Supporting Statement A

Pediatric Palliative Care Campaign Pilot Survey (NINR)

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LIST OF ATTACHMENTS

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, end of life care, and research training. 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 2012, NINR developed the Pediatric Palliative Care Campaign to address the communication challenges faced by health care providers who recommend and provide palliative care to pediatric populations. The campaign is being piloted by health care providers at two hospitals. To inform the development of the campaign, NINR conducted planning activities including a roundtable discussion with leading palliative care and end-of-life experts, a strategy planning workshop with leaders in the field, an environmental scan of existing programs and campaigns, and a review of the literature.

The purpose and overall goal of the Pediatric Palliative Care Campaign is to increase the use of palliative care for children living with serious illness or life-limiting conditions. Campaign materials and messages such as:

- *Palliative care is an integral part of treatment for pediatric patients and their families living with a serious illness or life-limiting condition;*
- *Palliative care can be delivered in tandem with curative or life-prolonging care and is not only appropriate at the end of life;* and
- *Referring patients, families and caregivers for palliative care services can improve patient outcomes and increase overall satisfaction with care;*

are designed to assist health care providers in initiating and facilitating ongoing conversations about palliative care with pediatric patients and their families.

Health care providers at two hospitals will pilot the materials for a period of 9 months. A kick-off workshop was done at each site to introduce the materials.

The purpose of the Pediatric Palliative Care Campaign Pilot Survey (see Attachments 1 and 2) is to collect information on how the campaign materials are used by the health care providers, how the campaign affects communication about pediatric palliative care, and the health care providers' attitudes, perceptions, and beliefs about pediatric palliative care. This method will help gather feedback on the campaign materials and messages so that these can be refined before launching the campaign. The survey will be administered after the 9-month pilot campaign.

Campaign materials were reviewed and discussed by a focus group representing the target audience. The focus group was approved under the 0925-0653 - Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NINR). Focus

group members assessed the draft campaign materials and included physicians, nurses, and social workers who spend some of their workday in a hospital consulting with children living with a serious illness or life-limiting condition and their families. This assessment was completed on June 21, 2012. The recommendations from the focus group centered on selection of a campaign name, tagline, and logo and reactions to rough drafts of the campaign materials. Recommendations from the focus group were incorporated into the materials for the pilot campaign.

During the pilot campaign, two communications tools – an interactive worksheet/tear-off pad and video modules – will be provided to health care providers to assist with palliative care conversations with pediatric patients and their family members.

The *interactive worksheet/tear-off pad* (see Attachment 4) is a one page communications tool that includes static talking points that appear on the cardboard backing of an 8.5”x11” size note pad that health care providers can reference when approaching a patient and/or a family member about palliative care. The worksheet component that “tears off” is a customizable document that the provider can complete during a conversation with the patient and/or family member and includes static information about palliative care in lay terms as well as customizable fields that the provider can update with appropriate palliative care information about available services and/or treatment related to the patient’s needs. The back of the tear-off worksheet is a form that patients or families can use to track or log important information related to treatment and care, which can be used to help facilitate subsequent palliative care-focused conversations.

The *video modules* are a series of three vignettes that focus on a range of topics related to starting and managing a palliative care conversation between a provider, pediatric patient, and his/her family. The modules, which are directed towards the health care provider audience, convey the benefits of palliative care and provide tips that providers can incorporate into practice.

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 for a pilot of the Pediatric Palliative Care Campaign. Specifically, clearance is requested for a 26-item web-based survey of health care providers to be administered one time.

A.2 Purpose and Use of the Information Collection

The purpose of the Pediatric Palliative Care Campaign Pilot Survey is to collect feedback from health care providers who are involved in the pilot to ensure that the information being disseminated as part of the pilot is effective, relevant, and useful to target health care providers. Data collected will also indicate the effectiveness of the campaign materials in initiating and continuing a palliative care conversation and addressing the communication needs of providers.

Information obtained through this assessment will provide strategic and actionable guidance for refining the campaign materials. Without this information NINR risks the possibility of inefficiently and ineffectively expanding the campaign nationwide.

This data collection is designed to answer the following questions:

1. Has the campaign (including its messages and materials) been effective in shifting attitudes, perceptions, and behaviors related to pediatric palliative care practices?
2. Were the materials useful in initiating and guiding a conversation about pediatric palliative care?
3. What attributes of the materials, if any, would health care providers change to make them more useful?

Two hospitals are participating in the pilot. These sites have neonatal intensive care units and/or pediatric intensive care units that serve the target populations of interest to NINR. Sites have the capability and willingness to be an active collaborator in the assessment activities. Since the pilot materials are only in English, the sites serve a primarily English-speaking population.

At both pilot hospitals, data will be collected one time in a post-program survey. The survey will be voluntary and will be conducted online.

Health care providers, including physicians and nurses, at the two participating pilot sites will be asked to complete the assessment survey. The survey (see Attachments 1 and 2) takes approximately 30 minutes to complete and contains 26 questions. The survey includes the following components.

- PERCEPTIONS OF and BEHAVIORS TOWARD PEDIATRIC PALLIATIVE CARE -- a section in which health care providers are asked to define pediatric palliative care and answer questions related to their palliative care experiences.

- INFORMATION NEEDS -- explores resource needs.

- PERCEPTIONS OF THE CAMPAIGN, MATERIALS and PILOT PROGRAM -- includes questions for providers to evaluate the pilot campaign materials.

- BACKGROUND INFORMATION- includes questions related to the health care provider's discipline, area of specialty, and whether they have received pediatric palliative care training.

The data collection period is estimated to last no more than one month at each site. There has been no previous collection of this information.

A.3 Use of Information Technology and Burden Reduction

To reduce respondent burden, the survey will be deployed and submitted using a web-based electronic tool. Since respondents have known email addresses through their hospitals, they will be sent an active URL link via email to access the survey. Given the busy schedules of this audience, this methodology will allow survey respondents to provide information at their convenience. In addition, use of an online survey will ensure quality and accurate collection of data, while also providing the greatest privacy to respondents and the least burden of time.

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 cleaning of the data will also be facilitated through online administration.

The NIH Center for Information Technology will program and deploy the online survey and host a secure website for the survey administration.

An email notification/invitation letter (see Attachment 3) will be sent by the NIH Center for Information Technology to health care providers participating in the pilot campaign. The letter will inform the providers about the survey and about the importance of their participation. In addition, the letter will state that the survey is being conducted by NINR 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. A separate email (see Attachment 3) will include a URL link to a secure website and a unique login code which providers can use to complete the survey anonymously.

NINR has submitted a Privacy Impact Assessment (see Attachment 6) for this IT system using the HHS Security and Privacy Online Reporting Tool even though personally identifiable information will not be collected.

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

The Pediatric Palliative Care Campaign Pilot Survey 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.

In addition, NINR conducted online exploratory research on several Internet search engines to identify existing campaigns and programs and their corresponding evaluation programs. It was concluded that this type of campaign and data collection effort has not taken place previously.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this study. The health care providers involved in the pilot campaign are hospital-based and part of a large health network.

A.6 Consequences of Collecting the Information Less Frequently

Currently there is a lack of research and data to understand the delivery of pediatric palliative care. Assessment of this pilot program will be used to help the National Institutes of Health with future communications efforts. The viability and utility of the Pediatric Palliative Care Campaign Pilot Survey may be adversely affected if the information is not collected.

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). Due to the small sample size, this data collection will not provide the statistical rigor necessary to generalize the results.

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

As required by 5 CFR 1320, a 60-day notice of this proposed data collection was published in the Federal Register, Volume 77, Number 247, Page 76053 on December 26, 2012, and allowed 60-days for public comment. No public comments were received.

In 2012, NINR consulted with several individuals outside the agency regarding the proposed information collection including Ogilvy Washington, a communications consultancy with expertise in communication campaigns, and the NIH Center for Information Technology, an office with expertise in online surveys. They provided comments and suggestions on availability of data, data collection, clarity of instructions and recordkeeping, disclosure, reporting format, and data elements to be recorded disclosed, or reported. These consultants include the following campaign staff and subject matter experts:

- Patricia Eitel Taylor, PhD, Vice President, Ogilvy Washington
  202-729-4271; trish.taylor@ogilvy.com
- Matthew Escoubas, Vice President, Ogilvy Washington
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- Raquel García-Pertusa, Vice President, Ogilvy Washington
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- Jenna Norton, MPH, Senior Account Executive, Ogilvy Washington
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- Aileen Kelly, Staff Member, NIH Center for Information Technology
  301-496-6674, kellya@mail.nih.gov
- Rick Rowland, Consultant, NIH Center for Information Technology
  301-402-8767, rowlandr@mail.nih.gov

A.9 Explanation of Any Payment of 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 email letter and invitation and reminder email, if necessary, which includes information about the questionnaire (Attachment 3). The beginning of the web-based survey includes information about privacy (Attachments 1 and 2). NINR, the NIH Center for Information Technology, and NINR's contractor, Ogilvy Washington, will follow best practices to maximize privacy and security of all data.

The health care provider surveys will be anonymous. The NIH Center for Information Technology will assign respondents a confidential login code (i.e. ID number). Files will be kept in a secure environment and no one outside of this study will have access to them. NINR and its contractor will use contact information (i.e. business email addresses) for requesting subject participation and for subsequent follow-up in the case of non-response. The final report to NINR will aggregate the respondents' characteristics. No survey data will be displayed on an individual basis.

An informed consent form (Attachment 7) will be shown to all potential participants before they start the survey. The form describes the purpose of the survey 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 participants. The consent form will state the following:

- Information provided by respondents will be kept private and secure to the extent permitted by law. The information will be used only by the researchers conducting this study and will not be disclosed except as required by law.
- A transcript of the questionnaire will be stored securely and will only be accessible to the research team.

- Respondents will not be asked any personally identifying information when responding to the questionnaire.
- Response to the survey is voluntary, and the respondent can choose not to answer questions or can withdraw from the questionnaire at any time.
- That NINR is authorized to conduct the questionnaire under section 42USC 285q of U.S. Law.
- In order to protect respondents' privacy, all presentation of data in reports will be in aggregate form, with no links to individuals.

As mentioned in section A.3, NINR has submitted a Privacy Impact Assessment (see Attachment 6) for this IT system even though personally identifiable information will not be collected. With regards to the Institutional Review Board, this data collection is exempt from the regulations. NINR received the following guidance from the Office of Human Subjects Research Protections regarding what is considered exempt: "Program evaluations in which the results of the evaluation are shared only within the program or entity in which the program operates, i.e., the data from the activity are produced by the program and returned to the program" (see 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. Nevertheless, 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

Health care providers will participate in one survey. Response burden estimates are shown in Table A-12-1. The average time for completing the Pediatric Palliative Care Campaign Pilot Survey is 30 minutes. The pilot campaign is expected to involve 50 health care providers. A response rate of 80% is expected. This response rate is expected because these health care providers have agreed to participate in this campaign. The total annual burden is estimated to be 25 hours (see Table A-12-1).

Table A-12-1 Estimates of Annual Burden Hours				
Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Average Time per Response (in hours)**	**Total Burden Hours**
Physicians	25	1	30/60	12.5
Nurses	25	1	30/60	12.5
Total	50			25

The total annual cost to respondents is estimated at $1494.00 as shown in Table A-12-2. Annualized costs were calculated using the mean hourly wage provided by U.S. Department of Labor, Bureau of Labor Statistics, Occupation Employment and Wages, May 2011, 19-1042 Medical Scientists, Except Epidemiologists (available at http:/stats.bls.gov/oes. Accessed 1/12/12) mean hourly wage. Respondents to this questionnaire are nurses and physicians.

Table A-12-2: Annualized Cost to Respondents					
Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Average Time per Response (in hours)**	**Hourly Wage Rate**	**Total Respondent Cost**
Physicians	25	1	30/60	$86.96	$1087.00
Nurses	25	1	30/60	$32.56	$407.00
Total	50				$1494.00

A.13 Estimate of Other Total Annual Cost Burden to Respondents or 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 annualized cost to the government for conducting the evaluation is estimated at $29,000. Cost estimates cover the development, deployment, data collection, and analysis of the survey, including:

- Development of the survey instrument
- Programming and deployment of the survey using the NIH Center for Information Technology, and management of survey implementation
- Data analysis and reporting
- Creation of a final written summary report for NINR
- Staff time for pilot site relationship management

The annualized government cost distribution is summarized in the Table A-14-1.

Table A-14-1 Annualized Government Cost Distribution

	Estimated Costs
Contractor Costs	$18,000
Survey Programming & Administration	$2,000
Analysis & Reporting	$9,000
Total	**$29,000**

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 in June 2013 or after OMB approval is received. The project schedule for completing data collection, processing, and data analysis is presented in Table A-16-1.

Table A-16-1. Project Time Schedule	
Activity	**Estimated Time Schedule after OMB approval**
Begin data collection	2 weeks after OMB approval
Finish data collection	6 weeks after OMB approval
Data analysis & reporting	2 months after OMB approval
Begin using results for program planning, pilot expansion and/or promotion	3 months after OMB approval

This survey will obtain data from participating health care providers at the two pilot sites for the Pediatric Palliative Care Campaign. Sources of information will be combined to analyze data for program improvement, assessment of campaign materials, and the effectiveness of this communications campaign.

Analysis Plan

Quantitative and qualitative data analyses will be done. Quantitative data analysis will include descriptive statistics to describe the frequency and use of campaign materials and categorization of knowledge, attitudes, and self-efficacy of health care providers related to pediatric palliative care discussions. While the majority of data collected via the online surveys will be quantitative, some open-ended questions will be included to collect qualitative data. These questions, such as providing feedback on how materials were used in practice, will be coded and categorized and treated as categorized values.

At the close of the survey, key findings will be summarized and NINR will draw strategic implications and recommendations. While results from the two sites will show only directional changes due to a small sample size, results will be used to refine the materials to best meet health care providers' needs moving forward.

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

NINR intends to display the OMB control number and expiration date in the upper right hand corner of the survey. 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.