

SUPPORTING STATEMENT A For:

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

OMB # 0925-0641 Expiration Date: 1/31/2021

This is a Reinstatement without change of a currently approved submission.

Date: January 15, 2021

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing Collection in Use Without an OMB Number

Federal Government Employee Address:

Name: Amy Williams

Address: 31 Center Drive, Bldg. 31 Room 10A28, MSC 2580 Bethesda, Maryland 20892

Telephone: (240) 781-3406

Fax: (240) 451-4517

Email: amy.williams@nih.gov

Table of Contents

A.	JUSTIFICATION.....	1
A.1	CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY.....	1
A.2.	PURPOSE AND USE OF THE INFORMATION.....	5
A.3	USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION.....	7
A.4	EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION.....	9
A.5	IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES.....	10
A.6	CONSEQUENCES OF COLLECTING THE INFORMATION LESS FREQUENTLY.....	10
A.7	SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5.....	10
A.8	COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE AND EFFORTS TO CONSULT OUTSIDE THE AGENCY.....	12
A.9	EXPLANATION OF ANY PAYMENT OR GIFT TO RESPONDENTS.....	13
A.10	ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS.....	15
A.11	JUSTIFICATION FOR SENSITIVE QUESTIONS.....	17
A.12	ESTIMATES OF ANNUALIZED BURDEN HOURS AND COSTS.....	17
A.13	ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS AND RECORD KEEPERS.....	19
A.14	ANNUALIZED COST TO THE FEDERAL GOVERNMENT.....	19
A.15	EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS.....	20
A.16	PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE.....	20
A.17	REASON(S) DISPLAY OF OMB EXPIRATION DATE IS INAPPROPRIATE.....	22
A.18	EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS.....	22

LIST OF ATTACHMENTS

1. Attachment 1 - Memo from NIH Privacy Act Officer
2. Attachment 2 - Privacy Impact Assessment (PIA)
3. Attachment 3 - OHSRP Exemption
4. Attachment 4 - Interview Guide
5. Attachment 5 - Profile Completion Questionnaire

A. JUSTIFICATION

This is a request for OMB to approve the Reinstatement without change 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. 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 (interviews) and quantitative (paper, phone and in-person 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.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 always 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
- Providing information and educational opportunities
- 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 utilize interviews to gather information. We plan to hold a post-activity phone call 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 the Institute and prepare advocates for engagement.

OAR has also requested information from advocates in order to match them appropriately to NCI activities using the Profile Completion Questionnaire (**Attachment 5**). 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 had previously extracted the necessary information from the resume or biosketch to input into the online database of individual advocates. The ability to have advocates enter their own research advocate interests and experiences into the database has streamlined the process, allowed for standardization of information collected and helped avoid documentation errors.

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**. OAR's database of individual research advocates can be 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. OAR is 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.

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. **OAR uses the Profile Completion Questionnaire (Attachment 5), 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 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 continue to use the 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. In the previous three years, OAR has welcomed 49 advocates into our network. Advocates have contributed to over 30 activities, ranging widely in scope and duration. Several examples include speaking engagements, Task Force appointments, Steering Committee appointments, webinars, Advisory Board appointments, etc.

At the end of a successful match, we may decide to conduct a post-activity interview (**Attachment 4**) to the advocates who participated in the activity to ensure they received proper support. In the post-activity interview, 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.
- *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.

- **Advocate Information** –OAR uses 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’s Council of Research Advocates.
- **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.

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.

A Privacy Impact Assessment (PIA) has been completed and was approved by HHS on April 29th, 2020 (Attachment 2). The IT system name is “NCI Office of Advocacy Relations (OAR) Research Advocate System (RAS) (P-4190804-047456).”

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.8.1 Comments in Response to the Federal Register Notice

The 60-day Federal Register notice soliciting comments on OAR's efforts prior to initial submission to OMB was published on (October 8, 2020) (Vol. 85 PAGE 63565). No public comments were received.

A.8.2 Efforts to Consult Outside Agency

The questionnaires previously used by OAR were developed with consultation from a number of scientists and research advocates. External stakeholders helped craft current research instruments for the OAR.

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 1**). 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 (**Attachment 3**). 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. **Information on gender will be limited to self-reported gender.**
Information regarding sex assigned at birth is unnecessary for this project and thus won't be

included or asked of participants. In addition, many health care providers do not routinely discuss sexual orientation or gender identity (SO/GI) with patients, and many health care facilities have not developed systems to collect structured SO/GI data from all patients. Without this information, lesbian, gay, bisexual, and transgender (LGBT) patients and their specific health care needs cannot be identified, the health disparities they experience cannot be addressed, and important health care services may not be delivered. Collecting SO/GI data in electronic health records (EHRs) is essential to providing high-quality, patient-centered care. SO/GI data collection has been recommended by both the National Academy of Medicine^{1,2} and the Joint Commission³ as a way to learn about which populations are being served and to measure the quality of care provided to LGBT people. In discussions OAR has with members of the advocacy community, we've learned that it's often important to be aware of advocates' specific gender identity when referring them to program staff for specific projects and having discussions with them about issues within their communities. When considering a particular topic, the issues facing patients who identify as Transgender Male might be very different than issues facing patients who identify as Transgender Female, therefore, it's important for our database to capture this specific information so we can work with these specific audiences and have discussions that best inform NCI's work. In addition, having an option for advocates to identify as "Other" will allow us to best understand how they self-identify and allow us to conduct this work inclusive of the entire community.

A.12.1 Estimated Annualized Burden Hours

The number of respondents will vary depending on the nature of the NCI activity involving advocates or the topics being addressed by interviews as well as number of advocates recruited to NCI. 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 36 respondents annually, for a total annual burden hours of 18. The NCI anticipates that over the three-year life of the project, there will be a total of 108 respondents, amounting to a burden of 54 hours.

Table A.12-1 Estimated Annualized Burden Hour

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Individuals	Individual In-Depth Interviews	6	1	30/60	3
	Profile Completion	30	1	30/60	15
Total			36		18

A.12-2: Annualized Cost to the Respondents

It is estimated that the annualized cost to the respondents will be \$896.04.

Table 12-2 Annualized Cost to the Respondents

Type of Respondents	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Respondent Cost
Individuals	18	\$49.78	\$896.04
Total			\$896.04

The wage rate of \$49.78/hour was calculated by averaging the wage rates from the Bureau of Labor statistics for the following occupation codes: General Public wage rate (occupation code 00-0000) of \$25.72/hour, the Physicians and Scientists rate (occupation code 29-1228) of \$97.81/hour, Miscellaneous Life, Physical, and Social Science Technicians (occupation code 19-4099) of \$25.80/hour.
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 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 contractor is \$4,704.95 for maintenance and interviews. NCI staff time required participating in planning and designing activities, collecting data, and conducting analysis is estimated below by percent effort and salary; this figure corresponds to a total average of \$854.00 over 12 months. The total annualized cost to the government is \$5,558.95, which amounts to an estimated \$16,676.85 over the course of three years.

Cost Descriptions	Grade/Step	Salary**	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Director – Office of Advocacy Relations	15/10	\$170,800	0.5%		\$ 854.00
Contractor Cost		\$94,099	5%		\$4,704.95
Travel					\$0
Other Cost					\$0
Total					\$5,558.95

**The Salary in the table above is cited from: Office of Personnel Management <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB.pdf>.

A.15. Explanation for Program Changes or Adjustments

This is a Reinstatement without change. Previously, the database needed to be built and more frequently edited to meet the needs of OAR and the advocacy community, which necessitated a large number of burden hours. In its current form, the database is fully developed, and we haven't needed to make nearly as many changes as in previous years. In addition, the work of our office has not necessitated any sub-studies, nor does it anticipate any in the near future. Therefore, the program is asking for a reduction in burden hours. Annual burden hours for previous submission (2017) were proposed at 45, annual burden hours for current submission

(2020) are proposed at 18, for a 27-annual burden-hour reduction. Previous submission (2017) respondents were 90 and proposed respondents (2020) are now 36, this is a reduction of 54. Proposed costs to the Government and the number of respondents has also been reduced. Government costs for previous submission (2017) were proposed at \$25,613 per year, Government costs for current submission (2020) are proposed at \$5,558.95 per year, for a proposed reduction in costs of \$20,054.05 per year. Due to budgetary restrictions, OAR does not offer any type of incentives or gifts.

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

OAR staff will search the data to match advocates to NCI activities, including looking at their experience in the advocacy and cancer research fields. Number of activities at the Institute and number of advocates participating in these activities may be published in an OAR newsletter.

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 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
Complete profile online (collect information)	Ongoing
Review profiles	Ongoing

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.