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Ethical Research in Palliative Care: a guide through the Human Research Ethics Committee process

M. Masso

University of Wollongong, mmasso@uow.edu.au

S. Dodds

University of Wollongong, sdodds@uow.edu.au

D. Fildes

University of Wollongong, dfildes@uow.edu.au

H. Yeatman

University of Wollongong, hyeatman@uow.edu.au

K. Eagar

University of Wollongong, keagar@uow.edu.au

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Masso M, Dodds S, Fildes D, Yeatman H and Eagar K



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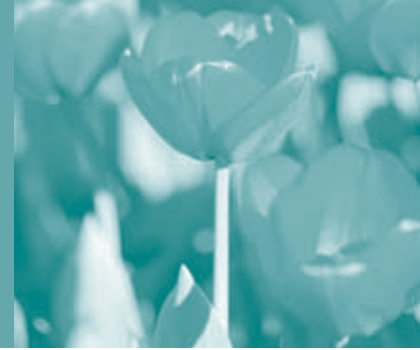
The opinions expressed in this document are those of the authors and not necessarily those of the Australian Government. This document is designed to assist palliative care researchers to gain ethics approval for their research projects.

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How to use this guide



This guide is designed to assist palliative care researchers to prepare sound research ethics applications for review by Human Research Ethics Committees and to undertake ethical palliative care research that is consistent with NHMRC Guidelines.

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Section 1 Why this booklet?



This booklet aims to provide a guide to the research community wishing to conduct ethical research in palliative care. The need for this booklet has arisen in response to the expanding provision of palliative care services and associated research in Australia.

In October 2000 the Australian Health Ministers Advisory Council (AHMAC) endorsed the National Palliative Care Strategy. The Strategy is a partnership between the Australian Government, State and Territory governments, palliative care service providers and community-based organisations. It is designed to guide the development and implementation of consistent Australian palliative care policies, strategies and services and to promote the delivery of quality palliative care that is accessible to all people who are dying.

A core objective of the Strategy is to ensure that good quality evidence is available on how to best provide palliative care. In more recent years, this has led to increased impetus for palliative care research through the establishment of a specific program of research with the National Health and Medical Research Council.

However, palliative care researchers have reported difficulties in obtaining Human Research Ethics Committee (HREC) approval for their projects. In addition, a number of important research projects, funded through the National Palliative Care Program and the NHMRC administered Palliative Care Research Program have been subjected to lengthy delays as a result of the difficulties in gaining HREC approval.

Researchers in the field perceive that some HRECs are over cautious in the application of the guidelines outlined in the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Research Involving Humans*¹ (referred to throughout the remainder of this booklet simply as the *National Statement*) and believe that some HRECs are unaware of the potential benefits of palliative care to terminally ill patients and their families.

Some issues have been identified as being of particular significance to palliative care and each is covered in later sections of this booklet:

- the risks and benefits of palliative care research
- informed consent
- patient vulnerability
- balancing the role of clinician and researcher.

Researchers can educate and inform HREC members on the overall benefits of high quality research into palliative care by adopting a rigorous, informed and consistent approach to writing HREC applications. This booklet is designed to be of immediate benefit to new researchers funded through the National Palliative Care Program and also to assist the broader research community wishing to conduct ethical research in palliative care.

Section 2 What is palliative care?



Palliative care is care that ‘palliates’, or relieves pain and other symptoms. Palliative care is provided when it is recognised that a person has a life-limiting illness. This may be early in the course of the disease when particular symptoms need to be controlled or later in the disease as death approaches. Palliative care aims to ease the pain, distress and physical, emotional and spiritual problems that may be present during the course of a life-limiting illness.

The timing of palliative care varies from person to person. Many palliative care patients are well at the time of their initial referral to palliative care and consider that they are living with a life-limiting illness rather than dying. Other patients may not be referred to palliative care until they are in the terminal phase of their illness.

Palliative care is provided for a person:

- who has an active, progressive, far advanced disease with little or no prospect of cure
- for whom the primary treatment goal is now quality of life rather than cure of the disease.

The ‘consumers’ of palliative care also include the patient’s family and friends because they too need to be prepared for the death of someone they love. Grief and bereavement support services for the family and carers are an integral part of palliative care.

Palliative care includes care provided in the community and in hospital settings

We know that a patient is receiving palliative care when:

- the person receives a multidisciplinary assessment and/or management of their physical, psychological, emotional and spiritual needs
- there is a grief and bereavement process for the person and their carers/family.²

Core values of Palliative Care

The goal of palliative care is to achieve the best possible quality of life for patients and their families and friends. Palliative care³:

- affirms life and regards dying as a normal process
- neither hastens nor postpones death
- provides relief from pain and other distressing symptoms
- integrates the psychological, emotional and spiritual aspects of patient care
- offers a support system to help patients live as actively as possible until death
- offers a support system to help the family cope during the patient’s illness and in their own bereavement.

Many aspects of palliative care, such as pain management and symptom control, are also applicable earlier in the course of the illness in conjunction with treatment aimed at cure.

Equally, procedures such as radiotherapy, chemotherapy and surgery have a place in palliative care provided that the symptomatic benefits of treatment clearly outweigh the disadvantages. Investigative procedures are targeted to ensuring that the findings will directly assist in maximising the patient’s level of function and/or level of comfort or give specific information to patients and their families.

Palliative care providers

Palliative care may be provided by specialist palliative care providers and services. Alternately, palliative care may be offered by medical, nursing and allied health professionals in other specialties and in primary care who use a *palliative care approach* to care for patients with a life-limiting illness.

Specialist palliative care providers are clinicians who provide primary or consultative care to patients with a life-limiting illness. They typically work in a *specialist palliative care service* and have generally undertaken advanced training recognised by an accrediting body.

Palliative care patients⁴

Palliative care can be provided to anyone who has a life-limiting illness. Most people receiving palliative care have cancer. However, people with diseases such as motor neurone disease, HIV/AIDS and end stage heart, lung or kidney failure are increasingly receiving palliative care.

Implications for Palliative Care HREC applications

Palliative care research is research that aims to improve the quality of care offered to people with a life-limiting illness.

HREC members may not be familiar with palliative care. Consider including a concise explanation in your application.

Be explicit about:

- Who will provide the palliative care in your research study.
- Whether the palliative care patients who are participants in your proposed study know that they are now receiving palliative care (ie, treatment and care with the goal of improving the quality of life of the patient and their carers and not treatment and care that is designed to increase the patient's prospects of cure).
- Whether the family and/or carers who are participants in your proposed study know the patient is now receiving palliative care.
- If any of the participants have or need to have unequal knowledge on these matters, you will need to make this clear in the application and explain how this will be addressed.

If (at least some of) the participants in your research may not be aware that the patient is now regarded as palliative, be explicit about:

- what you propose to do if this is identified in the process of the current research
- how you propose to deal with any unexpected consequences.

Section 3 When is approval of a HREC required?

An important step early in the process of preparing a research proposal is to determine whether your project will require ethics approval.

In general you will need to obtain ethical clearances to undertake your research if your project involves asking people outside your professional setting such as carers, patients, interested community members or volunteers, about their opinions.

Some research activities and processes such as quality assurance can be undertaken without independent ethics review as long as appropriate consents are obtained and relevant privacy considerations are addressed.

The *National Statement* includes the following note about projects that do not require ethics approval:

‘Human Research Ethics Committee approval is not required for projects which only seek to obtain publicly available information or only seeks the professional view of an office holder on the basis of that person’s professional role (ie, asking about the official role but not asking for personal judgement or opinion)’.⁵

The NHMRC guidelines about quality assurance activities⁶ state that:

An activity can proceed without ethics review if BOTH:

- (a) ‘the activity is undertaken with the consent of patients, carers, health care providers or institutions involved;

or

is consistent with National Privacy Principle 2.1(a)⁷, which states:

‘An organisation must not use or disclose personal information about an individual for a purpose (the secondary purpose) other than the primary purpose of collection unless the following apply:

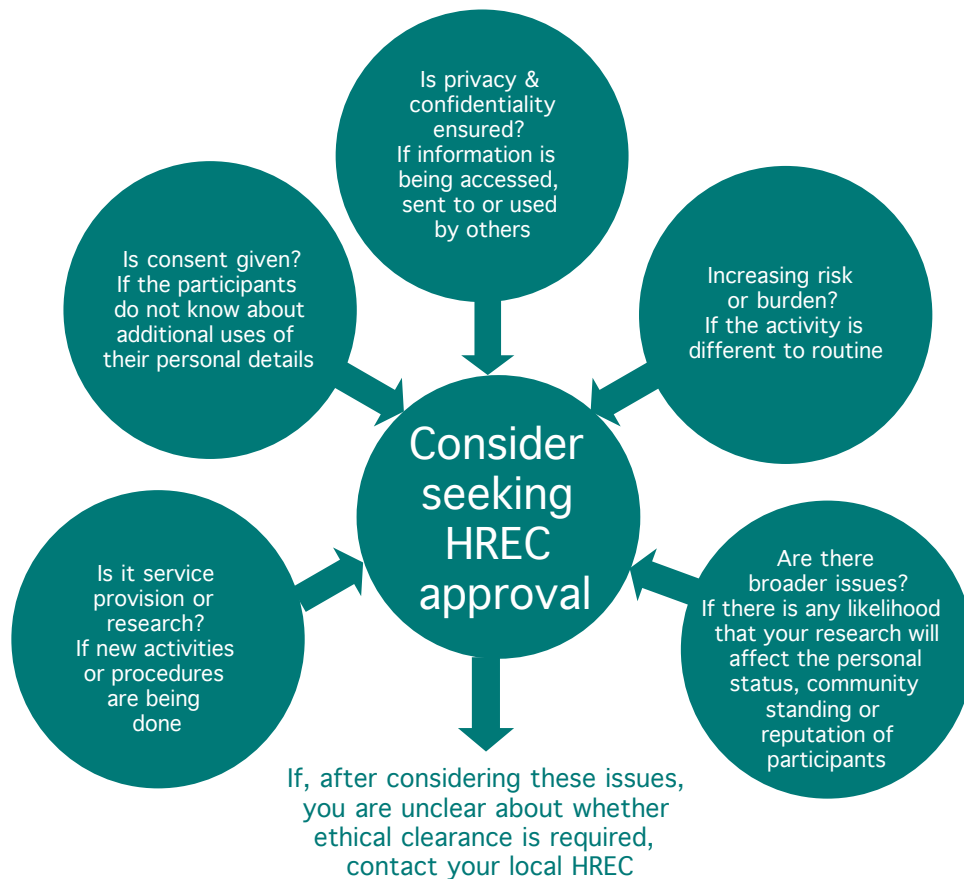
- i. the secondary purpose is related to the primary purpose of collection and, if the personal information is sensitive information, directly related to the primary purpose of collection;
- ii. the individual would reasonably expect the organisation to use or disclose the information for the secondary purpose’;

AND

- (b) it is an activity where participants, including patients, carers, health care providers or institutions are unlikely to suffer burden or harm (physical, mental, psychological, spiritual or social)’.

The *National Statement* also poses a number of specific issues for you to consider as highlighted on the next page:

Key questions to answer when considering HREC approval



Implications for Palliative Care HREC applications

If unsure whether your project requires HREC approval, use the checklist on the next page to help you decide. If in doubt, consult your local HREC.

Checklist for deciding whether ethical approval is required

| HREC Concerns | Questions to ask | Relevance to your proposal. |
|--|---|--|
| Consent | | |
| If the participants do not know about additional uses of their personal details, consider seeking ethics approval. | Would the participants (patients, family, carers, professionals) expect the information collected to be used in the ways that you plan to use them? For example: Do participants realise case notes may be used in a research paper, evaluation report or conference paper? Feedback on a training program – will the feedback be used in reports that could be used for other purposes, eg comparing effectiveness of different services/personnel? | Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Risks & burden | | |
| If the activity is different to routine, consider seeking ethics approval. | Does the project involve routine activities of the organisation, or does it involve different activities/procedures? Do these different activities expose participants to any risks or burdens beyond those that would be expected as part of routine care or professional activity? For example: Risks: psychological, spiritual, social harm eg stigmatisation Burdens: intrusiveness, discomfort, inconvenience, eg phone calls, additional hospital visits, completing long questionnaires | Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Privacy & confidentiality | | |
| If information is being accessed, sent to or used by others, consider seeking ethics approval. | Is personal information being used by someone who would not normally have access to it as part of their work? For example: Is the agency or professional collecting information that will be passed on to another person/s for the purposes of evaluation or research? If sensitive health information is being passed on (eg by letter, fax or email) to someone outside the agency the patient attends, could this information be read by someone for whom it is not intended? | Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Service provision or research? | | |
| If new activities or procedures are being done, consider seeking ethics approval. | Does the activity include a change in routine care? Does the activity include randomisation into particular groups for different types of care? Does it involve the use of control groups or of a placebo? Is more information to be collected than would normally be collected as part of routine care or routine training? | Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/> |
| Broader issues | | |
| If the activity changes the status, standing or reputation of participants, consider seeking ethics approval. | Does the activity have the potential to infringe the rights, privacy or professional reputation of carers, health care providers or institutions? Consider potential changes to the personal status, community standing or reputation of participants. | Relevant? Yes <input type="checkbox"/> No <input type="checkbox"/> |

Implications for Palliative Care HREC applications

If any of the issues identified above are relevant to the activities you are proposing, then you should seek HREC approval.

Research activities that propose to answer new questions or provide new knowledge through information gained from patients, carers or families as participants require HREC approval.

Section 4 What is a Human Research Ethics Committee (HREC)?



Human Research Ethics Committees (HRECs) are committees established by research institutions, community organisations, health services or other bodies in accordance with the *National Statement*.⁷ Duly constituted HRECs are accountable to and supported by the Australian Human Ethics Committee (AHEC) of the NHMRC.

HREC responsibilities

HRECs are responsible for the ethical review and approval of all research that involves humans and ‘has potential for infringing basic ethical principles.’⁸ HRECs are expected to use the *National Statement* as the primary reference point in the ethical evaluation of research and to consider other relevant guidelines (especially those developed by the NHMRC and AHEC) and legislation (for example, State and Commonwealth Privacy Acts) that are relevant to the research proposals under review.

According to the *National Statement*, the ‘primary purpose of a statement of ethical principles and accompanying guidelines for research involving humans is the protection of the welfare and rights of participants in research...’ ‘There is an important secondary purpose of a statement of ethical principles and accompanying guidelines, and that is to facilitate research that is or will be of benefit to the researcher’s community or to human kind.’⁹

The *National Statement* sets out the minimal composition and operating procedures of HRECs.

Composition

Each HREC has a membership of at least seven members including both men and women and comprising at least:

- (a) A chairperson;
- (b) Two lay members, one man and one woman, who have no other affiliation with the institution or organisation (these are usually from the community, and are not scientific or medical researchers or lawyers);
- (c) One member with knowledge and current experience in the areas of research that are regularly considered by the HREC;
- (d) One member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- (e) One member who is a minister of religion, or a person who performs a similar role in a community such as an Aboriginal elder; and
- (f) A lawyer (*National Statement*, §2.6¹).

Institutions have an obligation to ensure that membership will be adequate to ensure that the HREC is sufficiently informed about all relevant considerations arising from the kind of research likely to come before the HREC (*National Statement*, §2.7-8). Therefore, the HREC should also include additional members with the skills required to review the type of research that is likely to be referred to it. For example, an organisation that provides child welfare services is likely to receive applications for HREC approval of research that investigates children’s psychological well-being, so that organisation might include a child psychologist in its membership.

HRECs do not include members with expertise in all areas of research and will not normally include members with specialist knowledge of palliative care research.

¹ Throughout the remainder of this document the *National Statement on Ethical Conduct in Research Involving Humans* is referenced simply as the *National Statement* followed by the relevant Section (§) numbers.

While the *National Statement* provides HREC members with principles and guidelines on which to assess research proposals, ‘the primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC’ will protect the welfare and rights of participants in the research (*National Statement*, §2.5).

The process of obtaining HREC approval to conduct research

HRECs have some flexibility to establish their own operating procedures and there are variations between committees that researchers need to consider when preparing their applications. For example:

- Most HRECs hold regular meetings at which they consider applications for ethics approval but some committees with smaller workloads consider applications as they arise.
- Most HRECs request that applications be presented in a standard format such as an application form. Some HRECs will accept applications for multi centre research in the format used by another HREC, but others require applications in the form used by their own institution (NB. There are plans for an electronic National Application Form in the future to reduce duplication of effort).
- Some HRECs require researchers to pay an application fee to cover the costs of administering the HREC process. Others only charge fees for review of research funded by a commercial sponsor (eg, Phase III clinical trials).
- A HREC may develop processes for expedited review of research that involves minimal risk of harm. Expedited review usually occurs outside of the regularly scheduled HREC meetings and involves review of the proposal by a subcommittee or member(s) with delegated authority to review these proposals. Where expedited

review is available, the HREC should be able to provide clear guidelines on the kinds of research that may be reviewed in this way and the process for such review.

Implications for Palliative Care HREC applications

Researchers should contact the Ethics Officer, HREC Secretary or HREC Chair to find out agenda deadlines, application format, application fees (if any) and other specific requirements of the HRECs they will be approaching for approval well in advance of the time when they wish to commence research.

It is not unusual for the HREC approval process to take 8-10 weeks (or longer) from initial submission of an application to final HREC approval. Build a realistic time lag into your research plan.

The HREC meeting

The HREC may invite researchers to attend the HREC meeting for the discussion of their HREC application, to answer questions and to provide background on the research project. However, most HRECs rely primarily on the written information provided in the HREC application.

Members of the HREC are not experts in the intricacies of palliative care research, nor is this their job. The onus is on committee members to consider every application on its merits within the national guidelines. The onus is on the researcher to present material that provides a full and clear explanation of the proposed research, its justification, aims, and risks and potential benefits (if any) in language that is clear (non-technical) and readily understood by all HREC members.

Where the HREC requires expert advice to assist it in consideration of a particular proposal, it may seek advice and assistance from experts, but must first ensure that the experts have no conflicts of interest in relation to the research under consideration (*National Statement*, §2.19). This would meet the responsibility of institutions to ensure that HRECs are fully informed to review a proposal (*National Statement*, §2.7-2.8).

HRECs are consensus committees. This means that, while some HRECs may ask members to vote on proposals, they are expected to reach decisions by general agreement.

The decision

HRECs may:

- approve a proposal
 - require amendment of a proposal
- or
- reject a proposal on ethical grounds.

Different HRECs may come to different conclusions about the same research project, legitimately, because HREC decisions are based on the ethical judgements of each of the HREC's members.

HRECs should inform researchers in writing of the outcome of their application and provide researchers with reasons if their proposal is rejected.

Researchers should not assume that a request for amendment or clarification of information in relation to their research proposal means that the Committee intends to reject their application. A very large proportion of research proposals are approved after amendment or clarification. Requests for amendment or clarification are particularly likely where the research is ethically sensitive, involves chronically ill patients, raises cultural sensitivities or involves investigation of matters that are illegal or socially unacceptable.

In the HREC approval letter, the Committee will state any conditions on the approval, including requirements for reporting adverse events, or unexpected risks that arise in the course of the research, the period of approval and any requirements for monitoring or final reports on the research.

Researchers are required to conduct their research in accordance with the approved protocol and must inform the HREC in writing of any events or changes to the protocol that may affect the ethical acceptability of the research.

Section 5 How the HREC will review your research proposal



The *National Statement* identifies a number of principles of ethical conduct that HRECs are to consider in ethical evaluation of research proposals. These are described in a number of ways in the first section of the *National Statement*, initially identified as integrity and justification, justice, beneficence and respect for persons. These principles relate to four sets of questions (identified below) that HRECs need to consider in reviewing proposals.

The principles articulated in the *National Statement* are not applied mechanically by HRECs. HREC members have to judge which principles have priority and how the principles apply to particular cases.

The following address the basic and essential elements of HREC consideration of a proposal. Researchers should be aware, however, of the other specific matters addressed in the *National Statement* that may be relevant to their research proposal including:

- research involving people with mental or intellectual impairments (*National Statement*, §5)
- research involving persons highly dependent on medical care (*National Statement*, §6)
- research involving persons in dependent or unequal relationships (*National Statement*, §7)
- clinical trials (*National Statement*, §12)
- epidemiological research (*National Statement*, §14)
- use of human tissue samples (*National Statement*, §15).

Integrity and Justification

Integrity and justification can be understood as values reflecting the attitudes and behaviours of

researchers and the appropriate grounding and priorities of their research activities. In assessing research integrity and justification, HRECs may consider the following points:

- The integrity, qualifications, expertise, skills and facilities of the researchers (*National Statement* §1.1, 1.15).
- Whether the research is ‘justifiable in terms of its potential contribution to knowledge’ (*National Statement*, §1.13), is well-grounded in the relevant literature, demonstrates an understanding of relevant prior research, and whether the method of the research is appropriate to its aims.
- Whether the research is likely to lead to published findings that ‘permit scrutiny and contribute to public knowledge’ (*National Statement*, §1.18).
- Whether the research proposal demonstrates that respect for persons (protection of the welfare and dignity of participants) takes precedence over the potential benefits of the knowledge gained (*National Statement*, §1.4).

Justice

Justice concerns the fair distribution of benefits and burdens in research and the proper balance between the risks and potential benefits of research for particular research participants.

In assessing whether research proposals demonstrate the principle of justice, HRECs may consider the following issues:

- Whether the research promises to benefit the same group of people who may be asked to bear the burdens of research as participants ie, will the potential benefits of research reach the group of people who are asked to participate in the research? Whether any

of the burdens or risks associated with the research are unfair or unjust and whether the research has been designed to minimise risks. Whether there are potential benefits to participants that can balance the risks of participation (*National Statement*, §1.3, 1.5, 1.6).

- Whether the selection of participants is fair and whether the criteria for inclusion or exclusion in the research are arbitrary, irrelevant or discriminatory (*National Statement*, §1.5).
- How results or outcomes of the research will be reported and whether participants will be told of the research findings (*National Statement*, §1.18).

Beneficence

The principle of beneficence concerns the researchers' responsibilities to conduct research in ways that protects participants' welfare, minimises risk of harm to participants (and their communities), respects privacy and protects the interests of vulnerable participants (especially children). A HREC considering the principle of beneficence will look at the ways in which research proposals address the following issues:

- How might the research pose risk of harm to participants? Are these risks minimised? Are the risks balanced by potential benefits from participation? How will the researcher respond to unexpected risks that emerge in the course of the research? (*National Statement*, §1.3, 1.14, 1.17).
- How will privacy and cultural sensitivities be protected when records are accessed, used, destroyed or stored? Will data concerning specific participants be stored in a way that will allow for subsequent identification and follow-up? (*National Statement*, §1.19, 1.20).
- Does the research involve children or other participants who may not be able to consent to their participation? If so, how does the

researcher ensure that participation is not contrary to the interests of participants? (*National Statement*, §1.11, 6, 4.3).

Respect

The principle of respect for persons has several aspects including respect for the values, interests and autonomy of research participants and the notion that respect for participants as persons should take precedence over researchers' interests in 'using' participants in their research.

Respect for participants as persons may be evident where researchers treat research participants as partners in research.

Two important aspects of respect for persons in research are the way in which participants are recruited and the process for obtaining consent to research participation. In considering whether a research proposal demonstrates appropriate respect for persons a HREC may consider the following:

- Whether the research demonstrates 'regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage, both individual and collective' of participants (*National Statement*, §1.2).
- Whether participants' dignity and respect for their interests is given due regard (*National Statement*, §1.4).
- How is consent obtained? Whether it is adequately informed (that is, whether information is given in a manner that can be understood by potential participants, concerning the research 'purpose, methods, demands, risks, inconveniences, discomforts, possible outcomes' including publication). Whether the participant is able to exercise choice to consent; has the competence to consent; is subject to any coercion or undue influence that limits their freedom to consent or to refuse consent; and, whether consent is clearly established (*National Statement*, §1.7, 1.8, 1.9, 1.10).

- Whether the participant can withdraw their consent once the research project has commenced with appropriate knowledge about the consequences of withdrawing consent (*National Statement*, §1.12).

Implications for Palliative Care HREC applications

As part of their aim to protect participants in research, HRECs may exaggerate the risks that research proposals present to participants. For example, anecdotal reports from researchers suggest that some HRECs have been known to exaggerate psychological risks, in a way that overemphasises the burdens associated with research, relative to its benefits.

If researchers can refer in their application to studies that document that participants do not experience the kind of research being proposed as burdensome, this can counter the possibility that the HREC may be over-protective.

Section 6 What is a good HREC application?



Your HREC application should be written for an informed lay person in a clear and concise manner. It should address the research ethics principles in the *National Statement* and any specific issues arising from multi centre research or clinical trials. Be aware of the type of questions (see examples below) that the HREC members will ask in relation to each principle and address them clearly in your application and supporting material. In essence you need to demonstrate that your research is sensitive to, and respectful of, the needs, rights and vulnerabilities of participants.

Integrity, Justification and Methodology

- Clearly spell out the gaps in knowledge that have prompted the research. What justifies undertaking your research (especially if the research involves discomfort, inconvenience or risk for participants)? How will you demonstrate the contribution to knowledge that follows from your research? Consider including references to relevant research findings that support your research direction.
- Do you and your research team have the qualifications, skills and resources needed to conduct this research properly? Spell these out. How will research assistants be trained?
- Describe the methodology clearly in terms a lay person can understand. HRECs need to be able to understand what each participant's involvement in the research entails, in a step by step manner.
- If the research methodology is unusual, intrusive or risky, provide an explanation of why the methodology has been chosen over alternative methodologies – is the research method validated? Use references to the literature to justify your method.

Justice

- Clearly identify the potential benefits of participation in your research for the different groups that may be affected but do not 'oversell' the potential benefits. Be realistic and accurate in identifying who may benefit from the research and how. Consider providing appropriate feedback or reports on the research to participants or their families as a potential benefit.
- Clearly identify both the direct and indirect risks, discomforts and inconveniences associated with your research and consider whether these are fairly distributed, in the context of existing vulnerabilities or injustices faced by that group of participants.
- HRECs may well be concerned that some palliative care research poses risk, burden or discomfort (emotional distress, exhaustion, use of time) to terminally ill participants or their carers, while offering little benefit to those participants. It may be helpful if you can refer to other research that demonstrates possible benefits of the kind of research you propose.
- Justify the recruitment process: consider whether those who are asked to bear the burdens of the research are also those most likely to benefit from the research. Consider whether the mode of recruitment is appropriate given the vulnerability of the particular group of participants. Potential participants should not be excluded from research for arbitrary reasons, such as whether the person is fluent in English. Use of interpreters or translators may be required.

Beneficence

- Identify how the research may pose risk to participants and explain how these have been minimised eg, making initial approaches to participants through an organisation or through their clinicians; obtaining only de-identified records; providing referrals to appropriate counsellors if participation causes distress. Be explicit about how unexpected risks that emerge during the research will be managed (eg, will back-up support be available?).
- Where your research involves professional or unpaid carers, be aware of the potential burdens that the research may pose to this group of participants, including risks to employment, identification of unacceptable institutional practices, emotional distress, and distress to families of patient/clients. Explain how these will be minimised or otherwise addressed.
- Explain how privacy and cultural sensitivities will be protected. For example, who will have access to identifiable data, how will data be linked and how will data be stored?
- If your research involves children or those not able to consent to participation, explain how the research is not contrary to the participants' interests and how the welfare of participants will be protected.

Respect

- Provide clear information and consent packages for each group of participants as part of your application and include examples of any recruitment advertisements, posters or letters that you will be using. Make sure that the information for participants is jargon-free and reflects the level of understanding of potential participants. If your research involves participants in activities that are staged over time, you should demonstrate how you will obtain consent initially and how you will

confirm continued consent for each stage of the research.

- Consent processes should ensure that consent is obtained freely and without undue pressure or coercion. Explain the process you will use.
- If your research involves participants whose competence to consent is questionable, explain how you support the capacity to consent of those who are able to consent, and how the consent of those who are not able to consent will be obtained from someone with appropriate authority to provide proxy consent. The states and territories have different mechanisms for obtaining consent. In these cases, you may need to consult your state's Guardianship Board, or equivalent body, to determine the appropriate process for consent.
- If your research targets or is likely to involve Aboriginal and Torres Strait Islander peoples, you should consider how the values found in the *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* apply to your research and take necessary steps to ensure that your research is culturally appropriate (see Section 7 below).
- If your research targets or is likely to involve culturally diverse participants, you should consider the cultural appropriateness of the research for those participants, as well as appropriate use of translators and/or interpreters throughout the research starting with recruitment and consent.

Multi centre research

- If your research is going to occur at various sites, you should provide each HREC with the details of the other centres involved, whether your application for HREC approval has been successful or not, and any conditions or amendments imposed on the research.
- HRECs will take the determinations of

other HRECs into consideration but are not bound by the decisions of those HRECs in making their own judgement.

Clinical trials

- If your research involves clinical trials of a drug or therapeutic device following the Therapeutic Goods Administration's (TGA) schemes, your HREC application will need to include all of the information required for HREC review of clinical trials as spelled out in Section 12 of the *National Statement* and the requirements of the TGA.

Section 7 Research Involving Aboriginal and Torres Strait Islander Peoples



In 2003 the NHMRC released its *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*.¹⁰ The *Values and Ethics Guidelines* have the same status and authority as the *National Statement* in evaluating the ethical acceptability of health research involving Aboriginal and Torres Strait Islander peoples. The six values underpinning the *Values and Ethics Guidelines* are informed by, but are not reducible to, the research ethics principles articulated in the *National Statement*.

The *Values and Ethics Guidelines* reflect the values and understandings shared by Aboriginal and Torres Strait Islander peoples and also reflect the history of relationships between researchers and Aboriginal and Torres Strait Islander communities. In particular, the *Values and Ethics Guidelines* encourage researchers to understand research participants as members of communities and highlight the need for researchers to engage in discussion and deliberation with those communities throughout the process of developing a research proposal, through the HREC process and in the on-going conduct of research.

The application of the Guidelines

The *Values and Ethics Guidelines* are intended to apply to all health research involving Aboriginal and Torres Strait Islander peoples and not only research that targets Aboriginal and Torres Strait Islander communities or identifies Aboriginal and Torres Strait Islander peoples in the inclusion criteria. Researchers should demonstrate recognition of the values identified in the *Values and Ethics Guidelines* in framing research projects that may include Aboriginal and Torres Strait Islander peoples along with the general cross-section of the community.

The use of Aboriginal HRECs or sub-committees (described in Appendix 2 of the *Values and Ethics Guidelines*) would normally only occur when:

- the population who are likely be recruited include a significant proportion of Aboriginal or Torres Strait Islander peoples
 - the research is focussed on Aboriginal and Torres Strait Islander issues
- or
- the research raises specific matters of significance to Aboriginal and Torres Strait Islander communities.

Researchers should consult the State or Territory Department of Health, local HREC, or local Aboriginal and Torres Strait Islander communities to determine how approval from an Aboriginal HREC or sub-committee is to be obtained.

The values applied in review of research involving Aboriginal and Torres Strait Islander peoples

The six interrelated values articulated in the *Values and Ethics* guidelines are:

- spirit and integrity
- reciprocity
- respect
- equality
- survival and protection
- responsibility.

Examples of the ways that researchers can demonstrate each of these values are included in the *Values and Ethics Guidelines*.

Questions that you need to consider include:

- Does your research demonstrate respect for the cultural inheritance of past, current and future generations and the links that bind the generations together?
- Is your research likely to require indigenous interpreters and, if so, how will you deal with the issue of close kinship relations to potential participants in the research?
- Does your research demonstrate respect for Aboriginal and Torres Strait Islander peoples' knowledge and wisdom?
- Have you negotiated, or set up processes for negotiating, with the Aboriginal and Torres Strait Islander communities where you plan to undertake the research?
- Does your research demonstrate respect for Aboriginal and Torres Strait Islander peoples' cultural beliefs, particularly those concerning death and dying and those concerning kinship and responsibility?
- Does your research threaten social cohesion and the responsibilities of Aboriginal and Torres Strait Islander peoples?
- Have you consulted with Aboriginal and Torres Strait Islander community members about the scope and terminology used in the research to find out whether it is respectful of Aboriginal and Torres Strait Islander peoples' values and culture?
- Does your research provide potential positive benefits for the Aboriginal and Torres Strait Islander participants, or their communities, involved in your research (eg, research training, education, resources and so on)?
- Are there any consequences of your research that may be damaging for Aboriginal and Torres Strait Islander communities?
- How will your research outcomes be communicated to the Aboriginal and Torres Strait Islander participants and communities involved?

Implications for Palliative Care HREC applications

All researchers whose activities may involve Aboriginal or Torres Strait Islander participants should be aware of the values articulated in the *Values and Ethics Guidelines* and develop research proposals and methods that are consistent with these Guidelines.

Research that specifically includes Aboriginal and Torres Strait Islander communities or targets Aboriginal and Torres Strait Islander participants may require approval from an Aboriginal HREC or sub-committee (see Appendix 2 of the *Values and Ethics Guidelines*).

Section 8 Special issues to consider and address in your application



Some issues regarding palliative care research have been identified as being particularly significant and are discussed in this section. They include:

- the risks and benefits of palliative care research
- informed consent
- patient vulnerability
- balancing the role of clinician and researcher.^{11,12}

The *National Statement* provides the context for considering these and other issues and includes the following statements regarding research involving those who are terminally ill:

- ‘Research in terminal care is distinguished by the short remaining life expectancy of participants and their potential vulnerability to unrealistic expectations of benefits.
- Researchers must take care that the prospect of benefit from research participation is neither exaggerated nor used to justify a higher risk than that involved in the patient’s current treatment.
- Researchers must respect the needs and wishes of participants to spend time as they choose, particularly with family members’ (*National Statement*, § 6.6).

While some HREC members believe that research involving terminally ill patients is unacceptable on the grounds that it risks harm with little potential benefit for patients, experience suggests that such patients will often gladly participate in research.¹³

The risks and benefits of palliative care research

Clearly articulating expected risks and benefits poses specific challenges in palliative care research.

A range of issues is likely to be considered by a HREC. For example, a HREC will need to make a judgement about the scientific merit of a research proposal because projects without scientific merit expose participants to unnecessary risks and waste resources.¹⁴ These are legitimate ethical issues for the Committee to consider.

Applications must attempt to weigh up the potential benefits against any potential risks or harms to participants. Although most frequently understood in physical terms, “harm” can also encompass psychological distress, discomfort, social disadvantage, invasion of privacy and infringement of rights. It may be that the magnitude of potential benefits is largely unknown. If this is the case, it should be clearly stated in the application for ethics approval.

Many research projects are not designed to benefit participants directly but to increase knowledge to benefit the wider community. The justice principle dictates that absence of direct benefit should be matched by the absence of anything but the slightest risk. In the case of palliative care patients, life expectancy virtually precludes any indirect benefit from increases in knowledge in the future. Therefore, any research involving palliative care patients that potentially carries anything other than the slightest risk for participants should also have the potential to provide some direct benefit for participants eg, improved symptom management.

One way of describing research that may be helpful is to distinguish between therapeutic and non-therapeutic research. Therapeutic research is designed with the intention of yielding benefit to participants while non-therapeutic research seeks to derive knowledge with no direct benefit to participants. According to the NHMRC ‘the distinction can be used in the ethical assessment of an acceptable balance, for research participants, between the benefits and the risks of research.’¹⁵

There are two particular difficulties in weighing the potential risks and benefits of palliative care research:

- Defining research risks and benefits. The risks and benefits important to patients with a life-limiting illness may be more difficult to define because patients' goals for care change substantially as they near death. For example, there may be a decreased emphasis on survival and a strong focus on symptom relief, dignity and meaning, social relationships and control.
- Measuring risks and benefits. There is no single agreed standard against which a researcher or a HREC can assess the risks and benefits of research. At one extreme there is the general idea of what would be considered 'reasonable' by well people involved in research for which they will receive no benefit. Assessing the risks and benefits of research involving terminally ill patients, particularly therapeutic research, sits at the other extreme. In moving from one to another, it is difficult for a HREC to achieve the right balance between being too restrictive and too permissive.^{16, 17}

Of particular interest to a HREC will be the use of any strategies to minimise harm and it is important to be explicit about these. Examples include:

- frequent monitoring of participants
- presence of trained personnel to respond to emergencies
- coding of data to protect confidentiality
- debriefing for participants and/or the availability of a counselling service
- review and monitoring of data as it is collected to identify any risks or harms
- exclusion of vulnerable groups or individuals
- consideration of alternative research methodologies.¹⁸

The care and attention devoted to harm minimisation strategies can do much to overcome

any misgivings by members of a HREC regarding the merits of a research proposal.

Implications for Palliative Care HREC applications

- Clearly identify the potential risks to your research participants and be clear about how you will deal with these if they arise.
- Emphasise what steps you will take to minimise any potential harm to patients, their family and friends, and staff.
- Identify any potential benefits to your research participants and provide any evidence you have of these potential benefits.
- Identify the potential benefits of your research findings to future generations of palliative care patients.
- Be honest about what you don't know.

Informed consent

Informed consent occurs when patients are given sufficient information about the proposed research, are capable of understanding that information and have the power of free choice that allows them to either give or withhold consent to participate.¹⁹ The three issues of information, comprehension and voluntary choice form the basis of the current national guidelines on informed consent.²⁰ Information provided to potential participants in a study should include:

- a statement that participation is voluntary
- a statement regarding the right to withdraw consent to participate at any time without reprisal
- details of why the research is being undertaken
- details of how the research will be conducted
- information about the anticipated benefits

and potential risks of the study

- information about potential inconveniences or discomforts to participants
- details of any costs to participants
- a statement describing how the confidentiality of records identifying participants will be maintained
- information relating to possible conflicts of interest
- details of the institutional affiliations of the researchers
- information relating to possible outcomes, including the likelihood and form of any publications.^{21, 22}

Some palliative care research involves the use of data held by a third party. For example, a researcher may be interested in the relationship between, say, symptom control and the use of medical services. The proposed research will collect measures of symptom control from participants and will seek to establish whether there is any relationship between these and the frequency of seeing a doctor. In this case, participants need to give their informed consent for the researcher to collect the symptom control measures. They will also need to give informed consent for the Health Insurance Commission (HIC) to provide their identified data to the researcher. In research such as this, the researcher will need to meet the requirements of their HREC as well as the requirements of any third party such as the HIC or the various cancer councils. At times, these requirements will be at odds with each other. The researcher should consult with all relevant third parties about their requirements prior to submitting their application and allow sufficient time to achieve the necessary approvals from all relevant bodies.

The level of detail and type of terminology required to ensure that all necessary information is included may result in a more complex consent process than is typically the case for therapeutic interventions.²³ The lay members are the HREC's 'litmus test' for the readability, clarity

and completeness of the patient information and consent forms. It may be worth considering using a volunteer or other member of the community to scrutinise a HREC application for suitable language and vocabulary prior to submission.

HRECs will be interested in knowing which members of the research team will be involved in the consent process, especially if researchers are also professionals involved in the care or support of the participant. This is relevant because the HREC will need to be confident that the relationship between the researcher and participant does not impair the participant's freedom to refuse or withdraw consent.

Although there is broad understanding of the need for informed consent there is still uncertainty about whether and how it is achieved in practice. There has been some empirical research regarding disclosure and understanding of informed consent but little work on other aspects of informed consent.²⁴

The mixed results from the research suggest that a 'one size fits all' approach to disclosure is not appropriate and researchers should provide for some flexibility to tailor information to the needs of individuals, while providing fair and complete disclosure to all participants.²⁵ Palliative care researchers need to consider these lessons from the literature when preparing ethics applications.

The issue of informed consent is also pertinent to family members in palliative care research as they are often the focus of studies and interventions. This means that researchers need to develop an effective and efficient process to ensure informed consent that meets the very different needs of patients, family members and carers. These issues are not unique to palliative care research. For example, it is quite common in dementia research where informed consent is often obtained simultaneously from family members and patients. This 'dual consent' ensures that caregivers understand the research in which they and the patients are participating and that they are willing to carry out their study responsibilities.²⁶

There is no inherent reason why patients who are terminally ill are less able to make informed decisions about whether or not to participate in research.²⁷ As with any other group of potential research participants, they will vary in their decision-making capacity. Use of tools that assess decision-making capacity²⁸ may be more useful than ‘blanket prescriptions about safeguards and assessments of capacity.’²⁹ If there is any likelihood that the cognitive impairment of a participant will increase during the course of a study then the consent process should include discussion of willingness to continue participation and the circumstances under which consent will remain valid.³⁰

HRECs, in reviewing a palliative care research proposal, will consider whether specific sections of the *National Statement* should be applied in their considerations, especially *National Statement* §6.6-10 concerning terminal care research, and research involving persons with impaired capacity for communication or consent. HRECs may approve research where applying the principle of consent is not feasible. Researchers will need to demonstrate that inclusion in the research is not contrary to the participant’s interests; that the research poses no greater risk to the participant than is inherent in their condition or treatment; and that the research is properly grounded (*National Statement*, §6.9).³¹

Things to remember about informed consent:

Keep it simple - simpler presentations in consent forms improve comprehension. For example, think about techniques such as simplification of information; provision of information in a story book or video using a lower reading level; use of a larger typeface; quizzing and use of audiovisuals.

Patient vulnerability

The premise that a palliative care patient is in a vulnerable position and can be exploited can further cloud the ethical issues surrounding informed consent. Vulnerability can express itself in a number of ways:

- A compulsion to participate in research out of a sense of desperation ie, patients willing to try anything in the hope that they will benefit.
- An obligation to participate because of a feeling of dependency on the research institution or investigator.
- Feeling the need to ‘give something back’ to show gratitude for care received.
- A real reduction in decision-making capacity due to illness.
- An inability or unwillingness to concentrate for a sufficiently long period of time to understand all of the information relevant to a particular study.
- The presence of a cognitive impairment.^{32, 33, 34}

The issues around desperation and obligation to be involved in palliative care research are, to varying degrees, relevant to all clinical research and do not constitute a specific argument against palliative care research.³⁵ Ethical concerns regarding these issues can be resolved by the use of techniques such as:

- Emphasising the distinction between clinician and researcher by delegating recruitment of participants to a ‘third’ party.
- Mitigating feelings of desperation by using a ‘lead in’ period for the research to optimise symptom management prior to recruitment of participants (although this is problematic given that symptom control for palliative care patients is often the subject of the research).
- Repeatedly making it clear to participants involved in research that they are free

to withdraw their consent at any time without in any way jeopardising their future treatment or care. There may be a need to revisit the consent process during the course of the research project and renegotiate participation.

- Sensitivity on the part of researchers to any signs that participants no longer wish to be involved.^{36, 37, 38}

Anecdotal evidence suggests that some HRECs have real concern about involving dying patients in research because of their vulnerability. The response to this position is well summarised by Lee and Kristjanson:

‘The suggestion that palliative care patients should not be involved in research denies these individuals an active role in living and prevents them from contributing to knowledge about how to improve care for others.....they have the right to choose to participate in an activity that may bring benefit to others, particularly when the research they choose to be involved in has little risk of harm to them.....participation in research projects by palliative care patients can bring forward a number of extremely positive opportunities. These include an opportunity for patients to reflect upon their care and illness experience, a sense of contributing to a greater community good and a feeling of pride in being able to offer information that may benefit others.’³⁹

In fact, the evidence suggests that the majority of palliative care patients would not hesitate to be involved in research as long as they are well informed about the purpose and potential benefits, irrespective of whether they would receive any direct benefit or not.⁴⁰ Family care givers of palliative care patients have also reported positive benefits from their involvement in research⁴¹ and interviews with terminal patients and bereaved family members are often valued by subjects.⁴²

Participant burden

A HREC will take particular interest in the techniques used by researchers to minimise inconvenience and discomforts for participants. The HREC may wish to have advice from professional carers about whether the participants have been over-researched, and whether the staff who may be involved in the research will have the time to participate or provide the required support.

The following list summarises some of the issues that may need to be considered by palliative care researchers when designing studies to minimise participant burden:

- Maximise the use of routinely collected data to reduce the need to collect the same data from participants.
- Make allowances for the unpredictable nature of terminal illness. For example, participation by palliative care patients in longitudinal studies is almost impossible.⁴³
- Distress from complex symptoms and impaired mental competence resulting from high doses of medication make consistent participation difficult.⁴⁴
- The burden of care giving makes it difficult for family members to be involved in research.⁴⁵
- Competing demands on health care professionals means that their involvement in palliative care research may not be easy.⁴⁶
- Patients who are relatively well may want to spend as much time as possible with family and friends or pursuing leisure activities. Conversely, family members may prefer that the patient spend time with them rather than become involved in research.⁴⁷
- Recruiting participants for research is complicated by the heterogeneity of the study population and the fact that patients and their families typically receive care in many different care settings and geographic locations.⁴⁸ This presents a challenge in minimising inconvenience to patients and their care givers.

Balancing the role of clinician and researcher

This issue concerns the nature of the clinical and research roles. There are two main scenarios in which ethical issues can arise:

- The researcher is independent from the care giving process.
- The researcher is a clinician involved in the care of research participants.

An ethical issue arises when the researcher obtains information that may have significance for a patient's clinical management but the information is not available to those caring for the patient. This is not unique to palliative care but the emotional and physical ill-health of palliative care patients, together with the complex family dynamics surrounding many palliative care patients, does make it likely to occur. In this situation there are three options:

- Never divulge information to the patient's care provider out of a duty to maintain confidentiality and ensure that patients give complete and accurate information. Any breach of confidentiality might jeopardise the validity of the research.
- Disclose all clinically important information, thus maximising the benefit and minimising the harm of the research.
- Take a middle ground between these two extremes. The responsibility of the researcher is to recommend that the patient contact his or her provider regarding the information that has become available. For example, the researcher may become aware that a patient has pain that is not well controlled by current medication. The researcher should not contact the provider without the patient's permission. This recognises the fundamental right of patients to make informed decisions about their treatment, preserves the confidentiality of information divulged and meets the obligation of researchers to engage in ethical conduct.⁴⁹

The particular strategy to be adopted by researchers in this situation should be included in the ethics application. In general, the last approach is recommended, unless there is a good reason not to do so. Researchers will have to anticipate how they will respond to revelations by patients, carers and families, that may arise in the research context (and may need to spell these out in their ethics application), noting that patients may reveal information to researchers that they would not reveal to those who have been involved in their care. Some serious issues present particular challenges to the middle ground approach including suicidal intention, the stockpiling of medications, the presence of a dangerous weapon, a carer who intends to end a patient's life or an incompetent patient who is being mistreated by a carer.

Furthermore, researchers may have legal or professional responsibilities to report specific information that is divulged during research (eg, mandatory reporting of abuse).

Privacy issues, including issues in linking data

Confidentiality refers to the situation that arises when one person receives information from or about another and has an obligation to only use that information for the purposes for which it was collected. Privacy is a broader concept and relates to anyone who might have access to information that someone else believes should be kept private.⁵⁰

The issue of privacy is complex. An in-depth discussion of the issues is contained in a comprehensive paper by Roger Magnussen from the Faculty of Law of the University of Sydney.⁵¹ Magnussen identifies four layers of regulation governing the ‘circumstances in which it is lawful to collect, store and disclose identifying, or identifiable (coded, but re-identifiable) data for research purposes.’ (p.7):

- common law duties of confidence
- statutory duties of non-disclosure
- privacy legislation
- the *National Statement*.

The *National Statement* clearly distinguishes three types of personal data:

- identified data that allows the identification of a specific individual
- potentially identifiable (or coded, re-identifiable) data where a code replaces identifiers and the personal identity of the person could be re-identified
- de-identified (not re-identifiable, anonymous) data where the process of de-identification is not reversible.⁵²

Researchers should clearly state in their application to a HREC whether the information they propose to collect is potentially identifiable and explain the circumstances (if any) under which it may be possible to re-identify information. This typically can occur in two ways:

- Some form of coding system is used to de-identify information at point of collection but each code identifies a participant, enabling re-identification of participants if required.
- Data are collected from different sources, each of which is de-identified, but the collation of data about individuals may allow for identification. Data matching refers to the situation where new information is obtained by matching personal information from two or more databases.

The circumstances under which a HREC may allow research based on linking records to take place without consent are set out in the *National Statement*, §14.4 and 18.5.

The principles governing collection and use of information for the purposes of research are set out in the Commonwealth Privacy Act, 1988 and included as an appendix in the *National Statement*. Issues covered include:

- Information can only be collected if it is for a purpose, and directly related to that purpose.
- An individual understands the purpose for which information about them is collected.
- The collection of information is not unreasonably intrusive.
- Safeguards are taken against loss, unauthorised access, use, modification, disclosure or other misuse.
- Information obtained for a particular purpose will not be used for any other purpose without consent (unless there are reasonable grounds to believe that there is a serious and imminent threat to the life or health of a person).

Where a research proposal includes collection, use or disclosure of health information without consent, the Privacy Act and state privacy legislation are likely to place additional conditions on researchers.

Issues in qualitative research

Qualitative research methods may include in-depth, open-ended interviews; direct observation of behaviours and interactions; written and documentary information; and various means of relating experience and knowledge.⁵³

Palliative care is well suited to qualitative research methodologies, particularly in terms of getting a rich insight into service delivery. However, some HRECs may be dismissive of such methodologies as being merely anecdotal.⁵⁴ Committees may not include members with qualitative research training and expertise and this can result in ‘negative judgements about the merits and rigour of the study.’⁵⁵ Consequently, interventions of potential benefit to palliative care patients and carers may be overlooked, including studies that have a focus on care related issues rather than disease specific outcomes.

Although some members of a HREC will be appointed for their research expertise, it is more likely that this expertise will be in the more traditional areas of research such as clinical trials using random assignment rather than qualitative research. The HREC may need to seek additional expertise to adequately review such research. If a research proposal is in any way unusual it is recommended that one of the researchers contact the chair of the HREC to seek their advice before submitting a formal application. Researchers can also express a willingness to appear before a HREC to answer any questions that committee members might have.

The risks of qualitative research may be difficult to quantify but may also be very real. There may be risk in greater self-knowledge that the participant is unable to cope with. There may be a risk of greater understanding of the severity of the patients’ situation. There is also the risk of emotional distress or even psychological disturbance as a result of some qualitative research although this is an area that is not clearly understood and requires further work.⁵⁶

As has been stated, a HREC has a legitimate

role in assessing whether the scientific merit of a proposal has been established. However, it is not the role of a HREC to tell a researcher how they should conduct their research. This distinction can be a fine line at times and the cause of much anguish and frustration for researchers. The onus is on the researcher to explain the merit of their proposal in clear, unambiguous, terms.

There are some particular issues with qualitative research that warrant attention when preparing applications for HRECs:

- For some qualitative studies it may be appropriate to obtain verbal consent rather than written consent or waive the requirement for consent altogether. In the case of the latter the NHMRC requirements are as follows:

‘It is ethically acceptable to conduct certain types of research without obtaining consent from participants in some circumstances, for example, the use of de-identified data in epidemiological research, observational research in public places, or the use of anonymous surveys’ (*National Statement*, §1.11).

- The nature of some qualitative research requires the establishment of a level of rapport between researcher and participant. This can be problematic in certain circumstances, for example, in small communities and where ‘peers’ take on the role of researcher. If there are any concerns that there may be such complications between researcher and participant the ethics application should clearly detail how these circumstances will be dealt with.
- Confidentiality is difficult to guarantee in qualitative research, primarily because of the way data are collected. For example, a face-to-face interview is not anonymous and no matter what controls are put in place the identity of the participant will be known to the researcher.

Section 9 The practicalities



The following checklist is designed to assist you in preparing an application for HREC approval:

- Is HREC approval required? If in doubt, complete the checklist on page 6. If still in any doubt, seek advice from the relevant HREC(s). Do not be surprised if you get different answers from different committees.
- How much time do you need? Allow sufficient time between submission of an application for ethics approval and the time you plan to start your research.
- Applying to multiple HRECs? Plan a strategy for how you will do this. If you have enough time it is recommended that you apply to your local HREC first and then use that approval to support further applications. Your research may only involve one location but multiple providers eg, public hospital, private hospital, community health service, division of general practice. Each provider may be willing to accept ethical approval from one HREC but you should check with each one first.
- Access to a HREC? Some providers may not have their own HREC. Plan a process of liaison and negotiation to find a HREC willing to consider your application.
- Different HRECs with different requirements? Each HREC you apply to may require different amendments before approval will be granted. Be ready for this and don't be surprised if it happens.
- Forms and deadlines. Contact the secretariat of each HREC to identify what forms need to be completed and the deadlines for submission of applications. Missing a deadline by one day could well result in a delay of at least a month until the Committee next meets.

As you prepare your application, consider:

- What are the possible vulnerabilities of palliative care patients, carers or staff you propose to include in your study? Ask yourself whether you have adequately addressed these issues in your ethics application. For example, how will you deal with the situation where a patient willingly participates in a study and their family subsequently makes it clear that they are not happy with this?
- Does your research depend on the support of carers or staff, or support groups? If so you should consider negotiating with these groups in advance, and seeking letters of support for your research from these groups and include copies in your ethics application.
- Are there any implications of your research for the Aboriginal and Torres Strait Islander peoples? Advice may be required on the need to submit an ethics application to a separate Aboriginal HREC or sub-committee. Additional time will need to be allowed for if this is the case.
- English as a second language? Consider the implications of your research proposal for people who may not be able to speak English well enough to ensure informed consent. Obtaining translations for participant information sheets and consent forms can be expensive and time consuming. Simply excluding those who do not speak English may be considered a violation of the justice principle by a HREC.

Checklist before submitting your application

| Issues to consider as you prepare your research ethics application | Relevant to your application? | | Adequately addressed in your application? | |
|--|-------------------------------|-----------------------------|---|-----------------------------|
| The application uses language and terminology that will be readily understood by an informed lay person. | | | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The role of palliative care services is clearly described. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Gaps in knowledge that have prompted the research are clearly described. | | | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The application and consent documentation contain information about who will bear any risks and who may benefit from the research. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Risks, potential harms and inconveniences for participants are clearly described in the application and consent documentation. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The method is clearly described and the application includes adequate justification for this method. | | | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The application clearly distinguishes different categories of participants involved in the research and provides separate consent information as required | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The application clearly distinguishes different research activities and makes it clear what the activities are, when they will occur and how they relate to the overall aim of the research | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The application contains information on procedures to ensure informed consent including what information will be provided, to whom, when and by whom. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Procedures to minimise any inconvenience or risk to participants are clearly described. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Steps to be taken in the event of any adverse reaction by participants are clearly described. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Steps to be taken to deal with any real or perceived conflict of interest between the roles of clinician and researcher are clearly described. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| Logistic issues associated with multi centre research including timing, formats and communication processes are considered and built into your planning. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The requirements of the Values and Ethics Guidelines have been addressed in proposals for research involving Aboriginal and Torres Strait Islander peoples. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |
| The Chair of the HREC has been consulted for advice if the proposal is unusual in any way or if the research is primarily qualitative research and your local HREC mainly considers research using quantitative methods. | Yes <input type="checkbox"/> | No <input type="checkbox"/> | Yes <input type="checkbox"/> | No <input type="checkbox"/> |

Section 10 What guidelines are available to help write an ethics application?



Many HRECs provide guidelines for filling in their HREC application form. Often these are available via the Web.

The 1999 NHMRC *National Statement on Ethical Conduct in Research Involving Humans* is available online (html and pdf) at:

<http://www.nhmrc.gov.au/publications/synopses/e35syn.htm>

The 2001 NHMRC *Human Research Ethics Handbook: Commentary on the National Statement on Ethical Conduct in Research Involving Humans* can be obtained at:

<http://www.nhmrc.gov.au/publications/synopses/e42syn.htm>

Particularly relevant sections in the Commentary on the *National Statement* in the *Research Ethics Handbook* include:

- Section 3 Multi centre research
- Section 6 Research involving persons highly dependent on medical care
- Section 7 Research involving persons in dependent or unequal relationships

Relevant sections in the *Research Ethics Handbook* include:

- Statement of research question
- Consent
- Multi-centre research
- General Practice research
- Emergency and intensive care research
- Research involving persons highly dependent on medical care
- Qualitative research
- Consent

- Privacy

The 2003 NHMRC *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research* is available as a pdf document online at:

<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>

The Australian and New Zealand Society of Palliative Medicine, 1998, Ethical Guidelines #7, *The Australian and New Zealand Society of Palliative Medicine Journal* vol 12, p. 42.

Useful links to Australian privacy and confidentiality resources can be found at the web site of the ANU Data Mining Group at:

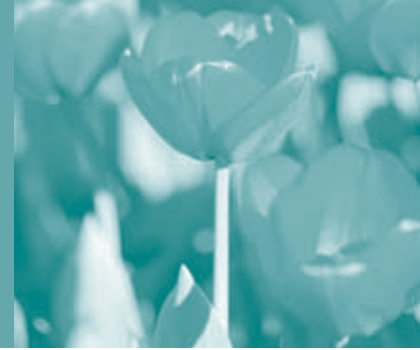
<http://datamining.anu.edu.au/projects/linkage.html>.

These include links to the following sources:

- Office of the Federal Privacy Commissioner - Guidelines on privacy in the health and medical research sectors
- New South Wales Department of Health Information Privacy Code of Practice - see in particular Section 11.5 which deals with record linkage

<http://www.health.nsw.gov.au/iasd/information-privacy/>

Section 11 Recommended further reading



In addition to the references cited in this booklet, the following are recommended further reading:

Daly J (1996) *Ethical Intersections: Health Research, Methods and Researcher Responsibility*. Sydney: Allen & Unwin.

de Raeve L (1994) *Ethical issues in palliative care research*. *Palliative Medicine*. Vol. 8 1994: pp.298-305.

Dodds S, Albury R and Thomson C. (1995) *Ethical Research and Ethics Committee Review of Social and Behavioural Research Proposals*. Report to the Department of Human Services and Health. Canberra: Commonwealth of Australia

Emanuel E, Wendler D and Grady C (2000) *What Makes Clinical Research Ethical?* *JAMA*. Vol 283 No 20 (May 24/31 2000); 2701-2711.

Jones JH (1981) *Bad Blood: the Tuskegee syphilis experiment*. New York: Free Press

Neuman WL (1997) *Social Research Methods, Qualitative and Quantitative Approaches*. (3rd Ed), Chapter 17, '*Ethical and political issues in social research*'. pp 442-475, Boston: Allyn and Bacon.

Randall F & Downie RS (1996) *Palliative Care Ethics*. Oxford: Oxford University Press, 1996.

Australian and New Zealand Society of Palliative Medicine (1998) *Ethical Guidelines #7*, *The Australian and New Zealand Society of Palliative Medicine Journal*. Vol 12, p. 42.

References

¹ National Health and Medical Research Council (1999) National Statement on Ethical Conduct in Research Involving Humans. Available electronically at:

<http://www.health.gov.au/nhmrc/publications/synopses/e35syn.htm>

² Eagar K (1997) Defining an Episode of Care: a study of five Case Types. Australian Health Review. Vol 20, No 3, 105-119, 1997

³ Palliative Care Australia (PCA) http://www.pallcare.org.au/pca_aboutpalliativecare.html

⁴ Palliative Care Australia (PCA)

⁵ NHMRC (1999)

⁶ National Health and Medical Research Council (2003) When does quality assurance in health care require independent ethical review? Available electronically at:

<http://www.health.gov.au/nhmrc/issues/pdfcover/qualassu.htm>

⁷ Op cite

⁸ NHMRC (1999) page 8

⁹ NHMRC (1999) page 1

¹⁰ National Health and Medical Research Council (2003) Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research. Available electronically at:

<http://www.nhmrc.gov.au/publications/synopses/e52syn.htm>

¹¹ Casarett DJ and Karlawish JH (2000) Are special ethical guidelines needed for palliative care research? Journal of Pain & Symptom Management. 20: 130-9.

¹² Illhardt FJ and Have HT (2001) Research ethics in palliative care. The Ethics of Palliative Care: European Perspectives. D. Clarke. Buckingham UK: Open University Press.

¹³ National Health and Medical Research Council (2001) Human Research Ethics Handbook. Available electronically at:

<http://www.health.gov.au/nhmrc/publications/synopses/e42syn.htm>

¹⁴ NHMRC (1999)

¹⁵ NHMRC (1999) page 6

¹⁶ Casarett and Karlawish (2000)

¹⁷ Jubb AM (2002) Palliative care research: trading ethics for an evidence base. Journal of Medical Ethics. 28(6): 342-6

¹⁸ NHMRC (2001)

¹⁹ Rees E (2001) The ethics and practicalities of consent in palliative care research: an overview. International Journal of Palliative Nursing. 7(10): 489-92.

²⁰ NHMRC (1999) 1.7

²¹ NHMRC (1999)

²² World Medical Association WMA (2000) Ethical Principles for Medical Research Involving Human Subjects. World Medical Association Declaration of Helsinki

²³ McLaughlin KJ, Brindley AF et al. (2004) Informational video for potential participants of clinical studies used in the process of seeking informed consent. Cochrane Database of Systematic Reviews.

²⁴ Sugarman J, McCrory DC et al. (1998) Getting meaningful informed consent from older adults: a structured literature review of empirical research. Journal of the American Geriatrics Society. 46(4): 517-24.

²⁵ Sugarman J, McCrory DC et al. (1998)

- ²⁶ Casarett and Karlawish (2000)
- ²⁷ Casarett and Karlawish (2000)
- ²⁸ Lee S and Kristjanson L (2003) Human research ethics committees: issues in palliative care research. International Journal of Palliative Nursing. 9(1): 13-8.
- ²⁹ Casarett D, Knebel J A et al. (2003) Ethical challenges of palliative care research. Journal of Pain & Symptom Management. 25(4): S3-5. p S4
- ³⁰ Casarett, Knebel et al. (2003)
- ³¹ NHMRC (2002) Research on Unconscious Patients HREC Bulletin of the Australian Health Ethics Committee, No 6, p. 2-3
- ³² Casarett and Karlawish (2000)
- ³³ Rees (2001)
- ³⁴ Jubb (2002)
- ³⁵ Karim K (2000) Conducting research involving palliative care patients. Nursing Standard. 15(2): 34-6
- ³⁶ Rees (2001)
- ³⁷ Jubb (2002)
- ³⁸ Lee and Kristjanson (2003)
- ³⁹ Lee and Kristjanson (2003) p14, p15, p18
- ⁴⁰ Bruera E (1994) Ethical issues in palliative care research. Journal of Palliative Care. 10(3): 7-9
- ⁴¹ Hudson P (2003) The experience of research participation for family caregivers of palliative care cancer patients. International Journal of Palliative Nursing. 9(3): 120-3
- ⁴² Casarett, Knebel et al. (2003)
- ⁴³ Lee and Kristjanson (2003)
- ⁴⁴ Lee and Kristjanson (2003)
- ⁴⁵ Lee and Kristjanson (2003)
- ⁴⁶ Lee and Kristjanson (2003)
- ⁴⁷ Karim (2000)
- ⁴⁸ Lee and Kristjanson (2003)
- ⁴⁹ Casarett and Karlawish (2000)
- ⁵⁰ NHMRC (1999)
- ⁵¹ Magnussen R (2002) Data Linkage, Health Research and Privacy: Regulating Data Flows in Australia's Health Information System. Sydney Law Review. 24(5): 5-56. Available at <http://www.law.usyd.edu.au/~slr/v24/n1/magnusson.pdf>
- ⁵² NHMRC (1999) p 9
- ⁵³ NHMRC (2001)
- ⁵⁴ Jubb (2002)
- ⁵⁵ Lee and Kristjanson (2003) p15
- ⁵⁶ Wilke P (2001) Ethical issues in palliative care. In Field D and Clarke D Researching Palliative Care. Buckingham, UK, Open University Press