Mini Supporting Statement:

Web-Based Survey to Understand Public Perceptions of Genetic Testing

OMB # 0925-0046-10

May 19, 2008

Under Generic Study Titled:

Pretesting/Formative Research for NCI Communications Messages

(OMB No. 0925-0046, Expiration Date 1/31/2010)

Submitted By:

Nina Goodman, MHS
Senior Analyst
Office of Market Research and Evaluation
Office of Communications and Education
National Cancer Institute
6116 Executive Blvd., Suite 400
Rockville, MD 20892-8351
301-435-7789
goodmann@mail.nih.gov

Table of Contents

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary.....1
A.2 Purpose and Use of the Information Collection.....2
A.3 Use of Improved Information Technology and Burden Reduction.....3
A.4 Efforts to Identify Duplication and Use of Similar Information.....3
A.5 Impact on Small Businesses or Other Small Entities.....4
A.6 Consequences of Collecting the Information Less Frequently.....4
A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5.....4
A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency.....4
A.9 Explanation of Any Payment or Gift to Respondents.....5
A.10 Assurance of Confidentiality Provided to Respondents.....5
A.11 Justification for Sensitive Questions.....5
A.12 Estimates of Burden Hours and Costs.....6
A.13 Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers.....7
A.14 Annualized Cost to the Federal Government.....7
A.15 Explanation for Program Changes or Adjustments.....7
A.16 Plans for Tabulation and Publication and Project Time Schedule.....8
A.17 Reason(s) Display of OMB Expiration Date is Inappropriate.....8
A.18 Exceptions to Certification for Paperwork Reduction Act Submissions.....8

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Respondent Universe and Sampling Methods.....9

B.2. Procedures for the Collection of Information.....10
B.3 Methods to Maximize Response Rates and Deal with Non-response.....11
B.4 Test of Procedures or Methods to be Undertaken.....12
B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data.....13

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Since the recent completion of the Human Genome Project, the advent of detailed, personalized genetic knowledge has been characterized by its rapidly-accelerating pace of discovery. In many ways, this flood of new knowledge validates the long-standing hope of scientists and clinicians that genomics will become a powerful tool for better health care, especially through enhanced capacity to better tailor care to the genetically-based needs of each individual patient. Understanding the molecular signatures of cancer is a leading area of current research.

A newly emerging marketplace, where genetic tests are marketed directly to the consumer, often by electronic media, provides consumers with personal genome-based information outside of the traditional medical care delivery system. These services, where consumers provide samples at home and receive the results directly, are becoming increasingly common, with multiple organizations offering numerous and sophisticated tests. The types of tests can be broadly categorized by the type of information that is provided: genome-wide scan, disease specific screening, and ancestral origin.

In the months since consumer genomic information services or "direct-to-consumer" genetic testing, has become widely available, there has been considerable reaction to them. In a number of venues, the usefulness of the current offerings is being reviewed. In addition, the appropriate response by various sectors (including health care professionals and government regulators) is being considered. These services have the potential to improve consumer engagement in medical decision-making, but consumers may not know or have access to the information necessary to evaluate the quality of the

information that is provided. Underlying the emergence of commercial products and services are unknown factors motivating consumer interest and value for this type of health information.

To move toward understanding the consumer interest and need in the use of genetic testing, HHS's Initiative on Personalized Health Care is sponsoring a half day workshop to look more broadly at the roles that consumer genomic information may be able to play over a longer time-frame – and in particular to examine those roles in the context of the nation's consensus health care goals. Because little is know about this newly emerging area, HHS has teamed with NCI and proposes to conduct a web-based survey to help understand consumer knowledge and interest for genetic testing. The results of this survey will, in the short-term, be used to inform and stimulate discussion at the workshop and, in the longer-term, will inform future communications strategies, concepts, and messages of NCI and other HHS agencies.

As this a newly burgeoning area, little research has been conducted to determine consumer knowledge in this area. The results of this survey would provide basic understanding of the current state of the field and may be useful for evaluating future educational future initiatives. Current authorization for NCI's education and information dissemination activities is contained in Section 410 of the Public Health Service Act (42 USC *§* 285a-2).

A.2 Purposes and Use of the Information Collection

At HHS, there is a growing respect for the extent of genetic and other molecular-level knowledge that will be needed to successfully apply genomics in health

maintenance and health care. New discoveries often reveal the shallowness of our knowledge as much as they add new information. Neither the consumer nor the average physician has adequate familiarity with genomics to make confident use of the wide new range of genetic information that can now be made available.

The objective of this survey is to collect formative data to inform NCI and HHS of the consumer's attitudes, knowledge, and behaviors related to genetic testing. This information will allow the government to better understand the public's perceptions of this relatively new and rapidly growing area and will aid in the development of communication resources that will help the public understand the language, issues, and complexities inherent in "direct-to-consumer" genetic testing.

A.3 Use of Improved Information Technology and Burden Reduction

As appropriate, automated information technology will be used to collect and process information for this survey to reduce the burden on the public. The survey will be conducted on a dedicated, secure, and encrypted Web site. People outside of the site will not receive the survey material. Responses will be collected online.

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

The technology for broad genetic testing for disease risk is still emerging, and little is known about consumer understanding of this technology or understanding of risk for various diseases, although some research has been conducted on consumer knowledge for genetic testing involving hereditary breast cancer (BRCA1 and 2 genes).[1-2] NCI has

[1] www.cdc.gov/MMWR/preview/mmwrhtml/mm5327a1.htm
[2] http://www.ahrq.gov/clinic/tp/genovctp.htm

monitored the popular and scientific press surrounding the advent of increasingly rich genetic knowledge and consulted with outside experts to evaluate available information. These sources suggest that very little data is available on this subject.

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

No small businesses will be involved in this survey.

A.6 Consequences of Collecting the Information Less Frequently

Participation will be voluntary and users will be asked to complete this survey only once. The survey is considered appropriate to measure the current knowledge level, attitudes, and interest for genetic tests to identify cancer and other disease risk. Without this survey, information will not be adapted to meet customer needs in the development of future resources. The survey results will be administered, analyzed, and interpreted by the National Cancer Institute and appropriate contractors.

A7. Special Circumstances Related to the Guidelines of 5 CFR 1320.5

This survey will be implemented in a manner that fully complies with 5 C.F.R. 1320.5.

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

A 60-day Federal Register notice soliciting comments on the "Pre-testing of NCI Communication Messages" was published on August 14, 2006, Volume 71, Number 156,

Page 46486. In response to the notice, there were no public comments. The 30-Day Federal Register notice was published on October 23, 2006, Volume 71, Number 204, Page 62114. In response to the notice, there were no public comments.

In 2008, NCI has been consulting with Keisha Arrowood Burdick, Research Director, Yankelovich (phone: 919-932-8622; email: kburdick@yankelovich.com) in order to assist with the design of the survey instrument. During consultation, there have been no major problems that could not be resolved.

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

No payment or gift will be provided to survey participants.

A.10. Assurance of Confidentiality Provided to Respondents

Individual respondents will not be identified and participation will be strictly voluntary. Names are not recorded, nor are personal identifying data maintained in the database. Respondents will be assured that neither their participation/non-participation nor any responses to items will have any effect on their eligibility for, or receipt of, services.

A.11 Justification for Sensitive Questions

No questions will be asked of a personal or sensitive nature. Participants may choose to withdraw from the survey at any time.

A.12 Estimates of Burden Hours and Costs

There will be a maximum of 1000 respondents and with an average response time of 7 minutes to complete the on-line survey, which culminates in a total annual hour burden to be 166.66 hours (Table A.12-1).

Table A.12-1 Estimates of Hour Burden

Types of Respondents	Number of Respondents	Frequency of Response	Average Response Time	Annual Hour Burden
General Public	1000	1	7/60	116.66

The annualized cost to the respondents is estimated to be at $1983.33 (Table A.12-2).

Table A.12-2 Annualized Cost to Respondents

Types of Respondents	Number of Respondents	Frequency of Response	Hourly Wage Rate	Respondent Cost
General Public	1000	1	$17.00	$1983.33

Table A.12-3 below comes from page 23 of the full supporting statement and indicates the estimated hour burden of an omnibus study over a 3 year period, showing the expected total of respondents to be 2000 per year. In the past, we have typically conducted two omnibus studies per year, with 1000 participants each.

Note: The burden table below reflects what NCI anticipates would be accomplished over the total 3-year life of the project. (Annual burden, therefore, is one-third of the total figures presented here.)

Table A.12-3	Total Number of Respondents	Frequency of Response	Hours Per Response	Total Hours
Individual In-Depth Interviews	600	1	.75	450
Focus Group Interviews	540	1	1.5	810
Intercept Interviews: Central Location	1800	1	.25	450
Intercept Interviews: Telephone	30,000*	1	.08	2400
Self-Administered Questionnaires	1200	1	.25	300
Gatekeeper Reviews	1200	1	.50	600
Omnibus Surveys	6000	1	.17	1020
Totals	41,340			6030

- Brief interviews with CIS callers to test message concepts and strategies following their call-in request to the 800 number.

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

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

A.14. Estimates of Costs to the Federal Government

This current survey will have minimal impact on the total original cost that was estimated in the full supporting statement.

A.15. Explanation for Program Changes or Adjustments

This is a new survey under the existing generic study titled “Pretesting of NCI Communication Messages” (OMB #0925-0046). This represents the tenth sub-survey in this generic study and, once approved, will be indicated by 0925-0046-10.

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

If OMB approval is secured, the survey will be administered within 2-4 weeks. We anticipate that it will take no more than 1 week to collect information from a maximum of 1000 participants. Results for this survey will be tabulated within 2-4 weeks after the completion of the survey. Results of selected findings may be presented at a HHS workshop to stimulate discussion on the topic of consumer interest and information needs in services that provide genetic testing for cancer and other diseases.

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

This survey will display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

These surveys will comply with the requirements in 5 CFR 1320.9. No exceptions to certification are requested.

B. Collections of Information Employing Statistical Methods

B.1 Respondent Universe and Sampling Methods

For this formative research, NCI and HHS will be conducting a web-based omnibus survey with members of the general public, ages 18 and older, as all adults are candidates for genetic testing. Potential participants will include both men and women residing in geographic regions across the United States, and representing all racial, ethnic, and educational backgrounds.

Because the purpose of the survey is to collect information to establish a baseline understanding of beliefs and experiences associated with genetic testing for predicting disease risk, the sampling methods will focus on obtaining, with the greatest efficiency possible, a sample of nationally representative respondents that has demonstrated proficiency in using the web. To this end, the survey will be conducted among individuals who self-select into participation by clicking on a survey link advertised in a banner on a webpage – also known as real time sampling. Potential respondents generally have experience taking online surveys, and, because they have responded to the banner advertisement, have already indicated an expressed interest in completing web-based surveys, and have explicitly agreed to participate in surveys presented to them about issues both unrelated and related to health. Recruitment will continue until the target sample size for the completed survey is reached.

The following description of an omnibus survey is stated in the full supporting statement for OMB#0925-0046, of which this mini statement is a substudy:

> An omnibus survey is a telephone interview survey in which different organizations add questions to a single questionnaire, thereby sharing the cost.

This technique uses random-digit-dialing (RDD) to speak to approximately 1000 adults who are nationally representative of the U.S. population. Because these surveys are conducted on a weekly or bi-weekly basis, they are an efficient way to obtain pretest data from a larger number of consumers in a short period of time. To get such a quick and cost-effective turnaround, however, the vendor can make up to only four callbacks, resulting in a lower response rate than for custom surveys (where additional callbacks are made). It is industry standard to accept a response rate of 50-60 percent for surveys. Generally, for the most cost-effective approach, computer-assisted telephone interviewing (CATI) is used to complete the interviews.

B.2. Procedures for the Collection of Information

This survey, which will be no more than 5-10 minutes in length, will be administered as part of a web-based omnibus study. Participants will be asked to answer a brief, self-administered, interactive web-based survey which includes questions about attitudes toward genetic testing, including personal interest in testing, thoughts about the usefulness of such testing, and personal concerns related to genetic testing. NCI will use the results of the survey to create a baseline understanding of the consumer perspective on genomics in order to inform future communication documents. In addition, these summarized results may be presented at a HHS workshop to stimulate discussion on the topic of consumer interest and information needs in services that provide genetic testing for cancer and other diseases.

A web-based omnibus study is an internet interview survey in which different organizations add questions to a single questionnaire, thereby sharing the cost. This technique uses real time sampling to survey approximately 1000 adults who are nationally representative of the U.S. population. Real time sampling means that respondents are self-selecting into the survey by clicking on a banner advertisement on a webpage. In order to attract a broad range of individuals to the survey, these advertisements are placed on a variety of websites that are visited by varied demographic groups. In order to further ensure diversity among respondents, when potential respondents click on the survey link they are first taken to a page of demographic questions. Responses to these questions, which include age and gender, are monitored using quotas - or predetermined required numbers of respondents in subgroups (e.g. men) - to make sure that the omnibus study has proportions for these demographic groups that approximate U.S. census data. Upon completion of these questions, respondents are then directed to the omnibus study until the target sample size is reached. Because these surveys are conducted on a weekly or bi-weekly basis, they are an efficient way to obtain pretest data from a larger number of consumers in a short period of time. It is industry standard to accept a response rate of 50-60 percent for surveys.

B.3 Methods to Maximize Response Rates and Deal with Non-response

For a full discussion about respondent recruitment pertaining to this generic sub-study, refer to Section B.1. For the survey, potential participants have “opted-in” to the survey, as explained earlier; this will facilitate successful and efficient recruitment of participants, and with the established demographic quotas will make it easier to obtain a

sample representative of the broader population. As this sub-study is designed to gain preliminary understanding of attitudes toward genetic testing – this recruitment strategy will suffice to achieve the primary goal of obtaining an adequate number of participants to allow representation of attitudes toward genomic testing among a broad cross-section of adults, as well as meaningful comparisons across subgroups of several demographic domains, including gender, age and region, again in order to acquire baseline understanding of consumer attitudes toward genetic testing. Non-response will be dealt with by continued banner advertisement recruitment of potential participants until the target sample size is reached.

B.4 Test of Procedures or Methods to be Undertaken

The formative testing methodology planned for this project represents the standard state-of-the-art approaches adapted from marketing and communications research. For this formative research, a self-administered web-based survey will be used, as it is both a reliable and efficient methodology that has been employed in previous research by the NCI and other governmental agencies. This survey will be accessed on-line at a designated Internet location.

The objective of the survey is to help NCI assess consumer attitudes toward genetic testing in order to create a baseline understanding of these attitudes. Research on this topic has been extremely limited to this point. The total sample size of 1000 will allow for reliable inferences to be drawn across the total population, as well as meaningful comparisons across subgroups in several demographic domains, including

gender, age and region - in order to acquire baseline understanding of consumer attitudes toward genetic testing.

B.5 Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Responsibility for collecting and analyzing information obtained from this survey will rest with Scott Boyle, Ph.D., AAAS Science and Technology Policy Fellow, Personalized Health Care Initiative, HHS/IOS (202.205.8730, scott.boyle@hhs.gov) and Nina Goodman, MHS, Office of Communications and Education (OCE), National Cancer Institute, NIH, HHS. All data collection and analysis will be performed in compliance with OMB, Privacy Act, and Protection of Human Subjects requirements.