

**Supporting Statement A for:**  
NIH/National Institute of Nursing Research (NINR)  
End-of-Life and Palliative Care Science Needs Assessment:  
Funding Source Questionnaire

August 22, 2011 (revised February 2012)

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## **LIST OF ATTACHMENTS**

Attachment 1: Funding Source Questionnaire

Attachment 2: Invitation Letter

Attachment 3: Informed Consent

Attachment 4: NIH Privacy Act Officer's Letter

Attachment 5: IRB Approval

## **A. Justification**

### **A.1 Circumstances Making the Collection of Information Necessary**

The National Institute of Nursing Research (NINR) supports and conducts clinical and basic research and research training on health and illness across the lifespan. The research focus encompasses health promotion and disease prevention, quality of life, health disparities, and end of life. NINR's activities are authorized under 42 USC 285q, wherein it is stated:

“The general purpose of the National Institute of Nursing Research (in this subpart referred to as the "Institute") is the conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training, and other programs in patient care research.”

In 1997, the Director of the National Institutes of Health (NIH) designated NINR as the lead Institute for end-of-life (EOL) research. The NINR End-of-Life and Palliative Care (EOL PC) Research Program places specific emphasis on the application of biological, behavioral, and social science strategies in order to advance understanding of these dynamic factors and develop interventions that optimize patient and caregiver quality of life across care settings and cultural contexts. In fiscal year (FY) 2009, NINR created a central coordinating Office of Research on End-of-Life Science and Palliative Care, Investigator Training, and Education (OEPC). One of the charges to the OEPC is to comprehensively evaluate critical issues within EOL PC science and realize new initiatives that will expand the capacity and capability of EOL PC science across NIH.

Despite the multiple recommendations from the Institute of Medicine (IOM) calling for investment in EOL PC research (IOM, 1997, 2001, 2003a, 2003b), there is a limited understanding of who the stakeholders in EOL PC science are, the funding trends for EOL PC science (now and in the future), and the impact of past, current, and future partnerships between government, philanthropic organizations, academic research institutes, and/or others in building this important field of science. While no data were available, findings from this review indicate that directed funding streams for EOL PC research by federal and major philanthropic sources are not fully addressing the breadth and depth of EOL PC scientific issues encompassing the field, and research funding may be shrinking. There is an immediate need for a clearer analytic picture of EOL PC research themes and funding sources.

NINR seeks to implement a needs assessment of EOL PC science funding trends. This formative data will inform NINR, NIH Institutes and Centers, and other Federal and non-Federal Agencies about current EOL PC funding trends and priorities and create synergies for federal, private, and academic research networks to stimulate research capacity in this field. In addition, findings from this evaluation will guide modification of the NINR EOL PC Research Program to achieve these goals. NINR will conduct the evaluation needs assessment with assistance from NOVA Research Company (NOVA).

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), NINR is requesting clearance from the Office of Management and Budget (OMB) to conduct a data collection procedure as part of this EOL PC Science Needs Assessment. Specifically, clearance is requested for a short, seven-item, one-time Web-based questionnaire of the first authors of publicly-available EOL PC research publications who do not list a funding source or the source is unclear within their publications.

## **A.2 Purpose and Use of the Information**

The purpose of the Funding Source Questionnaire is to identify funding organizations of EOL PC research studies published from 1997 through 2010, when a funding source was not cited or the funding source information was unclear in the publication. This information will be used in the analysis of the published EOL PC research literature to determine which, if any, agencies or organizations funded the published study. A copy of the questionnaire can be found in Attachment 1. The Funding Source Questionnaire will collect the following information: name of funding institution, type of funding, name of funded study, start year of funded study, and duration of funded study. This information will aid in understanding EOL PC research funding trends so that funding of future research efforts can be better coordinated by NIH, other Federal agencies, and non-government organizations and philanthropic groups.

## **A.3 Use of Improved Information Technology and Burden Reduction**

In an effort to minimize the burden of data collection, responses will be collected through a Web-based survey, which will permit electronic submission. Since most of the potential responders, i.e., published researchers, have known e-mail addresses and are likely to have access to the Internet, the Web-based questionnaire will be an easy and convenient mechanism to use. Respondents will be able to click on a URL within the e-mail to be directed to the questionnaire Web site.

Online administration of the questionnaire is efficient because the respondent will enter the data directly into the database, avoiding the separate step of key entry of paper questionnaire data into a database. The Web-based survey will allow entry of valid data only. The cleaning of the data will also be facilitated through online administration.

An email invitation letter (see Attachment 2) will be sent to the first author of EOL PC research publications where the funding source was not cited or the sources were ambiguous within their published EOL PC research. However, if contact information for the first author is not available, the second author will be contacted. The invitation email will inform the target population about the NIH EOL PC needs assessment and the importance of their participation in the evaluation. The letter will indicate that the study is conducted by the National Institute of Nursing Research of the National Institutes of Health and will succinctly inform readers of the purpose and importance of the questionnaire, the confidentiality of the data, the procedures for maintaining the privacy of respondents, and that response is voluntary. The letter will include a URL link to a secure website where the author can complete the questionnaire.

A Privacy Impact Assessment (PIA) was done for the database being used to collect this information.

## **A.4 Efforts to Identify Duplication and Use of Similar Information**

The Funding Source Questionnaire has not previously been used in this population. There is no similar information available for use. No other questionnaire or data could provide the information required for the proposed study.

## **A.5 Impact on Small Businesses or Other Small Entities**

No small businesses or other small entities will be involved in this study.

## **A.6 Consequences of Collecting the Information Less Frequently**

This is a one-time study collection. The rationale for this collection method is to gather information about the funding source of published EOL PC research when it was not cited in the publication.

## **A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

No special circumstances are anticipated. This information collection fully complies with 5 CFR 1320.5(d) (2).

## **A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency**

As required by 5 CFR 1320, a 60-day notice of this proposed data collections was published in the Federal register, Volume 76, Number 116, Page 35221 on June 16, 2011, and allowed 60-days for public comment. No public comments were received.

Outside consultation was conducted with the End-of-Life and Palliative Care Science Needs Assessment ad hoc Evaluation Advisory Committee to obtain their views on the availability of data, frequency of collection, and on the data elements to be recorded, disclosed, or reported from the Funding Source Questionnaire during a meeting on January 13, 2011. Committee members provided comments and suggestions on the NINR End-of-Life and Palliative Care Science Needs Assessment Funding Source Questionnaire. Members include:

Noreen Aziz, MD, PhD, MPH, Program Director, NIH/National Institute of Nursing Research, One Democracy Plaza, Suite 710, 6701 Democracy Boulevard, Bethesda, MD 20817, (301) 594-2542.

F. Amos Bailey, MD, Birmingham VA Medical Center, 6th Floor Safe Harbor Unit, 700 19th Street South, Birmingham, AL 35233, (205) 933-8101, ext. 5355.

Nancy Berlinger, PhD, MDiv, The Hastings Center, 21 Malcolm Gordon Road, Garrison, NY 10524-4125, (845) 424-4040, ext. 210.

Amanda Greene, PhD, MPH, RN, NIH/National Institute for Nursing Research, 6701 Democracy Boulevard, Suite 710, Room 724, One Democracy Plaza, Bethesda, MD 20892, (301) 496-9601.

Mary Sue Hamann, PhD, NIH/National Institute of Dental and Craniofacial Research, Claude D Pepper Building, 5B55, 31 Center Drive, Bethesda, MD 20892, (301) 594-4849.

Andrea Harabin, PhD, NIH/National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 10174, Bethesda, MD 20892, Tel: (301) 435-0222.

Pamela Hinds, PhD, RN, FAAN, Department of Nursing Research and Quality Outcomes, Children's National Medical Center, 111 Michigan Avenue, NW, 6th Floor Research, Washington, DC 20010, (202) 476-4432.

Gail Hunt, National Alliance for Caregiving, 4720 Montgomery Lane, 2nd Floor, Bethesda, MD 20814, (301) 718-8444.

Linda Lloyd, DrPH, MPH, The Institute for Palliative Medicine at San Diego Hospice, 4311 Third Avenue, San Diego, CA 92103, (619) 278-6542.

Lisbeth Nielsen, PhD, NIH/National Institute on Aging, 7201 Wisconsin Avenue, #533, Bethesda, MD 20892-9205, (301) 402-4156.

Deborah McGuire, PhD, RN, FAAN, University of Maryland School of Nursing, 655 West Lombard Street, 325B, Baltimore, MD 21201, (410) 706-8351.

Jeri Miller, PhD, CCC-SLP, Office of End-of-Life Science and Palliative Care, Investigator Training, and Education, NIH/National Institute of Nursing Research, 6701 Democracy Boulevard, Room 710, Bethesda, Maryland 20892-4870, (301) 594-6152.

Judith Peres, LCSW-C, The Transformation Project, 4848 Battery Lane, Suite 202, Bethesda, MD 20814, (301) 455-5140.

Judy Sangl, MPH, ScD, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, (301) 427-1308.

Meryl Sufian, PhD, NIH/National Center for Research Resources, One Democracy Plaza, 992, 6701 Democracy Boulevard, Bethesda, MD 20817, (301) 435 0757.

Joan Teno, MD, MS, Warren Alpert School of Medicine at Brown University, 121 South Main Street, Room 613, Providence, RI 02912, (401) 863-9627.

In addition, outside consultation was conducted with a public health consulting firm (NOVA Research Company) who has expertise in health research and survey methodology, to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported. The following individuals provided us with comments and suggestions on the NINR End-of-Life and Palliative Care Science Needs Assessment Funding Source Questionnaire for clearance:

S. Lisbeth Jarama, Ph.D., Senior Evaluator, NOVA Research Company, 4600 East-West Highway, Bethesda, MD, 20814; (240) 483-4188.

Natalie Gay, M.S., Evaluator, NOVA Research Company, 4600 East-West Highway, Bethesda, MD, 20814; (301) 986-1891.

Paul Young, M.P.H., M.B.A., Project Manager, NOVA Research Company, 4600 East-West Highway, Bethesda, MD, 20814; 240) 483-4190.

## **A.9 Explanation of Any Payment or Gift to Respondents**

Participants responding to this questionnaire will not receive remuneration for their participation.

## **A.10 Assurance of Confidentiality Provided to Respondents**

Information provided by the respondents will be kept private to the extent permitted by law. This information will be communicated to respondents by means of an introductory email letter (Attachment 2) and informed consent preceding the questionnaire (Attachment 3). NINR and its contractor, NOVA Research Company, will follow best practices to maximize privacy and security of all data.

Respondents will be assigned a confidential ID number. Personal identifying information will be stored separately from responses. Files will be kept in a secure environment and no one outside of this study will have access to them. NOVA will use contact information for requesting subject participation and for subsequent follow-up in the case of non-response.

An informed consent form will be shown to all potential study participants before they start the questionnaire. The form describes the purpose of the questionnaire and the confidentiality of the data. Participants will be prompted to accept or decline participation by selecting the appropriate button at the bottom of the electronic form. By giving consent, participants indicate that they have read the form, understand what they are consenting to, and are aware of their rights as research participants. The consent form will state the following:

- The questionnaire is sponsored by the National Institute of Nursing Research, part of the National Institutes of Health.
- Reports will be used to guide EOL PC research within NINR and the NIH, and provide a national picture of funding trends in EOL PC research in order to identify gaps, evaluate funding opportunities and plan new strategies and partnerships to forward this area of research.
- Information provided by respondents will be kept private. Personal identifying information will be used only by researchers following up with respondents; identifying information will not be disclosed except as required by law.
- Response to the questionnaire is voluntary, and there are no penalties for not responding to the information collection as a whole or to any particular questions.
- At the end of the study, participants' personal information will be discarded, though NINR will retain a de-identified data file for future analysis.
- In order to protect respondents' privacy, all presentation of data in reports will be in aggregate form, with no links to individuals preserved.

The information collected in this study is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Questionnaires Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD" <http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm>. (See Attachment 4 for NIH Privacy Act Officer's Letter). The NOVA Institutional Review Board (IRB) granted education exemption of the Funding Source Questionnaire on December 3, 2010, in accordance with 45 CFR 46. A copy of the IRB exemption is found in Attachment 5.

### **A.11 Justification for Sensitive Questions**

No questions of a sensitive nature will be asked. Questions are of a general nature and disclosure would not create harm to individuals. Never the less data will be kept private and information will be reported in the aggregate rather than attributed to specific individuals. All respondents have the right not to answer a particular question or to stop their participation at any time without any consequence.

### **A.12 Estimates of Annualized Burden Hours and Costs**

Response burden estimates are shown in Table A-12-1. The questionnaire will require 5 minutes to complete. A preliminary review of the literature from 1997-2010 using key search terms related to EOL and PC identified 2300 related publications for which a funding source was not cited or the information was unclear. Although the target sample consists of 2300 participants, the number of expected respondents is 1840, associated with a target response of 80 percent. A high response rate is expected because the authors have published their EOL PC research in journals, as such, the authors have a responsibility to their audience to provide information associated with their studies. **In addition, these authors are researchers who**

want their work and research support mechanisms to be recognized, which can influence their future research awards. The total annual burden is estimated to be ~~10.8~~ 147.2 hours.

Table A-12-1 Estimates of Annual Burden Hours				
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Annual Burden Hours
Researchers	1840	1	.08	147.2

The total annual cost to respondents is estimated at \$6136.77 as shown in Table A-12-2. Annualized costs were calculated using the mean hourly wage of the U.S. Department of Labor, Bureau of Labor Statistics, Occupation Employment and Wages, May 2010, 19-1042 Medical Scientists, Except Epidemiologists (available at <http://www.bls.gov/oes/current/oes191042.htm>)<sup>1</sup> mean hourly wage. Respondents to this questionnaire are researchers who conduct research dealing with the understanding of human diseases and the improvement of human health and engage in clinical investigation, research and development, or other related activities.

Table A-12-2: Annualized Cost to Respondents					
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Hourly Wage Rate	Total Respondent Cost
Researchers	1840	1	.08	\$41.69	\$6136.77

### A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital or startup costs for the data collection efforts requested; nor are there any costs associated with operation, maintenance, or purchase of services.

### A.14 Annualized Cost to the Federal Government

The estimated total cost to the government to conduct and analyze the one-time questionnaire is \$30,736. The budget includes the costs of questionnaire design and development, all data collection and follow-up, data file preparation and documentation, initial analyses, and other miscellaneous costs such as supplies and expenses. Professional service time is included for study management and overhead costs. The overall government distribution is summarized in the following table:

<sup>1</sup> Assessed 10/11/2011.

<b>Table A-14-1 Government Cost Distribution</b>	
	<b>Estimated Costs</b>
Contractor Costs	\$26,689
Analysis	\$ 4,047
<b>Total</b>	<b>\$30,736</b>

Thus, estimated annual cost to the government over the 12-month period is approximately \$30,736.

**Contractor Costs of \$26,689:** These costs were extracted from the larger contract budget which this survey is part of. These costs include the following tasks to be completed by the contractor: develop questionnaire items, develop/program Web-based questionnaire including response options, skip patterns, and data repository, testing of web-based questionnaire prior to pilot, pilot testing of questionnaire and cognitive interview with pilot participants, reporting pilot test findings, obtaining IRB approval, administering questionnaire (i.e., pre-questionnaire email notification, questionnaire invitation email, follow-up non-response), and preparing database with responses for analysis. The following contract personnel expertise are required to perform these tasks: contract project manager, survey/evaluation experts, and Web developer/programmer.

**Analysis costs of \$4,047:** This includes organizing and cleaning data, conducting statistical analysis of the data, drafting the findings report including required graphs and tables, and writing the final report of findings. This task requires expertise in evaluation, surveys, statistics, and science writing with management by the contractor project manager.

### **A.15 Explanation for Program Changes or Adjustments**

This is a new collection of information.

### **A.16 Plans for Tabulation and Publication and Project Time Schedule**

The plan is to begin the questionnaire one month after OMB approval has been received. The project schedule for completing data collection, processing, and analysis is presented in Table A-16-1.

<b>Table A-16-1. Project Time Schedule</b>	
<b>Activity</b>	<b>Estimated Time Schedule after OMB approval</b>
Initial e-mail invitations	1 month
Follow-up emails	1.5 months
Completion of data collection	2.5 months
Analysis of data	3 months
Preliminary report	3.5 months
Final interim report	4 months

This questionnaire will obtain data from authors of EOL PC research publications for whom a funding source is unknown. Sources of information will be combined to analyze overall EOL PC scientific funding and linkages between the data collected. Quantitative data analysis will include descriptive analyses. Descriptive statistics will be used to describe the number and type of EOL PC research studies funded, funding organizations, type of funder, and duration of funded studies.

**Descriptive Statistics.** Table A. 16 – 2 indicates an example of descriptive data that could provide important guidance as to what entities are funding EOL PC research. For example, we will examine the proportions of funding source types.

<b>Table A. 16-2 Percent of Agencies Funding EOL PC Research</b>	
<b>Agencies</b>	<b>Percent of Sample</b>
U.S Government	
Academic Institution	
Private Foundation	
Commercial Entity	
Professional Organization	
State/Local Government	

#### **A.17 Reason(s) Display of OMB Expiration Date Is Inappropriate**

NINR will display the OMB control number and expiration date in the upper right-hand corner of all data collection instruments. No waiver is being sought to display the expiration date for OMB approval.

#### **A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

NINR is in full compliance with the provisions contained within the Certification for Paperwork Reduction Act Submissions. No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.

## References

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