National Center for Complementary and Alternative Medicine

Communications Program Planning and Evaluation

Request for Renewal

0925-0530

Refer questions to:

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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 is 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 and CAM health care, and the media.

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

- Individual indepth interviews
- Focus group interviews
- Intercept interviews
- Self-administered questionnaires and bounceback cards
- Gatekeeper reviews
- Surveys (adding questions to existing omnibus surveys or commissioning custom surveys).

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 and the level of satisfaction with existing services.

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 and the effectiveness of its communication strategies. 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 generic clearance will enhance NCCAM's ongoing program planning and evaluation 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
- Evaluate how well communications programs reach and resonate with their intended audiences
- Confirm OCPL's identification of appropriate communication channels

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

A.3. Use of Information Technology To Reduce Burden

Improved technology in the collection and processing of data will be used to reduce respondent burden and make processing maximally efficient. For example, telephone **focus groups** will be convened where geographic diversity is important and participants come from hard-to-recruit populations, such as physicians. When **telephone interviews** are used, computer-assisted telephone interviewing (CATI) will be employed whenever possible. For **self-administered questionnaires** and **bounceback cards**, closed-ended questions (e.g., multiple-choice) and machine-readable answer sheets will be used when feasible. Transmission of data collection instruments and responses by e-mail or fax will be used as appropriate.

As NCCAM's Web site continues to develop and reach an ever-growing audience, opportunities for OCPL to pretest and evaluate messages and materials on the Internet using either Web site questionnaires or online focus groups will increase. Using computer-assisted information technology to transmit data collection instruments and/or collect responses will continue to reduce the burden on respondents.

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

A.4. Efforts To Identify Duplication

NCCAM has undertaken surveys to assess the effectiveness of its outreach and the quality of its responses to the public:

- From 2003 to 2006, NCCAM assessed customer satisfaction with its telephone information service under OMB no. 0925-0520, expiration date June 30, 2006. NCCAM also assessed customer satisfaction with its quarterly print newsletter in 2004 and 2006 under this clearance. OMB renewed clearance for these activities, amended to include the online version of the quarterly newsletter, in September 2006. The telephone information service survey is ongoing, and additional newsletter surveys will be conducted.
- In 2003 and 2004, NCCAM used the NIH Generic OMB Clearance for Online Surveys to assess customer satisfaction with its e-mail information service (OMB no. 0925-0486-2501-01, expiration date April 30, 2004), Web site (OMB no. 0925-0486-2501-02; expiration date April 30, 2004), and quarterly online newsletter (OMB no. 0925-0486-2501-03; expiration date April 30, 2004).

Our communications program plans and evaluation 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.

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 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 1320.5.

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 72, number 59, page 14587, on March 28, 2007. No comments were received in response to the notice. 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 indepth individual interviews with physicians and other health care providers, and for gatekeeper reviews. However, NCCAM does not plan to offer incentives for intercept interviews with the general public, self-administered questionnaires, or household-level random digit dialing omnibus surveys.

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

Information provided by respondents is kept confidential and private and is not disclosed to anyone except for the researchers or other persons conducting the surveys, except as required by law. Data collection instruments include assurances of confidentiality. Before any data are collected, participants are advised of the following:

- Nature of the data collection or activity
- Purpose and use of the data collected
- NCCAM sponsorship
- Voluntary nature of participation at all times.

All participants are 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 question.

As a further assurance of confidentiality, all data are reported in aggregate form; no links to individuals are preserved. Reports are used only by project staff for research purposes and for the development and evaluation of NCCAM products and programs.

The NIH Privacy Act is not applicable. 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 assured that the information is voluntary and confidential; 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.

Data collection method	Estimated number of respondents	Frequency of response	Average burden hours per response	Estimated annual burden hours requested*
Individual indepth interviews	30	1	0.75	22.5
Focus group interviews	60	1	1.5	90
Intercept interviews (central location)	100	1	0.25	25
Self-administered questionnaires	200	1	0.25	50
Gatekeeper reviews	50	1	0.50	25
Omnibus surveys	2,000	1	0.25	500
TOTAL	**2,440**			**712.5**

*Slight variations in estimates are due to rounding.

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

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 $15,950. The estimated cost to health care providers is about $3,675 (about $2,310 for physicians and $1,365 for other health care providers).

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 $25 per hour for individuals, $66 per hour for physicians, and $39 per hour for other health care practitioners and an annualized estimated total burden of 708 hours, the annualized cost to all respondents would be about $19,625.

Type of respondents	Number of hours	Hourly wage	Respondent cost
Individuals	638	$25	$15,950
Physicians	35	$66	$2,310
Other health professionals	35	$39	$1,365
TOTAL	**708**		**$19,625**

A.12.3. Estimates of Annualized Cost to Respondents for the Hour Burdens

Estimates of annualized costs to respondents for the hour burdens are provided in section A.12.2.

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

The annualized cost to the Federal Government is estimated to be no more than $115,000 per year (or $345,000 over a 3-year period).

This annual estimate is based on up to three indepth interview studies at $8,000 each ($24,000), two focus group studies at $10,000 each ($20,000), two central location interview studies at $7,500 each ($15,000), two self-administered questionnaire studies at $6,500 each ($13,000), one gatekeeper review study at $6,000 ($6,000), and the addition of questions to two telephone omnibus surveys at $3,500 each ($7,000).

These figures include the costs of study design, training for interviewers, participant recruitment, facility rental (e.g., for focus groups), data collection, data management 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

Costs have been updated to reflect 2007 market rates. Burden hours remain the same.

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 (for example, 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.

While the primary purpose of NCCAM's communications research is to inform the Center's product and program development, OCPL plans to make results available to a variety of health program planners at Government agencies, voluntary organizations, health professional organizations, and medical institutions. In addition, OCPL may present findings at meetings of professional associations. Research conducted by OCPL may sometimes be summarized on the NCCAM Web site and in news-related publications such as the *NIH Record*.

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