Supporting Statement A

Palliative Care: Conversations Matter Evaluation (NINR)

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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 *Palliative Care: Conversations Matter*, a pediatric palliative care campaign to address the communication challenges faced by health care providers who recommend and provide palliative care to pediatric populations. 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, a focus group, a pilot of the materials and a review of the literature.

The purpose and overall goal of *Palliative Care: Conversations Matter* 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.

The purpose of the *Palliative Care: Conversations Matter* Assessment (see Attachments 1 and 2) is to measure the effectiveness of the campaign. Because no comparison group exists, a baseline survey will be conducted, followed by a post-survey 12 months later. A kick-off workshop will be done at each site to introduce the campaign and its materials.

Campaign materials were initially 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.

Two communications tools – a tear-off pad and video modules – will be provided to health care providers in up to ten select sites, to assist with palliative care conversations with pediatric patients and their family members. The materials were piloted in two hospital systems starting in fall 2012. Seven health care providers gave feedback on the materials. This information was used to refine the campaign materials.

The *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 tear-off pad is available in English and Spanish.

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 the *Palliative Care: Conversations Matter* Campaign. Specifically, clearance is requested for two 15-20 item web-based surveys of health care providers to be administered at two different time points – baseline (15 items) and post (20 items).

A.2 Purpose and Use of the Information Collection

The purpose of the *Palliative Care: Conversations Matter* Evaluation is to collect feedback from health care providers to ensure that the campaign is effective, relevant, and useful to target health care providers. Data collected is intended to indicate how effective the campaign is in initiating and continuing a palliative care conversation and addressing the communication needs of providers.

Information obtained through this assessment will provide strategic guidance for future campaign efforts. Without this information, NINR risks the possibility of inefficiently and ineffectively expanding the campaign in the future.

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 types of additional communications materials would be helpful for NINR to develop?

NINR will invite up to 10 hospitals to utilize the materials and provide their feedback through the evaluation surveys. Selected sites will have neonatal intensive care units and/or pediatric intensive care units that serve the target populations of interest to NINR. Sites will have the capability and willingness to be an active collaborator in the assessment activities.

At each hospital, data will be collected twice - one time at baseline and one time in a post-survey. The surveys will be voluntary and will be conducted online.

Health care providers, including physicians and nurses, at the participating sites will be asked to complete the assessment surveys. The surveys (see Attachments 1 and 2) take approximately 20 minutes each to complete and contain 15 and 20 questions, respectively. The surveys include the following components.

- PERCEPTIONS OF 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 and MATERIALS -- includes questions for providers to evaluate the 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 two months 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 surveys 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 surveys. Given the

busy schedules of this audience, this methodology will allow survey respondents to provide information at their convenience. In addition, use of online surveys 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 questionnaires 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 surveys 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 at participating campaign sites. The letter will inform the providers about the surveys and about the importance of their participation. In addition, the letter will state that the surveys are being conducted by NINR and will succinctly inform readers of the purpose and importance of the questionnaires, the confidentiality of the data, the procedures for maintaining the privacy of respondents, and that responses are 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 surveys anonymously.

NINR has submitted a Privacy Impact Assessment (PIA) (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. It was determined that the existing PIA for the pilot surveys can be amended for this new collection. Attachment 6 includes the email correspondence regarding this determination.

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

The *Palliative Care: Conversations Matter* Evaluation has not previously been used in this population. The only similar information available for use is data from the pilot campaign, which was limited in scope and assessed the materials, not the overall campaign. 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 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 campaign will be used to help the National Institutes of Health with future communications efforts. The viability and utility of the *Palliative Care: Conversations Matter* campaign 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 78, Number 115, Page 35942 on June 14, 2013, and allowed 60-days for public comment. No public comments were received.

In 2013, 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:

- Raquel García-Pertusa, Vice President, Ogilvy Washington
  202-729-4269, raquel.garciapertusa@ogilvy.com
- Jenna Norton, MPH, Senior Account Executive, Ogilvy Washington
  202-729-4043, jenna.norton@ogilvy.com
- 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

Payment for participating in an interview or survey is standard practice when seeking participation of health care providers such as physicians, nurses, and social workers. The incentive payment is an effective method of drawing health care providers' attention to the study and gaining cooperation in completing the survey. It is not intended to be a payment for their time, but an incentive to increase response rate. Historically, health care providers are one of the most difficult populations to survey, partly because of the demands on their professional time. Consequently, incentives assume an even greater importance with this group.

The use of an incentive is consistent with OMB standards for incentive use because the incentive will help improve coverage of specialized respondents (i.e., health care professionals). Two recently approved Federal surveys involved providing incentives to health care professionals at a rate of $50-$75 for a 20 minutes survey: "Health Care Professional Survey of Prescription Drug Promotion" (OMB No. 0910-0730, Expiration Date 2/29/2016) and "Survey of Primary Care Physicians on Oral Health" (OMB No. 0990-0403, Expiration Date 11/30/2015).

NINR believes that in order to achieve an adequate response rate for this survey, it is essential to offer a modest incentive of a $25 gift card for completing each survey. There is considerable evidence in the literature showing that the most effective way to increase response rates among health care professionals is by offering a monetary incentive. The following studies have examined the influence of incentives on health care professional participation in research:

- VanGeest et al. (2007) conducted a meta-analysis on methodologies for improving response rates in physician surveys. They examined 21 studies published between 1981 and 2006 that investigated the effect of monetary incentives on response rates in surveys of physicians. Looking at the results from all studies, the odds of responding to a survey with an incentive were 2.13 times greater than responding to a survey without incentives. (VanGeest, J., T. Johnson, and V. Welch. Methodologies for Improving Response Rates in Surveys of Physicians: A Systematic Review, *Evaluation and the Health Professions*, vol. 30, pp. 303-321, 2007.)
- Thorpe et al. (2008) conducted several studies with physicians in Canada. They found that when they applied the Dillman tailored design approach and used monetary incentives (gift certificates), their response rates increased from 48% to 74–76%. (Thorpe, C., B. Ryan, S. McLean, et al. How to Obtain Excellent Response Rates When Surveying Physicians, *Family Practice*, vol. 26(1), pp. 65-68, 2008.)
- VanGeest and Johnson (2011). Similar to the meta-analysis conducted with physicians, the authors examined 22 published reports on strategies for increasing response rates with nurses. The authors found that monetary incentives were beneficial in boosting response rates. (VanGeest, J. and T. Johnson. Surveying Nurses: Identifying Strategies to Improve Participation, *Evaluation and the Health Professions*, vol. 34(4), pp. 487-511, 2011.)

- Dykema, J. et al. (2011) conducted an incentive experiment on a survey of physicians selected from the American Medical Association's Physician Masterfile. Physicians were randomly assigned to one of four treatment groups: no incentive (6.2% response rate), $200 lottery (8.6% response rate), $50 incentive (15.4% response rate), or $100 incentive (25.4% response rate). As shown, response rates were highest in the groups with $50 and $100 incentives. (Dykema, J., J. Stevenson, B. Day, et al. Effects of Incentives and Prenotification on Response Rates and Costs in a National Web Survey of Physicians, *Evaluation and the Health Professions*, vol. 34, pp. 434-447, 2011.)
- Martins et al. (2012) conducted a review of published oncology-focused studies to investigate methods for improving response rates. The meta-analysis showed that monetary incentives were effective at increasing response rates. (Martins, Y., R. Lederman, C. Lowenstein, et al. Increasing Response Rates From Physicians in Oncology Research: A Structured Literature Review and Data From a Recent Physician Survey, *British Journal of Cancer*, vol. 106(6), pp. 1021-6, 2012.)

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 invitation and reminder email, if necessary, which includes information about the questionnaires (Attachment 3). The beginning of the web-based surveys include information about privacy (Attachments 1 and 2). NINR and the NIH Center for Information Technology 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 NIH Center for Information Technology will use contact information (i.e. business email addresses) for requesting subject participation and for subsequent follow-up in the case of non-response.

An informed consent form (Attachment 7) will be shown to all potential participants before they start the surveys. The form describes the purpose of the surveys 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 questionnaires 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 questionnaires.
- Responses to the surveys are voluntary, and the respondent can choose not to answer questions or can withdraw from the questionnaires at any time.
- NINR is authorized to conduct the questionnaires 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 two surveys. Response burden estimates are shown in Table A-12-1. The average time for completing one of the surveys is 20 minutes. The campaign is expected to involve up to 300 health care providers (approximately 30 health care providers at each of the 10 potential sites). A response rate of 60% is expected. This response rate is expected because these health care providers will have an introduction to NINR and the campaign in the workshop. The total annual burden is estimated to be 200 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	150	2	20/60	100
Nurses	150	2	20/60	100
Total	300			200

*The average time for completing one of the surveys is 20 minutes; this includes reading the consent form on page 1 of the survey.

The total annual cost to respondents is estimated at $9,796.00 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, Medical Scientists, Except Epidemiologists, (NAICS code 541900) (available at http://data.bls.gov/oes/industry.do. Accessed 3/22/13) hourly mean 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 Mean Wage**	**Total Respondent Cost**
Physicians	150	2	20/60	$65.85	$6585.00
Nurses	150	2	20/60	$32.11	$3211.00
Total	300				$9796.00

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 $27,633. Cost estimates cover the development, deployment, data collection, and analysis of the survey, including:

- Development of the survey instrument

- Programming and deployment of the surveys using the NIH Center for Information Technology, and management of survey implementation
- Producing materials and conducting the workshops
- Staff time for campaign site relationship management

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

Table A-14-1 Annualized Government Cost Distribution	
Item	**Estimated cost**
Survey development – this will be done by NINR staff	N/A
Production of hard copy materials (300 DVDs and 300 tear-off pads)	$7,500
Shipping materials	$300
Gift cards for respondents ($25 each x 2 surveys x 180 expected respondents)	$9,000
CIT programming, screenshots, and hosting for 2 surveys	$2,500
Survey analysis- in-house	N/A
Travel for one NINR staff member to facilitate 10 non-local workshops	$8,333
Total	**$27,633**

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 deploy the baseline questionnaire in October 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	12-13 months after OMB approval
Data analysis & reporting	14 months after OMB approval
Begin using results for program planning, expansion and/or promotion	20 months after OMB approval

The surveys will obtain data from participating health care providers at up to ten sites for the *Palliative Care: Conversations Matter* campaign. Sources of information will be combined to analyze data to measure 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.

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 surveys. 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.