

Special Article

Qualitative Methods in End-of-Life Research: Recommendations to Enhance the Protection of Human Subjects

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Abstract

Qualitative research has the potential to contribute important new knowledge to care near the end of life, but research is often hampered by questions about how best to protect dying patients and their family members who serve as research subjects. Due to lack of familiarity with the techniques of ethnographic or observational research, as well as concerns about the vulnerability of the dying, members of Institutional Review Boards (IRBs) are often unable to evaluate the benefits and potential harms of studies. In addition, policies derived from standards based on interventional medical research or clinical trials may be applied inappropriately. We offer comprehensive recommendations aimed at improving the translation of human subjects guidelines into meaningful protections for subjects in qualitative studies, including education for IRBs. Policies must be flexible and should be guided by empirical findings documenting the actual impact of research participation, rather than a priori assumptions about patient vulnerability. Sensitive topics, such as drug use, may require added protections. *J Pain Symptom Manage* 2003;25:S43–S52. © 2003 Cancer Pain Relief Committee. Published by Elsevier. All rights reserved.

Key Words

End-of-life care, research ethics, qualitative methods, palliative care research

Introduction

Qualitative research methods have made a unique contribution to research about care of patients near the end of life. Two seminal ethnographic studies by sociologists Barney Glaser and Anselm Strauss helped establish care of the dying as a legitimate field of inquiry, reveal-

ing the complex nature of communication between patients and caregivers.^{1,2} Qualitative research in palliative care can address: “basic” or foundational questions, such as the nature of communication and decision-making processes; “applied” clinical research questions, such as how physicians respond to requests for hastened death; or quality improvement in clinical practice, such as identifying institutional barriers to pain control. Qualitative research can identify and describe phenomena that are not known to be important in advance of a research project, can ask questions about meaning that are not easily quantified, and in some

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cases may provide the background for further studies using other methods.

Because of the unique aims and techniques of data collection, often including observation of actual behavior and in-depth interviews, standard Institutional Review Board (IRB) procedures are not well suited to protecting subjects from harm. In some cases, IRBs have required procedures that, while suitable for interventional biomedical research, were confusing and burdensome for subjects in qualitative studies. In other cases, IRBs have blocked qualitative research on palliative care because of assumptions made about the vulnerability of dying patients, and their need for enhanced protection. Based on a review of the literature, as well as our extensive experience conducting qualitative end-of-life (EOL) research, we argue that subjects participating in qualitative studies require types of protection that differ significantly from what is needed for subjects participating in clinical trials. In this paper, we describe how qualitative research contributes to palliative care, explore in detail why IRB procedures designed for clinical trials are often inappropriate for studies using qualitative methods, and make recommendations aimed at enhancing the protections needed for qualitative research subjects, while at the same time assuring that regulations will not needlessly hinder beneficial research designed to improve care near the end of life.

Background: Qualitative Methods, Research Ethics, and EOL Care

Different types of qualitative research include strategies of inquiry that share assumptions about the nature and meaning of knowledge that vary from other paradigms of inquiry. Clark categorizes these paradigmatic assumptions according to modes of reasoning (inductive, rather than deductive); of validity (authenticity); of sampling (theoretical/purposive); of descriptions (“thick”); and of observation (interactive).³

There is a “closeness of fit” between qualitative approaches to inquiry and unique questions raised by the care of seriously ill and dying patients.⁴ The data obtained are often naturalistic—derived from real-world situations either in real-time (observations); through re-

flections or recollections (interviews); or based on past records (source documents).^{3,5} Because of the uniqueness and particularities of real-world situations, qualitative research is not easily generalizable.

A full review of the contributions of qualitative research would require a separate manuscript. Jennings, for example, describes how ethnography is uniquely suited, both theoretically and methodologically, to the study of complex ethical decision making in intensive care settings, using the care of dying infants in the neonatal intensive care unit (ICU) as an example.⁶ However, even a brief review reveals that these methods allow access to a range of “meaning-centered” questions that would be difficult to address using other techniques. Seminal studies of patients’ experience of dying have been particularly useful in understanding notions of quality care.^{7,8} Naturalistic studies of communication,⁹ as another example, can demonstrate best practices and may also reveal the distance between the “ideal” pronouncements of policies and actual clinical care. A recent ethnographic study documents how doctors and patients may collude in maintaining false optimism about outcomes, in spite of the goal of open disclosure of information.¹⁰ The nature of communication about advance care planning has also been illuminated by qualitative research,¹¹ as has our understanding of how patients come to be understood as “terminally ill” or “dying.”¹² Finally, the experience of patients from varied cultural backgrounds has been carefully documented, demonstrating the range of issues created when patients are confronted with the western ethical assumptions underlying EOL clinical practice.^{13,14}

Unique human subjects protection issues that arise in qualitative data collection require special attention. Ethical dilemmas may stem from the role conflict experienced by researchers.¹⁵ The intense, personal nature of qualitative data gathering techniques (i.e., in-depth or narrative-based interviewing; long-term continuity and availability to patients or families in participant observation) requires the development of caring or empathic relationships with research subjects, oftentimes similar to the experience of a clinical encounter.¹⁶ Some interactions, for example discussions about advance care planning, may have characteristics

of counseling sessions that could be misconstrued as part of a clinical or therapeutic relationship.³ Patients may feel obligated to continue study participation due to the relational nature of the subject-researcher encounter. Finally, observing and recording in clinical settings may disrupt the study environment itself.³

The vulnerability of subjects who are dying, as well as the heightened sensitivity of recently bereaved family members, is of great concern to researchers. Riches and Dawson recommend avoiding an “instrumental approach to vulnerable people,” where subjects are treated as means to an end (data).¹⁷ The authors define the right time to begin applying sensitivity to the feelings, views, and experiences of potentially vulnerable patients as the point of initial recruitment. Some suggest that access to these patients should not be “cold” but through some third, trustworthy party.¹⁸ Rosenblatt also raises the issue of potential coercion for study participation by family members despite following IRB guidelines for recruitment.¹⁹ He illustrated this dilemma through the story of bereaved parents where the wife/mother coerced an extremely reticent and grieving husband/father into being interviewed.

Current efforts to review and reform the human subjects protection enterprise in the U.S. have examined the impact of existing federal regulations. A recent survey of social science professional organizations catalogued the concerns of researchers, which focused on regulatory burden as well as possible violations of academic freedom.²⁰ When federal human subjects protection guidelines were developed in the 1960s and 1970s, social and behavioral science research was subject to the same procedural scrutiny as invasive experimental medical procedures. Many social scientists complained that this placed undue burden on their work, while adding little in the way of real protection for subjects. Although some modifications for social science research were adopted in later revisions (e.g., expedited review, the concept of “minimal risk”), the general framework of treating all human subjects in research identically—using a calculus of risks and benefits based on invasive medical procedures—has remained intact. Recently, work carried out by the National Bioethics Advisory Committee and regulatory agencies such as the Office of Human Research Protec-

tions documents a growing recognition that the entire system is in need of reform. There is renewed attention to developing regulatory guidance that is specifically targeted to the methods used in social and behavioral science research. Both the National Science Foundation and the Institute of Medicine of the National Academy of Sciences have convened expert groups to make recommendations about whether revisions in the system are warranted.

General codes of “research ethics” such as the Helsinki guidelines fail to address issues peculiar to qualitative research, particularly research conducted with patients near the end of life. The Helinski declaration (1997 revision), for example, begins by stating: “The purpose of biomedical research involving human subjects *must be to improve* [emphasis added] diagnostic, therapeutic and prophylactic procedures and the understanding of the etiology and pathogenesis of disease.” The fact that ill patients die, and that research to improve the care they receive is essential, seems to be a topic unworthy of consideration.

Codes of ethics developed for social science researchers who regularly conduct qualitative research offer more substantive guidance on issues such as relationships with research subjects in the course of observational research and how to balance the researcher’s often conflicting obligations. (See for example, the codes of the American Anthropological Association or the American Sociological Association.) However, these codes of ethics are often highly idealistic, making pronouncements about the researcher’s primary duty to protect the welfare of subjects without providing clear guidance that might be of use for EOL research.

The very fact that subjects are known to be near the end of life may raise special concerns for IRB reviewers. A 1985 study of patterns of approvals/disapprovals of research protocols in 157 university human subjects committees showed that “socially sensitive” proposals were twice as likely to be rejected than those that dealt with less sensitive sociopolitical concerns.²¹ Sensitive protocols that did not contain overt ethical problems (e.g. deception) were rejected on the basis of “methodological” issues, in which the protocol was judged on the basis of standards for clinical trials or quantitative empirical research. Thus sensitive research is

not banned outright, but rather blocked indirectly.

Unique Human Subjects Issues Raised by Qualitative Palliative Care Research Studies

Do Subjects in Qualitative Research Require Special Protections If They Are Dying?

There is an intriguing irony in our thinking and practice about research with dying patients. On the one hand there are instances when IRBs treat patients who are dying as vulnerable and in need of special protections from researchers who seek to study improved pain management techniques or best practices in communication. (Those recently bereaved are often included in this vulnerable category.) On the other hand, a patient's "terminality" may be used to justify exposing that person to *greater* risks than would be allowed with a non-terminal patient. This is most common in the field of oncology drug trials. It is considered appropriate to ask "terminal" cancer patients (including parents as proxies for their children) to consent to participation in research with no expected benefit.²² Phase I drug studies, for example, have the intention of evaluating the maximal safe and tolerable dose of a new compound. It is generally terminally-ill patients who have failed all previous therapies who are invited to participate in such trials, even though research has documented that patients and families often agree to participation based on the "therapeutic misconception"—a misunderstanding and miscommunication about the true goals of research in which researchers themselves are often complicit.²²

This same group of patients—those for whom no cure is likely—are at the same time deemed by some IRBs to be in need of special "protection" from researchers whose goal is to improve the quality of dying. We argue that is generally less risky for subjects to participate in an interview study asking about their EOL experience than in a clinical trial of a new agent. Well-designed qualitative research has inherent checks and balances that enhance subject protections. For example, when conducting an interview it is easier to "pace" the questions to the subject's mood and energy level than when conducting research using a structured assess-

ment instrument. When used by a well-trained interviewer, open-ended questioning can be specifically tailored to the subject's level of knowledge and is less likely to cause distress. A good example concerns the issue of disclosure of diagnosis. In a study to gauge subject's desires for active involvement in ethical decision making about their care, interviewers were trained never to use a technical term for a patient's diagnosis, such as cancer, but to ask the patient how they referred to their illness and then follow the patient's lead.¹⁴

Problems with IRB Use of Procedures Designed for Clinical Trials: Is Qualitative Research in Palliative Care Blocked by IRBs?

Some have taken the extreme position that patients near the end of life should never be asked to participate in *any* form of research, regardless of the methods or techniques planned.²³ Anecdotal reports suggest that qualitative research designs face greater hurdles than other methodologies when reviewed by IRBs whose members are more familiar with conventional clinical trials or experimental designs. Why does this problem exist? In some cases there is the assumption that research lacking a hypothesis or a definitive quantitative conclusion, a simple outcome stated as a "p" value, is by definition without merit. This low "benefit" thus becomes a justification for imposing undue burdens on researchers or banning projects altogether. Some may also mistakenly assume that research must be "generalizable" to a broader population in order to be of value.^{24,25}

When not blocked outright, qualitative studies may be subject to considerable administrative burdens before an IRB grants approval. The arbitrary application of rules derived from more straightforward biomedical research does not aid in the protection of human subjects. In fact, it may cause additional anxiety to subjects. For example, on a consent form for a study of communication in end-of-life care, one of us was required by an IRB to include language indicating that confidentiality could not be *guaranteed*, exactly as mandated for studies providing backup data for a new Food and Drug Administration (FDA) drug application. In fact, the researchers *could* guarantee a higher level of protection, since there was no need to preserve the real names of participants

in case of FDA audit. (Those names could be destroyed on completion of the project.) On another occasion, an IRB required the inclusion of a frightening document, the “Experimental Subjects Bill of Rights,” on the consent form for a similar study of decision making, a study in which no intervention beyond conversational interviews was employed. Subjects were left wondering why we were warning them of study-caused physical harms and dangers. In a multi-site study of women with end-stage HIV disease, two of three IRBs agreed with the researcher that written informed consent could be waived in order to avoid retaining the real names of subjects who were active IV drug users or sex workers. (A verbal consent process was allowed.) A third IRB required written consent based solely on the justification that their policy was *never* to waive written consent. No appeal was possible even though this IRB’s policy violates the intention of the federal guidelines to allow such protections.

Case Study: Qualitative, Prospective, and Retrospective Research with Patients Considering Physician-Assisted Suicide (PAS)

The sensitivity of clinical negotiations about appropriate EOL care, combined with the intensity of involvement between researcher and dying patient and family, yields unique ethical, in some cases also legal, concerns. A qualitative study of physician-assisted suicide that consisted of longitudinal interviews of patients seriously pursuing PAS and their family members illustrates these unique ethical and legal issues.²⁶

One goal of this study was to describe domains of quality medical care for this group of patients. For example, patients described how they would attempt to initiate discussions about PAS, only to find that their physicians would block discussion of this controversial topic. This finding identified the domain of “open discussions” as something highly valued by these patients. These data point to the need for physician skill in cultivating open discussions, rather than “blocking” particular topics. This finding would not have been possible in a study using a quantitative approach, for example asking patients to rate the adequacy of communication with their physicians. A quantitative instrument could not have produced the insight that physician communication skills were both insufficient in a positive aspect (cre-

ating safety for a delicate topic) and prominent in a negative aspect (blocking talk about PAS).

The researchers anticipated the possibility that in the course of conducting interviews they would discuss plans for PAS—an illegal activity—with patients. Existing regulations covering interviewers who were also clinicians (in Washington state) mandated that they should call a mental health professional if a subject displayed serious suicidal intent. Taken literally, this would have required that the interviewer-clinicians report every case, a situation which would have destroyed the ability of the researchers to study the phenomena of PAS, since one possibility under study was that physician-assisted suicide was different than suicide secondary to psychiatric illness. The IRB recognized this potential conflict, and the researchers and IRB agreed that clinician-interviews would only have to report patients with suicidality related to psychiatric illness. (The dilemma of when researchers should intervene for the protection of subjects is commonplace in qualitative research. Kayser-Jones faced this problem in study of the treatment of acute illness in nursing home patients near the end of life.²⁷)

The possibility that investigators would observe patients involved in illegal acts of PAS, or would learn of physicians or family members illegally assisting patients, raised concern that research participants could be subject to legal action if the identities of the subjects were discoverable. The researchers found that standard methods for protecting subject confidentiality were not adequate. Study interviewers could destroy records of subject names and phone numbers, but could not “erase” their memories, meaning that if they were subpoenaed they might be required by a court to provide identifying information about subjects. It was unclear how subject confidentiality could be protected if an organization or individual opposed to PAS decided to pursue the identity of research subjects through court action. The research team unsuccessfully sought a Certificate of Confidentiality from the Department of Health and Human Services, which was denied on the grounds that it was “unnecessary.”

This study illustrates how qualitative research can be valuable even if it does not make a specific claim of generalizability. The research described actual patients pursuing PAS; the study identified important aspects of doctor-patient

communication vital to understanding this phenomenon. These insights can guide future thinking about PAS, dying, and negotiated death even if they are not “generalizable” to all patients seeking PAS (for instance, to those people in Oregon where PAS is legal under certain circumstances), or all dying patients.²⁶

This study also illustrates the way in which informed consent works in a qualitative study. Consent is a process rather than a specific event. Subjects were provided with a written information sheet about the study, and verbal consent was obtained before each interview. The fact that the subjects appeared for subsequent interviews when they knew that they would be audiotaped indicates a tacit agreement to participate, but the verbal check-in before each interview served as another episode in an ongoing consent process. In this way, qualitative studies may embody ideals of informed consent not always met in other types of studies. However, the need to maintain subject confidentiality meant that paperwork for each encounter does not exist.

Recommendations

The current system of human subjects protection is inadequate for qualitative palliative care research studies. We acknowledge the need to be pragmatic in making suggestions for reform, but when IRBs judge qualitative studies using yardsticks developed for clinical trials, the procedures recommended can be at worst burdensome and counterproductive, and at best ineffective. Reform of the existing system, rather than drastic change requiring lengthy legislative battles, may be preferable. Most of our recommendations can be implemented within major legal change.

1. Patients near the end of life should not be defined as “vulnerable” or in need of special protections simply because of their closeness to death. Dying patients should not be excluded from research simply because they are near the end of life. Similarly, bereaved family members should not be defined a priori as vulnerable.

We question two commonly held ideas: first, that a patient’s terminal status justifies exposure to risks in a therapeutic experiment that would be inappropriate in a patient who is expected to survive, and second, that patients near the end of life are particularly vulnerable and thus in need of special protections. In fact, we assert that since dying patients invited to participate in research on

improving the quality of EOL care are unlikely to be influenced by a “therapeutic misconception,” one could argue that it is ethical to ask dying patients to accept greater risk of participation in this type of research than in another research domain, such as cancer chemotherapy trials.

Assumptions about the need to protect the bereaved from participation in research are just that, assumptions lacking validation, in need of empirical research. There is little systematic data to support requiring researchers to wait for specified time periods prior to contacting potential research subjects. Interviews, or other data collection strategies conducted with bereaved family members, present a challenging regulatory dilemma. Research is needed to identify the actual burden on family members from contact with researchers following a loved one’s death, yet current practice argues for protecting the bereaved by controlling researchers who seek to make contact with such potential informants. The “correct,” or least harmful moment to request consent is not known; additional research is needed.

2. Education for IRB members who review biomedical and social science research needs to include information about the unique attributes of qualitative research methodologies. Education about research ethics issues particular to EOL care—for example how to weigh and assess risk and benefit in patients who are terminally ill, and whether such subjects should be considered “vulnerable”—is also needed.

Educational materials should include information on the types and variety of qualitative research methods, explaining their unique contributions to the study of culture, social context, and meaning. Such materials can also provide examples of how regulations may be tailored to qualitative methods, for example discussion of when waiver of written consent is warranted.

3. IRB review of informed consent requirements in qualitative research must be flexible and tailored to the research design and methods employed.

Review need not follow “formulas” derived from other research settings. Specific considerations for different aspects of qualitative methods are suggested below:

a. *Observational research.* Observational research requires that the researcher observe behavior in a naturalistic setting, with as little intrusion as possible into ongoing events. It is more akin

to field biology than to experimental work in a laboratory. Observational research (termed “participant observation” in anthropology) requires specific procedures for the protection of human subjects in two domains, informed consent for such observations and considerations of privacy and confidentiality. A strict and inflexible interpretation of current regulations could preclude all observational research, requiring, for example, that the researcher announce him or herself whenever an unfamiliar person entered the social setting under observation, such as a busy clinic, and “stop the action” in order to obtain written informed consent. Clearly such requirements would make observational research impossible while providing little in the way of real protection from harm (primarily breach of privacy, depending on the setting) for those being observed. For example, in the case of observational research in a clinic with a stable staff, individuals can be approached prior to the start of the research and asked for consent. Practitioners who object could request that data not be collected about their behavior. In instances where observational techniques are intrusive—for example directly observing an interaction between a nurse and a patient in an exam room—fully-informed consent of an ill patient is essential, although written documentation may not be necessary. If a researcher is conducting participant observation with a hospice care team and occasionally encounters a patient while working on an inpatient unit, but does not interact with that patient, it may be appropriate for the IRB to waive explicit informed consent since the risk to the patient is minimal.

b. *Interview-based studies.* Qualitative studies employing interviews are sometimes automatically considered to qualify for “expedited review.” However this assessment should depend on the content of the interview and the specific conditions of the interviewee, as well as any status and power differences between researcher and subject.

IRBs unfamiliar with qualitative interview techniques may require researchers to submit exact questions ahead of time, which defeats not only the scientific purpose of open-ended questioning but eliminates the built in protections—subjects can be queried in language they understand and are comfortable with. IRBs familiar with qualitative techniques allow

researchers to submit the broad area of questioning for review, and do not require that exact questions be vetted in advance and then read verbatim from a text. When evaluating protocols, IRBs should consider plans developed by investigators that ensure interviewer training.

c. *Special issues in informed consent.* Since the concerns patients experience near the end of life often involve relationships with others, respect for persons may require looking beyond the individual when obtaining informed consent. Researchers and IRBs should not presume that the dying person, and that person only, controls access to other family members. If a study is targeted to family caregivers, this requirement may not be applicable.

Qualitative techniques extend the research “net” to individuals beyond the patient him or herself. IRBs should not assume that all subjects require the same procedures for consent. Some IRBs mistakenly believe that human subjects protections extend only to subjects who are patients and do not require that investigators consider physicians or other health professionals as human subjects in need of protection. For example, physicians in training may need special protection from their clinical supervisors when participating in EOL research that evaluates quality of care. One type of human subject in a study may require formal written informed consent, while in another instance, a less formal information sheet may be appropriate.

4. *Patients need not be explicitly identified as “terminally-ill” or “dying” in order to participate in EOL research. Withholding such a designation when conducting research should not be considered “deception,” requiring special consideration by IRBs or other regulatory agencies.*

In prospective research and observational studies, a major hurdle has been identifying patients near the end of life, and in finding appropriate terminology to describe them. Some IRBs have arbitrary requirements that consent documents include the actual title of a funded study. For example, if a study is titled “Communication Patterns in Patients Near the End of Life,” that language would be *mandated* on the official study description, or a special exception to excluding the title of the funded project would be required. It should not be considered “deception” if patients

and families are not told *explicitly* that they are being asked to participate in research because there is a high likelihood they are near the end of life. In fact, given the difficulty in making such predictions, and the widespread barriers and delays in physicians conveying such information to their patients,^{28,29,30} it may be inappropriate for researchers to broach this sensitive topic directly.

This approach is particularly important in pediatric research where the prediction of outcomes is much less certain, given the varied trajectories to death and the wide range of causes of death in the pediatric age group.³¹ With good training of interview staff, and the use of sensitive “what if” (or other indirect) questioning strategies, it is possible to avoid conveying harmful information to subjects. Subjects willing and able to confront their dying generally reveal themselves and thus can be questioned directly.

5. *Requirements that a patient’s primary care physician (or other health care provider) be notified about research participation, or that contact with patients must be controlled by a clinician gatekeeper, should be considered on a case by case basis, and not be deemed a necessary, routinely required practice.*

The work of Christakis²⁸ and others reveals that physicians are often reluctant to prognosticate, and tend to overestimate the likelihood of a patient’s survival, particularly if their relationship with that patient is a close one. Thus, traditional requirements that primary care physicians or other caregivers must give “permission” for their patients to be approached about research need to be reconsidered. (We believe this is a problematic requirement in many domains of research, but presents particular obstacles for EOL researchers.) In many situations, IRBs require that a patient must be invited to participate in a study by their current physician or caregiver. Contacts by others are considered an inappropriate breach of privacy. Such requirements may effectively halt certain types of research, for example studies seeking to improve EOL care for transplant patients, when physicians might be unwilling to consider the notion that their patients may not survive. The role of “gatekeepers” should be evaluated, and could be studied formally by comparing the outcomes of research designs that do and do not require such prior approval.

6. *The Department of Health and Human Services (DHHS) should add “sensitive” EOL research to its*

current listing of types of research that justify the department’s issuing a “Certificate of Confidentiality,” both to protect participants in research and to enable critical research to proceed.

By definition, research collected using qualitative techniques can never be completely “anonymized.” Unlike situations in which a researcher employs a mailed survey, a personal bond has been established between researcher and subject. Thus protection of subject privacy and confidentiality of research data may be particularly complex in qualitative studies. Examples of sensitive research warranting the issuance of a certificate of confidentiality are studies of negotiated death, including physician-assisted suicide, and the use of illegal drugs for symptom management.

7. *Peer reviewers, journal editors, and others should respect the need for making changes in narrative data in order to protect confidentiality.*

In order to respect the confidentiality of research subjects, including patients, family members, professional care givers, policy makers and other potential subjects in palliative care research, narrative data may need to be altered when published. Making small changes in narrative data in order to avoid disclosing a subject’s identity should not be considered a violation of research integrity because the compromise of data integrity is justified by the need to protect confidentiality. However, such data alterations should be commensurate with the potential risk to subjects’ confidentiality.

One model for allowing the intentional “alteration” of data in order to protect confidentiality is the presentation of complex family pedigrees in genetics research. Alterations must be disclosed in the publication, and authors must maintain the original data in order to assure that the modifications do not significantly harm integrity of the research. However, if a subject gives specific (and authentic) written consent for his or her identity to be used in publications, this request should not generally be overruled by IRBs or other authorities.

8. *Federal funding should be allocated to studies of “research ethics” in conducting studies relevant to care near the end of life.*

Efforts such as the current NIH funding of research ethics should be expanded, and fund-

ing by other appropriate federal agencies should be mandated. Private foundations should be encouraged to fund this work. One novel way of providing funding for work on palliative care research ethics would be to add this dimension to a conventional "request for applications," for example for research leading to improvements in symptom management. By building the research ethics questions into the call for proposals, researchers can be encouraged to incorporate innovative research ethics questions into their protocols.

9. *IRBs, with the support of OHRP, should be empowered to grant "waivers" to allow researchers to experiment with novel mechanisms of consent or means of contact with subjects.*

For example, if a researcher wished to conduct a study using an entire family as the unit of analysis, an IRB could grant a waiver of individually obtained consent, and allow the researchers to present the study to an entire family unit, with all members signing a single consent document (if written consent were the appropriate documentation). Similarly, if a researcher wished to study EOL decision making in an ICU using direct observation, an IRB could allow a waiver of individual consent, perhaps substituting other methods of informing hospital staff and patient's families about the researcher's goals.

10. *Funders of EOL research should be encouraged to allow investigators to build in to their research budgets the cost of follow-up services for subjects (primarily family members) who agree to participate in potentially stressful research.*

Research protocols should include funding for necessary follow up services for family members or other survivors. Qualitative interviews, because they probe subjects for their reactions to events and experience, may elicit intense reactions. Simply disclosing this risk to subjects in advance may meet the letter of the law but is inadequate when preventing or minimizing harm may be possible. Access to bereavement or "debriefing" could protect subjects from unintended harm, and is an acknowledgement of the subjects' valuable contribution to the research. The provision of funding for such services parallels approaches that have been used in human genetics research.

11. *IRBs should ask that researchers demonstrate an awareness of potential conflicts likely to occur during observational research, and to develop specific plans about when and whether it is appropriate to intervene in order to protect the welfare of subjects.*

12. *The Office of Human Research Protection within DHHS, with input from its policy development arm, (formerly) the National Human Research Protections Advisory Committee, should evaluate the final recommendations proposed by this NINR-sponsored workshop, and consider adopting the recommendations, using them as "guidance" for the IRBs they oversee.*

Guidance for IRBs on the review of EOL studies (including research using qualitative methods) should include recommendations about the importance of membership of social scientists on review panels.³²

Conclusion

Qualitative research has the potential to contribute important new knowledge to care near the end of life, but IRB members are often poorly prepared to evaluate these studies and are hampered by inappropriate policies. Protections needed for subjects in qualitative studies differ significantly from those required by subjects in clinical trials. Revised policies should be based on empirical research that takes into account the unique attributes of qualitative methodologies. Gaining this knowledge will require that IRBs exercise judgment and flexibility in weighing the benefits and harms of innovative research.

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