

SUPPORTING STATEMENT A For:

**A Generic Submission for Formative Research, Pre-testing, Stakeholder
Measures and Advocate Forms at NCI**

OMB # 0925-0641

**This is a revision of a currently approved submission.
Changes are indicated in yellow highlights.**

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3. Memo from NIH Privacy Act Officer
4. Privacy Impact Assessment (PIA)
5. OHSRP Exemption

This is a request for OMB to approve the revision of the generic collection titled, “A Generic Submission for Formative Research, Pre-testing, Stakeholder Measures and Advocate Forms at NCI” for an additional three years of data collection. The Office of Advocacy Relations (OAR) disseminates cancer-related information to a variety of stakeholders, seeks input and feedback, and facilitates collaboration to advance NCI’s authorized programs. It is beneficial for NCI, through the OAR, to pretest strategies, concepts, activities and materials while they are under development. Additionally, administrative forms are a necessary part of collecting demographic information and areas of interest for advocates. Pre-testing, or formative evaluation, helps ensure that the products and services developed by NCI have the greatest capacity of being received, understood, and accepted by their target audiences. Since OAR is responsible for matching advocates to NCI programs and initiatives across the cancer continuum, it is necessary to measure the satisfaction of both internal and external stakeholders with this collaboration. This customer satisfaction research helps ensure the relevance, utility, and appropriateness of the many initiatives and products that OAR and NCI produce. The OAR will use a variety of qualitative (focus groups, interviews) and quantitative (paper, phone, in-person, and web surveys) methodologies to conduct this research, allowing NCI to: 1) understand characteristics (attitudes, beliefs, and behaviors) of the intended target audience and use this information in the development of effective strategies, concepts, activities; 2) use a feedback loop to help refine, revise, and enhance OAR’s efforts—ensuring that they have the greatest relevance, utility, appropriateness, and impact for/to target audiences; and 3) expend limited program resource dollars wisely and effectively. The anticipated respondents will consist of: adult cancer research advocates; members of the public; health care professionals; and organizational representatives.

A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Cancer Institute (NCI) is the Federal Government's principal agency for research, training, health information dissemination, and other efforts with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients [Section 410 of the Public Health Service Act (42 USC § 285)].

The NCI Office of Advocacy Relations (formerly the Office of Liaison Activities) was established in 1996 in order to promote the Institute’s mission and support its programs. The Office of Advocacy Relations (OAR) is NCI’s liaison to patient advocacy organizations,

individual patient advocates, and professional societies concerned about cancer. The OAR disseminates cancer-related information to these stakeholders, seeks their input and feedback, and facilitates collaboration between the Institute and these external partners to advance NCI's authorized programs [Section 412 of the Public Health Service Act (42 USC § 285a-1)]: "The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer."

The OAR works with the internal NCI and NIH communities to identify opportunities for patient advocates to participate in NCI and NIH activities. For example, patient advocates participate as volunteers in peer review of grant applications and as members of advisory boards and committees. Once an opportunity is identified, the OAR then works with the external advocacy community to identify advocates who have the appropriate experience for that particular activity. Although most patient advocates participate in many different kinds of advocacy (patient support, fundraising, lobbying, etc.), OAR seeks to identify advocates who work specifically in research advocacy. Given NCI's research mission, advocates who do not have experience in research advocacy may not be appropriate participants in NCI activities.

The process of engaging advocates in NCI activities has several distinct steps that benefit from program evaluation research and standardized information collection. The steps in the process are:

- Recruitment of advocates
- Application process for advocates
- Training advocates and providing information

- Matching advocates to NCI activities
- Tracking and evaluating advocate engagement at NCI
- Promotion of advocate engagement at NCI

In the past the OAR has conducted research with both internal (NCI staff) and external (advocates) stakeholders and also collected information to enable the advocate engagement process. Past research has enabled OAR to monitor stakeholder trends, design and develop materials based on user feedback, assess the impact of activities, and improve service delivery.

OAR will now primarily utilizes questionnaires (written surveys), interviews, and focus groups to gather information. We plan to send a post-activity survey to the advocates who participated in the activity to ensure they received proper support. This information has helped OAR to adjust the matching process to better meet the needs of advocates. Through a series of interviews and focus groups¹, OAR gathered feedback on the perceptions of research advocates, and the perceived value of partnership with the advocacy community (**Attachment 1**). The information collected through these mechanisms guides OAR's strategic planning and helps improve training and customer service.

OAR has also requested information from advocates in order to match them appropriately to NCI activities. Due to the diversity of NCI activities that advocates participate in and the diversity of advocates' experience and preferences, there are many variables to consider when matching advocates to NCI activities. Since no administrative form was available in the past, individual advocates have submitted resumes or biosketches describing their experiences in research advocacy. In a tedious and time-consuming process, OAR staff have extracted the necessary information from the resume or biosketch to input

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into the online database of individual advocates². The resumes and biosketches submitted are not standardized or consistent in any way and often the advocate has to be contacted by OAR staff to provide additional information or clarification.

The lack of administrative forms to collect information from advocates in the past has also resulted in OAR needing to re-contact individual advocates to determine their interest and experience with new scientific topic areas that did not exist when the original resume or biosketch was submitted. New areas such as nanotechnology, proteomics, and genomics generate new NCI granting opportunities and other activities that involve advocates. It is imperative that OAR have information about advocates' experiences with these new areas in order to appropriately match them to NCI activities and to provide appropriate training opportunities. OAR's database of individual research advocates is often changed to accommodate this new information.

Past research conducted by OAR were sub-studies under an OMB generic clearance held by the Office of Communications and Education (OCE) under OMB #: 0925-0046 **Expiry Date 5/31/2016**. Past information collection activities provided general guidance to advocates but no online form or mechanism was provided for information collection. The OAR is now seeking to renew its own OMB generic clearance to expand the capacity of NCI to submit generic sub-studies in order to conduct formative research on program initiatives, pre-test of educational materials, and gather information about stakeholder knowledge, skills and satisfaction. OAR is also seeking to renew its own OMB generic clearance to allow OAR to continue to create and update in real-time administrative forms used in the advocate involvement process.

² PIA SORN 09-25-0106

A.2. Purpose and Use of the Information

The Office of Advocacy Relations has collected data from different stakeholder constituencies: NIH and NCI staff, NCI-funded scientists and staff from universities and cancer centers, research advocates and their advocacy organizations, and members of scientific and professional societies and their organizations concerned about cancer. In the past, OAR used an administrative form to capture applicant information such as basic contact information, age, gender, race and ethnicity, work focus, employment status, health experiences, and research advocacy experience. OAR will be rolling out a new database system which will allow this information to be collected electronically. The purpose of collecting the information electronically is to easily and appropriately match advocates to NCI initiatives and activities as well as to assist NCI researchers in finding advocates to support their activities.

At the end of a successful match, we may decide to send a post-activity survey to the advocates who participated in the activity to ensure they received proper support. In the post-activity survey, respondents may provide information about:

- *Expectations* – In an effort to manage expectations, OAR may collect data on whether anticipated beliefs about advocacy performance, extent of participation, and program support were met. For example, “Did your overall contribution to the activity or project meet your expectations?”
- *Facilitators and Barriers* – The OAR strives to facilitate advocate involvement and reduce barriers to it. Items to be measured include program awareness, availability of adequate travel funds, ease of advocate request process, appropriate orientation and activity preparation, and timely follow-up.

- Program Recommendations – The OAR has greatly benefited from incorporating stakeholder feedback into efforts to improve program structure and processes. For example, the OAR is redesigning its advocate involvement program based on input from research advocates and other stakeholders. Questions to elicit recommendations would include, “What would you like to see improved at OAR?”
- Recruitment – A diverse pool of qualified advocates must be recruited and matched to NCI-activities based on scientific advances and the subsequent needs of researchers and other staff. The OAR would support its recruitment efforts by identifying “What experiences and skill sets are required of advocates for this activity?” and also by asking advocates if they have these experiences and skills in the administrative forms. Due to natural attrition and changing scientific needs, OAR will need to continually recruit new advocates to participate in NCI activities.
- Application –OAR anticipates using an electronic administrative form to capture information such as basic contact information, age, gender, race and ethnicity, work focus, employment status, health experiences, and research advocacy experience. This form will be continually updated and adjusted to meet NCI’s changing scientific needs in emerging scientific areas. Additional forms may be used for application to various advocate programs such as the NCI’s only all consumer advisory board – the NCI Director’s Consumer Liaison Group (DCLG).
- Satisfaction –OAR is working to help foster an organizational atmosphere that values the contributions of research advocates. To help determine if this goal is being met, it’s important to measure staff satisfaction with the process of requesting advocates, the extent to which advocates abilities and experiences matched the activity, and the overall contribution of the advocate. Advocates and organizations will also provide feedback on their satisfaction working with the NCI and the information they receive from NCI.
- Training Needs – Advocate training is a necessity because science is rapidly advancing and research advocates need new knowledge and skills to fully contribute as equal partners in the research process. Training needs are identified with questions

such as, “Are there any specific areas in which you believe advocates should be trained?”

- *Knowledge and Behavioral Assessment* – Advocates may be asked about their knowledge of NCI, research advocacy, and their behavior in various scientific activity scenarios.

One sub-study had been approved which will allow us to collect information until September 30, 2014. From 2012 through 2013, OAR went through a transition in leadership and staff, and the office did not have dedicated staff to collect and update NCI research advocate information. Since summer 2014, we have been able to focus on rebuilding our pool of advocates and have spoken to several individuals who have expressed interest in becoming NCI research advocates. As the online system is not yet functional for the advocate to submit their own information, we have been inputting it for them. This OMB renewal will allow us to continue to gather the necessary information about our advocate pool to ensure we have a wide range of individuals at varying levels of expertise and experience.

A.3. Use of Information Technology and Burden Reduction

As computer technology has continued to improve and become more widespread, opportunities to pretest messages on the Internet using either Web site questionnaires or on-line focus groups with Internet users have increased. Improved technology in the collection and processing of data has the potential to reduce the time burden for respondents and data collectors. For example, respondents can access and respond to data collection requests at a time and place that is convenient to them, eliminating the need to travel for in-person or group interviews. Also, individual NCI advocates can update their resume information online at a

time and place that is convenient to them, and as often as their experiences and interests change. This eliminates the need for Federal Government staff and contractors to contact advocates individually to determine their interests and experiences with new scientific topics. Wherever possible, NCI will make use of Web- or computer-based data collection methods. Transmission of data collection instruments and responses by electronic mail or facsimile will be utilized as appropriate. NCI anticipates that of the majority of data will be collected electronically. Privacy safeguards will be undertaken with assistance from the NCI Privacy Act Coordinator and the Information Security Office during the data collection process to mitigate any risks.

On-line surveys represent an especially convenient option for eliciting feedback from consumers of Web-based products. With online surveys developed by the NCI or approved contractors, respondents can easily submit feedback during or immediately after using a Web-based product. They also allow participation from international audiences with virtually no additional costs.

A Privacy Impact Assessment (PIA) has been completed and published by HHS on February 22, 2011 (**Attachment 4**). The IT system name is “NIH NCI Office of Liaison Activities Database (OLA).”

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

The general areas in which information needs to be gathered (as described in A.2. above) are similar to questions asked previously of NCI stakeholders. However, because advocates are continually paired to new activities with different researchers, the measurement of these experiences for individual performance, met expectations, facilitators/barriers, and satisfaction do not impose unnecessary duplication. Currently, there is no similar information that would serve the agency's need and purpose.

Literature searches, professional-to-professional discussions, use of data collections in the private sector, as well as other government surveys or pilot studies will be employed whenever possible to meet the needs of NCI. Additionally, NCI has an internal review process for surveys that will be used by this generic clearance to assess the quality of each survey prior to its use. The NCI will provide direct oversight for any and all surveys conducted under this generic clearance to avoid duplication of effort and information collected.

The administrative forms will be used to collect demographic information and to assess research advocates' experience and skills. This information is only available from the research advocates themselves, and cannot be found anywhere else. Having an administrative form to collect this information will lessen the burden hours required for advocates to submit information to become involved in NCI activities.

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

Small businesses that are non-profits and independently-owned may be participants in this generic submission. The small businesses we may include are physicians, other health

care providers, and highly specialized individuals for evaluation of NCI's communication information and customer satisfaction materials. When small businesses are asked to complete an information collection, all efforts will be made to reduce their burden by using a short survey and interviewing more small businesses than larger ones.

A.6. Consequence of Collecting the Information Less Frequently

For the most part, formative research, pre-testing, and stakeholder satisfaction information will be collected only one time for each material tested or activity completed. Administrative forms about the experience of research advocates will be completed once initially for each advocate and then updated by the advocate when they believe it is appropriate. However, there may be occasion where a pre- and post-test to assess differences in knowledge, attitudes, or practices may be useful for a particular sub-study. Additionally, previous respondents may be contacted to participate in follow-up studies if they have originally granted consent for such and if the subsequent study uses that population.

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

There are no special circumstances.

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

The 60-day Federal Register notice soliciting comments on OAR's efforts prior to initial submission to OMB was published on July 18, 2014 (79 FR 42023). No public comments were received.

The questionnaires previously used by OAR were developed with consultation from a number of scientists and research advocates. External stakeholders, including some members of the Advocates in Research Working Group (e.g., Jane Perlmutter, PhD, Founder – Gemini Group, (734) 604-5263) will help craft future research instruments for the OAR (**Attachment 2**). Also, the OAR will also consult with several internal experts across NCI (e.g., Rick Moser, PhD, Psychologist, 301-496-0273 and Gordon Willis, PhD, Cognitive Psychologist, 301-534-6652- both from the Division of Cancer Control and Population Sciences). Additionally, a number of outside experts will be contracted to review the plans for program development research and evaluation of OAR activities.

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

No incentives will be given.

A.10. Assurance of Confidentiality Provided to Respondents

Information provided by respondents will be kept secure to the extent provided by law. This will be communicated to respondents by means of introductory letters, explanatory texts on the cover pages of questionnaires, scripts read prior to focus groups and consent forms. There will be a separate consent form for each generic sub-study, and the consent form will be submitted to OMB for review with each sub-study submission. Respondents will

also be advised of the following: the nature of the activity; the purpose and use of the data collected; NCI sponsorship; and the fact that participation is voluntary at all times. Because responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions.

As a further guarantee of security, all presentation of data in reports will be in aggregate form, with no links to individuals preserved. Reports will be used only for research purposes and for the development of communication messages and educational materials. Only NCI staff and contractor personnel conducting the information collection will have access to individual-level survey, interview, or focus group data. All project/contractor staff conducting the information collection will sign a confidentiality agreement, and all electronic and hard-copy data will be maintained securely throughout the information collection and data processing phases. While under review, electronic data will be stored in locked files on secured computers; hard-copy data will be maintained in secure building facilities in locked filing cabinets. Before any data are released for public use data sets, any identifying information will be stripped from each respondent's record and the identifying information will be destroyed.

The NIH Privacy Act Officer has reviewed the work scope of this proposal and has determined that the Privacy Act is applicable to this data collection and is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD" (**Attachment 3**). The NIH Privacy Act Officer will be asked to review

the protocols of each sub-study under this generic clearance to ensure that NCI adheres to privacy requirements.

Personally identifiable information (PII) will be collected (see Section A.11 for further details). Although some PII will be collected, data will not be retrieved by personal identifiers unless the respondent voluntarily agrees to provide the information, so he/she can be contacted for follow-up. Instances could arise for activities that, for example, gather and retain respondent names and contact information.

The Office of Human Subjects Research (OHSR) considers pre-testing efforts described in this proposal exempt from the “Regulations for the Protection of Human Subjects,” in accordance with paragraph (b)(3) of 45 CFR Sec. 46.101 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101>), and as deemed by the OHSR. The OAR will work with OHSR in determining which sub-studies should be submitted for review/exemption.

A.11. Justification for Sensitive Questions

As mentioned in sections A.2. and A.10. , some studies require the inclusion of people who match selected characteristics of the target audience that NCI is trying to reach. Therefore, PII such as gender, age, race/ethnicity, address, telephone number, email address, education, medical/health status, occupation, and ability to travel may be required to be asked on the initial screening questionnaire used for recruiting. Potential participants are informed that this is being done to make sure that NCI speaks with the kinds of people for whom its messages are intended. Again, respondents are assured that the information is voluntary and

will be kept secure to the extent provided by law. All information on race/ethnicity will comply fully with the standards of OMB.

A.12. Estimates of Annualized Burden Hours and Costs

The number of respondents will vary depending on the nature of the NCI activity involving advocates or the topics being addressed by interviews or focus groups. Table A.12-1 below provides an example of a distribution of respondents and hours by type of data collection. It is estimated that there will be 975 respondents, for a total annual burden 1,025 hours. The NCI anticipates that over the three-year life of the project, there will be a total of 2,925 respondents, amounting to a burden of 3,075 hours.

Table A.12-1- Annualized Burden Hour

Respondent Type	Form Name	Number of Respondents	Frequency of Response	Average Time Per Response (Minutes/Hour)	Annual Burden Hours
Individuals	Self-Administered Questionnaires	800	1	1	800
	Individual In-Depth Interviews	75	1	1	75
	Focus Group Interviews	100	1	90/60	150
Total		975			1,025

It is estimated that the annualized cost to the respondents will be \$43,544. The NCI anticipates that over the three-year life of the project, the total cost to respondents will amount to \$130,632 (Table A.12-2). The wage rate of \$44.66 was calculated by averaging the wage rates for each of the four respondent types: adult cancer research advocates; members of the public; health care professionals; and organizational representatives. The members of the general public wage rate is based on the estimate of \$22.00/hour. The general public rate was obtained from http://www.bls.gov/oes/current/oes_nat.htm#00-0000 occupation code 00-0000. The health care professionals wage rate is based on the physicians and scientists rate which is approximately \$90.00/hour obtained from <http://www.bls.gov/oes/current/oes290000.htm> occupation code 29-1069. The adult cancer care research advocates wage rate \$21.97 based on the category “Miscellaneous Life, Physical, and Social Science Technicians occupation code 19-4090 from http://www.bls.gov/oes/current/oes_nat.htm#19-0000 Organizational representatives constitute federal employees who are fulfilling their job responsibilities hence they are not included in the respondent costs. Table A.12-2 represents the best estimate that can be given based on estimates of who the respondents are for upcoming generic sub-studies. The number and types of respondents may vary from this estimate. All of these estimates are based on 2013 data from the Bureau of Labor Statistics.

A.12-2: Annual Respondent Costs

Form Name	Total Annual Burden Hours	Hourly Respondent Wage Rate	Annual Cost	Three Year Cost
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Self-Administered Questionnaires	800	\$44.66	\$35,728	\$107,184
Individual In-Depth Interviews	75	\$44.66	\$3,350	\$10,050
Focus Group Interviews	100	\$44.66	\$4,466	\$13,398
Total	975		\$43,544	\$130,632

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Record keepers

There are no capital or start-up costs to 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 annual cost to the government for the services of the evaluation contractor is \$85,000 for interviews and focus groups. NCI staff time required participating in planning and designing activities, collecting data, and conducting analysis is estimated below by percent effort and salary. These figures correspond to a total average of \$42,615 over 12 months. Finally, there are government costs associated with data analysis, which total \$2,540/year. The total annualized cost to the government is \$160, 155, which amounts to an estimated \$480,465 over the course of three years.

Data for the focus groups and in-depth interviews will be collected in NCI space requiring advocates to travel from other states incurring transportation costs (e.g. airline ticket, parking fees, lodging and per diem) to participate. Transportation costs will be

determined on a case-by-case basis and dependent on the particular information collection activity being requested. In any such instances, compliance with Federal rules and regulations specified in the NIH Manual Travel Policies and Procedures (<http://oma.od.nih.gov/manualchapters/management/1500/>) will be followed.

The overall government distribution is summarized in the following table:

Table A.14-1 Government Cost Distribution

	GRADE/SALARY/ PERCENT EFFORT	ANNUAL AVERAGE	THREE-YEAR PROJECT PERIOD
Contractor Staff Costs	10%	\$85,000	\$255,000
NCI Staff/Oversight	GS-13/7 (\$107,909 x 15%) GS-11/1 (\$63,091 x 25%) GS-7/1 (\$42,631 x 25%)	\$42,615	\$127,845
NCI Staff/Analysis	GS-11/1 (\$63,091 x 2%) GS-7/1 (\$42,631 x 3%)	\$2,540	\$7,620
Travel/Transportation		\$30,000	\$90,000
Total		\$160,155	\$480,465

A.15. Explanation for Program Changes or Adjustments

This is a revision. This submission has been active over the past couple of years and anticipates a continued activity at the current level. Since less of the previously requested burden hours were used over the course of the past three years, the program is asking for a slight reduction in burden hours. Additionally, over the last two years, OAR has phased out

the CARRA program. OAR still maintains and utilizes its robust network of research advocates (including former CARRA members) and plans to broaden the pool by including research advocates with varying levels of experience to best match NCI's activity requests as they arise. The end of the CARRA programs meant many functions of the database are no longer necessary. Due to budgetary restrictions, OAR will not offer any type of incentives or gifts. In addition, statistical analysis will no longer be performed because of the slimmed down advocate matching process.

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

There are no plans for statistical analysis. OAR staff will search the data to match advocates to NCI activities, including looking at their experience in the advocacy and cancer research fields. No results will be published. This project will be ongoing.

While the primary purpose of all OAR studies is to provide information for the purposes of improving programs and activities, NCI shares information internally and also makes results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. Information provided internally may include respondent demographics, basic descriptive data, comparisons across demographic and stakeholder subgroups, and recommendations for improving programs and products,.

A.16.1 Project Time Schedule

Activity	Months after OMB Approval
Contact potential research advocates	0 – 2
Complete profile online (collect information)	Begin immediately, ongoing
Review profiles	Begin immediately, ongoing
Follow-up call to verify information	Begin immediately
Update profile	12 months

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

The OMB control number and expiration date will be displayed in the upper right-hand corner of all data collection instruments.

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

NCI is in full compliance with the provisions contained within the Certification for Paperwork Reduction Act.