RESEARCH POLICY

PERFORMANCE STANDARD

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

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/whanau/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, MPH as an institution can potentially be harmed when it supports an ill-conceived or mismanaged study (e.g. tarnished reputation, financial drain, 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 MPH 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 MPH.

SCOPE

This policy applies to anyone who undertakes research involving human subjects at MPH, whether a MPH 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 peer review process involving continuous improvement of care (refer MPH Audit Policy).
- NZ Health & Disability Ethics Committee (NEAC) - 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 MPH Research Fellow.
- Adverse event - when research-related activity causes more than minimal harm to a MPH 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 MPH Research Fellow. The PI may use the MPH 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 MPH Application Form – Part B and the pertinent supporting documents specified for each application. If using the MPH application, the PI is advised to first discuss the application with the Research Director so 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 MPH. The Research Fellow will especially support MPH staff who wish 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 MPH application) is received, the MPH 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 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 MPH Research Fellow. Once a majority of the reviewers recommend the research proceed, the Research Director will discuss the study's potential impact on MPH with pertinent parties (e.g., MPH 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 MPH staff will be submitted in writing to the PI. MPH holds the right to refuse any research requests. Rationale for such a refusal will be given. However, given MPH commitment to support research, if a proposal is initially rejected, it is likely that MPH will make recommendations to the PI for how to make the proposed study possible at MPH. Once a proposal is approved, the PI can expect the support of the MPH Research Fellow in gaining entry to MPH to commence the study.

Investigator reporting mechanisms

The PI will submit a Final Report to the MPH 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 MPH 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 MPH Research Fellow. Depending on the nature of the study, researchers may also be asked to document in the Patient Record (chart) a MPH 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 MPH staff directly caring for this person, and in consultation with MPH 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 MPH Research Fellow or Director of Palliative Care. The PI may use the NZHDEC or MPH Serious Adverse Effects form. MPH reserves the right to terminate a research project if it proves to be unexpectedly harmful to participants or MPH.

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 MPH with the application. Those applications which MPH reviews and supports prior to the PI obtaining Ethics Committee approval will be approved pending ethics approval.

MPH monitoring and governance

The MPH 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 MPH.

The MPH 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 MPH 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 MPH Research Director 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, MPH will void its approval for the study.

Responsibilities: cost, intellectual property, ethical conduct

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

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

All members of a research team involved at MPH 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 - MPH Review
Appendix 3 - Final Report
Appendix 4 - Progress Report
Appendix 5 - Serious Adverse Event Report
Appendix 6 - Self Audit

RELATED MPH DOCUMENTS

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

REFERENCES AND RELEVANT LEGISLATION/ STANDARDS

1. Ministry of Health. (2012). *Standard Operating Procedures for Health and Disability Ethics Committees.* Wellington: Author http://www.ethics.health.govt.nz.

2. National Ethics Advisory Committee. (2012). *Ethical guidelines for observational studies: Observational research, audits and related activities* (Rev. ed.). Wellington, NZ: Ministry of Health.

3. 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.

4. Health (Retention of Health Information) Regulations 1996 [administered by MOH].

5. 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.gove/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

MPH 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.

Appendix 1

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: _____
Fax: _____
Email: _____

Faculty Mentor (if student research): _____
Title/Position: _____
Employer: _____
Address: _____
Work telephone: _____
Fax: _____
Email: _____

A.3 – Other research team members (please state name, qualification, role in research team): _____
_____

A.4 – Source of funding: _____

A.5 – Research proposal: _____
_____

Aims/Purpose: _____
_____

Significance/Background: _____
_____

Design/Methods (sampling framework, procedure, tools, data management & analysis): _____

Ethical considerations (e.g. consent process, strategies for securing data):
_____
_____

Cultural considerations (e.g. how you will handle the data collected in a culturally respectful manner): _____

_____

What are the possible risks to participants and MPH that this study could incur? What will you do to manage the risk? _____

_____

A.6 – PI Profile (What training or experience do you have that qualifies you to conduct this research study?): _____

_____

_____

_____

Part B

B.1 – What resources and support do you think you will require from MPH?

_____

_____

_____

_____

_____

_____

B.2 – Do you agree to the following? *(Please check box to indicate yes or no)*:

	Yes	No
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).	☐	☐
I agree to share the findings of my research with MPH staff.	☐	☐
I agree to make available for audit each participant's consent to the Research Director.	☐	☐
I agree to report (or have a member of my research team report) any adverse event this study may cause immediately to the MPH clinician providing direct care for this patient, and then submit a completed Adverse Event Report form for each event to the Research Director or Director of Palliative Care.	☐	☐
[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 MPH staff involved in this study participant's care. [If appropriate] I agree that my research funds will cover the cost for this therapeutic intervention.	☐	☐
I agree to submit a completed Final Report at the end of the study, and Annual Reports as necessary.	☐	☐
I agree to securely maintain the data for an appropriate period of time after the study is completed (at least ten years).	☐	☐

I agree to allow an independent auditor access to my data, if requested.	☐	☐
I agree that Mary Potter Hospice accepts no financial liability for this research project.	☐	☐
I agree to be responsible for (including to insure, if appropriate) the research property that I bring on the MPH premises.	☐	☐
I agree that all members of my research team will wear name tags when on MPH premises and behave in accordance with MPH polices and philosophy.	☐	☐
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 MPH.	☐	☐

Signed

_____ Date: _____

Name (Please Print)

_____

Signature

When submitting this application, please also provide the following documentation:

- Ethics Committee approval (if necessary).
- For non-MPH 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.
- MPH Confidentiality Agreement with your signature.

Appendix 2

Mary Potter Hospice Research Review Form

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

Appendix 3

Final Report

Title of Research Project: _____ _____
Principal Investigator: _____
Summary of Study Findings (in 250-500 words):
Please comment on how MPH was helpful and/or unhelpful to you as you conducted this study:

Appendix 4

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 MPH be more helpful to you as you complete your research?

_____

_____

_____

_____

_____

_____

Appendix 5

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 MPH staff member was notified? When were they notified? _____

_____

_____

Appendix 6

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 MPH Research Director.	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 Research Director at MPH, or the Ethics Committee.

Principal Researcher: ……..

Date: ……..……