ATTACHMENT 5: Memo from NIH Office of Human Subjects Research

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX: 301-480-3441 **Exempt: #:** 4399

To: Massett, Holly
NCI
6116 Executive Blvd.

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
NCI proposes using focus groups to conduct qualitative research with members of the general public. NCI will convene 12 consumer focus groups using standard focus group methodologies to elicit formative information and gain an understanding of consumer knowledge, attitudes, perceptions, opinions, and interest in genetic testing, with specific interest in the newly emerging area of direct-to-consumer (DTC) genetic testing. The focus groups will also ask questions related to the public's information needs in regard to an informational Web site about DTC genetic testing that is being developed by the NIH. Focus group

Original Request Received in OHSR on: 10/16/2008

Responsible NIH Research Investigator(s): Holly Massett, PhD NCI

OHSR review of your request dated Fri, Sep 26, 2008 has determined that:

☐ Federal regulations for the protection of human subjects do not apply to above named activity. No further action is necessary.

☒ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Note:

Office Person SPC Admin Asst. CB

/Jerry Menikoff, MD, JD/ Director, OHSR 10/21/2008

Signature Title Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: Yes

OHSR Use Only
☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

4399

REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443) or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: Sept 26, 2008

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: _____
(ORO Signature)

From: Nina Goodman
(Signature)

Through: _____
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Name of OMRE NIH Principal Investigator(s): Holly Massett, PhD
IC NCI **Laboratory/Branch** Office of Communications and Education
Building & Room No: 6116/400 **Tel. No:** 301-594-8193 **FAX No:** 301-480-3441

Name of OMRE NIH Co-Principal Investigator(s): Nina Goodman, MHS
IC NCI **Laboratory/Branch** Office of Market Research & Evaluation
Building & Room No: 6116/400 **Tel. No:** 301-435-7789 **FAX No:** 301-480-3441

Is the Principal investigator an NIH employee? X **Yes** _____ **No**

If no, please explain: _____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):
NCI proposes using focus groups to conduct qualitative research with members of the general public. NCI will convene 12 consumer focus groups using standard focus group methodologies to elicit formative information and gain an understanding of consumer knowledge, attitudes, perceptions, opinions, and interest in genetic testing, with specific interest in the newly emerging area of direct-to-consumer (DTC) genetic testing. The focus groups will also ask questions related to the public's information needs in regards to an informational Web site about DTC genetic testing that is being developed by the

NIH. Focus group participants will be asked for feedback about the extent to which the information is comprehendible, credible, relevant, and useful. Recommendations for content improvement will also be obtained.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name	Institution	Address Tel. # FAX #
Tom Lehman	AED	1825 Connecticut Avenue, NW Washington, DC 20009 (202) 884-8863

3. Proposed start date of your research upon IRB approval
Proposed completion date December 30, 2008

4. Will you be _____these samples or data?

Collecting [Yes]/No
Receiving Yes/[No]
Sending [Yes]/No

5. Do the samples or data:
(a) Already exist?___Yes __X__No

(b) Or are they being collected for the express purpose of this study? _X_Yes ___No
If "yes," please describe:
The proposed study will gather information through focus groups on the general public's opinions and perceptions of genetic testing.

(c) Or a combination of (a) and (b)? ____Yes __X__No

6. What role will you have in this research project? (Check all that apply)

_X_ Analyze samples/data only.

_X_ Consultant/advisor to collaborator(s) listed above.

_X_ Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

_X_ Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

_X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

NCI will serve as the decisional authority over the design and implementation of the research that will be taking place.

_____Other (If necessary, use this space to describe your role in this research).

_____

_____

7. Where are the subjects of this research activity located?
A maximum of 108 respondents (12 groups with maximum of 9 individuals per group) will participate in the focus groups. The participants will be recruited through a recruiting firm using lists of laypersons who have chosen to opt-in for participation in such surveys. The participants will be recruited using a screener (attached here).
The participants in these consumer focus groups will be members of the general population ages 18 and older. Potential participants will include both men and women, and represent all racial, ethnic, and educational backgrounds. All groups will be recruited to attempt to include a mix of income and education levels.

The subjects will be located in the Washington, DC metropolitan area as well as in two other locations that are to be determined.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) _X_ Yes ____No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?
Using a moderator guide (attached), a trained facilitator will lead all discussions. During the discussions respondents will be asked about their thoughts, opinions and perceptions of genetic testing as well as the relatively new and rapidly growing area of "direct-to-consumer" (DTC) genetic testing. The information gathered from the focus groups will aid in the development of formative communication resources that will help the public understand the language, issues, and complexities inherent in the area of genetic testing.

The moderator for the group discussions will be:

- Trained in focus group moderation
- Experienced in facilitating discussions on sensitive topics
- Educated in the Human Participants Protection Education for Research Teams online course, sponsored by NIH
- Skilled at diffusing conflict
- Skilled at discouraging and immediately redirecting a group discussion back to the moderator guide if a participant begins to disclose unsolicited, inappropriate, and potentially damaging personal information

Individual respondents will not be identified and participation will be strictly voluntary. Names or images will not be recorded, nor will personal identifying data be maintained in the focus group data records. 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 data will be collected by the contractor, the Academy for Educational Development (AED), and all personal identifiers will be excluded from the data records.

The interviews will be audiotaped. The researcher will not have access to identifying information (such as consent agreements) that would link the data on the audiotapes to a participant's identity. Audiotapes will be used to aid report writing, and will be secured in a locked area. Audiotapes will be destroyed by December 31, 2013. No names will be used when reporting findings.

Consent agreements will be collected by the recruiting facility and provided AED. Upon receipt AED will forward these consent forms to an NCI researcher. Consent agreements with the participants' full names and signatures will be kept by NCI staff and stored in a secure, locked area. They will be kept separate from any discussion data associated with the study.

10. If the samples, data do not come from an IRB approved protocol, do they come from:

(a) Repository ____Yes _X__ No

(b) Pathological waste ___ Yes __X__No

(c) Autopsy material ___ Yes _X__ No

(d) Publicly available source ___Yes _X__ No

(e) Other_____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

(a) __X_ Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)

(b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.

(c) ___ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

(a) __X_ No, I will not send results back to the provider(s).

(b) ___ Yes, I will send aggregate results to the provider(s).

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

13. Has the research activity <u>that you are proposing in this form</u> been approved by an Institutional Review Board (IRB) elsewhere?

__X__ Yes, the NIH research activity has been reviewed by the following IRB (s) (Please provide the following information for **each** IRB):

Academy for Educational Development	Name of institution that provided the review
1825 Connecticut Ave, NW Washington, DC 20009-5721	Address of reviewing institution
Thomas Lehman	Name of PI for the IRB approved protocol
Focus Groups to Assess Consumers' Perceptions of Direct-to-Consumer Genetic Testing (AED protocol # 3721-03-001)	Title of IRB approved protocol and protocol #
#00007501	Federal Wide Assurance (FWA) number**

_____No IRB review of the research activity described in question #1 above has taken place

(**An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

14. Per NIH guidance***, have conflicts of interest by NIH employees, if any, been resolved?
__X__Yes _____No

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html

Genetics and Common Disease – Focus Group Discussion
Consent Form

About the Project

We have asked you to join a focus group discussion with up to eight other people. You will be asked about your thoughts and opinions related to genetic testing for common diseases. The information collected as part of these research efforts will allow the government to better understand the public's perceptions of this relatively new and rapidly growing area. The talk will last about 2 hours. A trained leader will conduct it.

Researchers will watch the discussion through a one-way mirror. We will record this talk by audiotape. We will listen to the tapes and write down what is said. We do all this to write a report. We will not allow anyone outside this research project to listen to anything recorded. All that you say will be kept private as required by law. We will not put your name in the report or on the tapes. The tapes will be kept in a locked cabinet. The tapes will be destroyed by December 31, 2013.

There will be no risk to you. You do not have to answer anything. You may stop at any time.

This project is sponsored by the National Cancer Institute. The Academy for Educational Development is helping to do this research. If you have any questions about this project, please call Holly Massett, Ph.D. at 301-594-8193. You may call this number if you have questions about your rights as a participant in this project or if you think you have been harmed. Leave a message with your name and phone number, and someone will call you back as soon as possible.

We thank you for your time.

Participant Consent

My signature verifies that I have read the **About the Project** and understand my rights as a participant. I agree to participate in today's discussion. I understand that the group will discuss thoughts and opinions related to genetic testing for common disease. I agree to be audio-taped only and observed through a one-way mirror. I understand that only the people working on this project will be able to hear the tapes or observe this group. I understand that neither my name nor any other identifying characteristics will be used in any report or other products that may result from this project.

Name (*Please print*): _____

Signature: _____

Date: _____

OMB#0925-0046-11
Exp. Date: 1/31/2010

Genetic Testing
Consumer Focus Groups
National Cancer Institute
9/25/08

Moderator's Guide (90-minute session)

OVERARCHING RESEARCH QUESTIONS

1. What are consumers' levels of knowledge and awareness of genetic testing (in general and direct-to-consumer) that provides a person with their risk of developing various common diseases?
2. What additional information do consumers want to know about genetic testing for common diseases (in general and direct-to-consumer)?
3. Through what channels and from what sources would consumers look for additional information about genetic testing for common diseases (in general and direct-to-consumer)?
4. What are the greatest benefits to consumers of genetic testing for common diseases (in general and direct-to-consumer)?
5. What are the greatest barriers/concerns of consumers about genetic testing for common diseases (in general and direct-to-consumer)?
6. What are consumers' expectations and/or experiences with the direct-to-consumer genetic testing for common diseases process and results?
7. What kind of information on genetic testing for common diseases would consumers like the government (NIH) to provide to the American public (in general and direct-to-consumer)?
8. What are consumer reactions to draft Web content on genetic testing for common diseases (in general and direct-to-consumer)?

I. OPENING REMARKS AND INTRODUCTIONS [10 min]

A. Introduction and Purpose

1. Hello and welcome. My name is _____ and I work for the Academy for Educational Development, or AED.

2. We're working with the National Cancer Institute, or NCI, on a project, and talking to people in several cities to find out what you think about genetic testing. We really want to hear about your thoughts and experiences so we can create some useful materials.
3. We appreciate you taking the time to talk with us today and share your opinions. Thank you for being here.

B. **Confidentiality and Process**

1. Before we get started, I'd like to tell you how groups like this usually work. First, you'll notice that we're taking notes as well as tape recording our conversation. The audio recording is to help us remember what you said, and the note-taking is a back up in case the recorders break.
2. None of the information that is written down and recorded will be connected to you in any way.
3. After we have written a report about all the opinions we have heard here and in other cities, the tapes and notes will be destroyed.
4. When we have groups like this, we usually set ground rules that we can all agree on. I'm going to show you some that may be important to you. Let me know if you have others to add. [POST LIST]
5. Can we agree on these ground rules? Are there any others you would like to add?

GROUND RULES

1. There are no right or wrong answers.
2. It's okay to disagree.
3. Each person's comments are important and valued.
4. One person speaks at a time.
5. Speak loudly and clearly.
6. Don't have to answer every question.
7. Please be honest and tell us how you really feel.

C. **Self-introductions**

1. First name, one of your favorite Web sites.

I. KNOWLEDGE AND AWARENESS - OVERALL [20 min]

A. What do you think of when you read or hear the term "genetic testing"?

B. What questions come to mind when you think about genetic testing?

C. What do you think of when you read or hear about genetic testing that can tell a person what their risk is of getting certain common diseases, like different types of cancers, diabetes, or Alzheimer's Disease?

D. What have you heard others saying (such as Web sites, newspapers, magazines, doctors, etc.) about genetic testing?

E. What would make/what has made you want to get a genetic test to learn what <u>your</u> risk is of getting certain common diseases like these?

- What do/did you want to learn from this kind of test?
- What do/did you not want to learn?
- What disease or diseases are you most interested in learning your level of risk?
- Are there some diseases that you don't want to know what your risk is of getting them? Which ones?

F. What would make you not want to get this kind of genetic test to learn what <u>your</u> risk is of getting certain diseases?

G. How would/did you go about making the decision to either get a genetic test to learn <u>your</u> risk of getting certain diseases or not?

- What thoughts would be/were running through your mind?
- Would/did you talk to anyone about it? If so, why?
- Who would/did you talk to?
- What would/did you say to them?

H. If you did get a genetic test to learn your risk of getting certain diseases, what would you be/were you worried or concerned about afterwards?

I. Do you ever hear any words or phrases with regard to genetic testing that you don't understand? What are they?
PROBE: genome, DNA, phenotype, gene scan, etc.

J. If a person gets a genetic test to find out their risk for a disease, such as cancer, diabetes or Alzheimer's Disease, how should a physician be involved once that person gets their test results?

II. KNOWLEDGE AND AWARENESS – DIRECT-TO-CONSUMER [5 min]

Throughout the rest of our discussion, we're going to talk about genetic testing services that are being offered by companies, usually through company Web sites, which people can purchase and have tests done without going through their physician. For the purposes of our discussion, we're going to refer to these kinds of genetic tests as "direct-to-consumer" tests, because the testing happens directly between the company and the person. The person's physician is not involved.

[Note: Read "DTC" as "direct-to-consumer"]

A. What have you heard about DTC genetic testing services?

- Has the topic of this kind of genetic testing ever come up in conversations with your family, friends or coworkers? If so, what do you talk about?
  PROBE: reasons for doing it, benefits, risks, process, companies providing it

B. As someone who has looked into/participated in this kind of genetic testing service, what is it that you most want(ed) to learn?

- For what reasons?

C. What would cause/caused you to look into getting DTC genetic testing and not go through your doctor?

III. INFORMATION SOURCES AND TRUSTED SOURCES [5 min]

A. Where did you first hear about DTC genetic testing services?

B. Has your physician ever mentioned DTC genetic testing? If so, what did he/she say?

- What was the conversation like?
- Did you or your doctor start the conversation?

C. After you first heard about it, where did you get your information on DTC genetic testing?

D. What makes you feel that the information you found or got about this kind of genetic testing is accurate?
[For Early Adopters, information learned before purchasing test]

- If you don't think it's accurate, where would you look or go to get trusted information on this kind of genetic testing?
  PROBE: physician, government Web site, medical orgs

IV. BARRIERS AND BENEFITS [10 min]

A. As you were/are making the decision to either participate or not participate in DTC genetic testing, what concerns or worries did/do you have?
PROBE:
- Done by a company
- No physician input
- Effect on health insurance, future employment
- Fear
- Privacy
- Cost
- Ability to handle results
- Compared to getting it through your doctor
- Impact on/reactions from family members

B. How much would you be willing to pay for this kind of test? (out-of-pocket costs not covered by insurance)

C. What are the downsides of DTC genetic testing?

D. What are the benefits?

E. How would/did your test results affect your health decisions or life planning?

V. [EARLY ADOPTERS ONLY] TESTING EXPERIENCE [10 min]

A. As someone who has done a DTC genetic test, what would you tell others about your experience?
PROBE: Process, test results, learning this information about yourself
- If yes, would you recommend it others?
- If you had the decision to make all over again, would you do it? Why, why not?
- What, if anything, do you wish you had known before doing a DTC genetic test?

B. Are you satisfied with your results?
- What parts of your results were hard to understand?
- Did you get your questions answered?
- Who did you share your results with?
  PROBE: doctor, family, friends, children

  [Need to add question about how they are interpreting their results]

C. Do you trust the results you received?
- What is it about the company you used that makes you feel like you can trust your results?
- What do you wish the company would have done so you could feel like you can trust your results?

D. How did you use, or plan to use, your results?
PROBE: share with doctor, family, change lifestyle, seek healthcare, reproductive decisions

E. Tell me about any positive or negative outcomes that resulted from you taking a DTC genetic test?
- Positives
- Negatives
- Unexpected/unanticipated

VI. INFORMATION NEEDS [5 min]

A. What information does a person need about DTC genetic testing to make an informed decision to participate in the testing process?
PROBE: what they can find out, how it works, cost, how to interpret results, security/confidentiality

B. **[Rejectors only]**
What information about DTC genetic testing did you get that made you decide not to participate in this kind of test?

- Where did you get this information?
- What information might make you change your mind?
- What other factors might make you change your mind?
  PROBE: reduced cost, ADD OTHERS…

C. **[Contemplators only]**
What information about DTC genetic testing might help you make a decision to participate in this kind of test or not?

- What other information might help you make a decision?
- What other factors might help you make a decision?
  PROBE: cost, confidentiality, security of information

D. **[Early Adopters only]**
What information about DTC genetic testing did you learn that made you decide to participate in this kind of test?

- Where did you get this information?
- What other information helped you make your decision?
- What other factors helped you make your decision?
  PROBE: cost, what you wanted to learn (e.g., family history)

E. What types of information are/were most helpful to you in making an informed decision about participating in DTC genetic testing?
PROBE: statistics/facts, testimonials, visual/graphic depiction of information

- What types of information do you think are still needed?

F. What questions do you still have about DTC genetic testing?

VII. WEB CONTENT REACTIONS [10 min]

Now, I'd like to show you an example of information that is being considered for a Web site about genetic testing services that are offered to people directly without having to go through their physician.

A. What do you like about it?
   - Layout/design
   - Images
   - Colors
   - Types of information

B. What don't you like about it?

C. Of the information included, what is confusing or hard to understand?

D. Which information would be most useful to someone thinking about getting DTC genetic testing?

E. What would you improve or do differently?

F. What is missing?

G. If you knew this Web site existed, would you go to it for information on DTC genetic testing? Why/why not?

VIII. ROLE OF GOVERNMENT [5 min]

A. What kinds of information about genetic testing in general would you expect the government to provide?

B. What information would you want to find on a government Web site about DTC genetic testing, specifically?

C. How can government agencies help people make informed decisions about whether to participate in DTC genetic testing?

IX. CLOSING REMARKS [5 min]

A. Thank you for helping us to learn more about what you think about genetic testing. We will be using your input to develop helpful information about this topic.

B. Is there anything else you would like to tell us about anything we talked about today?

C. Do you have any questions for me?

D. Each of you will receive your gift for participating today as you leave the building.

THANK YOU!

ATTACHMENT 5: Memo from NIH Office of Human Subjects Research

TRANSMISSION VERIFICATION REPORT

TIME : 10/15/2008 10:33

DATE,TIME	10/15 10:28
FAX NO./NAME	3014023443
DURATION	00:05:26
PAGE(S)	18
RESULT	OK
MODE	STANDARD ECM

ATTACHMENT 5: Memo from NIH Office of Human Subjects Research

Office of Communications & Education
Office of Market Research & Evaluation
User-Centered Informatics Research Lab
6116 Executive Boulevard, Suite 400
Rockville, Maryland 20852
Phone: 301-451-4687 (main)
Fax: 301-480-3441

Date: 10/15/08

To: OHSR

Fax: 301-402-3473

From: MARIE PIENZO

Phone: 301-451-2413

Comments: GENETICS FOCUS GROUP - CONSUMERS.

PLEASE CC ME WHEN A DECISION IS REACHED

_____ pages including coversheet

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Thursday, October 16, 2008 2:16 PM
To: Massett, Holly (NIH/NCI) [E]
Cc: Goodman, Nina (NIH/NCI) [E]; Rienzo, Marie (NIH/NCI) [C]
Subject: Requests for Review Rec'd-OHSR

Good afternoon Dr. Massett,

This email is to verify that OHSR has received your Requests for Review of Research and are currently being processed as OHSR #4398 and #4399. Please use these numbers in any future correspondence regarding these studies.
We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

#4398-Genetics focus group-Physicians
#4399-Genetics focus group-Consumers

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

Chris Brentin

Administrative Assistant

OD/OHSR/NIH

10 Center Drive, Rm. 2C-146

Bethesda, MD 20892

301-402-8631 (Direct)

301-402-3443 (Fax)