

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

FAX: 301-435-7547  
To: Moser, Richard  
NCI  
DCCPS/BRP

Exempt #: 13082

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The purpose of this study is to field questions that were previously used in the NCI Health Information National Trends (HINTS) survey, using an alternative online platform for survey administration, including Amazon Mechanical Turk (mTurk; www.mturk.com). HINTS collects nationally representative data routinely about the American public's use of cancer related information and collects data using a probability-based sample. This project will enable us to compare data collected from non-probability based samples to HINTS

Original Request Received in OHSR on: 11/19/2015

Responsible NIH Research Investigator(s): Richard Moser, PhD NCI

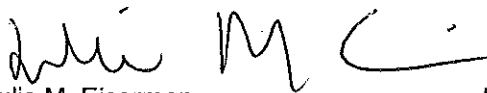
OHSR review of your request dated Wed, Nov 18, 2015 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.
- 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

Office Person JE

Admin Assist. CB

Note:  
3/15/16: Anonymous survey using mTurk

  
Julie M. Eiserman

Policy Analyst, OHSRP

3/15/2016

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1  2  3  4  5  6

9-11-2015

## OHSRP REQUEST FOR DETERMINATION FORM

## II. SHOULD I STOP OR GO FORWARD WITH AN OHSRP SUBMISSION?

1. Have you already started or completed your research activity
  - Yes (**Stop here.** Please consult OHSRP.)
  - No
  
2. Is the proposed activity a component of a **protocol that is under NIH IRB review**, e.g. the results of this activity will be used in support of the protocol?
  - Yes (**Stop here.** You will likely need to amend the NIH protocol for the proposed activity. Please consult the IRB if you are unsure. Do not submit this request.)
  - No
  
3. Is this a research collaboration in which the NIH investigator has access to individually identifiable specimens/data (including coded specimens/data for which the investigator has the code key), and wants to send specimens/data that are either coded or anonymous to collaborators? *If the specimens/data are not individually identifiable, but the identity of the subjects may readily be ascertained by the investigator or associated with the information because of a small sample size or other reason, please answer "Yes" below.*
  - Yes (**Stop here.** You must obtain IRB approval of an amendment to the original protocol or IRB approval of a new protocol. Do not submit this request.)
  - No
  
4. Does this activity involve prisoners?
  - Yes (**Stop here.** Please consult the IRB. Do not submit this request.)
  - No
  
5. Please select the type of activity or materials involved in your project. (*Select all that apply.*)
  - 5a. **Single Case Report** that does not contain any identifiable information about the participant; and no changes were made to the participant's care for the sake of reportability
  - 5b. **Program Evaluation**, the results of which will only be shared with the relevant program or institution; and the participants have not been assigned to groups for comparison; and no comparison of a standard versus non-standard intervention is taking place
  - 5c. **Quality Assurance/Quality Improvement activity with a clinical practice focus**, that does not introduce an untested clinical intervention or collect patient outcomes for the purposes of collecting scientific evidence about how well the intervention achieves its intended results, **in which the sole purpose is to**

improve internal practice and not to also conduct research to develop or contribute to generalizable knowledge

- 5d. **Quality Assurance/Quality Improvement activity with a non-clinical practice focus**, e.g. usability testing or evaluation of websites, workshops, conferences, tools, policies, etc., **in which the sole purpose is to improve a product or service and not to also conduct research to develop or contribute to generalizable knowledge**
- 5e. **Clinical Consulting**
- 5f. **Diagnostic Testing for Clinical Purposes** (*Other approvals may be needed if investigational tests are used. Please consult your IC FDA representative or the FDA.*)
- 5g. **Autopsy Materials, Specimens/Data from Deceased Persons** (*Please contact your privacy officer for further guidance.*)
- 5h. Specimens/data purchased from a **commercial repository** which will contain no identifying information
- 5i. **Derivatives** of materials (e.g. DNA, RNA, cell fragments or sub-parts, viruses or parasites) obtained from humans which will contain no identifying information
- 5j. **Established NIH Human Embryonic Stem Cell Lines that are available to qualified investigators and require no ethical review according to the registry.** The cell line must be listed here: [http://grants.nih.gov/stem\\_cells/registry/current.htm](http://grants.nih.gov/stem_cells/registry/current.htm) and not be identifiable to the NIH researchers.

*If 5a. - 5j. is selected above, and your proposed project involves **ONLY** these activities: **STOP** answering questions here. No submission or determination is required from OHSRP or an IRB. However, other NIH policies or IC requirements apply. Please retain this documentation for your files.*

*If your proposed project involves **any of these activities above and other activities not listed here or involves none of these activities above**, please continue with the request for determination form.*

### III. WHAT ADDITIONAL DOCUMENTATION MUST BE SUBMITTED TO OHSRP WITH THE REQUEST FOR DETERMINATION FORM?

*There are three categories of research that require additional documentation to be submitted to OHSRP with the request for determination form. The categories are:*

**PART I: GENERAL INFORMATION**

*This fillable form must be typed and submitted in pdf format, upon receipt of all required signatures. This form must be completed by NIH staff only.*

1. Date of Request: **11/18/2015**
2. Is this a **new** request for determination or an **amendment** to a previously OHSRP-approved project? (**Please note** if this is an amendment, we ask that you use your previously submitted request for determination form to answer the questions on this form.)
  - a. New project
  - b. Amendment

If an amendment, provide the determination number of the original approved project: OHSRP#:

3. Project Name: Formative Research to Investigate a Web Panel and to Determine Feasibility of Web-Based Cognitive Pretesting

4. Project Description (*Please describe the research activity that will be performed in lay terms, including its purpose. Explain the roles of the NIH investigator and collaborator(s) on the project; and what each party will contribute to the research. As you type, the box will increase to allow for additional text.*):

**The purpose of this study is to field questions that were previously used in the NCI Health Information National Trends Survey (HINTS), using an alternative online platform for survey administration, Amazon Mechanical Turk (mTurk; www.mturk.com). HINTS collects nationally representative data routinely about the American public's use of cancer-related**

**information and collects data using a probability-based sample.**

**This project will enable us to compare data collected from a non-probability based sample to HINTS data collected from a nationally representative probability-based sample to assess the quality and comparability of the data. The proposed study will also use cognitive probes to explore how respondents are interpreting/understanding particular questions utilizing a novel form of probing that is self-administered, web-based, and collected among a large sample of respondents.**

**Primary objectives:**

- 1. To compare estimates collecting data using a non-probability sampling method to responses using established probability sampling methods**
- 2. To examine whether associations between variables are consistent across the various sampling approaches**
- 3. To conduct cognitive testing of select survey questions using a novel internet-based method to assess feasibility of using this method, and to**

assess how respondents are interpreting those questions

5. Proposed Start Date: / /

Proposed Completion Date (Required): / /

6. Requestor Details:

Name: Institute/IC:
Phone Number: ( ) -
Email Address:

7. Are you the Senior Investigator (SI) for this project? (i.e., the team lead. The term "SI" on this form does not refer to one's official NIH title. The SI must be an NIH FTE.)

[ ] Yes [ ] No

7.1. If no, what is your role?

- [ ] a. Administrative Support
[ ] b. Other investigator
[ ] c. Other, specify:

8. If not already included above, provide SI details (See instructions in Q. 7.):

Senior Investigator Name:
Institute/IC:
Phone Number: ( ) -
Email Address:

SI Signature (Required): \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

9. Supervisor Name:

(Please note the supervisor cannot be a member of the research team for this specific project.)

I (the supervisor) certify that the IC concurs that this project may proceed if it meets regulatory and NIH policy requirements.

Supervisor Signature (Required): \_\_\_\_\_ Date: \_\_\_/\_\_\_/\_\_\_

10. Is there someone other than the SI, conducting this research (e.g. a junior investigator, contractor, fellow, student, etc.)?

[ ] Yes [ ] No

10.1. If yes, provide the following information:

Table with 3 rows: NIH Investigator Name, Institute/IC Name, Email Address.

3. To conduct cognitive testing of select survey questions using a novel internet-based method to assess feasibility of using this method, and to assess how respondents are interpreting those questions

5. Proposed Start Date: 01/01/2016

Proposed Completion Date (Required): 12/31/2016

6. Requestor Details:

Name: Richard P. Moser, PhD Institute/IC: NCI
Phone Number: (240)276 - 6915
Email Address: moserr@mail.nih.gov

7. Are you the Senior Investigator (SI) for this project? (i.e., the team lead. The term "SI" on this form does not refer to one's official NIH title. The SI must be an NIH FTE.)

[X] Yes [ ] No

7.1. If no, what is your role?

- [ ] a. Administrative Support
[ ] b. Other investigator
[ ] c. Other, specify:

8. If not already included above, provide SI details (See instructions in Q. 7.):

Senior Investigator Name:
Institute/IC:
Phone Number: ( ) -
Email Address:

SI Signature (Required): [Handwritten Signature] Date: 11/18/2015

9. Supervisor Name: William Klein, PhD
(Please note the supervisor cannot be a member of the research team for this specific project.)

I (the supervisor) certify that the IC concurs that this project may proceed if it meets regulatory and NIH policy requirements.

Supervisor Signature (Required): [Handwritten Signature] Date: 11/18/15

10. Is there someone other than the SI, conducting this research (e.g. a junior investigator, contractor, fellow, student, etc.)?

[X] Yes [ ] No

10.1. If yes, provide the following information:

NIH Investigator Name: Dana Wolff-Hughes

Institute/IC Name: <b>NCI</b>
Email Address: <b>dana.wolff@nih.gov</b>

11. Please provide the name(s) and email(s) of anyone else, who should receive a copy of the OHSRP determination:

Name: <b>Dana Wolff-Hughes</b> <b>dana.wolff@nih.gov</b>	Email	Address:
Name: <b>Gordon Willis</b> <b>willisg@mail.nih.gov</b>	Email	Address:
Name:	Email Address:	

12. What role(s) will the **NIH Investigator(s)** have on this research project? (*Select all that apply.*)

- a. Interacting directly with subjects to collect specimens/data
- b. Receiving specimens/data from a collaborator to conduct research
- c. Analyzing specimens/data
- d. Generating genomic data (e.g. GWAS, WES/WGS; *Additional NIH requirements may apply: <http://gds.nih.gov/03policy2.html> )*
- e. Running laboratory assays for research
- f. Sending specimens/data to a collaborator to conduct research
- g. Interacting directly or indirectly with subjects to recruit for or conduct surveys, interviews/focus groups, observation of public behavior, educational research or tests, or research on public benefit or service programs
- h. Consulting/advising the collaborator(s)
- i. Authoring publication(s)/manuscript(s) pertaining to this research
- j. Other, *specify:*

13. Will the SI be **collaborating on this research project with** any other person (*not on the NIH research team*) outside or inside the NIH?

- Yes     No

13.1. If no, will the senior investigator **only be sending** specimens/data to someone not on the research team?

- Yes     No (*If yes, please still add these individuals under Q.14 below.*)

14. Please include the details of each collaborator, his or her role, and when applicable, what will be sent or received. For any more than three collaborators, please provide the information requested below in the email request at the time of submission. *Provide the Federalwide Assurance (FWA)\* number for each non-NIH collaborating institution (for more information contact OHSRP). Ask your collaborator for the FWA number or use this link to look it up:*

<http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>

\*A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/Office of Human Research Protections (OHRP) to institutions which receive Federal funds/**support** to conduct non-exempt human subjects research. An FWA is an assurance of compliance with the U.S. Federal Policy for the Protection of Human Subjects, 45 C.F.R. 46.

a. Collaborator Name: <del>David Cantor</del>
Institution/IC Name: <del>Westat, Inc</del> FWA #: <del>55551</del>
City/State/Country: <del>Rockville, MD</del>
Email Address: <del>david.cantor@westat.com</del>
Sending specimens/data: <input type="checkbox"/> Receiving specimens/data: <input checked="" type="checkbox"/> Both: <input type="checkbox"/>
Describe what will be sent/received: <del>Dr. Cantor is an expert in survey methods and analysis and will be collaborating on creating the sample and analyzing the data.</del>

b. Collaborator Name :
Institution/IC Name: FWA #:
City/State/Country:
Email Address:
Sending specimens/data : <input type="checkbox"/> Receiving specimens/data: <input type="checkbox"/> Both: <input type="checkbox"/>
Describe what will be sent/received :

c. Collaborator Name :
Institution/IC Name : FWA #:
City/State/Country:
Email Address:
Sending specimens/data: <input type="checkbox"/> Receiving specimens/data : <input type="checkbox"/> Both: <input type="checkbox"/>
Describe what will be sent/received :

15. For this project, will NIH be conducting a research activity with de-identified specimens or data **in support of FDA-regulated research** that is currently under IRB review at another institution?  
 Yes  No

15.1 If yes, has the **collaborator confirmed** that the planned research activity, which will occur at NIH, is included in the IRB/ethics committee-approved *protocol and consent form* at his/her institution?  
 a. Yes, the NIH activity is IRB-approved at the collaborating institution  
 b. No, the NIH activity has not yet been IRB-approved at the collaborating institution (**Stop here. Do not submit this request until your collaborator has confirmed IRB approval at his or her institution**)

16. Does this activity include any of the following? (Select all that apply.)



- a. NIH research team is interacting directly with subjects in person or has **access to identifiers** to conduct survey, interview/focus group procedures, observation of public behavior, educational tests, educational research, or research on public benefit or service programs (*If a. only, skip to question 25., otherwise continue.*)
- b. Research with Specimens/Data
- c. NIH BTRIS Query
- d. Case Series
- e. Program Evaluation (*not meeting the definition in the Instructions, Part II, Q. 5b.*)
- f. QA/QI (*not meeting the definition in the Instructions Part II, Q. 5c. or 5d.*)
- g. Other, *specify:*

- 16.1. If e. or f. is selected above, does the activity involve **the NIH research team interacting directly with subjects in person or access to identifiers** to conduct survey, interview, or focus group procedures only?
- Yes (*Skip to question 25.*)
  - No (*Continue.*)

**PART II: RESEARCH WITH SPECIMENS AND DATA**

17. Identify the types of specimens/data involved in this project. (*Select all that apply.*)

- a. Medical Records, *specify:*
- b. Specimens, *specify:* ~~Answers to survey questions~~
- c. Data, *specify:* ~~Answers to survey questions~~
- d. Imaging, *specify:*
- e. Pathological Waste/Results
- f. Autopsy Materials/Specimens/Data from deceased persons (*Please contact your privacy officer for further guidance.*)
- g. Audio Recording
- h. Video Recording/Conferencing
- i. Fetal Tissue Additional NIH requirements apply:  
<https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/fetal-tissue-research>
- j. iPSC lines (*Additional NIH requirements apply:*  
<https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/use-human-stem-cells/guidelines-human-embryonic-induced-pluripotent-stem-cells>
- k. hESC lines (*Additional NIH requirements apply:*  
<https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/use-human-stem-cells/guidelines-human-embryonic-induced-pluripotent-stem-cells> AND  
<https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/use-human-stem-cells/areas-prohibited-research>
- l. WES/WGS
- m. GWAS
- n. From a repository

If an NIH Repository, *specify*:

- o. From a publicly available source (*meaning unrestricted access by anyone*), *specify*:  
 p. Other, *specify*:

18. Do all the specimens/data or information already exist?

- a. Yes  
 b. No  
 c. Some exist, and other specimens/data will be collected in the future

19. The specimens/data in this project were (or will be) originally collected for:

- a. Clinical purposes only  
 b. Research purposes (*even if also collected for clinical purposes*)

20. Is there active IRB/ethics committee approval for the use of the specimens/data at your collaborator's site?

- Yes  No

21. Can you identify the subjects, who are the source of the specimens or data, directly or through codes linked to individual identifiers?  Yes  No

22. Please select the response(s) that best describe(s) the specimens/data that will be shared/used for this activity. (*Please confirm this with your collaborator prior to submitting this form.*)

- a. Specimens/data will not contain any identifiable information, and **cannot be linked to individual subjects by you or your collaborators.**
- b. Specimens/data will be coded, however that **code cannot be used by either the sender or the receiver** to identify specific individuals.
- c. Specimens/data will be coded **so that the sender of the samples/data can link them to specific individuals**, but the receiver will not be able to do so.
- d. Specimens/data will contain **individually identifiable information.**
- e. Specimens/data currently contain identifiable information but data will be recorded in such a manner that subjects **cannot be identified directly, or through identifiers linked to subjects (e.g. a retrospective chart review), or an honest broker will be utilized for de-identification.**

23. If existing identifiable specimens/ data will be de-identified (including coded) before the research activity commences, please indicate who will conduct the de-identification:

- a. Collaborator(s)  
 b. Senior investigator or a member of the research team at the NIH

- c. Honest broker (*For use only when identified specimens or data are coming from an NIH investigator; must be someone who will not be conducting the research*) (*The agreement can be found here: <https://federation.nih.gov/ohsr/nih/formtmp.php> (NIH Login required)*)

24. Will recipient of specimens/data be returning results to the sender? (*Select all that apply*)

- a. Yes, coded results will be returned to the sender who can link them to individual subjects
- b. Yes, coded results will be returned, but neither the sender nor the recipient will have a link to the code key
- c. Only aggregate results will be returned (e.g. summary statistics, **not individual line-item data**)
- d. No, results will not be returned

24.1. If a.- c. is selected above **AND the sender is external to NIH**, is there IRB/ethics committee approval at his or her institution for the planned research activity to be conducted at NIH?  Yes  No

***For all requests, other than those involving survey, interview/focus group procedures, observation of public behavior, educational research or tests, or research on public benefit or service programs, stop here. Otherwise, continue to Part III.***

*Prior to submitting, review the instructions to insure that you include **the correct supportive documentation**. All documentation should be submitted in **.pdf format via email** to OHSRP to [ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov). Please write **'Request for Review'** in the subject line of the e-mail.*

### **PART III: RESEARCH INVOLVING EDUCATIONAL RESEARCH OR TESTING, SURVEY OR INTERVIEW PROCEDURES, OR OBSERVATION OF PUBLIC BEHAVIOR**

25. Specify the nature of the data to be collected by: (*Select all that apply*)

- a. Educational Research
- b. Educational Testing
- c. Survey or Interview/Focus Group Procedures
- d. Observation of public behavior
- e. Research on public benefit or service programs
- f. Other, *specify:*

26. How will recruitment and data collection take place? (*Select all that apply*)

- a. In-person at my collaborator's institution(s) or research site(s), *specify:*
- b. In-person at an NIH site

- c. In-person at another site(s), *specify:*
- d. Online
- e. Over the phone
- f. Other, *specify:*

27. Who will be conducting the data collection? (Select all that apply)

- a. NIH investigator or another member of the research team
- b. Non-NIH collaborator
- c. Off-site contractor, *specify* what company:
- d. Online survey tool, specify: ~~XXXXXXXXXXXXXXXXXXXX~~ Amazon mTurk, Nielsen, Survey Sampling International (SSI), Precision Sample
- e. Other, specify:

28. What is the age range of subjects involved in the research?

- a. Children aged < 18 years
- b. Adults aged ≥ 18 years

28.1. If a. is selected above, and the project involves observation of public behavior, will the NIH investigator(s) participate in the activities being observed?

Yes  No

29. Does your project fall into any of the categories of 'clinical research' as defined by the NIH? (See <http://grants.nih.gov/grants/glossary.htm#ClinicalResearch> for the full NIH definition of 'clinical research'.)

- a. Epidemiological and behavioral studies\*
- b. Outcomes research and health services research\*
- c. NONE OF THE ABOVE

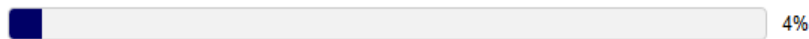
*\*If you a. or b. is selected above, please be sure to include the 'Planned Enrollment' Table described in Part II of the instructions.*

*Prior to submitting, review the instructions to insure that you include **the correct supportive documentation**. All documentation should be submitted in **.pdf format via email** to OHSRP to [ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov). Please write **'Request for Review'** in the subject line of the e-mail.*

OMB No: 0925-0589

Expiry Date: 07/17/2017

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0589). Do not return the completed form to this address.

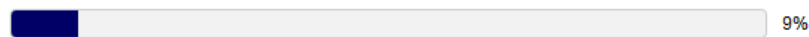


Next

**1. Welcome to the \_\_\_\_\_ Survey. Today you will be answering questions about \_\_\_\_\_. You will also be asked questions about yourself.**

**You will be asked to respond to multiple choice and open-ended questions. The survey takes approximately 15 to 20 minutes to complete. If you would like to continue with the survey, please click on the agree button below.**

- Yes, I agree to participate and am at least 18 years of age
- No, I do not agree to participate



Prev

Next

**2. Have you ever looked for information about health or medical topics from any source?**

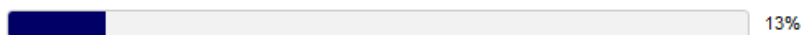
- Yes
- No -->GO TO Q5 on next page

**3. The most recent time you looked for information about health or medical topics, where did you go first?**

- Books
- Brochures, pamphlets, etc.
- Cancer organization
- Family
- Friend/Co-worker
- Doctor or health care provider
- Internet
- Library
- Magazines
- Newspapers
- Telephone information number
- Complementary, alternative, or unconventional practitioner
- Other (please specify)

**4. Based on the results of your most recent search for information about health or medical topics, how much do you agree or disagree with each of the following statements?**

	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree
It took a lot of effort...	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You felt frustrated...	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You were concerned about the quality of the information...	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
The information you found was hard to understand...	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



**5. Sometimes people use the Internet specifically for health-related reasons.**

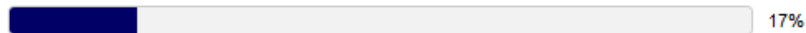
**In the past 12 months, have you used the Internet for any of the following reasons?**

	Yes	No
Looked for health or medical information for yourself	<input type="radio"/>	<input type="radio"/>
Looked for health or medical information for someone else	<input type="radio"/>	<input type="radio"/>
Looked for information about quitting smoking	<input type="radio"/>	<input type="radio"/>
Bought medicine or vitamins on-line	<input type="radio"/>	<input type="radio"/>
Looked for a health care provider	<input type="radio"/>	<input type="radio"/>
Downloaded health-related information to a mobile device, such as an MP3 player, cell phone, tablet computer or electronic book device	<input type="radio"/>	<input type="radio"/>
Kept track of personal health information, such as care received, test results, or upcoming medical appointments	<input type="radio"/>	<input type="radio"/>
Used e-mail or the Internet to communicate with a doctor or doctor's office	<input type="radio"/>	<input type="radio"/>

**6. Sometimes people use the Internet to connect with other people online through social networks like Facebook or Twitter. This is often called "social media."**

**In the last 12 months, have you used the Internet for any of the following reasons?**

	Yes	No
Visited a social networking site, such as Facebook or LinkedIn	<input type="radio"/>	<input type="radio"/>
Shared health information on social networking sites, such as Facebook or Twitter	<input type="radio"/>	<input type="radio"/>
Watched a health-related video on YouTube	<input type="radio"/>	<input type="radio"/>



Prev Next

**7. Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?**

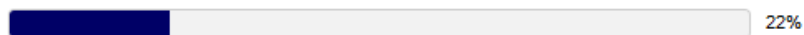
- Yes
- No

**8. The following questions are about your communication with all doctors, nurses, or other health professionals you saw during the past 12 months. How often did they do each of the following:**

	Always	Usually	Sometimes	Never
Give you a chance to ask all health-related questions you had?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Give you the attention you needed to your feelings and emotions?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Involve you in decisions about your health care as much as you wanted?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Make sure you understood the things you needed to do to take care of your health?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Explain things in a way you could understand?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Spend enough time with you?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Help you deal with feelings of uncertainty about your health or health care?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

**9. Overall, how would you rate the quality of healthcare you received in the past 12 months?**

- Excellent
- Very good
- Good
- Fair
- Poor



Prev

Next



**10. Please indicate how important each of the following statements is to you.**

	Very important	Somewhat important	Not at all important
Doctors and other health care providers should be able to share your medical information with each other electronically	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
You should be able to get to your own medical information electronically	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

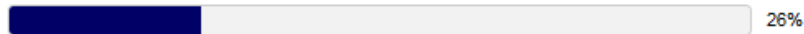
**11. Have you ever heard of HPV?**

**HPV stands for Human Papillomavirus. It is not HIV, HSV, or herpes.**

- Yes
- No

**12. A vaccine to prevent HPV infection is available and is called the cervical cancer vaccine or HPV shot. Before today, have you ever heard of the cervical cancer vaccine or HPV shot?**

- Yes
- No



[Prev](#) [Next](#)

**13. Have you ever been diagnosed as having cancer?**

- Yes
- No --> GO TO Q5 below

**14. What type of cancer did you have? [Mark all that apply]**

- Bladder cancer
- Bone cancer
- Breast cancer
- Cervical cancer (cancer of the cervix)
- Colon cancer
- Endometrial cancer (cancer of the uterus)
- Head and neck cancer
- Hodgkin's lymphoma
- Leukemia/Blood cancer
- Liver cancer
- Lung cancer
- Melanoma
- Non-Hodgkin's lymphoma
- Oral cancer
- Ovarian cancer
- Pancreatic cancer
- Pharyngeal (throat) cancer
- Prostate cancer
- Rectal cancer
- Renal (kidney) cancer
- Skin cancer, non-melanoma
- Stomach cancer
- Other (please specify)

**15. Have any of your family members ever had cancer?**

- Yes
- No
- Not Sure



**16. How worried are you about getting cancer?**

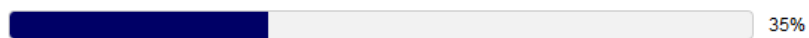
- Not at all
- Slightly
- Somewhat
- Moderately
- Extremely

**17. How likely are you to get cancer in your lifetime?**

- Very unlikely
- Unlikely
- Neither unlikely nor likely
- Likely
- Very likely

**18. How much do you agree or disagree with each of the following statements?**

	Strongly agree	Somewhat agree	Somewhat disagree	Strongly disagree
It seems like everything causes cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There's not much you can do to lower your chances of getting cancer.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
There are so many recommendations about preventing cancer, it's hard to know which ones to follow.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
When I think of cancer, I automatically think of death.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>



Prev Next

**19. In general, would you say your health is...**

- Excellent
- Very good
- Good
- Fair
- Poor

**20. Overall, how confident are you about your ability to take good care of your health?**

- Completely confident
- Very confident
- Somewhat confident
- A little confident
- Not confident at all

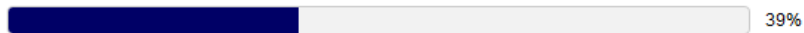
**21. About how tall are you without shoes?**

Feet

Inches

**22. About how much do you weigh, in pounds, without shoes?**

Pounds



[Prev](#) [Next](#)

**23. Have you smoked at least 100 cigarettes in your entire life?**

- Yes
- No --> GO to Q25 below

**24. How often do you now smoke cigarettes?**

- Everyday
- Some days
- Not at all

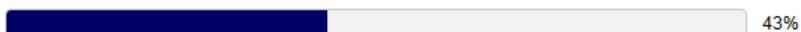
**25. New types of cigarettes are now available called electronic cigarettes (also known as e-cigarettes or personal vaporizers). These products deliver nicotine through a vapor.**

**Compared to smoking cigarettes, would you say that electronic cigarettes are**

- Much less harmful
- Less harmful
- Just as harmful
- More harmful
- Much more harmful, or
- I've never heard of electronic cigarettes

**26. A hookah pipe (or shisha) is a large water pipe. People smoke tobacco using hookah pipes in groups at cafes or bars. Compared to smoking cigarettes, would you say that smoking tobacco using a hookah is...**

- Much less harmful
- Less harmful
- Just as harmful
- More harmful
- Much more harmful, or
- I've never heard of hookah



Prev

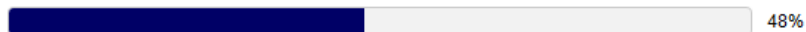
Next

**27. In a typical week, outside of your job or work around the house, how many days do you do leisure-time physical activities specifically designed to strengthen your muscles such as lifting weights or circuit training (do not include cardio exercise such as walking, biking, or swimming)?**

- None
- 1 day per week
- 2 days per week
- 3 days per week
- 4 days per week
- 5 days per week
- 6 days per week
- 7 days per week

**28. Over the past 30 days, in your leisure time, how many hours per day, on average, did you sit and watch TV or movies, surf the web, or play computer games? Do not include “active gaming” such as Wii.**

Hours per day



Prev

Next

29. About how many cups of fruit (including 100% pure fruit juice) do you eat or drink each day?

**1 cup of fruit could be:** 1 small apple, 1 large banana, 1 large orange, 8 large strawberries, 1 medium pear, 2 large plums, 32 seedless grapes, 1 cup (8 oz.) fruit juice, ½ cup dried fruit, 1 inch-thick wedge of watermelon

- None
- ½ cup or less
- ½ cup to 1 cup
- 1 to 2 cups
- 2 to 3 cups
- 3 to 4 cups
- 4 or more cups

30. About how many cups of vegetables (including 100% pure vegetable juice) do you eat or drink each day?

**1 cup of vegetables could be:** 3 broccoli spears, 1 cup cooked leafy greens, 2 cups lettuce or raw greens, 12 baby carrots, 1 medium potato, 1 large sweet potato, 1 large ear of corn, 1 large raw tomato, 2 large celery sticks, 1 cup of cooked beans

- None
- ½ cup or less
- ½ cup to 1 cup
- 1 to 2 cups
- 2 to 3 cups
- 3 to 4 cups
- 4 or more cups



Prev

Next

**31. Are you male or female?**

- Male
- Female

**32. What is your age?**

Years old

**33. What is your current occupational status? [Mark only one]**

- Employed
- Unemployed
- Homemaker
- Student
- Retired
- Disabled
- Other (please specify)

**34. What is your marital status?**

- Married
- Living as married
- Divorced
- Widowed
- Separated
- Single, never been married



Prev

Next



**35. What is the highest grade or level of schooling you completed?**

- Less than 8 years
- 8 through 11 years
- 12 years or completed high school
- Post high school training other than college (vocational or technical)
- Some college
- College graduate
- Postgraduate

**36. Including yourself, how many people live in your household?**

Number of people

**37. How many children under the age of 18 live in your household?**

Number of children under 18

**38. Were you born in the United States?**

- Yes
- No

**39. How well do you speak English?**

- Very well
- Well
- Not Well
- Not at all



**40. Are you of Hispanic, Latino/a, or Spanish origin? One or more categories may be selected. [Mark all that apply]**

- No, not of Hispanic, Latino/a, or Spanish origin
- Yes, Mexican, Mexican American, Chicano/a
- Yes, Puerto Rican
- Yes, Cuban
- Yes, another Hispanic, Latino/a, or Spanish origin

**41. What is your race? One or more categories may be selected. [Mark all that apply]**

- White
- Black or African American
- American Indian or Alaska Native
- Asian Indian
- Chinese
- Filipino
- Japanese
- Korean
- Vietnamese
- Other Asian
- Native Hawaiian
- Guamanian or Chamorro
- Samoan
- Other Pacific Islander



Prev

Next

**42. Thinking about members of your family living in this household, what is your combined annual income, meaning the total pre-tax income from all sources earned in the past year?**

- \$0 to \$9,999
- \$10,000 to \$14,999
- \$15,000 to \$19,999
- \$20,000 to \$34,999
- \$35,000 to \$49,999
- \$50,000 to \$74,999
- \$75,000 to \$99,999
- \$100,000 to \$199,999
- \$200,000 or more

**43. What is your zip code?**

Zip code



Prev

Next

In this next section we want to ask you a little bit about the questions in this survey and how you answered them. All of the feedback you give will help us to understand how well the questions are working. The more you can tell us, the better



Prev

Next

Earlier in the survey, you were asked the following question:

Sometimes people use the Internet to connect with other people online through social networks like Facebook or Twitter. This is often called "social media."

In the last 12 months, have you used the Internet for any of the following reasons?

Shared health information on social networking sites, such as Facebook or Twitter.

Yes

No

**44. What types of websites were you thinking about when you answered this question? Can you give some examples besides Facebook and Twitter?**



Prev

Next

Earlier in the survey, you were asked the following questions:

Please indicate how important each of the following statements is to you.

Doctors and other health care providers should be able to share your medical information with each other electronically.

- Very important
- Somewhat important
- Not at all important

You should be able to get to your own medical information electronically

- Very important
- Somewhat important
- Not at all important

**45. What types of medical information were you thinking about when you answered these questions? Can you give some examples?**



Prev

Next

Earlier in the survey, you were asked the following question:

How likely are you to get cancer in your lifetime?

- Very unlikely
- Unlikely
- Neither unlikely nor likely
- Likely
- Very Likely

**46. You said you were likely to get cancer in your lifetime. Why do you think that?**



Prev

Next

Earlier in the survey, you were asked the following question:

Have you smoked at least 100 cigarettes in your entire life?

- Yes
- No

**47. When you were asked this survey question, how did you mentally calculate the answer?**



Prev

Next

Earlier in the survey, you were asked the following question

Over the past 30 days, in your leisure time, how many hours per day, on average, did you sit and watch TV or movies, surf the web, or play computer games? Do not include "active gaming" such as Wii.

**48. When answering questions like these, some people already know the answer, some people mentally calculate, and some people just guess. How did you arrive at your answer to the question?**



Prev

Next

You have completed the survey. Thank you for your participation.



Prev

Done

## Eiserman, Julie (NIH/OD) [C]

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Monday, March 14, 2016 11:06 AM  
**To:** Eiserman, Julie (NIH/OD) [C]  
**Cc:** Willis, Gordon (NIH/NCI) [E]  
**Subject:** RE: Survey Project

Hi Julie:

I made some minor edits to the description you sent to simplify it since we are only using Mturk and not the other panels. See my edits below.

Also, we would like to request that the title of our submission be adjusted to be: "Formative Research to Investigate a Web Panel and to Determine Feasibility of Web-Based Cognitive Pretesting" to match our (eventual) OMB submission.

Thanks.

-Rick

The purpose of this study is to field questions that were previously used in the ~~NIH~~ NCI Health Information National Trends Survey (HINTS), using an alternative online platforms for survey administration, including Amazon Mechanical Turk (mTurk; www.mturk.com). HINTS collects nationally representative data routinely about the American public's use of cancer-related information and collects data using a probability-based sample.

This project will enable us to compare data collected from a non-probability based samples to HINTS data collected from a nationally representative probability-based sample to assess the quality and comparability of the data. The proposed study will also use cognitive probes to explore how respondents are interpreting/understanding particular questions utilizing a novel form of probing that is self-administered, web-based, and collected among a large sample of respondents.

Primary objectives:

1. To compare estimates collecting data using a non-probability sampling methods to responses using established probability sampling methods
2. To examine whether associations between variables are consistent across the various sampling approaches
3. To conduct cognitive testing of select survey questions using a novel internet-based method to assess feasibility of using this method, and to assess how respondents are interpreting those questions



## **Eiserman, Julie (NIH/OD) [C]**

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Friday, March 11, 2016 2:33 PM  
**To:** Eiserman, Julie (NIH/OD) [C]  
**Subject:** RE: Survey Project  
**Attachments:** MTurk Schematic.doc

Hi Julie:

Here are my answers to your questions:

- 1) Westat will not be involved in any parts of this updated study. They can be removed from the request.
- 2) We will not be involving any vendors/panels for this study.
- 3) MTurk participants are a group of people who have agreed to complete tasks. The NCI will create a task and publish it through the Mturk website. Those who are interested will accept the task and will given a link to the survey. Once they complete the task, the NCI will verify and then send them their incentive, which in this case will be \$1.50. I've attached a graphic that helps explain the process if that's helpful.
- 4) We do not have control over who accepts and completes the task, though you have to be 18 or older to accept tasks. We have included some demographic variables in our survey (e.g., gender) so we do have information about them, but we are not collecting PII.

I hope this answers your questions. I'm in my office now if you would like to talk: 240-276-6915.

-Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Friday, March 11, 2016 12:15 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Survey Project

I left you a vm. If you want to call or respond to my questions there via email....

I am here until 2:45 p.m. today.

Thank you.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Friday, March 11, 2016 11:35 AM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Cc:** Sharon Zack <[SharonZack@westat.com](mailto:SharonZack@westat.com)>; Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>; Wolff, Dana (NIH/NCI) [F] <[dana.wolff@nih.gov](mailto:dana.wolff@nih.gov)>  
**Subject:** RE: Survey Project

Dear Julie:

To answer your questions:

- 1) The NCI will set up the task on the mTurk platform and those who want to participate will be sent a link to the survey. Westat will not be involved in any aspects of this process for contacting respondents.
- 2) The NCI will collect information about the respondents but it does not include PII
- 3) The data will be returned directly to the NCI. Westat will not receive any data.

Hope that answers your questions. I can talk by phone as needed.

Regards,  
Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Thursday, March 10, 2016 4:36 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Cc:** Sharon Zack; Willis, Gordon (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Subject:** RE: Survey Project

Okay. Could you please clarify a few things so that I can amend the form prior to providing a determination?

Can you clarify how you will recruit and connect participants with the link for the survey and whether NIH or Westat will be doing it? I'm assuming the plan would be to email the link to people and then not collect any identifiers as a part of the actual survey itself? What will Westat's role be in this new design? For example, will Westat obtain the data and provide it to you or will NIH download the data directly from the website?

Thank you.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)  
Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)  
Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Thursday, March 10, 2016 3:33 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Cc:** Sharon Zack <[SharonZack@westat.com](mailto:SharonZack@westat.com)>; Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>; Wolff, Dana (NIH/NCI) [F] <[dana.wolff@nih.gov](mailto:dana.wolff@nih.gov)>  
**Subject:** RE: Survey Project

Dear Julie:

Thanks very much for all your time and attention to this matter. This is a new paradigm for us and appreciate you helping us think through the unique issues here.

It may work well to do as you say and consider re-evaluating the nature of the project. However, we certainly understand and respect your concerns about including the survey vendors in the project without further information from them. So, in the interest of time and hopefully getting something in the field soon (that is, after OMB review), for our first demonstration project we are going to remove the survey vendors from the design. That is, there will be no outside entities collecting data, and we will simply go with the Amazon.com Mechanical Turk (mTurk) platform for data collection. Note that use of mTurk does not involve any external survey vendor, and please recall for our initial project using the MTurk platform (with Stephanie Fowler as the PI), OHSRP had provided an approval in the form of a determination that the project did not constitute Human Subjects Research (HSR). That said, a determination of Exemption would also allow us to move ahead to the OMB step.

If this is acceptable to you, we will revise our plan for now, in the hope of receiving an Exemption (or possibly a determination of no HSR?) for the revised project that eliminates the vendors. Then, for our next project, we can attempt to work through how to include those vendors in a way that is either considered not HSR, or Exempt research.

Please let me know how to best proceed here. Thanks.

Regards,  
Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Thursday, March 10, 2016 1:49 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Cc:** Sharon Zack; Willis, Gordon (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Subject:** RE: Survey Project

Dear Dr. Moser,

If you would like to us to consider your project as non-research, you could re-submit the request for determination explaining that you consider this project to be something other than research and the rationale for this in **the project description section**. I could review the application with my supervisor to see if we believe the new project description falls outside of the definition of research. Accordingly, we might ask you to do a consult with us to discuss the project. In addition, if the Westat IRB agrees with Dr. Willis, that your project does not meet the definition of research OR views the vendors as being involved in only “exempt human subjects research”, I am open to hearing their perspective.

If you don't believe that you are conducting research, I am not clear if you view this project as meeting the definition of quality assessment as described on the request form. Accordingly, in preparing your request, you may want to review the following FAQs on the OHRP website which addresses when quality improvement (assessment) activities meet (or don't meet) the definition of research under the human subjects regulations:

<http://www.hhs.gov/ohrp/policy/faq/quality-improvement-activities/index.html>

Thank you.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst

Office of Human Subjects Research Protections

Office of Intramural Research, Office of the Director

National Institutes of Health

10 Center Drive, Bldg. 10, Suite 2C146

Bethesda, MD 20892-1154

Direct Phone: 301-402-8665

Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Eiserman, Julie (NIH/OD) [C]

**Sent:** Wednesday, March 09, 2016 5:29 PM

**To:** Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>

**Cc:** Moser, Richard (NIH/NCI) [E] <[moserr@mail.nih.gov](mailto:moserr@mail.nih.gov)>; 'Sharon Zack' <[SharonZack@westat.com](mailto:SharonZack@westat.com)>

**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hello Dr. Willis,

We have been having on-going communications about this project for almost 3.5 months now and this is the first I have heard that the project isn't research. At the beginning of December, I believe I had a call with you and Dr. Moser and discussed the need for reliance agreements with the vendors to address their engagement in human subjects research for this project. If the research part was in question, I would have expected this topic to be discussed at this time when I raised this point. In addition, Westat's IRB also interpreted this project as research and human subjects research and initially provided expedited review (not exempt or not human subjects research).

So the questions to be asked are the following and we ask them in relationship to all parties, so in this case, NIH, Westat, and the three vendors.

- 1) Is this research?; 2) Is this human subjects research? and 3) Is this exempt human subjects research?

As you know the definition of research is: (d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

I was not aware that whether your project constituted research or not was ever in question. In fact, there are boxes on the form that one could check to address this issue and they were not checked. See attached and below:

5d. Quality Assurance/Quality Improvement activity with a non-clinical practice focus, e.g. usability testing or evaluation of websites, workshops, conferences, tools, policies, etc., in which the sole purpose is to improve a

product or service and not to also conduct research to develop or contribute to generalizable knowledge

and

16f. QA/QI (not meeting the definition in the Instructions Part II, Q. 5c. or 5d.)

I hope you understand my wariness at now being told that I should review the project as 'not research' at this point. I'm concerned that there are many different conversations going on independently about this project and that we are not all on the same page. Let's set up a call with Sharon and Dr. Moser and the PI at Westat to attempt to resolve this issue.

Thank you.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst

Office of Human Subjects Research Protections

Office of Intramural Research, Office of the Director

National Institutes of Health

10 Center Drive, Bldg. 10, Suite 2C146

Bethesda, MD 20892-1154

Direct Phone: 301-402-8665

Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Willis, Gordon (NIH/NCI) [E]

**Sent:** Wednesday, March 09, 2016 4:12 PM

**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>

**Subject:** FW: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

I'm one of the NCI co-Investigators on the project you've been discussing with Westat.

My take on this is that, based on the nature of the work we are doing, it isn't human subjects research to begin with – so the issues with FWA, etc. are not relevant. By definition, we are not seeking generalizable knowledge – as our objective is to assess data quality from one or more vendors. There's no intention to generalize the results to any other vendors, or to a wider universe, because that would go well beyond the data we are obtaining. So we are investigating a mechanism for data collection – as opposed to collecting survey data that are intended to inform cancer research, public health, etc.

From that point of view, would it even be necessary to submit to OHSRP? Or, based on following the Determination form, can we proceed directly to OMB?

Or, if the Westat IRB determines this not to be human subjects research, on this argument, would that suffice?

Thanks for your advice –

Gordon

Gordon Willis, PhD  
NCI

---

**From:** Eiserman, Julie (NIH/OD) [C] [<mailto:julie.eiserman@nih.gov>]  
**Sent:** Wednesday, March 09, 2016 3:10 PM  
**To:** Sharon Zack  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Perhaps I could correspond directly with the PI.

I understand that Westat isn't engaged.

I really want to understand more about the data collection process at the vendor end. I have worked on projects that use these types of panels from these firms before and in the previous cases, the vendors were conducting hsr but it was considered exempt. We learned that the sites have identifiers for all of the participants on their panels and the participants are typically contacted by email. The data in their system at times may be linked to identifiers (minimally an email address) at their site (albeit through various firewalls). I would feel better if I got saw something in writing (an email would suffice) from each vendor explaining how data is collected and that no identifiers are ever linked to the data even in their computer systems. Perhaps the PI or whomever is corresponding with the vendors could obtain that.

I apologize if I sound overly picky but this is an NIH research project and in this case we would typically require the other site have an FWA and require that there be a formal exemption at the other site when there isn't IRB review.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Sharon Zack [<mailto:SharonZack@westat.com>]  
**Sent:** Wednesday, March 09, 2016 2:59 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie, my PI resubmitted her application> in so doing, explained that the vendors will not maintain any identifiers. Once a de-identified data set is transferred to Westat, vendors will destroy all survey data. Therefore, Westat and its vendors may not be considered "engaged" in HSR. I wanted to run that by your office before moving forward. Thanks for your patience as we get through this.

Best,  
Sharon

Sharon Zack, MS  
IRB Administrator, Westat  
1600 Research Blvd.

Rockville, MD. 20852  
[www.Westat.com](http://www.Westat.com)  
301-610-8828 (Work)  
301-294-3928 (Fax)  
[sharonzack@westat.com](mailto:sharonzack@westat.com)

Sharon Zack, M.S.  
IRB Administrator  
1600 Research Blvd. RB 4157  
Rockville, MD. 20850  
(W) 301-610-8828  
(F) 301-294-3928  
[www.westat.com](http://www.westat.com)

---

**From:** Eiserman, Julie (NIH/OD) [C] [<mailto:julie.eiserman@nih.gov>]  
**Sent:** Friday, March 04, 2016 11:31 AM  
**To:** Sharon Zack  
**Subject:** FW: Response Requested: Request for Determination for OHSRP #13082

*Julie M. Eiserman, MA, CCRP* [C]  
Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)  
Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)  
Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Friday, March 04, 2016 11:07 AM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Cc:** Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

I have some updated information for you regarding our study. I've attached an updated disposition from the Westat IRB finding the study exempt from IRB review.

I also have contact information for the Westat IRB representative if that would be helpful:

Sharon Zack

301-610-8828

[SharonZack@westat.com](mailto:SharonZack@westat.com)

Thanks.

-Rick



## **Eiserman, Julie (NIH/OD) [C]**

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Friday, March 04, 2016 2:50 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

No. But I would want to see a formal memo or letter that says that the Westat IRB has made a formal determination that \_\_\_\_, \_\_\_\_, \_\_\_\_ are engaged in exempt research under the regulations.....

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Friday, March 04, 2016 2:18 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

I appreciate you explaining all the different scenarios here. I wanted to clarify something: If Westat works with the vendors and determines that the vendors are Exempt, does Westat still need reliance agreements with them?

Thanks.

-Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Thursday, March 03, 2016 4:02 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

They get to review the study and make a determination as to what type of research they think it is. Typically they would just review their own role in the project unless a reliance agreement is in place. Then they would also review the other sites' roles.

The choices are:

## **Eiserman, Julie (NIH/OD) [C]**

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Thursday, March 03, 2016 4:02 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

They get to review the study and make a determination as to what type of research they think it is. Typically they would just review their own role in the project unless a reliance agreement is in place. Then they would also review the other sites' roles.

The choices are:

- #1: not human subjects research because there is no interaction with human subjects or use of identified data
- #2: human subjects research (interaction with human subjects or use of identified data) that is **exempt from IRB review** and approval (meets certain criteria)
- #3: human subjects research that can have expedited IRB review and approval
- #4: human subjects research that must have full IRB review and approval

Westat determined that this is #3 above which means they believe that they (or the other sites) need IRB review. That means that those other sites need local IRB review or a reliance agreement with Westat.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)  
Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)  
Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Thursday, March 03, 2016 3:42 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

I'll get back to you regarding funding.

I can check with Westat regarding the agreements they have in place. Just to clarify, is there an issue with the Westat memo mentioning 'expedited authority' as opposed to being exempt?

-Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Thursday, March 03, 2016 3:15 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Dr. Moser,

I still have some unanswered questions. Is DHHS funding be used to fund the research being done with these companies? If so, they must have an FWA.

My original guidance I believe is that there needed to be either IRB approval at each of the sites below OR Westat would need to do authorization agreements with these institutions to rely on Westat's IRB. Can you send me an email from Westat clarifying that these agreements are in place? Was this topic ever discussed with them? The situation isn't clear in the letter.

Sometimes survey research is exempt from IRB review but the letter suggests that Westat's IRB didn't think it was exempt and instead provided expedited review of the project.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)  
Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)  
Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Thursday, March 03, 2016 3:02 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

See below.

-Rick

b. Collaborator Name: Precision Sampling, LLC

Institution/IC Name: private sector FWA #: none

City/State/Country: Denver, Colorado, USA

Email Address: [yan@precisionsample.com](mailto:yan@precisionsample.com)

Sending specimens/data: \_\_\_ Receiving specimens/data: \_\_ Both: \_XX\_

Describe what will be sent/received or role:

Precision Sampling will send Westat a de-identified dataset of survey responses from 500 members of their panel.

b. Collaborator Name: Survey Sampling International (SSI)

Institution/IC Name: private sector FWA #: none  
City/State/Country: Shelton, Connecticut, USA  
Email Address: [Scott.Nixon@SurveySampling.com](mailto:Scott.Nixon@SurveySampling.com)  
Sending specimens/data: \_\_\_ Receiving specimens/data: \_\_\_ Both: XX\_\_\_  
Describe what will be sent/received or role:  
SSI will send Westat a de-identified dataset of survey responses from 500 members of their panel.

b. Collaborator Name: Nielsen Opinion Quest

Institution/IC Name: private sector FWA #: none  
City/State/Country: New York, New York, USA  
Email Address: [Dana.DiGregorio@nielsen.com](mailto:Dana.DiGregorio@nielsen.com)  
Sending specimens/data: \_\_\_ Receiving specimens/data: \_\_\_ Both: \_XX\_  
Describe what will be sent/received or role:  
Nielsen will send Westat 2 de-identified datasets of survey responses: one with 500 responses from members of their panel and one with 500 responses from a probability sample of general population respondents.

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Thursday, March 03, 2016 12:36 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Yes. Thank you. The other thing we talked about is if the data collection was being conducting by any institutions other than Westat, they should be added to the form as collaborators as well. Can you send me the following information about these companies?

b. Collaborator Name

Institution/IC Name: FWA #:  
City/State/Country:  
Email Address:  
Sending specimens/data: \_\_\_ Receiving specimens/data: \_\_\_ Both: \_\_\_  
Describe what will be sent/received or role:

*Julie M. Eiserman, MA, CCRP* [C]  
Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)  
Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)  
Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Wednesday, March 02, 2016 4:43 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>  
**Cc:** Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

As you recall, we had a good conversation a couple of weeks back in regards to my OHSRP submission to use non-probability samples to compare results with an NCI-administered survey (see attached proposal). Per our discussion, our main contractor (Westat) was seeking approval from their IRB to administer the panels and you said to let you know when this happened so you could give a final determination. Westat has now received approval to work with the panels and I've attached the approval letter here. When we spoke, you mentioned that my study would be approved (considered Exempt?) if you received this information and I'm hoping that is still the case, but please let me know. Thanks.

Regards,  
Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Monday, December 14, 2015 1:53 PM  
**To:** Moser, Richard (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082  
**Importance:** High

Hello,

I don't believe I have heard back from you yet about your request for review. I just wanted to let you know that I will be out on vacation from Dec. 22 – Jan. 4 with no one to cover this work while I am out. If you are not able to schedule a call with me by Thursday, I will not be able to work on your request until after I am back from vacation.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Wednesday, December 02, 2015 12:43 PM  
**To:** Moser, Richard (NIH/NCI) [E] <[moserr@mail.nih.gov](mailto:moserr@mail.nih.gov)>; Wolff, Dana (NIH/NCI) [F] <[dana.wolff@nih.gov](mailto:dana.wolff@nih.gov)>  
**Cc:** OHSR (NIH/DDIR) <[ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov)>  
**Subject:** Response Requested: Request for Determination for OHSRP #13082

## Eiserman, Julie (NIH/OD) [C]

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Wednesday, January 06, 2016 4:33 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Feel free to propose a time.

Thank you.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443  
Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)  
Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>  
OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)  
Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Wednesday, January 06, 2016 4:33 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>; Wolff, Dana (NIH/NCI) [F] <[dana.wolff@nih.gov](mailto:dana.wolff@nih.gov)>  
**Cc:** Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

Happy New Year.

I'd like to set up a time to talk about our proposal. Let me know the best way to proceed. Should I propose a time through Outlook (I can see your availability) or would you rather send me some potential dates/times?

Thanks.

-Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Monday, December 14, 2015 1:53 PM  
**To:** Moser, Richard (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082  
**Importance:** High

Hello,

## **Eiserman, Julie (NIH/OD) [C]**

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Tuesday, December 15, 2015 3:34 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Sounds great. Thanks for letting me know.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Tuesday, December 15, 2015 2:20 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <[julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)>; Wolff, Dana (NIH/NCI) [F] <[dana.wolff@nih.gov](mailto:dana.wolff@nih.gov)>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Hi Julie:

As a follow-up, we will be working with our main contractor to work with their IRB to figure out a plan that will hopefully address any issues that you mentioned from working with the other vendors. I'll be back in touch after the holidays.

-Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Monday, December 14, 2015 1:53 PM  
**To:** Moser, Richard (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082  
**Importance:** High

Hello,

I don't believe I have heard back from you yet about your request for review. I just wanted to let you know that I will be out on vacation from Dec. 22 – Jan. 4 with no one to cover this work while I am out. If you are not able to schedule a call with me by Thursday, I will not be able to work on your request until after I am back from vacation.

## **Eiserman, Julie (NIH/OD) [C]**

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Monday, December 14, 2015 4:14 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Sounds good.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections  
Office of Intramural Research, Office of the Director  
National Institutes of Health  
10 Center Drive, Bldg. 10, Suite 2C146  
Bethesda, MD 20892-1154  
Direct Phone: 301-402-8665  
Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Monday, December 14, 2015 1:55 PM  
**To:** Eiserman, Julie (NIH/OD) [C] <julie.eiserman@nih.gov>; Wolff, Dana (NIH/NCI) [F] <dana.wolff@nih.gov>  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082

Ok, thanks, Julie. We're looking into some things on our end before talking to you. I hope to schedule something before you take off.

-Rick

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Monday, December 14, 2015 1:53 PM  
**To:** Moser, Richard (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Subject:** RE: Response Requested: Request for Determination for OHSRP #13082  
**Importance:** High

Hello,

I don't believe I have heard back from you yet about your request for review. I just wanted to let you know that I will be out on vacation from Dec. 22 – Jan. 4 with no one to cover this work while I am out. If you are not able to schedule a call with me by Thursday, I will not be able to work on your request until after I am back from vacation.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst  
Office of Human Subjects Research Protections



## **Eiserman, Julie (NIH/OD) [C]**

---

**From:** Eiserman, Julie (NIH/OD) [C]  
**Sent:** Wednesday, December 02, 2015 12:43 PM  
**To:** Moser, Richard (NIH/NCI) [E]; Wolff, Dana (NIH/NCI) [F]  
**Cc:** OHSR (NIH/DDIR)  
**Subject:** Response Requested: Request for Determination for OHSRP #13082  
**Attachments:** MoserR\_NCI\_13082\_CY2015.pdf

Hello Dr. Moser,

It sounds like you may be contracting with different companies in order to conduct your research. As part of your proposed project, we need to understand all the different entities that will be involved in the project (included if they are being subcontracted), e.g. who will be conducting recruitment, managing the data collection, maintaining identifiers, de-identifying data, etc. and have evidence of IRB review at these various sites. Private market research companies don't always have experience with obtaining IRB review so this can be complicated. The various entities would be added as collaborators in the collaborator section of the form. Then all of the questions about the sender, would then need to be answered with regard to each entity.

Given the complexity of the project, I think it's best if we set up a phone call to discuss the project and the form so I can determine what additional information is needed. Please let me know your availability to do this.

*Julie M. Eiserman, MA, CCRP* [C]

Health Science Policy Analyst

Office of Human Subjects Research Protections

Office of Intramural Research, Office of the Director

National Institutes of Health

10 Center Drive, Bldg. 10, Suite 2C146

Bethesda, MD 20892-1154

Direct Phone: 301-402-8665

Fax: 301-402-3443

Email: [julie.eiserman@nih.gov](mailto:julie.eiserman@nih.gov)

Site for the request for determination form: <https://federation.nih.gov/ohsr/nih/formtmp.php>

OHSRP website: <https://federation.nih.gov/ohsr/nih/index.php> (NIH login required)

Public site: <http://ohsr.od.nih.gov/>

**From:** [Moser, Richard \(NIH/NCI\) \[E\]](#)  
**To:** [OHSR \(NIH/DDIR\)](#)  
**Subject:** RE: Request for Review  
**Date:** Thursday, November 19, 2015 2:31:31 PM  
**Attachments:** [Survey Screen Shots.doc](#)

---

Hi Chris:

We are taking items from an existing probability-based survey, HINTS, and administering the items to several groups (using different vendors) that utilize non-probability based samples and want to compare the results. These will be done using on-line panels. I've attached screen shots of the on-line survey. Note: the OMB text on the first page is simply for demonstration purposes.

-Rick

---

**From:** OHSR (NIH/DDIR)  
**Sent:** Thursday, November 19, 2015 2:27 PM  
**To:** Moser, Richard (NIH/NCI) [E]  
**Subject:** RE: Request for Review

Hi Rick,

For this project, I'm unclear if you are collecting responses from past surveys, or if you are administering a new group of survey questions to participants. Please clarify.

If you are administering a survey to groups, please submit the survey you will use.

Thank you,

Chris Brentin

OHSRP

---

**From:** Moser, Richard (NIH/NCI) [E]  
**Sent:** Wednesday, November 18, 2015 3:08 PM  
**To:** OHSR (NIH/DDIR) <[ohsr\\_nih\\_ddir@od.nih.gov](mailto:ohsr_nih_ddir@od.nih.gov)>  
**Cc:** Willis, Gordon (NIH/NCI) [E] <[willisg@mail.nih.gov](mailto:willisg@mail.nih.gov)>; Wolff, Dana (NIH/NCI) [F] <[dana.wolff@nih.gov](mailto:dana.wolff@nih.gov)>  
**Subject:** Request for Review

Dear OHSR:

I've attached a Request for Determination for your review.

Thanks.

Sincerely,

Rick

Richard P. Moser, Ph.D.

Acting Chief, Science of Research and Technology Branch (SRTB)

Behavioral Research Program

Division of Cancer Control and Population Sciences  
National Cancer Institute

9609 Medical Center Dr., MSC 9761  
Room 3E604  
Bethesda, MD 20892

For Business Reply Mail, use: Bethesda, MD 20814-9692

(w): 240-276-6915  
(fax): 240-276-7907  
[moserr@mail.nih.gov](mailto:moserr@mail.nih.gov)

**From:** [OHSR \(NIH/DDIR\)](#)  
**To:** [Moser, Richard \(NIH/NCI\) \[E\]](#)  
**Subject:** Req for Determination Rec"d\_OHSRP #13082  
**Date:** Thursday, November 19, 2015 3:54:34 PM

---

Good afternoon Dr. Moser,

This email is to verify that OHSRP has received your Request for Determination and it is currently being processed as **OHSRP #13082**. Please use this number in any future correspondence regarding this study.

**Protocol Title:** Comparison of Survey Results and Feasibility of Cognitive Pre-Testing Using Probability and Non-Probability Samples

Thank you.

Sincerely,  
Chris Brentin  
Program Specialist  
Office of Human Subjects Research Protections (OHSRP)  
National Institutes of Health  
301-402-3444-Office  
301-402-8631-Direct  
301-402-3443-Fax



Please consider the environment before printing this e-mail