Hospice Research Basics: A Manual for Hospice Agencies

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# Table of Contents

1. **What is research?**
2. **Why do research?**
   - Assessing why you want to do research
   - Types of research
3. **Getting involved in research**
   - Ethics
   - Roles
4. **Establishing and maintaining systems**
   - Role of committee
   - Forming an agency Review Committee
   - Sample review forms
   - Policies and procedures
   - Research files, confidentiality and HIPAA
5. **Evaluating proposed research**
   - Assessing feasibility/practicality
   - Assessing impact on patients and families
   - Assessing protection of human subjects
   - Assessing public policy implications
   - Assessing impact on agency staff and volunteers
   - Assessing potential costs of research (time, resources, money)
6. **Working with researchers and students**
   - Project design – hospice input
   - Tracking systems
7. **Community-academic partnerships**
   - Identifying and forming partnerships
   - Working with academic partners
8. **Working with an IRB**
   - Description of the IRB
   - Advantages and disadvantages of working with an IRB
   - Deciding if IRB review is needed
   - Preparing an IRB application
9. **Resources**
1. What is Research?

Defining research within the context of hospice and palliative care settings is challenging because there is often a nebulous distinction made between “quality improvement” (QI) studies and “research.” So how does one determine which projects are “research” and which ones are QI? And is such a distinction necessary at all? For the purposes of this manual, we will be using the federal government’s definition of research:

“Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102 (d)

Some QI projects will be included within the scope of this definition. It is up to individual hospice agencies to determine whether their review processes will differ for research and QI projects.

“Research is formalized curiosity. It is poking and prying with a purpose. It is a seeking that he who wishes may know the cosmic secrets of the world and that they dwell therein.” -- Zora Neale Hurston

2. Why do Research?

The primary mission of hospice agencies is to provide quality end-of-life care to patients, families and communities. For many hospices, that mission extends to influencing public policy and practice. Why should hospice agencies initiate or participate in research?

- To answer a question that has arisen from the field (i.e. do patients who receive therapeutic touch report lower pain levels than those who do not receive therapeutic touch?)
- To discover possible solutions to a problem or dilemma facing an organization (e.g. what factors are associated with long-term staff retention?)
- To foster a relationship with an academic or community partner (i.e. participation in a collaborative demonstration project regarding inpatient hospice units in a hospital setting)
- To stimulate innovative “out-of-the-box” thinking (i.e. focus group project on ways to revolutionize hospice care)
- To improve systems of care (i.e. what are the optimum interdisciplinary staff mix and staffing ratios?)
- To provide data to illustrate areas of opportunity/potential growth in an organization (i.e. needs assessment of community regarding end-of-life service needs)
- To provide data to educate staff about a particular issue (i.e. palliative chemotherapy and radiation usage among hospice patients)
• To position the organization as a leader in the field (i.e. national demonstration projects testing a service or service delivery method)

• To inform quality improvement projects (i.e. focus groups with current and bereaved caregivers regarding caregivers’ feedback about hospice services)

• To demonstrate/evaluate the effectiveness of current practice (i.e. to what degree are visits by hospice nurses, social workers, home health aides and chaplains meeting the self-identified needs of hospice patients and families?)

• To compare potential approaches to an issue or problem (i.e. compare retention rates of nurses in two groups – those who participated in an intensive residency program at the hospice agency versus those who did not).

Assessing Why You Want to Do Research
Before beginning a research project, hospice agencies may want to ask themselves the following questions:

• Has this research already been done somewhere else? If so, why do we want to do it again? What lessons can we learn from previous research on the topic? (A thorough literature review can help you begin to answer these questions.)

• Do we need to do research to answer the question we are asking, or do we think we already “know” the answer? If we think we already “know” the answer anecdotally, what is the benefit of researching the question in a formal manner? (While anecdotes are valuable, they may not be generalizable and therefore may only provide insight under certain conditions).

• If we are doing the research to influence public policy, what are the intended outcomes?

• Is there a way we could answer this question without doing a research project?

• Are we doing this research to position ourselves as a “leader” in the field? If so, why? What do we hope will come out of this beyond name recognition?

• Is research the best way to accomplish our goal if organizational change is the intended outcome?

• Why do we want to undertake this research project at this point in time? Is this a good use of resources for our organization right now?

• What type of research is needed to answer the question at hand?

• Does this research pass the “so what” test?

• Is this research something that is relevant for our mission, staff, patients and/or families?

• Is this research feasible in our setting?

• Is the research design sufficiently strong to be able to address the research question?

• Does this research sufficiently address issues of human research subject protection?

Types of Research
In conducting research, hospice agencies may utilize a variety of types of research. In selecting a particular approach, researchers determine which method provides them with the needed information in the most efficacious manner. If they do not have someone with this expertise on
staff, hospice agencies may want to consider consulting with a research expert in designing and implementing a research project if they are not familiar with the application of these methods.

- Descriptive Method: Descriptive research is used to describe a behavior, condition, or situation. Data collection is conducted using questionnaires, observations and/or interviews. (Example: do attitudes about hospice differ between community residents over 65 and community residents ages 20-30?)

- Correlational Method: The purpose of correlational research is to determine the relationships between variables. (Example: is there a relationship between pain scores and opinions of hospice?)

- Causal-Comparative Method: This type of research is often used to determine whether there are cause-effect relationships in a behavior or a condition in groups of individuals. (Example: do high pain scores cause patients to have a more negative opinion of hospice?) However, it’s almost impossible to “prove” cause and effect. The example given might demonstrate an association, not true cause and effect.

- Experimental Method: This research method is used to support or refute a hypothesis. Experimental research typically has control and experimental groups. (Example: hypothesis -- using aromatherapy in cancer patients has no effect on pain scores.) A control group is the group to which you compare an intervention, so it is typically a group receiving usual or “standard” care. An experimental group typically receives usual care plus an intervention, or an intervention in place of usual care. When using the experimental method, it’s important to assign participants/subjects to intervention and control groups randomly. “Blinding” may be used to keep the researcher from knowing whether participants are in the treatment or control group.

- Historical Method: Historical research is used to predict or explain phenomena. The researcher analyzes documents and talks to “witnesses.” The researcher then formulates conclusions. (Example: What is the history of the Hospice Medicare Benefit?)

- Naturalistic Method (Qualitative): This type of research, often referred to qualitative research, seeks to answer “why” questions and to understand the “meaning” of an experience to the target group. The researcher strives to become part of the setting being studied and tries to write from the perspective of the participants. One limitation of this type of research is the fact that it may not produce results generalizable beyond the specific group studied. (Example: why do health care professionals come to work for hospice?)

“The acquisition of knowledge is the mission of research, the transmission of knowledge is the mission of teaching and the application of knowledge is the mission of public service.” -- James A Perkins, President, Cornell

“The trouble with research is that it tells you what people were thinking about yesterday, not tomorrow. It’s like driving a car using a rearview mirror.” -- Bernard Loomis, toy manufacturing executive
3. Getting involved in research

Ethics

“Reading about ethics is about as likely to improve one’s behavior as reading about sports is to make one into an athlete.” -- Mason Cooley, U.S. aphorist

Summarizing research ethics succinctly is a challenging task. Most hospice agencies are already well versed in the principles of ethics from their daily work with patients and families, but a review of these ethical principles as they pertain to research may prove helpful. Ethics is about balancing the rights of one individual with the needs of others, and is an invaluable component of a hospice research program.

THE ETHICAL PRINCIPLES OF THE BELMONT REPORT

1. Respect for Persons acknowledges the dignity and autonomy of individuals, and requires that people with diminished autonomy be provided special protection.
2. Beneficence requires us to protect individuals by maximizing anticipated benefits and minimizing possible harms.
3. Justice requires that we treat subjects fairly.

Each of these principles carries strong moral force, and difficult ethical dilemmas arise when they conflict. A careful and thoughtful application of the principles of The Belmont Report will not always achieve clear resolution of ethical problems. However, it is important to understand and apply the principles, because doing so helps to assure that people who agree to be experimental subjects will be treated in a respectful and ethical manner (Taken from Guidelines for the Conduct of Research Involving Human Subjects at The National Institutes of Health, 3/1995).

Note: Some bioethicists add “non-maleficence” (as a subset of beneficence) to their ethical principles, although non-maleficence is not expressly listed as part of the Belmont Report. Non-maleficence means not doing evil in Latin.

Roles

There are many ways in which hospice agencies can participate in or support end-of-life research. Before becoming involved in research, hospice agencies should decide what role they would like to play in the research process. Few hospice agencies have a full-time researcher on staff so for many hospice agencies, collaborative research or the use of external research consultants may prove to be the easiest way to begin conducting research. The roles hospice agencies can play in conducting research include:
Data collection site: As a data collection site, a hospice agency provides researchers access to their population of staff, patients, and families (depending on the study being conducted.) Typically, a data collection site has little control over the study, and minimal input into analysis and reporting of results, although this can often be negotiated ahead of time with the researchers. A hospice agency may be a data collection site in a single- or multi-site study.

Partner/collaborator: As a partner/collaborator in a research study, a hospice agency works together with another hospice agency, a student, a college/university faculty member, or other researcher to design and implement a research study. As a partner/collaborator, a hospice agency has more control over the focus of the study and can help shape how, where and when results of the research are disseminated.

Principal Investigator: As principal investigator, a hospice agency leads the research by identifying a topic, designing the study, collecting the data, analyzing the data and disseminating results. The actual principal investigator role is usually assumed by one individual at a hospice agency, and in the case of federal grants, the principal investigator is typically someone with an advanced degree (usually a Ph.D. or M.D). While the role of principal investigator carries with it increased autonomy and control over the research process and products, it also carries with it tremendous responsibility. The principal investigator is responsible for ensuring the rigor of the research, the integrity of the data collection process, and the accuracy of conclusions drawn. The principal investigator may be a contracted researcher to the hospice agency.

Consultant: As a consultant, a hospice agency provides input and feedback to another researcher, usually on a paid basis under a grant. The role of consultant is to provide expertise in a particular area to the researchers. Consultants typically have little control over analysis and dissemination of results, although hospice agencies may be called upon to provide consultative services in the interpretation of results within the context of the field of end-of-life care.

Hospice agencies have the opportunity to decide which role(s) the agency will play in conducting research and this may vary, depending on the project. Hospice agencies should assess their goals, skills, and organizational capabilities before deciding which role fits their needs sufficiently. Many hospice agencies participating in research have found that assuming the role of principal investigator works best for small internal projects (rather than large-scale federally-funded projects) as the hospice agency begins to develop its research program. Federal funding agencies (like the National Institutes of Health) are unlikely to fund hospice agencies with little or no experience conducting research, so if securing federal funding is an agency goal, it may be wise to consider partnering with a college- or university-based researcher or other end-of-life researcher with an established track-record in conducting research.

For hospice agencies new to research, partnering with a researcher with experience may prove to be beneficial, but it is also important to recognize the expertise that the hospice agency brings to that partnership. While an individual may be a luminary in the field of academic end-of-life research, they do not necessarily have experience with end-of-life care or settings. Thus, the experience and perspective the hospice agency brings to the collaboration is essential.
In collaborative research projects, hospice agencies may want to consider negotiating the terms of the partnership, in writing, before commencing the research so that there is clarity regarding roles and responsibilities of the parties involved. While this may seem to be a formality, putting the partners’ mutual understandings of the collaborative relationship on paper helps to facilitate a smooth working relationship with fewer misunderstandings.

**Hospice agencies may want to clarify the following before agreeing to participate/collaborate in a research project:**

- If the project will be grant-funded, who will write the grant proposal? Who will manage the funds? Who will be responsible for oversight and reporting of results to the funding agency?
- Who will manage the data collection activities of the research project? Will an external researcher handle this, or is the hospice agency expected to oversee data collection on site? How much time is anticipated to be required for data collection?
- What is the researcher’s goal in conducting this study? (e.g. If the goal is to change or influence public policy, how might this impact patient/family access to quality hospice services?)
- Which hospice agency personnel are expected to work on the project, and for how many hours?
- What funding does the researcher currently have for this research project? What funds are available for the hospice agency to offset the cost of supporting the research being conducted?
- If the research requires Institutional Review Board (IRB) approval, who will complete the IRB application and reports/updates? (See page 35 for detailed information about IRB’s.)
- Will the hospice agency have the right to review any and all publications and presentations before dissemination?
- Is there an option for the hospice agency to co-author articles and other publications jointly? If so, whose names go on the publications?

4. Establishing and maintaining systems

Before a hospice agency begins the process of conducting or participating in research, agencies may want to consider putting specific internal systems in place for the purpose of tracking research requests, evaluating potential research projects, designing new research projects, applying for and managing grant funds, and disseminating results.

**Role of Agency Review Committee**

Each hospice agency should decide what functions they want the research committee to provide. A sample purpose statement might read: “The review committee at XYZ Hospice will review research projects to ensure that the proposed research is potentially beneficial and minimally harmful to patients, families, staff, and the organization.”
Tasks of the committee may include:
- Establishing review criteria
- Reviewing research proposals
- Providing feedback to external and internal researchers
- Suggesting ways to adapt proposed research to hospice systems of care

Forming an Agency Review Committee

- An agency review committee might consist of:
  - Hospice CEO/administrator
  - Quality manager/director
  - Board members
  - Clinical staff members (representing the diversity of the IDT)
  - Community representatives (perhaps bereaved caregiver)
  - Program directors

For small agencies, the senior leadership team may be appropriate. When forming an agency Review Committee, let prospective members know the purpose of the committee and detailed information about what will be expected of them in terms of responsibilities and time commitment. Prospective members should be individuals who have had experience with the systems and standards of the hospice organization. A few members of the review committee should have a basic understanding of research methods as well. The organization will need to determine whether it would like the committee to meet on a regularly scheduled basis (for example, quarterly) or whether the committee should be convened on an as needed basis either by phone, e-mail, or in person as proposals are submitted throughout the year. For an organization new to research, it may make the most sense to convene the committee as needed until the volume of proposals increases.

Sample Review Forms

XYZ Hospice
Research Review Packet
Internal Research Review Committee
Summary Sheet
(To be completed by person in charge of research at your agency before distributing to review committee)

Title:
Investigator:
Supervisor:
Affiliation:

Purpose of the Study (Please state research question):

Timeline/Schedule:
- Start date
- End date

Protection of Human Subjects:
- Date IRB submitted:
- Date IRB approval received:
- Name of IRB:

Potential Policy Implications:

Potential Impact on Agency Staff and Volunteers:

Potential Impact on Patients and Families:

Potential Cost of Research:

Implementation Plan:

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Internal Review Committee Members (list names):

Instructions: Please reply via e-mail that you have reviewed the attached research proposal in the following review categories. (If your position is listed below a particular category (or categories), please make sure your review is focused primarily on this area). If you do not find the proposal satisfactory and feel it should either be revised or rejected, please state the reason(s) in your e-mail. Thank you.

Protection of Human Subjects
- (insert names of appropriate staff members)
Sample Policies and Procedures

Hospice agencies involved in research should have a set of policies and procedures for research. Written policies and procedures help to remove any ambiguity about the review process and help to guide the agency in carrying out research.

Sample #1

**POLICY:**

The XYZ Hospice requires a formal review and approval process before research may be conducted.

**PURPOSE:**

- To provide for the rights of the research subjects via a formal review.
- To improve patient/family care through support of quality research.
- To provide an opportunity for professionals/students to conduct research.
- To ensure that research projects support the vision and mission of the agency.

**PROCEDURE:**

1. All requests to conduct research shall be formally submitted in writing to ___________. This application is required of everyone - employees, students, and independent researchers. See Procedure for Obtaining Research Approval.
2. All research proposals shall be forwarded to the CEO/vice president/research director for preliminary review.
3. Research proposals shall then be forwarded to the Research Committee for discussion and the formulation of specific recommendations regarding the research project. The Research Committee meets quarterly, and proposals will be reviewed by the Research Committee at these scheduled meetings only. Researchers will be informed of the next scheduled Research Committee meeting.
4. When required, the proposal will be submitted to the University of ABC Institutional Review Board for approval.
5. When a research proposal is approved, ______________ shall designate a staff member to serve as liaison between the agency and the researcher.

6. Written reports of the research findings shall be submitted to the Research Committee within the time frames specified in the research proposal.

7. All manuscripts must be reviewed by the CEO prior to submission for publication. Investigators are asked to please send a copy of their manuscript to the CEO at least one month before their submission deadline. Hospice reserves the right to determine whether or not the organization shall be acknowledged in publications containing information secured through the association of XYZ Hospice.

8. XYZ Hospice reserves the right to claim joint ownership of all collected data related to research projects approved by the organization, unless other agreements are reached with the researcher prior to the commencement of their research.

Sample #2:

XYZ Hospice
Procedure for Obtaining Research Approval

1. Schedule an appointment with the ______________, to discuss your research proposal. Appointment may be made by calling ###-####.

2. All research proposals shall include the following: (Please limit to 10 pages maximum).
   - Cover Sheet
   - Purpose of the Study
   - Hypotheses or Research Questions
   - Benefits of the Study to Individuals or Humankind
   - Description of Research Methods
   - Time Line for Study (including review dates for Research Committee at specific intervals.)
   - Reporting Methods/Time Frames
   - Plans for Publishing Results (internally & externally)
   - Copy of Informed Consent Forms
   - Copy of Data Collection Tools
   - Curriculum Vitae of All Investigators in Study

3. Submit a copy of the entire proposal to ______________ or at least forty-five (45) days prior to the Research Committee meeting in which you would like your proposal reviewed. The committee meets quarterly and as needed.

4. If requested, plan to attend the Research Committee meeting when proposal is reviewed to answer questions about the study.

5. Anticipate notification of approval or disapproval of research proposal within two (2) weeks of the Research Committee meeting.
6. Upon completion of the study, a written report of findings must be submitted to _____________. This report is due within the time frame identified in the research proposal.

7. Research findings shall be publicized internally and/or externally as specified in the research proposal.

8. If the hospice is to be identified in any publication, the Executive Director requests the right to review the manuscript prior to submission for publication.

NOTE: XYZ Hospice reserves the right to claim joint ownership of all collected data related to research project approved.

Research Files, Confidentiality, and HIPAA

Hospice agencies need to maintain files of all documents pertaining to research projects. These files must be stored in a locked area (e.g. file cabinet) and should include documents such as grant proposals, research contracts, completed surveys and questionnaires, signed consent forms, and tapes and transcripts of interviews and focus groups. Hospice agencies should pay special attention to the Health Insurance Portability and Accountability Act (HIPAA) requirements pertaining to research, and should insure that their agency treats research information and documents in a manner that best protects the privacy of those involved. For more information about HIPAA, see the Department of Health and Human Services’ Office of Civil Rights web page at www.hhs.gov/ocr/hipaa.

5. Evaluating proposed research

Before a hospice agency agrees to participate in a research study (or before a hospice agency writes a grant proposal for conducting research), the proposed research should be evaluated thoroughly. This can be somewhat intimidating if hospice staff members are unaccustomed to evaluating research, especially if the researcher holds advanced degrees and presents themselves as an “expert” in the field. However, all hospice agencies have the ability to evaluate research on the following criteria, and should do so for each research project they consider undertaking. The following are questions hospice agencies can ask themselves in evaluating research proposals. Utilizing this information, agencies can then determine whether undertaking a particular research project is in the best interest of the agency, staff, and patients and families.

Assessing Feasibility/Practicality

- Does this project seem “do-able”?
- Does the researcher have a realistic understanding of the realities of conducting research in the hospice setting?
- Is the proposed timeline reasonable and does it allow for flexibility?
- Does the researcher have funds to support the proposed research activities at the hospice, or will the hospice agency provide time, services, space, etc. “in-kind”?
Assessing Impact on Patients and Families

- Is the proposed research respectful of the unique nature of the end-of-life journey in its methodology and implementation? (For example, does the research recognize that asking an imminently dying person to complete a one-hour survey/assessment may be an undue burden on someone who may prefer to spend their time with family and friends?)
- How might the proposed research impact how patients and families view hospice?
- How might the proposed research change the hospice experience of participating patients, families, and community members?

Assessing Protection of Human Subjects

- Has the researcher included protections for participants’ confidentiality and privacy?
- Does the research proposal contain detailed information about how informed consent will be sought, and by whom?
- Does the researcher intend to seek IRB approval of the research? If so, when and where?
- Is the research study designed in a way that makes it clear to participants that participation is voluntary and declining to participate would in no way effect services? (For example, are the patient care teams being asked to seek informed consent? If so, care must be taken to ensure that hospice patients and families do not consent to the study merely out of a sense of “obligation” in return for good care).
- Does the research proposal include samples of the informed consent form?

Assessing Public Policy Implications

- How will patients and families ultimately benefit from this research?
- How will hospice agencies ultimately benefit from this research?
- What is the stated goal/purpose of the research?
- If this goal/purpose is achieved and becomes a headline in The New York Times, what impact will the study have on hospice agencies nationwide?
- If this goal/purpose is NOT achieved and this becomes a headline in The New York Times, what effect will the study have on hospices nationwide?
- What could potentially go “wrong” with this research?
- What could potentially go “right” with this research?
- How would either of these possibilities impact hospice care?
- How might the proposed research impact hospice reimbursement models?
- What would critics of hospice do with the results of this study?
- What would supporters of hospice do with the results of this study?
- What could hospice agencies do with the results?

Assessing Impact on Agency Staff and Volunteers
• How much time will clinical staff need to spend on the proposed research?
• Will time at the bedside/"direct patient care” be negatively or positively affected by the proposed research?
• How much time will administrative and support staff need to spend on the proposed research?
• How will volunteers be impacted by the proposed research?
• How might volunteers interested in research be used to assist in the research study (for example, data entry)?
• How might participation in the proposed research improve patient care?

Assessing Potential Costs of Research

• How will the hospice agency be compensated for the time it spends coordinating and participating in research activities?
• How will the hospice agency be compensated for the time that clinical staff is spending on the research rather than on direct patient care?
• What program/agency resources will need to be provided in order to participate in the proposed research project? (For example, where will research staff sit while at the hospice? Do they need their own space, desk, computer, phone line, etc.?)
• If the hospice agency had to “replace” the staff involved in research, how much would this cost?
• What value does the agency place on the proposed research? The agency may be more willing to commit agency resources (in-kind or otherwise) to the project if the research seeks to answer a question the hospice agency deems to be a high priority.
• Does the formal contract reflect in detail the entire scope of responsibilities the hospice is committing to and the compensation the hospice agency will receive for its participation in the proposed research?
• What benefits does the proposed research provide to the agency?

“Almost all scholarly research carries practical and political implications. Better that we should spell these out ourselves than leave that task to people with a vested interest in stressing only some of the implications and falsifying others. The idea that academics should remain “above the fray” only gives ideologues license to misuse our work.” – Stephanie Coontz, U.S. social historian.

6. Working with researchers and students

Researchers are a good resource for hospice agencies in that they often have the skills needed to explore questions of interest to hospice agencies through rigorous research. Students can be also a tremendous resource for hospice agencies to support research projects. Students often bring fresh ideas, innovative research methodologies, and tremendous enthusiasm to research projects. Many student research projects are unfunded -- students look to hospice agencies to provide
access to their staff, patients and families without compensation. However, students (as well as established researchers) may lack experience conducting research in hospice settings and thus will need mentoring and guidance in designing a research project that will be feasible and beneficial in the hospice setting.

**Project Design**

Ideally, hospice agencies will have input into the design of the research project early in the planning process. Often, “fully-formed” research projects are proposed to the hospice agency with few opportunities for input from hospice staff. As hospice agencies participate in research and begin to see the value of early input into research projects, many hospice agencies begin to require that researchers and students involve them at the earliest stage of the planning process. While researchers and students have valuable academic training in their particular disciplines, they may lack the “real-life” experience of hospice professionals who provide direct care for persons at the end of life. Early collaboration between researchers/students and hospice agencies results in a better quality research project that takes into account the realities of hospice care in the design of their research methodology. Some of the lessons hospice researchers have learned (through experience) include:

- Collecting extensive data during the admission visit is often inappropriate and/or impractical because of the emotional nature of the amount of information patients and families are asked to absorb. (The exception to this would be chart review of data already routinely collected during the admission visit).
- Patients and families may lack the energy or desire to complete lengthy surveys or questionnaires. Data collection works best with hospice patients and families when there is minimal intrusion into their lives. Time is precious to hospice patients and families, therefore respectfully minimizing burden on research subjects in the hospice setting is critical. Clinical staff members are tremendously busy. Minimize data collection responsibilities for clinical staff members and avoid burdening them with the task of data collection altogether if possible.

**Tracking Systems**

In working with students and researchers, systems are incredibly important to keep track of the research process and make sure the public policy implications of the research are assessed and monitored by the hospice agency. Some hospice agencies require “right of review” for all research conducted at the hospice before anything is published. It is good practice to request that the hospice review the final document even if the hospice agency does not require this. This can be a delicate issue with researchers accustomed to the concept of “academic freedom.” Additionally, hospice agencies should not ask that research results be altered before publication. However, hospice agencies, as partners in research, have the right to ensure that research in which they have collaborated contains a fair and accurate interpretation of the results and incorporates salient information about hospice care to illustrate the importance of various results. Hospice agencies are under no obligation to participate in research. Hospice agencies need to
have full knowledge that every research study has the potential to impact hospice care, both positively and negatively.

Two ways in which hospice agencies can monitor the research process are by the use of contracts/agreements between hospice agencies and researchers, as well as timesheets for staff and students working on research projects. Contracts should clearly delineate: (1) who will be listed as co-authors and co-presenters for publications and presentations, (2) who has the final right of review for publications and presentation, (3) what the responsibilities of the researcher/student and hospice agency are, (4) what compensation will be received for research services, and (5) how (and in what venues) results will be disseminated. Timesheets provide documentation of personnel costs of the research project.

7. Community-academic partnerships

When a hospice agency and a college or university work together in a formalized way toward a common goal, they are a community-academic partnership at its most basic level. Community-academic partnerships can be an effective way for a hospice agency to become involved in end-of-life research.

Working with Academic Partners
The world of hospice care differs dramatically from the world of academic teaching and research but the two can collaborate in meaningful partnerships if there is a mutual understanding of what drives each system. Within the typical academic setting, research may be seen as a way of testing a theory, gaining new information about a phenomenon, or refuting previously conducted research in a particular area. College and University researchers enjoy the benefits of what’s often referred to as “academic freedom,” defined as: “the right of scholars…to teach and discuss, to carry out research and to disseminate and publish the results thereof, to express freely their opinion about the institution or system in which they work, to be free from institutional censorship, and to participate in professional or representative academic bodies without fear, persecution, harassment, intimidation and violence, without discrimination and without constriction by prescribed doctrine.” (University of Chicago “Scholars at Risk”(2002) http://scholarsatrisk.uchicago.edu)

For a college or university researcher, academic freedom means that there are virtually no limits on what topics can be researched as long as such research is ethically conducted. Hence, the concept of academic freedom has become one of the keystones of scientific progress. However, hospice agencies conducting research are in a different position. For example, it might not be prudent for a hospice-based researcher “to express freely their opinion about the institution or system in which they work” in an article or other publication if such an opinion could harm the hospice agency. Likewise, hospice agencies may choose not to engage in research aimed at, for
example, eliminating the hospice Medicare benefit. This is not to say that hospice agencies should not research controversial or “difficult” topics.” Rather, it is essential that hospice researchers be cognizant of the potential ramifications of their work.

These differences may, at times, present some opportunities for growth for both partners. It is essential that hospice agencies retain their focus on the patients and families they serve and, at all times, that they prioritize the needs of the patient and family over the needs of research. Unlike a university whose primary mission it is to teach and to conduct research, the mission of a hospice agency is to provide quality end-of-life care. If research in any way interferes with the hospice agency’s ability to carry out its primary mission, than said research should be seriously reconsidered.

**Identifying and Forming Partnerships**

In exploring the possibility of utilizing community-academic partnerships in conducting research, hospice agencies may want to ask themselves the following questions:

- What are we looking for in a partnership in terms of skills (i.e. a skilled “number-cruncher,” skilled individuals to do focus groups, skilled individuals who can assist us in getting a grant, etc)?
- What are the short-term and long-term goals for the partnership?
- Does the hospice agency currently have established relationships with any educational institutions?
- What faculty members and/or students have previously worked with the hospice agency (for internships, research projects, etc)? What institutions were they associated with?
- What universities or colleges are located near the hospice agency?
- What end-of-life care researchers are located near the hospice agency?

Using this information, a hospice agency can then begin the process of identifying or establishing a community-academic partnership to assist them in accomplishing their research agenda. Steps to consider before forming (and/or formalizing) a community-academic partnership include:

- Investigate the academic institution and individual researchers before you contact them. (Information sources might include the Internet, reputation in the community, literature searches, etc.) Do the research interests of the individual somewhat match the agency’s interests? Does the academic institution have a strong reputation in any particular area of research?
- Identify the specific individual you would like to meet with from the academic institution. (This might be a faculty researcher, academic program director, or dean of a college of nursing, social work, medicine, etc.)
- Contact the individual to explain who you are and why you would like to meet with them. Mention that you are familiar with their work in XYZ area of research and that you would welcome the opportunity to talk to them about their work as it pertains to end-of-life research. Make it easy for the
individual to meet with you – offer to meet them at their office on campus. (For a future meeting, you can invite the individual to your hospice agency for a tour).

- Keep the meeting brief and focused. Be prepared with a list of the agency’s research goals/objectives as you speak with the individual.
- Be clear about what you are asking of the individual and their institution – do you want help writing grants, developing research methodology, etc?
- Identify specific benefits the collaboration/partnership would provide to the academic institution – the opportunity to work collaboratively with a leader in end-of-life care, opportunities for student researchers, access to a population of individuals at the end of life, etc.
- If the individual is interested in discussing the possibility of working together with your hospice agency, set another meeting date. At that time, go into greater detail about the collaborative relationship.
- Consider establishing an interdisciplinary community-academic partnership. Perhaps convene end-of-life practitioners, as well as researchers in social work, medicine, nursing, pharmacy, spiritual/religious studies, physical therapy, complementary and alternative medicine, etc. to form a “research-working group.”

“A little knowledge that acts is worth infinitely more than much knowledge that is idle.” -- Kahlil Gibran

8. Working with an IRB

Description of the IRB
As defined by federal regulations, an Institutional Review Board is “a specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.” According to the Office of Human Research Protections (a division of the U.S. Department of Health and Human Services, “The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB [Federal Policy §___.112]. The IRB also functions independently of but in coordination with other committees. For example, an institution may have a research committee that reviews protocols to determine whether the institution should support the proposed research. The IRB, however, makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected.”
Most IRB’s are housed in or affiliated with a college or university or a free-standing research center. For hospice agencies interested in conducting research, it may be possible to use a local college or university IRB for review and approval of research protocols. It is important to remember that IRB approval does not mean a particular research project is research in which your hospice agency “should” participate. IRB approval simply means that a particular research project has been reviewed by the IRB and has been found to offer adequate protection of human subjects. Hospice agencies still need to conduct their own reviews of research proposals to ensure that the proposed research is in the best interest of the agency, staff, patients, families, and the community.

Because most IRB’s are hospital-, college- or university-affiliated, it may be necessary for hospice agencies to partner with a faculty member willing to serve on research projects and co-author the IRB application. Some IRB’s may not be willing to process applications from individuals outside of the institution.

**Advantages of Working with an IRB**

When a hospice agency requires IRB approval of its research projects, it is demonstrating to the research community, staff, patients, and families that the organization takes the potential risks of research seriously and works to ensure staff, patients and families are adequately protected against such risk. Because many agencies do not have a research administrator or Director of Research on staff, the use of the IRB ensures that someone familiar with federal regulations regarding the protection of human subjects reviews each research project and judges the project to offer adequate protections for participants. The disadvantage of working with an IRB is the length of time it takes to process an IRB application. While most large universities have IRB’s that meet monthly, it may take anywhere from a month to 6 months to receive IRB approval, depending on the number of IRB applications the IRB is reviewing at the time. Hospice researchers should submit the IRB application as early as possible, preferably 3-4 months before the scheduled start-date of a particular research project.

**Deciding if IRB Review is Needed**

The federal regulations apply "to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency" that has adopted the human subjects regulations [Federal Policy §101(a)]. For hospice agencies not receiving federal funding to conduct research, IRB approval may not be required of their research. However, some hospice agencies have taken the step of requiring IRB approval for all research projects because of concerns regarding human subjects protection. If the goal is to publish the results of your research, most journals now require a statement of IRB review and approval. Some research may be exempt from the regulations requiring IRB review [Federal Policy §101(b)]. Examples of exempt research include:
“educational testing and survey procedures where no identifying information will be recorded that can link subjects to the data, and disclosure of the data could not reasonably place the subjects at risk of civil or criminal liability or be damaging to the subjects’ financial standing, employability, or reputation”

“research that involves the use of existing data, documents, or specimens, where no identifying information will be recorded that can link subjects to the data.”

(You may still need an IRB to grant “exempt” status. If you have any questions regarding whether the proposed project is in need of IRB review, contact your IRB for guidance.)

Preparing an IRB Application
Identify the primary contact person for the IRB. Colleges or universities may have copies of the IRB application that can be downloaded from their websites. Follow the instructions given for the IRB application exactly. Include a copy of all researchers’ Curriculum Vitae (c.v.) and copies of all data collection forms, consent forms, recruitment tools (fliers, mailings, etc). Remain in contact with the IRB (through the college or university’s Office of Research Compliance or Institutional Research) to ensure that you can respond to their need for additional documentation as quickly as possible. Once IRB approval is received, make sure to keep the IRB posted, in writing, of any changes you make to the research protocol or data collection tools. Once a research project has received IRB approval, make sure the consent forms used in the study bear the IRB stamp and study approval number. IRB’s also require annual review and reporting.

Hospices participating in federally-funded research being coordinated out of another site may need to complete a “federal-wide assurance” if they are not seeking their own IRB review. A federal-wide assurance indicates that the hospice will abide by the requirements of the IRB that did review and approve the research project. Information about federal-wide assurances can be found at http://www.hhs.gov/ohrp/assurances/assurances_index.html.

9. Resources

Confidentiality
NIH Certificates of Confidentiality Kiosk. Internet WWW page, at URL: http://grants1.nih.gov/grants/policy/coc/

Description: Place to apply for a Certificate of Confidentiality. “Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.”
Federal-Wide Assurances
OHRP Assurances. Internet WWW page, at URL: http://www.hhs.gov/ohrp/

Description: This page contains information about seeking federal-wide assurances for research projects. Hospices participating in federally-funded research being coordinated out of another site may need to complete a “federal-wide assurance” if they will not be seeking their own IRB review. A federal-wide assurance indicates that the hospice will abide by the requirements of the IRB that did review and approve the research project.

Funding
NIH Grants and Funding Opportunities. Internet WWW page, at URL: http://grants1.nih.gov/grants/index.cfm

Description: Links to information about funding and training opportunities offered through the National Institutes of Health.

Division of Allergy, Immunology and Transplantation, National Institute of Allergy and Infectious Diseases, National Institutes of Health. (1995). How to Write an NIH Grant Application; How to Revise an Unfundable Grant Application. Internet WWW page, at URL: http://www.meddean.luc.edu/lumen/DeptWebs/microbio/web-walk/nih-grt2.htm

Description: Helpful hints on writing and revising federal grant proposals.

HIPAA
Office for Civil Rights. Medical Privacy - National Standards to Protect the Privacy of Personal Health Information. Internet WWW page, at URL: http://www.hhs.gov/ocr/hipaa/

Description: Detailed information on HIPAA.

Human Subjects Issues

Description: Federal regulations regarding human subjects issues


Description: Checklist to ensure informed consent

Description: “The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations…. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.”

Institutional Review Boards

Description: “The Guidebook does not itself constitute regulations but rather has been prepared for the convenience and reference of IRB members and administrators.”

University of South Florida, Division of Research Compliance. Internet WWW page, at URL: http://www.research.usf.edu/cs/

Description: Links to sample IRB forms for the University of South Florida. Forms vary from IRB to IRB, but this will give you a sense of what information is gathered as part of the typical IRB application process.

Quality Improvement or Research?

Description: Article suggesting how to determine what is “research”

Research Design

Description: “The Research Methods Knowledge Base is a comprehensive web-based textbook that addresses all of the topics in a typical introductory undergraduate or graduate course in social research methods…. It uses an informal, conversational style to engage both the newcomer and the more experienced student of research.”
Research Ethics

Description: “Though "On Being a Scientist" is aimed primarily at graduate students and beginning researchers, its lessons apply to all scientists at all stages of their scientific careers.”

Acknowledgments
The Hospice Research manual represents a collaborative effort of the National Hospice and Palliative Care Organization, the National Council of Hospice and Palliative Professionals, researchers and hospice professionals. The value of the input the authors received cannot be overstated. The following people provided input, feedback and revision to the Hospice Research Manual during its development:

Barbara Bouton, MA
Linda Cain, PhD, RN
Inge Corless, PhD
Stephen Connor, PhD
Jeanette Forbis, MSN, RN, APN
Gary Gardia, MEd
Pat Gibbons, RN, BSN
Phyllis Grauer, BS, PharmD
Frances Hoffman, MAT, MHA
Anne King, R.N.
Jean Kutner, MD
Jill Lampley, MBA
Susan McMillan, PhD
Shareefa Sabur, MNO
Lynn Zuellig, RN BSN