DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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(Revised memo from previously submitted memo dated September 10, 2010)

To: Office of Management and Budget (OMB)

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From: Nina Goodman, Project Officer
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Subject: **Generic Sub-Study, "Genomics and Genetic Testing: Message Testing Research with Consumers and Advocates"** (OMB No. 0925-0046-04, Expiration Date 2/28/13)

The National Cancer Institute (NCI) submits for OMB review the proposed NCI research project, "Genomics and Genetic Testing: Message Testing Research with Consumers and Advocates." The NCI's Public Health Genomics Interest Group and Office of Communications and Education (OCE) have developed draft messages for the general public about personal genomics and genetic testing. The proposed message testing research with consumers and health advocates will allow NCI to better understand what messaging meets the information needs of and is of most interest to the general public, and will inform the refinement of messages and development of materials on the topics of personal genomics and genetic testing.

The research objectives guiding this sub-study are to:

- Assess the level of interest and perceived usefulness of draft genomics/genetic testing related health messages among the general public;
- Inform the development of final messages that will help the general public make decisions about personal genomics and genetic testing; and
- Explore preferences for formats and sources for related health information.

Background on Project

Since the completion of the Human Genome Project, the advancement of personalized genomic scans and genetic tests has been rapid. This has fueled the long-standing hope of scientists and clinicians that these new technologies will become a powerful tool for better health care, especially through enhanced capacity to tailor care to the genetically-based needs of individual patients. Today, a newly emerging marketplace provides consumers with the option of procuring personal genome-based information outside of the traditional medical care delivery system. Genetic tests are marketed directly to the

consumer, often by electronic media and possibly through local pharmacies soon. These "direct-to-consumer" (DTC) genetic services, where consumers provide samples at home and receive the results directly, are becoming increasingly common, with multiple organizations offering numerous and increasingly sophisticated tests. Other genomic and genetic testing is conducted through trained healthcare providers.

Previously the Trans-NIH Genetics of Common Disease Communications Group teamed with NCI to conduct two studies with consumers and primary care physicians focusing on their attitudes, perceptions, and opinions on genetic testing (in general and DTC). The formative research found that members of the general public who were interested in genetic testing had limited knowledge of the basic facts about personal genomics and genetic testing and low awareness of the pros and cons and options for getting these tests.

In order to educate the general public so that they can make informed health decisions, NCI has developed draft messages that communicate key information about personal genomics and genetic testing for this audience **(Attachment B1)**. Obtaining audience feedback is an important part of the communications and message development process. As NCI seeks to develop effective messaging for the public, it is critical to conduct research with two audiences: 1) consumers with some interest in and/or experience with personal genomics and/or genetic testing; and 2) advocates who represent the interests of and provide information to people affected by diseases with a genetic component.

The proposed data collection will inform the development of the messages and information materials (e.g., Web site content and a brochure) on the topics of personal genomics and genetic testing for the general public. The proposed methodologies for this data collection are focus groups and triads.

Background Information on Focus Groups

Focus groups, or group interviews, are used to obtain insights into target audience perceptions, beliefs, and attitudes in the early stages of the communication process (i.e., in concept, strategy and materials development).[1] Focus groups are usually composed of 6 - 10 people who have characteristics similar to the target audience or subgroups of the target audience. The groups are conducted by a professional moderator who keeps the session on track while allowing respondents to talk openly and spontaneously. The moderator uses a loosely structured discussion outline, which allows him/her to change direction as the discussion unfolds and new topics emerge. Focus groups are valuable in exploring consumer reactions to message concepts and content before additional resources are put into their final development.

Background Information on Triads

A triad is a form of group interviewing involving three participants. It offers many of the advantages of a focus group or group interview as well as some of those of an in-depth interview. Triad participants may be recruited to form a homogeneous group. As with the focus group, triads are facilitated by a professional moderator using a loosely structured discussion outline.

[1] Krueger, R.A., (1994). Focus groups: A practical guide for applied research, (2nd ed.) Thousand Oaks, CA: Sage Publications.

Proposed Research: Focus Groups with Consumers and Triads with Advocates

NCI proposes using focus groups to conduct formative qualitative research with consumers. These consumer groups will involve members of the general public who have some interest in the topics of personal genomics and/or genetic testing – the target audience for the messages and materials that NCI plans to develop and disseminate. Focus groups will consist of six in-person groups of 6 to 8 participants in two US cities.

	Washington DC - NCI	2nd Site – TBD
# of Focus Groups (# of participants)	3 (24)	3 (24)

NCI will also use triad discussions to explore how advocates perceive the draft messages and their constituents' information needs and preferences related to personal genomics and genetic testing. Three triads with 3 participants scheduled for each will be conducted remotely via teleconference with advocates who represent special interest groups with an interest in genomics and genetic testing.

	Advocates
# of Triads (# of participants)	3 (9)

The focus group and triad moderator guides **(Attachments #B2 and #B3)** will be used to help focus the discussions. Focus group and triad participants will be engaged in discussions that will include the following topic areas:

- Introduction and definition of key terms
- Perceptions and experiences related to genomics/genetics
- Feedback on eight draft messages
- Selection of the messages of greatest interest
- Preferences for sources, channels, and formats.

Proposed Focus Group and Triad Research Study Design, Methodology, and Limitations

NCI will use a contractor, AED, to conduct data collection activities. Six focus groups will be divided between two locations: Washington, DC (at NCI) and a second location (TBD). Three triad discussions will be held with advocates remotely using telephone and teleconferencing technology.

Focus groups participants will be screened on several key dimensions. Potential participants will be screened and recruited by a professional recruitment firm using a screening questionnaire (**Attachment #B4**). The focus groups will include three segments of the general public: 1) *Interested* – consumers who are aware of and thinking about taking a personal genomic test; 2) *Motivated* – interested consumers with a specific health reason or motivation to take a personal genomic test (e.g., family history of a genetic disease); and 3) *Experienced* – Have gotten a personal genomics scan or a genetic test (requested by a physician or provided DTC). For these focus groups, participants will include a diverse mix of adults – aged 21 to 74, men and women, different ethnicities, and various income levels. The focus groups will be in-person and will use handouts and message boards to explore participants' interest in and preferences among the eight draft messages **(Attachment B1)**.

Advocates will be identified with the help of NCI's Office of Advocate Relations (OAR) and recruited by AED from across the country. Participants will include advocates who represent geographic diversity and a mix of health advocacy specializations (by disease or subpopulation). Experienced AED staff will contact potential advocate participants, screen them (using **Attachment #B5**), and, if eligible, invite them to join a triad discussion. All triads will be conducted by telephone using an electronic conferencing system, such as GoToMeeting. This will permit the participants to review draft messages on-line and react to them. Screening for triads will only identify respondents as eligible when they have the ability to use the GoToMeeting tool.

Recruiters will use two screening questionnaires ("screeners") to identify eligible respondents **(Attachments #B4 for consumers and #B5 for advocates)**. The screeners are carefully thought out so that the questioning process is as short as possible, easy to-understand, friendly, and efficient. In addition, the moderator's guides for the focus groups and triads will be used to ensure that the questions are easy to understand and answer, well-organized, and flow well **(Attachments #B2 for consumers and #B3 for advocates)**. The moderators will also be instructed to keep focus group discussions to 90 minutes and triads to 60 minutes to limit respondent burden with respect to their time. Participation will be voluntary and respondents will be asked to participate only once.

All data will be collected by the contractor, AED, and all personal identifiers will be excluded from the data records. Participation will be strictly voluntary and individual respondents will not be identified. Any necessary identifying or potentially identifying information (e.g., signed consent agreements) will be secured and kept separate from the data records **(Attachment #B6)**. Focus group 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.

All information provided by respondents will be kept secure to the extent permitted by law. AED will do the analysis of the data and write the report of the findings. Findings in the report delivered to NCI will be reported in the aggregate and no identifiable individual responses will be provided. NCI and AED's Institutional Review Board (IRB) Research Integrity Officers will review the research instruments and ensure that all necessary human subject protection procedures are in place.

To prevent the misinterpretation of the data, particularly the perception that the results are generalizable, NCI will take steps to ensure that the research findings are not taken out of context, misrepresented, or misused. NCI will include the purpose and formative nature of the sub-study, as well as the qualitative research methodology along with its limitations, in any presentation of data and results generated from this sub-study.

Participant Burden

There will be a maximum of 57 respondents (six focus groups with 8 or fewer respondents per group and three triads with 3 participants per triad) plus the same number would be screened. For each focus group, up to 9 individuals will be recruited; and, based on prior focus group experience, we realistically expect six to eight individuals to show for the group. However, to ensure we accurately reflect a maximum burden potential, we are estimating the burden total on the assumption that 8 will attend each group. For triads, advocates will not be over recruited - three participants will be recruited for each triad scheduled. Focus group and triad participants will receive an honorarium of $75 for their time. Research on participation in focus groups indicates that, without providing minimal levels of monetary compensation, insufficient numbers of participants will attend and results will not be useful.

An average total participation time will be 75 minutes for triads (10 minutes to respond to the screener, 5 minutes to complete the consent form and get online and onto the teleconferencing Web site for the discussion, and 60 minutes to participate in the triad); and 110 minutes for focus groups (10 minutes to respond to the screener, 10 minutes to check-in and complete the consent form, and 90 minutes to participate in the focus group). This culminates in a maximum total annual hour burden of 100 hours (see Table 1).

Table 1: Estimates of Hour Burden

Types of Respondents	Methodology	Number of Respondents	Frequency of Response	Average Response Time (Hours)	Annual Hour Burden
Consumers-General Public	Screener for Focus Groups (Attachment B4)	48	1	10/60 (0.1667)	8
	Moderator's Guide for Focus Groups (Attachment B2)	48	1	100/60 (1.667)	80
Advocates	Screener for Triads (Attachment B5)	9	1	10/60 (0.1667)	2
	Moderator's Guide for Triads (Attachment B3)	9	1	65/60 (1.083)	10
TOTAL		**114**	**--**	**--**	**100**

The full generic study, approved on February 10, 2010, requested a total of 7,050 burden hours. There have been two previous sub-studies approved by OMB under this umbrella submission totaling 1012 burden hours requested to date. Approval by OMB of this study would bring the total burden hour requested to date for 0925-0046 to 1112, which is approximately 16% of the total requested hours.

Thank you for your consideration of this proposed sub-study 0925-0046-04. Please feel free to contact me at 301-435-7789 if you have any questions.

Attachments (attached below):

B1) Messages to be tested
B6) Consent form for consumers

Attachments (in a separate file):

B2) Moderator's guide for focus groups with consumers
B3) Moderator's guide for triads with advocates
B4) Recruitment screener for consumer focus groups
B5) Recruitment screener for advocate triads

Attachment B1:
NCI Personal Genomics Focus Groups

Revised Messages August 3, 2010

[These messages are expected to be included in a stand-alone brochure and on a Web site where additional content can be provided. This will not be specific to NCI but rather relevant across NIH.]

1. Family Health History
    - Knowing your family health history can be important to your own health.
    - Gather and become familiar with your family health history.

2. Gene-Environment Interaction
    - Most diseases are not caused by genes alone but by the interaction of genes with factors such as the environment, behavior, and infections.
    - Make healthy lifestyle choices – it will improve your health, regardless of your genes.

3. Genetic Test Results
    - Many genetic tests are intended to reveal your risk of getting a disease compared to the average person. Test results are not diagnoses and do not guarantee that you will or will not develop a health condition.
    - Before getting a genetic test, learn more about what the result will tell you.

4. Types of Genetic Tests
    - There are different types of genetic tests for various diseases and conditions. These include testing for a specific disease or mutation; providing a genome-wide scan; confirming a diagnosis; and identifying how a person will likely respond to a treatment or drug. Other genetic tests which we do not consider here may inform about the risk of disease in pregnancy and future offspring.
    - If you are considering getting a genetic test talk to your doctor about the type of test that would best meet your needs.

5. Pros and Cons
    - There are pros and cons to knowing your genetic risk information, both for you and for your family.
    - Before undergoing genetic testing consult credible sources, which might include a genetic counselor.

6. Direct to Consumer Testing
    - Genetic tests that you buy directly online, through the mail, or over the counter may not provide valid or useful results to help you to make informed health decisions.
    - Consult a health professional to better understand the reasons for and against getting a genetic test and how to interpret the results.

7. Consumer Protection
    - By law, you are protected against discrimination regarding health insurance coverage and employment based on your genetic information.
    - Find out more about how your rights are protected in the Genetic Information Nondiscrimination Act of 2008.

8. Oversight
    - At this time, commercial genetic testing labs are not regulated by the Federal government. The accuracy and reliability of test results may vary across labs.
    - Learn more about how genetic tests are evaluated: http://www.egappreviews.org/

Attachment B6:

Informed Consent Form for Consumers and Advocates

Identification of Project	**Focus Groups and Triads About Genetics and Genomics Information**
Statement of Age of Subject	I state that I am at least 18 years of age, in good physical health, and wish to participate in research being conducted by the Office of Market Research and Evaluation of the National Cancer Institute, Rockville, MD 20852.
Purpose	The information collected as part of these research efforts will allow NIH to better understand what messaging is of most interest and will be most useful to the general public around personal genomic tests and services. These findings will inform the refinement of the materials being developed to meet the information needs on these topics.
Procedures	Participants will be asked to join an in-person focus group, triad, or remote triad at which point they will be asked a series of questions their knowledge, attitudes, and behaviors related to genomics and genetics.
Confidentiality	All information collected will be kept secure to the extent permitted by law. I understand that the data I provide will be grouped with data others provide for the purpose of reporting and presentation, and that my name will not be used. I understand that the focus group or triad will be audiotaped, but my voice will not be played to others besides the research team without my written permission.
Risks	I understand that the risks of my participation are expected to be minimal in nature.
Benefits, Freedom to Withdraw, & Ability to Ask Questions	I understand that this study is not designed to help me personally but that the investigators hope to learn about what information people are looking for, in general, related to genomics and genetic testing. I am free to ask questions or withdraw from participation at any time and without penalty.
Contact Information of Investigators	Deputy Director, Office of Market Research and Evaluation, National Cancer Institute Telephone: 301-435-7789 Email: goodmann@mail.nih.gov

Printed Name of Research Participant _____

Signature of Research Participant _____

Date_____