Supporting Statement A For:

The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials (NCI)

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LIST OF ATTACHMENTS

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

To assess respondents' awareness and knowledge of NCI and measure awareness of NCI clinical trials at the NIH Clinical Center in Bethesda, Md., Mathews Media Group (MMG) has developed an e-mail survey to be sent to medical professionals who treat cancer patients. The survey was disseminated electronically in July of 2006 and August of 2007[1] to members of the American Medical Association (AMA) with a primary specialty of gastroenterology, medical oncology, radiation oncology, hematology/oncology, thoracic surgery, colon & rectal surgery, gynecological oncology, surgical oncology, or head & neck surgery. This year's survey has been slightly revised and will be sent to members of the same AMA primary specialty categories (**Attachment 1**). Results of the previous surveys have been used to shape the outreach methods used by MMG and NCI to promote CCR's trials, and this year's survey will serve the same purpose.

The Public Health Service Act, authorizes the Director of the National Cancer Institute (NCI) to, "continue and expand programs to provide health care professionals and the public with state-of-the-art information on the treatment of particular forms of cancers, and to identify those clinical trials that might benefit patients while advancing knowledge of cancer treatment" (Section 413 of the Public Health Service Act (42 USC *§* 285a-2)); and support programs for the "detection, diagnosis, prevention and treatment of cancer" (Section 412 ,42 USC *§* 285a-1), and to "collect, identify, analyze and disseminate…information on cancer research, diagnosis, prevention and treatment" (Section 413, 42 USC *§* 285a-2).

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[1] Approved by OMB under NCI's Generic Clearances OMB# 0925-0046-19 (2006) and 0925-0046-05 (2007). The former title was "NCI's Center for Cancer Research (CCR) Survey to Assess Health Care Professionals' Awareness and Promotional Preferences of NCI Intramural Clinical Trials."

The National Cancer Institute (NCI) Center for Cancer Research (CCR) is the largest component of the Institute's intramural (i.e., in-house) research program. One of its goals is to disseminate information about available cancer clinical trials to health care providers and to the public. Its outreach efforts focus on creating awareness of the CCR's clinical trial program within the health care professional community, with the ultimate goal of increasing patient referrals to ongoing clinical trials. MMG is now in the twelfth year of a partnership with the National Cancer Institute (NCI) Center for Cancer Research. The goal of the project is to promote a comprehensive approach to patient accrual through outreach and education.

The objectives of this e-mail survey are to:

- Ascertain the level of general awareness of the NCI intramural program in the HCP community,
- Assess how NCI compares to other institutions on key factors that are thought to impact referrals to clinical trials,
- Determine which outreach efforts contribute to an increase in awareness, and
- Identify additional outreach and communications strategies for increasing awareness and referrals.

This survey data will be used to assess the best methods for disseminating information about CCR's clinical trials to the public, especially to referring health care professionals. As described in Supporting Statement, Section A.2., data from previous surveys has already contributed to current outreach efforts. Using the best possible outreach methods helps ensure health care professionals have the information about CCR clinical trials they need to make a referral to a trial. By having the information in place, referrals to trials could be positively impacted, leading to trials being completed sooner. The sooner trials can complete, the more

opportunity for new therapeutic discoveries. This helps fulfill CCR's mission of reducing the burden of cancer through exploration, discovery, and the translation of novel approaches into compassionate and effective care for all cancer patients.

A.2 Purpose and Use of the Information

The Survey of Health Care Professionals' Awareness and Perceptions of the National Cancer Institute's Intramural Clinical Trials Survey will collect the following information:

- How health care providers prefer to receive clinical trial information
- Awareness and knowledge of NCI's functions in the medical community
- How many health care providers refer to clinical trials in general
- How many health care providers refer to clinical trials at NCI
- Regional referral habits and perceptions of NCI
- Perception of CCR compared to other cancer centers

This survey has practical utility because it uses electronic methods of survey distribution and data collection, making the administration and data collection fast and accurate. Many of the questions are closed-ended, leading to measurable, quantitative data.

The results of this year's survey will be used similar to the results of previous surveys[2]. The results of previous surveys have shaped MMG and CCR's outreach strategy (see **Attachment 2** for the 2007 Results Report). For example, because it was found that many survey respondents preferred e-mail as a source of clinical trial information, MMG now sends an e-mail one or more times a month highlighting a certain area of clinical research at CCR. MMG also targets referring health care professionals using electronic communications such as RSS feeds, Google campaigns, online advocacy outreach, and electronic quarterly newsletters. Previous

[2] Previous surveys were approved under NCI's Generic Clearances OMB# 0925-0046-19 (2006) and 0925-0046-05 (2007).

surveys also showed that the target audience learns about clinical trials from their colleagues, so MMG and CCR focus on “Dear Colleague” letters. Information via conferences and seminars is also well-received according to survey respondents, so MMG and CCR have created promotional materials to be distributed at these events. They include disease-specific folders and protocol summaries.

Without these survey results, CCR and MMG cannot use the data to target the most impactful and most cost-effective methods to reach referring health care professionals. The survey provides information that helps guide outreach tactics. Having evidence of the most effective tactics allows MMG and CCR to be as cost-effective as possible in these efforts, allowing only the tactics with the highest potential for success to be used.

This year’s survey includes a new aspect (questions #4 and #7), which is a comparison of CCR’s reputation to other leading cancer institutions. This data will give CCR an idea of how close they are to their goal of being known as a leading cancer research center. These results will help guide key message development based on the perception of CCR’s strengths\weaknesses when compared to other research-focused institutions. If survey results show CCR is not yet known as a leading cancer research center, efforts can be focused on promoting CCR’s services in the health care community, with the goal of increasing the number of patient referrals to clinical trials.

A.3 Use of Improved Information Technology and Burden Reduction

MMG will use electronic survey distribution methods to reduce respondent burden, reduce labor costs, and speed data analysis time. Select members of the American Medical Association (AMA) will receive an e-mail directly from AMA. The e-mail will include

information about the survey and a link to the survey. E-mail recipients can read the short e-mail, decide whether they would like to participate, and with one click have access to the survey. The 20-question survey is expected to take approximately 5 minutes to complete, and many of the responses simply require checking a box. There are no long open-text fields to be completed.

Because responses are being collected electronically, they are automatically housed in a database, eliminating the need for data entry into a statistical software program. The data can be analyzed quickly, leading to the results being reviewed and implemented quickly. NCI's Privacy Act Coordinator has been contacted to assess whether or not a Privacy Impact Assessment (PIA) is needed and if so, one will be completed.

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

Because the survey asks questions related to NCI's clinical trial patient recruitment and MMG is the only clinical trial patient recruitment vendor for CCR, MMG is the only entity with the need to collect this information on behalf of NCI. Therefore, the information being collected in this survey is not a duplication of information that already exists.

As noted above, this survey has been conducted twice in the past by MMG and the contract expects the survey to continue to be sent on an annual basis in hopes of identifying shifts in awareness and attitude. There is no secondary-research available or any other similar information other than the previous surveys sent by MMG.

A.5 Impact on Small Businesses or Other Small Entities

The survey questions have been kept to the minimum required for the intended use. The e-mail survey is made up of 20 questions, and completion of the survey requires approximately 5

minutes of the respondent's time. They can choose not to complete the survey. If they begin the survey, they are allowed to exit the survey at any time or skip questions.

A.6 Consequences of Collecting the Information Less Frequently

The questionnaire will be administered once per year. This will allow MMG to track trends over time, observing whether respondents' opinions and preferences are changing. This information will help NCI stay current in their efforts to disseminate clinical-trial–related information to the target audience, especially in a landscape of changing technologies that can influence how and by which avenues the target audience receives information. The results of the survey will also assist in formulating promotional messages based on the perception of CCR and competing institutions. It is crucial that these perceptions are measured regularly, because shifts in attitude may require changes in messaging that goes out to the public. If the data is not collected as often, NCI may allot funds to clinical trial recruitment efforts that are not as effective. The information gained from the survey helps guide NCI's outreach efforts to health care professionals who may be interested in referring patients to NCI clinical trials. Recruiting patients to NCI clinical trials helps advance the science being studied in the trials. There is an ongoing need for additional patients to enroll in clinical trials; many trials cannot be completed because of the lack of participants. This survey data can be applied to assist with the dissemination of information related to filling these trials.

There are no technical or legal obstacles to reducing burden.

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

No special circumstances are anticipated. All the guidelines of 5 CFR 1320.5 are met and the project fully complies.

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

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on April 22, 2010, Vol. 75, p. 20999. There were no public comments received.

In 2009, MMG consulted David Rockland, Ph.D., Partner and Managing Director of Ketchum's Global Research Network and Stromberg Consulting, and a member of the board of directors of the International Association for Measurement and Evaluation of Communication (AMEC). Dr. Rockland has also been the chair of the Institute for Public Relations (IPR) Measurement Commission. Dr. Rockland contributed to the survey's question development, ensuring that each question includes clear instructions and provides measurable and actionable data. Dr. Rockland can be reached at 646-935-4083. Allison Slotnick, Senior Research Analyst at Ketchum, was also consulted in 2008 regarding survey design. Allison may be reached at 646-935-4068.

No one else is conducting a similar study.

A.9 Explanation of Any Payment or Gift to Respondents

Participants responding to this questionnaire will not receive remuneration for their participation.

A.10 Assurance of Confidentiality Provided to Respondents

The National Institute of Health's Office of Human Subjects Research (OHSR) has determined this information collection exempt and does not need IRB review (**Attachment 3**). Respondents who opt to receive *BethesdaTrials News* (which is an option at the end of the survey) will be directed to a separate site where they will enter their information. This information will not be linked in any way with the survey responses.

While a consent form is not included in the e-mail to the respondents, a brief introduction included on the survey describes the purpose and use of the questions. Respondents imply consent in the completion and return of the survey.

A.11 Justification for Sensitive Questions

There are no questions considered to contain sensitive information. Though personally identifiable information (PII) is collected, the privacy act does not apply to this collection of information (**Attachment 4**). The survey data cannot be tracked to individual respondents and will be provided to NCI through its contractor in aggregate form.

A.12 Estimates of Annualized Burden Hours and Costs

a. Annual Burden Hours. Table A.12-1 describes the estimates of the respondent burden for completion of the Survey of Health Care Professionals' Awareness and Perceptions of the

National Cancer Institute's Intramural Clinical Trials (NCI). It is estimated that there will be 330 respondents per year and at a burden of 5 minutes/survey for those who complete the survey. This amounts to an estimated total burden of 83 hours over three years, or an annual burden of 28 hours.

A.12 - 1 Estimates of Annual Burden Hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Annual Burden Hours
Health care professionals who complete the survey	330	1	5/60 (0.083)	27.5 hours
Totals	**330**	**330**		**27.5 hours**

B. Annualized Costs to Respondents. At $75.00 per hour, the estimated annualized cost to respondents is $2,063 (Table A.12-2), or a total over three years of $6,188.

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Number of Respondents	Frequency of Response	Annual Burden Hours	Hourly Wage Rate	Respondent Cost
Health care professionals	330	1	27.5	$75.00	$2062.50
Total					**$2062.50**

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital costs, operating costs, or maintenance costs to report.

A.14 Annualized Cost to the Federal Government

The estimated total cost to the government for the services of the study contractor(s) and purchase of the AMA e-mail list for specific specialists over the duration of the e-mail survey is $57,000 (annualized cost of $19,000). These costs include the hours for OMB paperwork submission, crafting the survey, purchase of the AMA e-mail list for specific specialists, disseminating the e-mail survey, managing the replies, analyzing the response data and producing the final report.

The overall government distribution is summarized in the following table:

Table A.14-1 Government Cost Distribution

	TOTAL	ANNUAL AVERAGE
Contractor Costs including OMB clearance Crafting the survey Dissemination of e-mail Collecting responses Analysis Final report	$34,500	$11,500
Purchase of AMA e-mail list	$22,500	$7,500
Grand Total	$57,000	$19,000

A.15 Explanation for Program Changes or Adjustments

This is a new collection of information.

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

The project schedule for completing data collection, processing, and analysis is presented in Table A.16-1.

Table A.16-1. Project Time Schedule	
MILESTONE	***COMPLETION SCHEDULE AFTER OMB APPROVAL***
Conduct online survey	*September – October 2010*
Analyze online survey data	*October – November 2010*
Write comprehensive report and present to NCI	*November – December 2010*
Conduct online survey	*September – October 2011*
Analyze online survey data	*October – November 2011*
Write comprehensive report and present to NCI	*November- December2011*
Conduct online survey	*September- October 2012*
Analyze online survey data	*October – November 2012*
Write comprehensive report and present to NCI	*November – December 2012*

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

All instruments will display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.