

Supporting Statement A for

***Palliative Care: Conversations Matter*[®] Phase Two Evaluation (NINR)**

OMB#: 0925-0683, Expiration Date: 10/31/2016

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List of Attachments

Attachment 1: Survey – Microsoft Word version

Attachment 2: Screenshots of survey

Attachment 3: Correspondence for survey – Email invitation with survey link

Attachment 4: Correspondence for survey – Reminder email

Attachment 5: Documentation from the NIH Office of Human Subjects Research Protections

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

The National Institute of Nursing Research (NINR), part of the National Institutes of Health, 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 January 2014, NINR released new educational materials for health care providers as part of the first phase of its *Palliative Care: Conversations Matter*[®] campaign. This first phase of the campaign included materials designed to assist health care providers with starting and continuing conversations about pediatric palliative care with their patients and patients' families. NINR evaluated the first phase of its *Palliative Care: Conversations Matter*[®] campaign by surveying health care providers from three sites. The evaluation was conducted online and by phone, and helped NINR learn more about what did and did not work in implementing the campaign at the sites. NINR was approved by the Office of Management and Budget (OMB) for the evaluation under Palliative Care: Conversations Matter Assessment (NINR), OMB#: 0925-0683, Expiration Date: 10/31/2016.

In July 2015, NINR publically launched the second phase of the campaign, which focuses on patients and their families to raise awareness about the benefits of palliative care, empower families to begin a dialogue with health care providers, and seek out palliative care information and resources. The purpose and overall goal of the second phase of the *Palliative Care: Conversations Matter*[®] campaign is to increase the use of palliative care for children and teens living with serious illnesses. All materials developed in both English and Spanish during the second phase of the campaign were tested with families to make sure the materials were clear and relevant for the intended audiences. NINR was approved by OMB for the testing of these materials under Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery (NINR), OMB#: 0925-0653, Expiration Date: 04/30/2018.

Phase Two campaign materials and messages are designed to assist families and caregivers with ongoing conversations about palliative care. Examples of messages used include:

- Pediatric palliative care is tailored to the unique needs of your child and family.
- Pediatric palliative care can enhance the quality of life for your child and family.
- Pediatric palliative care can begin at any time and be provided alongside your child's primary treatment.
- A serious illness affects the entire family, and pediatric palliative care can help support everyone.
- Pediatric palliative care surrounds your family with a team of experts who work together to support you and your child in a variety of settings.
- Talk to your loved ones and health care team about how pediatric palliative care can help your child and family.

The purpose of the *Palliative Care: Conversations Matter*[®] Phase Two Evaluation is to measure the effectiveness of the second phase of the campaign and its educational materials.

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 a 21 item web-based survey of parents and caregivers at one point in time for three years.

A.2 Purpose and Use of the Information Collection

This information collection is a revision to the previously OMB approved, *Palliative Care: Conversations Matter Assessment (NINR)*, OMB#: 0925-0683, Expiration Date: 10/31/2016. The purpose of the revision is to conduct an evaluation of the second phase of the *Palliative Care: Conversations Matter*[®] campaign. This second phase evaluation involves collecting feedback from parents and caregivers to ensure that the campaign is effective, relevant, and useful for this specific audience; whereas the first phase of the campaign collected data from health care providers.

Phase One evaluation of the *Palliative Care: Conversations Matter*[®] campaign involved health care providers filling out a baseline and post survey online to inform NINR of how effective the campaign was in initiating and continuing a palliative care conversation. Participants were primarily registered nurses and specialist physicians who cared for pediatric patients on a regular basis. The baseline survey was conducted in December 2013 and the post survey conducted in December 2014. The baseline survey involved 45 health care providers and the post survey involved 17 health care providers, which was 38% of the baseline participants. The estimated time for completing the surveys was 20 minutes. Therefore, the total annual burden was approximately 21 hours and the total annual cost to respondents was about \$1,030.

For this revised collection, NINR expects to conduct an online survey with 150 parents and caregivers. The survey should take approximately 15 minutes to complete. The total annual burden is estimated at approximately 371 hours. The total annual cost to respondents is estimated to be about \$8,425. Data collected are intended to indicate how effective the campaign is in initiating and continuing a palliative care

conversation and addressing the communication needs of patients and their families. NINR requests OMB approval for three years.

Information obtained through this evaluation 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?
2. Have the dissemination methods for the campaign been effective in reaching the intended audiences?

NINR will invite 150 parents and caregivers to provide feedback through the evaluation survey. The survey will be voluntary and will be conducted online. The survey (see Attachments 1 and 2) should take approximately 15 minutes to complete and contains 21 questions. The survey includes the following components:

- GENERAL AWARENESS, KNOWLEDGE, AND PERCEPTIONS OF PEDIATRIC PALLIATIVE CARE – a section in which parents and caregivers are asked to define pediatric palliative care and answer questions related to their palliative care experiences, attitudes, and beliefs.
- CAMPAIGN AWARENESS AND PERCEPTIONS – a section where parents and caregivers are asked about their awareness of the campaign and its materials, and behaviours related to seeking out pediatric palliative care information and resources.
- BACKGROUND INFORMATION – includes questions related to the demographics of the respondent.

The data collection period is estimated to last no more than two months. There has been no previous collection of this information by NINR.

A.3 Use of Information Technology and Burden Reduction

To reduce respondent burden, the evaluation survey will be deployed and submitted using a web-based electronic tool. Respondents will be sent an active URL link via email to access the screener for the survey to ensure that the survey will only be administered to individuals to whom the information is relevant. Given the busy schedules of this specific audience, this online methodology will allow survey respondents to provide information at their convenience. In addition, the 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 selected data collection vendor, Edge Research, will program and deploy the online surveys through opt-in online survey sample providers and host a secure website for the survey administration.

An email notification/invitation letter (see Attachments 3 and 4) will be sent by the panel provider targeting their databases of parents and caregivers with children under the age of 18. The email will inform the individuals about the survey and about the importance of their participation. In addition, the email will state that the survey is being conducted on behalf of NINR and will 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 responses are voluntary. The email will also include a URL link to a secure website and a unique login code which individuals can use to complete the screener and the survey anonymously.

Currently a Privacy Impact Assessment (PIA) is pending and will be provided when complete.

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

An evaluation survey for the *Palliative Care: Conversations Matter*[®] campaign has not been previously conducted among this population. The only similar information available may be from organizations such as the National Hospice and Palliative Care Organization (NHPCO) or the Agency for Healthcare Research and Quality (AHRQ), who collect general data on issues related to pediatric palliative care. However, since NINR is using this survey to specifically evaluate the campaign, 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

Currently there is a lack of research and data to understand the awareness, attitudes, and behaviors surrounding the use of pediatric palliative care. Assessment of this campaign will be used to help NINR 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).

A.8.1 Comments in Response to the Federal Register Notice

As required by 5 CFR 1320, a 60-day notice of this proposed data collection was published in the Federal Register, Volume 81, Page 45169 on July 12, 2016, and allowed 60-days for public comment. No public comments were received.

A.8.2 Efforts to Consult Outside Agency

NINR consulted with several individuals outside the agency regarding the proposed information collection including Edge Research, a communications consultancy with expertise in communication campaigns. 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:

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A.9 Explanation of Any Payment of Gift to Respondents

A customary element of panel management is to offer those who complete surveys a certain number of points. Over time, panel members have the opportunity to turn in these points for small prizes. Individuals who respond to this survey will receive a number of points identified by the panel provider that panel members typically receive for a survey of a similar length and incidence.

For this specific survey, participants will receive My View Points (MVP) for completing the survey. MVP are reward points panelists collect for participating in surveys on the Critical Mix Panel over time. The reward points panelists collect after taking various surveys can eventually be traded in for a range of gifts. Therefore, the points they obtain for completing this survey are not directly tied to a specific gift.

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 questionnaire (Attachments 3 and 4). The beginning of the web-based survey includes information about privacy (Attachments 1 and 2). NINR and Edge Research will follow best practices to maximize privacy and security of all data.

An informed consent form 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.
- Responding to the survey is voluntary, and the respondent can choose not to answer questions or can withdraw from the questionnaire at any time.
- NINR is authorized to conduct the questionnaire under section 42USC 285q of U.S. Law.
- To protect respondents' privacy, all presentation of data in reports will be in aggregate form, with no links to individuals.

In addition, IT security procedures will be implemented to protect data during and after administration of the survey. Specifically:

- Data will be collected using secure servers.
- Once data are collected, any meta-data associated with data collection (e.g. email address, and operating system used by the device to complete the system will be stripped from the files).
- Both Edge Research and NINR will follow the prescribed security protocols including:
 - Secure access to physical facilities.
 - Use of network security software.
 - Strong password requirements to access networks and password policies requiring frequent changes in passwords.
 - No administrative privileges for users of work stations.
 - Disaster recovery plans.

Once data are collected, only the staff working on the project will have access to the data.

With regards to the Institutional Review Board (IRB), this data collection is exempt from the regulations. NINR reviewed the Office of Human Subjects Research Protections' (OHSRP) Request for Determination Form and upon answering the initial questions, determined that NINR did not need to seek IRB review. NINR also received the following guidance from OHSRP regarding what is considered exempt: "As long as your project fits the description of Quality Assurance/Quality Improvement activity with non-clinical

practice focus and is not to conduct research, you may proceed without obtaining OHSRP approval.” (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.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

The incidence of parents and caregivers who have a child with a serious illness is estimated to be about 5% of all parents with children under the age of 18. As a result, it is estimated that 10,000 possible participants will need to be screened to find 500 who qualify for the research. Among those respondents that successfully complete the screening criteria for the survey, a response rate of 30% (150/500) is expected. This response rate is expected because of the time limitations of the audience (parents dealing with the serious illness of a child). This estimated response rate would produce the 150 total completes necessary for the survey. These estimates and corresponding burden hour calculations are below.

The total annual burden is estimated to be 371 hours (see Table A-12-1).

Table A-12-1 Estimated Annualized Burden Hours					
Form Name	Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Annual Burden Hours
Screener	Parents and Caregivers	10,000	1	2/60	333
Main Survey	Parents and Caregivers of Children with Serious Illnesses – Completes	150	1	15/60	38
Total		10,150	10,150		371

A.12.2 Annual Cost to Respondent

The total annual cost to respondents is estimated at \$9,084 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 2014, All Occupations, mean hourly wage.* Respondents to this questionnaire are parents and caregivers of children with serious illnesses.

Table A-12-2 Annualized Cost to Respondents			
Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
General Public	371	\$22.71	\$8,425

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*Bureau of Labor Statistics: The General Public rate was obtained from http://www.bls.gov/oes/current/oes_nat.htm#00-0000

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 \$43,750. 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, and management of survey implementation

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

Government Personnel	Time Commitment	Average Annual Salary	Total
GS-12, Step 5	10%	\$88,000	\$8,500
GS-13, Step 5	5%	\$104,000	\$5,200
Total Salary Costs			\$13,700
Contract Costs			\$30,000
Total			\$43,700

A.15 Explanation for Program Changes or Adjustments

This is a revised information collection request to conduct an evaluation of the second phase of the *Palliative Care: Conversations Matter*[®] campaign, which involves collecting feedback from parents and caregivers to ensure that the second phase of the campaign is effective, relevant, and useful for this specific audience.

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

The plan is to deploy the evaluation questionnaire in January 2017 or after OMB approval is received. The project schedule for completing data collection, processing, and data analysis is presented in Table A-16-1.

Activity	Time Schedule
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

The survey will obtain data from parents and caregivers who have opted into an online survey panel. 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 conducted for this evaluation survey. 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 parents and caregivers 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 defining pediatric palliative care, 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 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 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.