth subjecting Mary Potter Hospice clients/staff to?	<input type="checkbox"/>	<input type="checkbox"/>
Design/Methods:	<input type="checkbox"/>	<input type="checkbox"/>
Is the sampling framework adequate? Or, will the proposed plan for sampling allow valid, trustworthy findings?	<input type="checkbox"/>	<input type="checkbox"/>
Is the procedure for data collection adequately planned and appropriate?	<input type="checkbox"/>	<input type="checkbox"/>
Are the instruments valid and reliable in this context?	<input type="checkbox"/>	<input type="checkbox"/>
Is the plan for managing and analysing the data adequate and appropriate?	<input type="checkbox"/>	<input type="checkbox"/>
Ethical & Cultural considerations:	<input type="checkbox"/>	<input type="checkbox"/>
Will the consent process allow study participants to comfortably make an informed decision?	<input type="checkbox"/>	<input type="checkbox"/>
Will the data be handled in ways that show ethical and cultural respect?	<input type="checkbox"/>	<input type="checkbox"/>
Are the potential risks of study participation identified and a plan for responding to significant adverse effects offered?	<input type="checkbox"/>	<input type="checkbox"/>
Do you think the PI is adequately prepared to conduct this research?	<input type="checkbox"/>	<input type="checkbox"/>
Comments:		

Final Report

Title of Research Project: _____

Principal Investigator: _____

Summary of Study Findings (in 250-500 words):

Please comment on how Mary Potter Hospice was helpful and/or unhelpful to you as you conducted this study:

Annual Report

Title of Research Project: _____
Principal Investigator: _____
Please provide us with any updated contact details for yourself or members of your research team (or faculty sponsor): _____ _____ _____ _____
How many participants have you recruited for your study thus far? _____
When do you anticipate completing data collection? _____
Please summarise in 1-3 paragraphs what your research project has accomplished thus far: _____ _____ _____ _____ _____
In what ways might Mary Potter Hospice be more helpful to you as you complete your research? _____ _____ _____ _____ _____ _____

Adverse Event Report

Today's Date: _____
Title of Research Study: _____
Principal Investigator: _____ _____
Please describe the adverse event caused by the research study: _____ _____ _____
Date/Time? _____
Place? _____
Who? _____
What happened? _____ _____ _____
What was done to ameliorate? _____ _____ _____
What was the study participant's response? _____ _____ _____
What Mary Potter Hospice staff member was notified? When were they notified? _____ _____ _____

Audit Tool

Self Audit for Researchers

This document has been designed to help researchers to reflect on their research conduct and to comply with guidelines for responsible research conduct.

Are all of the following *true* for your research project?

I am conducting the study in accordance with the protocol approved by the Ethics Committee. Any modifications have been reported to the committee and the relevant documents updated.	True	False	N/A
I have obtained signed consent forms from all participants (where applicable) and stored these securely. Copies are available for audit.	True	False	N/A
I have reported all serious and unexpected adverse incidents to the Ethics Committee and to the Mary Potter Hospice Research Fellow.	True	False	N/A
I have provided all study participants with a copy of the Participant Information sheet approved by the Ethics Committee.	True	False	N/A
I have provided a translator and/or a translated copy of the Participant Information sheet in his/her own language to all non-English speaking participants.	True	False	N/A
I have received ethics committee approval for all public advertising material that seeks volunteers to participate in the study.	True	False	N/A
Approaches to potential participants have been made only by the individuals (or persons in specified roles) approved by the ethics committee.	True	False	N/A
All paper-based questionnaires have the identifying information removed immediately after processing and are then identifiable only by a code. The 'code-key' is stored separately under lock and key at all times.	True	False	N/A
All principal computer files containing study data are stored on a secure network drive where they are regularly backed up.	True	False	N/A
All computer files containing study data are protected by passwords.	True	False	N/A
No personal identifying information has been transferred to portable drives including USB sticks or portable computers.	True	False	N/A
Participants know who to contact if they have a question, complaint or an emergency.	True	False	N/A
There is a regular meeting of the study team including the Principal Researcher/s to discuss the progress of the study.	True	False	N/A

If there are problems you can't fix, seek advice from the Mary Potter Hospice Research Fellow, or the Ethics Committee.

Principal Researcher: Date: