Supporting Statement, Section A (0925-0530)

National Center for Complementary and Alternative Medicine

Communications Program Planning

Request for Reinstatement

Refer questions to:

Christy Thomsen
Director, Office of Communications and Public Liaison
National Center for Complementary and Alternative Medicine
31 Center Drive, Room 2B-11
Bethesda, MD 20892-2182
Telephone: 301-594-1873
Fax: 301-402-4741
E-mail: thomsenc@mail.nih.gov

Table of Contents

Contents

Introduction

This submission to OMB is a request to reinstate generic clearance granted under OMB 0925-0530 for data collection efforts to inform communications program planning activities. This Supporting Statement describes in general terms the purposes of the proposed data collections, the types of data to be collected, and the methodologies to be used. The data collection instruments provided in conjunction with the ICR are samples only.

A separate request will be made to OMB for specific data collection efforts covered under this generic clearance. Each separate request will include the following:

Cover Memo
NCCAM letterhead
Date
Routing information
"NCCAM Communications Program Planning"
Title of the research
Submission Form
Date
Title of the research
OMB clearance number
Survey instrument titles
Internal control numbers for each survey instrument
Burden hours requested for each survey instrument
Total burden hours for the research
Research Plan Summary
Synopsis or outline of the research plan
Sampling plan, if applicable
Analysis plan, if applicable
Statement of compliance with Privacy Act, if applicable
Justification for sensitive questions, if applicable
Justification for multiple responses, if applicable
Justification for remuneration, if applicable
Survey Instruments
OMB clearance number in upper right
Expiration date in upper right
Internal control number
Survey questions
Burden disclosure information at bottom

A.1. Circumstances Requiring the Collection of Data

Pursuant to 42 USC 287c-21, the National Center for Complementary and Alternative Medicine (NCCAM), a component of the National Institutes of Health (NIH), is charged with "the dissemination of health information . . . with respect to identifying, investigating, and validating complementary and alternative treatment, diagnostic, and prevention modalities, disciplines, and systems."

NCCAM's mission is to explore complementary and alternative healing practices in the context of rigorous science, train complementary and alternative medicine (CAM) researchers, and disseminate authoritative information to the public and professionals. Our primary areas of focus are

- **Research.** We support clinical and basic science research projects in CAM by awarding grants across the country and around the world; we also design, study, and analyze clinical and laboratory-based studies on the NIH campus in Bethesda, Maryland.

- **Research training and career development.** We award grants that provide training and career development opportunities for predoctoral, postdoctoral, and career researchers.

- **Outreach.** We sponsor conferences, educational programs, and exhibits; operate an information clearinghouse to answer inquiries and requests for information; provide a Web site and printed publications; announce published research results; and hold town meetings at selected locations in the United States.

As the only entity within the Federal Government whose sole focus is CAM, NCCAM is committed to communicating clearly and effectively with all its constituencies, which include the general public, health care providers (both conventional and CAM), and researchers.

The Office of Communications and Public Liaison (OCPL) is NCCAM's chief source of education and outreach about CAM. NCCAM's OCPL is mandated to provide NCCAM's public information services. OCPL coordinates activities related to the dissemination of evidence-based information about CAM. OCPL develops and implements communication and outreach strategies to promote awareness and informed decisionmaking about CAM use; furnishes science-based information to its audiences; serves as the liaison with the media and other institutes and centers; explains rigorous reviews of research in consumer-friendly and actionable (from a social marketing standpoint) terms; and operates NCCAM's Clearinghouse.

CAM presents unique challenges in terms of health communications. In addition, often misleading and unreliable claims of health benefits from CAM products and approaches are delivered to the public by various sources. No other NIH institute or center is faced with the challenge of communicating the risks associated with untested and unproven healing practices being widely used by the public to the extent that NCCAM has faced. Further, each of our

constituencies is likely to have unique information needs and distinct health-information-seeking behaviors.

Information programs within OCPL create and use a variety of media, including print (e.g., brochures, posters, fact sheets, and information kits), audiovisual, and electronic formats (e.g., Web content, videocasts, online newsletters, and listserv bulletins), as well as continuing medical education materials. These media, as well as direct response through the NCCAM Clearinghouse, are used in conjunction with outreach efforts (including exhibits, lectures, and clinical trials promotion) to inform and educate target audiences about CAM. Production of these materials and promotion of outreach efforts are the primary ways that NCCAM conveys messages to the audiences it is mandated to reach.

Through continued market and consumer research, OCPL will refine its knowledge of the composition and characteristics of its target audiences, which include members of the general public, researchers, providers of both conventional health care and CAM, and the media.

In order to continue qualitative and quantitative research activities, OCPL requests extended authorization to use the following data collection methods:

- Individual in-depth interviews
- Focus group discussions
- Intercept interviews
- Self-administered questionnaires
- Omnibus surveys

For this reinstatement request, we have removed gatekeeper reviews from our previous package. Permission to collect these data is authorized under Executive Order 12862, which directs Federal agencies that provide services directly to the public to survey customers to determine the kind and quantity of services they want.

A.2. Purposes and Uses of the Data

Through ongoing qualitative and quantitative research, OCPL can focus its efforts to hone its messages and activities, and thus expend limited program resource dollars efficiently, as the Office gains a broader and deeper understanding of intended audiences. Continued data collection will help NCCAM meet its unique health communication challenges by providing information on the knowledge, attitudes, and behaviors of audiences faced with decisions about popular, yet unproven, healing practices.

The response data collected under this renewed generic clearance will enhance NCCAM's ongoing program planning efforts. NCCAM will use the findings to improve communications activities in the following ways:

- Segment key audiences and identify their information needs
- Develop additional program plans to meet the needs of our diverse audiences

- Continue to develop messages based on the knowledge, preferences, attitudes, and behaviors of core audiences

Specific and in-depth information regarding the methodologies that NCCAM will employ to gather the needed information can be found in Section B.

Since this generic package was approved in 2007, NCCAM has conducted several studies, including:

- Self-administered questionnaire for consumers to assess usability and resonance of a suite of educational materials regarding patient/provider communications around complementary and alterative medicine.
- Self-administered questionnaire for health care providers to assess usability and resonance of a suite of educational materials regarding patient/provider communications around complementary and alternative medicine.
- Self-administered questionnaire for newsletter subscribers to assess customer satisfaction.
- Self-administered questionnaire for health care providers to assess needs for an online health care provider portal of clinical information about complementary and alternative medicine.
- Focus groups with health care providers to assess needs and pretest an online health care provider portal of clinical information about complementary and alternative medicine (currently under OMB review).

A.3. Use of Information Technology to Reduce Burden

A number of steps have been planned to ensure the least burden possible is shouldered by the public. These steps have been updated from our previous approval in 2007, and include:

- Recruitment screeners have been designed for recruiters to quickly identify qualifying participants through a brief telephone conversation
- Discussion guides have been developed to ensure that interview and focus group discussions are well-organized, flow well together and are easy to understand. These guides will ensure that discussions are kept to the minimum time necessary
- Online focus groups will be convened where geographic diversity is important and participants come from hard-to-recruit populations
- For self-administered questionnaires, closed-ended questions (e.g., multiple choice) and machine-readable answer sheets will be used when feasible
- Secure electronic transmission of data collection instruments and responses will be used as appropriate

Further information about how the various methodologies will be used to minimize respondent burden can be found in Section B.

A.4. Efforts to Identify Duplication

Our communications program planning activities are first informed by data gleaned from the current literature and from NCCAM's past and ongoing data collection activities—or they incorporate data that can be obtained without incurring a public burden (e.g., quantity of materials disseminated, the number of public inquiries to the Clearinghouse and OCPL, and media activity). Additional data collection efforts will be limited to areas where information is not otherwise available.

A.5. Small Business

Physicians and other health care providers are sometimes the target audience for NCCAM products and programs. In addition, health care providers are sometimes gatekeepers for products designed for patients and the general public. When data collection efforts involve health care providers, OCPL works through established medical and professional societies to gain access to potential respondents and obtain feedback on instruments and data collection plans. The Office may also utilize its own newsletter subscription list as a means of identifying potential respondents. As a result, OCPL is able to minimize burden on health care providers. While physicians and CAM practitioners in private practice may be considered small businesses, they will not be asked to make available information from patient records; they will be surveyed as individuals, like other respondents, and will not be considered small businesses for the purposed of the proposed research.

A.6. Consequences of Not Collecting the Information

In most cases information is collected only once from each respondent during a given study, though there may be periodicity in some studies. Each specific data collection request will be submitted to OMB for approval under this renewed generic clearance. If periodicity is required, it will be explained and justified within individual data collection submission packages.

A.7. Special Circumstances Justifying Inconsistencies with Guidelines in 5 CFR 1320.6

The data collection fully complies with all guidelines of 5 CFR 1320.6

A.8. Consultation Outside the Agency

As required by 5 CFR 1320.8(d), comments on this information collection were solicited from the general public in a 60-day notice that appeared in the Federal Register, volume 75, number

164, page 52350, on August 25, 2010. One comment was received in response to the notice. The verbatim comment follows:

> "OUR GOVT SPENDS SO MUCH ON RESEARCH, THERE ARE NO TAX DOLLAS LEFT TO DO ANYTHING WITH. NO MONEY FOR ACTION. WE JUST KEEP ACCUMULATING AND ACCUMULATING MORE AND MORE INFO, WITH N O ACTION EVER RSULTING. THAT IS STUPID TO THE MAX.
>
> SECONDLY IF THIS AGENCY IS HIRING FOR THIS HIGH PAYING JOB PEOPLE WHO ARE "KNOW NOTHINGS" WHO NEED TO DO ALOT OF RESERACH TO KNOW ANYTHING, THEN THE PEOPLE WE ARE HIRING ARE JUST A LOT OF HOT AIR THAT WE DONT NEED IN THE FIRST PLACE. THE US GOVT PAYS HIGH SALARIES AND BENEFITS. THEY EXPECT TO HIRE PEOPLE WHO KNOW WHAT THE ISSUES ARE AND ARE GOING TO ACT ON THEM. WE SHUOLD NOT BE HIRING PEOPLE WHOSE FIRST ACTION AFTER GETTING THE JOB IS TO FIND OUT WHAT THE HELL THEY ARE SUPPOSED TO BE DOING.
>
> ALSO IT IS TIME THIS AGENCY STARTED LISTENING INSTAD OF "DISSSEMINATING". THAT IS WHAT IS WRONG WITH THIS GAENCY. YOU KEEP TELLING THE PUBLIC INSTEAD OF "LISTENING". YOU ARE PUBLIC SERVANTS. REMEMBER THAT.
> JEAN PUBJL,IC 153LMSTFLORHAMPARK NJ07392"

A 30-day Federal Register notice is being submitted in conjunction with this package.

In addition, NCCAM consults frequently with other Government entities (e.g., the U.S. Department of Health and Human Services, Public Health Service, and the Food and Drug Administration) to help ensure accurate, consistent messages and to avoid duplications of effort.

A.9. Payments or Gifts to Respondents

Incentives can be critical to the success of data collection activities such as focus groups and interviews with physicians and other medical staff. NCCAM anticipates that respondent incentives will be used for all focus group data collections, since focus groups often require travel, logistical arrangements, and related expenses. Remuneration may also be offered for in-depth individual interviews with physicians and other health care providers. However, NCCAM does not plan to offer incentives for intercept interviews with the general public.

If remuneration is considered critical to successful fielding of a specific data collection effort, OCPL makes a specific request to OMB with ample justification. The request identifies:

- The target audience
- The rationale for remuneration

- The dollar value of the individual payment
- The projected cost of remuneration for the specific data collection.

This information will be included in the submission package described in the Introduction to this section.

A.10. Assurance of Confidentiality

(This information has been updated since our 2007 approval.) Participation in each study is voluntary and respondents will be so informed before beginning the data collection. Respondents will provide their consent to participate in the studies by reading and signing a consent form. Respondents will be informed that the findings from this research will be used to develop communication materials to increase the public's awareness and knowledge about CAM. Respondents will be informed that participation in the studies are voluntary and no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions. All information provided by respondents will be treated in a secure manner and will not be disclosed unless otherwise compelled by law

During focus groups and interviews, only first names will be used. Audio-tapes and transcriptions will be stored in locked file cabinets, on password-protected computers, and accessible only to project staff. The audio recordings and self-administered questionnaire forms will be destroyed at the end of the study. These data security procedures will be described to respondents in the informed consent form.

The NIH Privacy Act is not applicable, as confirmed by the NIH Privacy Officer (see attached memo). Data are not retrieved by personal identifiers, and raw data that include personal information are not retained once data are aggregated.

A.11. Questions of a Sensitive Nature

Some studies need to include people representative of NCCAM's audiences. Therefore, research efforts may involve asking questions about age, race or ethnicity, income, education, or health status. Respondents are informed that the disclosure of information is voluntary and anonymous; all data are reported in aggregate. All information on race or ethnicity will comply fully with Statistical Policy Directive No. 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting" and "Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity" of the Office of Management and Budget.

To identify audiences' health information needs, NCCAM research may involve questions about health status and health-seeking behaviors. This information helps ensure the development of sensitive and effective products and programs. Again, participants are told that disclosure of this information is voluntary. Raw data about sensitive topics are aggregated, and personal identifiers are removed.

This information will be included in the submission packages as outlined in the Introduction to this section.

A.12 Estimates of Response Burden

The "Average Burden Hours per Response" calculations include the amount of time respondents need to receive instructions, to perform any reading or data gathering, and to answer questions, engage in discussion, and complete any forms. Proposed data collection methodologies are described in more detail in section B.

A.12.1. Number of Respondents, Frequency of Response, and Annual Hour Burden

The following table presents the estimated annual number of respondents, frequency of response, and burden hours for each of the 3 years covered by this request for renewal. The estimates are derived from NCCAM's past research experience, testing of sample instruments, and standards for health communications research. Slight variations in estimates are due to rounding.

Table 1. Annual Burden Hours *(adjusted from 2007 approval)*

Type of Respondents	**Estimated Number of Respondents**	**Estimated Number of Responses per Respondent**	**Average Burden Hours Per Response**	**Estimated Total Annual Burden Hours Requested**
In-depth interviews with general public	30	1	.75	23
Focus groups	20	1	1.5	30
Omnibus surveys	1,900	1	0.25	475
Intercept interviews with public and healthcare professionals	300	1	.25	75
In-depth interviews health professionals	50	1	.50	25
Self-administered questionnaires with health professionals	200	1	.25	50
TOTAL	**2,500***	**--**	**--**	**678**

* Annual total

A.12.2. Hour Burden Estimates by Each Form and Aggregate Hour Burdens

(Costs and hours have been updated from 2007 approval.) The following table provides an estimate of annualized costs for the hour burden for this information collection. There are no direct costs to the respondents. Indirect costs to respondents are calculated by estimating the cost of their time spent in participating in the research. Across all types of data collection, the annual estimated cost to members of the general public (individuals or households) for their time is about $13,083. The estimated cost to health care professionals is about $5,040.

When necessary and justified in individual data collection submission packages, members of the general public, particularly hard-to-reach populations may be reimbursed for their travel expenses and time.

Based on an estimate of $21 per hour for individuals, an average of $63 per hour for health care professionals, and an annualized estimated total burden of 703 hours, the annualized cost to all respondents would be about $18,123.

Table 2. Annual cost to respondents

Type of Respondents	**Number of hours**	**Hourly wage***	**Respondent cost**
In-depth interviews with general public	23	$21	$483
Focus groups	30	$21	$630
Intercept interviews with public	70	$21	$1,470
Omnibus surveys with public	475	$21	$10,500
Intercept interviews with healthcare professionals	5	$63**	$315
In-depth interviews health professionals	25	$63	$1,575
Self-administered questionnaires with health professionals	50	$63	$3,150
TOTAL	**678**	**--**	**$18,123**

* 2009 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm)
** Healthcare professional hourly wage was calculated by averaging the median hourly wage for physicians and surgeons ($84) and the median hourly wage for physician assistants, as representatives of the second tier of clinical care ($41) to get an average of $63 per hour.

A.13. Estimate of Total Capital and Startup Costs/Operation and Maintenance Costs to Respondents or Record Keepers

There will be no capital, operating, or maintenance costs to the respondents.

A.14. Estimates of Costs to the Federal Government

(Costs have been updated from 2007 approval.) The annualized cost to the Federal Government is estimated to be no more than $108,700 per year (or $326,100 over a 3-year period).

This annual estimate is based on the following studies with the general public: in-depth interviews ($11,500), focus groups ($21,800), and intercept interviews ($17,600). This estimate also includes research with health care professionals, including intercept interviews ($12,000), in-depth interviews ($20,200), and self-administered questionnaires ($18,600), and the addition of questions to two telephone omnibus surveys at $3,500 each ($7,000).

These figures include the costs of study design, participant recruitment, facility rental (e.g., for focus groups), data collection and analysis, and report or publication writing.

This estimate also includes monitoring by the Director of OCPL and involvement by NCCAM's Communications Specialist, projected to total about 750 hours of effort a year. Given an NCCAM personnel cost of $39.07 per hour, $29,302.50 would be spent annually on Government staff salaries (or $87,907.50 over the 3-year period).

A.15. Changes in Burden

This is a reinstatement to bring back 2,034 back on the books. The costs have been updated to reflect 2010 market rates *(adjusted from 2007 approval* and burden hours have been adjusted.

A.16. Plans for Publication, Analysis, and Schedule

The analyses conducted for each study are determined by the study's objectives and the data collection instrument used.

Techniques include qualitative analyses (e.g., content analysis for focus group interviews) and quantitative analyses using descriptive statistics. No complex analytic techniques will be used. Sample questions for each data collection method are included in the attachments to the ICR. Some studies may employ more than one collection method.

NCCAM has no current plans for publication of statistical data. Data and reports from the formative research are used only by NIH project staff for research purposes and for the development of NCCAM products and programs.

A schedule for a typical study is shown below (Table A.16-1).

A.16-1 Project Time Schedule

Activity	Time Schedule
Training staff	6 weeks after OMB approval and daily thereafter
Data collection	8 weeks after OMB approval and monthly thereafter
Data analysis	12 weeks after OMB approval and monthly thereafter
Report on survey	15 weeks after OMB approval and monthly thereafter

A.17. Approval to Not Display Expiration Date

No exemption is requested.

A.18. Exceptions to Item 19 of OMB Form 83-I

There are no exceptions to item 19, “Certification for Paperwork Reduction Act Submissions,” of OMB 83-I.