Westat | An Employee-Owned Research Corporation

# Memo

**Date:** July 31st, 2014

**To:** Terisa Davis, Project Director

**From:** Kerry Levin, Chair Westat IRB Kerry Levin

**Subject:** **Expedited Approval of FDA-NCI Health Communications Survey as part of the Health Information National Trend Survey (HINTS) 4, Project Number 8861**
**FWA 00005551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **FDA-NCI Health Communications Survey as part of HINTS 4, Project Number 8861.** The Westat IRB reviews all studies involving research on human subjects. This study is funded by National Cancer Institute and Food and Drug Administration.

This review included a request to approve a specific cycle of the survey focused on FDA issues, such as tobacco product use and beliefs, medication use, and food safety.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110]. This study can be considered minimal risk and is approved under expedited authority. Per [45 CFR 46.116(d)], a waiver of informed consent is approved as the research involves no more than minimal risk to the subjects; the waiver or alteration will not adversely affect the rights and welfare of the subjects; the research could not practicably be carried out without the waiver or alteration; and whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Per [45 CFR 46.117(c)], a waiver of documentation of informed consent is also approved as the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally conducted outside of the research context.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review before November 11, 2014.
- In the interim, notify the IRB Office as soon as possible if there are any injuries to subjects as well as problems or changes with the study that relate to human subjects.

cc: Institutional Review Board
Nancy Weinfield

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

FAX: 301-480-2198 **Exempt: #:** 5810

To: Hesse, Bradford
NCI
EPN 4068

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The Division of Cancer Control and Population Sciences, Behavior Research Program of the National Cancer Institute (NCI) is planning to conduct data collection for the Health Information National Trends Survey 4 (HINTS 4) over the course of three years starting in 2011. The purpose of HINTS is to assess the ways in which the general population uses communication channels to obtain information about health and cancer. The survey monitors the use of information resources while collecting information about respondents'

Original Request Received in OHSR on: 6/9/2011

Responsible NIH Research Investigator(s): Bradford Hesse, PhD NCI

OHSR review of your request dated Wed, Jun 1, 2011 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 TM 6/4/2014

☐ Other

Office Person SPC Admin Assist. CB

Note:
6/4/2014: David Cantor, Terisa Davis, Westat and adding more data

Charlotte Holden, JD — Signature
Acting Director, OHSR — Title
6/21/2011 — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

## Matose, Takunda (NIH/OD) [C]

| | |
|---|---|
| **From:** | OHSR (NIH/DDIR) |
| **To:** | Hesse, Bradford (NIH/NCI) [E] |
| **Cc:** | Blake, Kelly (NIH/NCI) [E]; Terisa Davis; Moser, Richard (NIH/NCI) [E]; Grant, Nicole (NIH/NCI) [E] |
| **Subject:** | Amendment Determination for OHSRP #5810 |
| **Attachments:** | Request for Amendment OHSRP #___ |

Dear Dr. Hesse,

Attached is the OHSRP determination of **Excluded from IRB Review** per 45 CFR 46 and NIH policy for the reception of additional data with your collaborators David Cantor, Terisa Davis, Westat, for your project *Health Information National Trends Survey 4 (HINTS 4).* **You may proceed with the project**.

Please retain this documentation as you would other research records. Amendments and or changes to the research must be submitted to OHSRP for review as changes may affect the determination. Please refer to **OHSRP #5810** for future amendments to this activity. To request future amendments, please use the attached email template modified to meet the specific changes needed for your project. If you have any questions or need further assistance, please feel free to contact us.

Best,

Takunda Matose
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

---

**From:** Hesse, Bradford (NIH/NCI) [E]
**Sent:** Wednesday, May 28, 2014 10:15 AM
**To:** OHSR (NIH/DDIR)
**Cc:** Blake, Kelly (NIH/NCI) [E]; Terisa Davis; Brentin, Christine (NIH/OD) [E]; Moser, Richard (NIH/NCI) [E]
**Subject:** Amendment Request for OHSR #5810

Dear OHSRP and Chris,

Thank you for providing us with the email template to request an amendment to our exempt submission.

Please amend OHSR #5810, Health Information National Trends Survey 4 (HINTS 4), OHSRP determination of exempt, to allow an additional data collection cycle as follows: To include a fifth survey cycle (FDA-NCI Health Communication Survey) to field in November-December 2014.

**NIH Senior Investigator:** Bradford W. Hesse, Ph.D.

**Additional Recipients of Amendment determination:** Kelly D. Blake, Richard Moser

**Collaborator:**
David Cantor, Westat, email: cantord1@westat.com
Terisa Davis, Westat, email: terisadavis@westat.com

**Collaborator's FWA#:** 5551

**IRB/EC Approval:** Granted June 9, 2011. Documentation attached.

**Original Protocol Title and ID# that Specimens are sourced from:** Health Information National Trends Survey 4 (HINTS 4), exemption #5810. Active protocol.

**Repository:** N/A

**Identifiability of Specimens/data:** De-identified

**De-identification agreement:** N/A (*use only if receiving coded specimens see Specimen/Data request form item #10 for sample language*)

**Conflicts of Interest by NIH employees:** No conflicts of interest.

**Special Instructions or questions:** As is outlined in our original, approved request for review (attached), HINTS 4 is a nationally-representative mail survey sampled using addresses selected from a file of residential addresses based on the US Postal Service Computerized Delivery Sequence File. The purpose of HINTS 4 is to assess the ways in which the general population uses communication channels to obtain information about health and cancer. The survey monitors the use of information resources while collecting information about respondents' knowledge, attitudes and behaviors related to health and cancer. HINTS 4 was to contain four data collection cycles to be fielded over three years. We've recently been given the opportunity to add a fifth data collection cycle of HINTS to be funded by the FDA. In preparing for the fielding of the FDA-funded instrument, we would like to secure documentation from OHSRP that this fifth HINTS cycle (referred to as the FDA-NCI Health Communication Survey) is exempt following the spirit of the original HINTS 4 IRB approval. Please note that all data collection procedures and considerations for the protection of human subjects are exactly the same for all cycles of HINTS 4, including this forthcoming FDA-funded cycle. The FDA-NCI module is an extension of the previously approved research.

Please let us know if we can provide you with further information or documentation to expedite the approval of this amendment.
Thank you,
Brad

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

FAX: 301-480-2198 **Exempt: #:** 5810

To: Hesse, Bradford
NCI
EPN 4068

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The Division of Cancer Control and Population Sciences, Behavior Research Program of the National Cancer Institute (NCI) is planning to conduct data collection for the Health Information National Trends Survey 4 (HINTS 4) over the course of three years starting in 2011. The purpose of HINTS is to assess the ways in which the general population uses communication channels to obtain information about health and cancer. The survey monitors the use of information resources while collecting information about respondents'

Original Request Received in OHSR on: 6/9/2011

Responsible NIH Research Investigator(s): Bradford Hesse, PhD NCI

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☒ 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.

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☐ Reliance

☐ Amendment

☐ Other

Note: Office Person SPC Admin Assist. CB

Charlotte Holden, JD — Signature
Acting Director, OHSR — Title
6/21/2011 — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#5810

**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), email to ohsr_nih_ddir@od.nih.gov, or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

**Date**: June 1, 2011

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

**From:** _____ Bradford Hesse
(Signature)

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

**Protocol Title:** *"Health Information National Trends Survey 4 (HINTS 4)*

**Name of NIH Principal Investigator(s):** _Bradford Hesse_____

IC NCI _Laboratory/Branch Health Communication & Informatics Research Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences
Building & Room No. _EPN 4068__ Tel. No. 301-594-9904 FAX No. _301-480-2198__

**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):** The Division of Cancer Control and Population Sciences, Behavior Research Program of the National Cancer Institute (NCI) is planning to conduct data collection for the Health Information National Trends Survey 4 (HINTS 4) over the course of three years starting in 2011. The purpose of HINTS is to assess the ways in which the general population uses communication channels to obtain information about health and cancer. The survey monitors the use of information resources while collecting information *about* respondents' knowledge, attitudes and behaviors related to health and cancer. There have been three previous rounds of HINTS data collection (2003, 2005 and 2007). HINTS 4

draws upon the lessons learned from prior iterations of HINTS and continues the work of the previous rounds of HINTS, while employing some new strategies. Based on the higher response rates for the mail survey (over the RDD survey) in HINTS 3, a single-mode mail survey will be implemented with the inclusion of the $2 incentive. The use of express mail, which was shown to be effective in HINTS 3 follow-up mailings, will also be employed. To try to increase participation by Hispanic respondents, all materials will be translated and respondents will have the option of completing the mail questionnaire in Spanish. To more quickly address emerging issues in the field of health communication while still maintaining the ongoing measurement of trends, HINTS 4 will include four data collection cycles over the course of 3 years. The instrument for each data collection cycle will include a core module of trended items in addition to special topic modules to be implemented in only some of the cycles, increasing capacity of the HINTS instruments to include additional topics and measures. The overall sample size for all four cycles of HINTS 4 combined will be approximately 14,000 respondents which is about twice the size of previous rounds of HINTS data collections.

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

| **Name** | **Institution** | **Address Tel. # FAX #** |
|---|---|---|
| David Cantor | Westat | 1650 Research Boulevard<br>Rockville, MD 20850<br>tel: 301-294-2080 fax:301-610-4886 |
| Terisa Davis | Westat | 1650 Research Boulevard<br>Rockville, MD 20850<br>tel: 301-294-2864 fax: 240-314-2344 |
| Wendy Hicks | Westat | 1650 Research Boulevard<br>Rockville, MD 20850<br>tel: 301-251-2299 fax: 301-294-2034 |

**3. Proposed start date of your research** October 1, 2011
**Proposed completion date** May 1, 2014

**4. Will you be _____ these samples or data?**

| | |
|---|---|
| Collecting | No |
| Receiving | Yes |
| Sending | No |

**5. Do the samples or data:**
(a) Already exist? No

(b) Or are they being collected for the express purpose of this study? Yes
If "yes," please describe: The goal of this research is to comprehensively assess the American public's current access to, and use of, information about cancer, that will include cancer prevention, early detection, diagnosis, treatment, and prognosis. The content of the survey will focus on understanding the degree to which members of the general population understand vital cancer prevention messages. More importantly, this NCI survey will couple knowledge-related questions with inquiries into the communication channels through which understanding is being obtained, and assessment of cancer-related behavior. HINTS 4 is intended to be the foundation of NCI's effort to build on the opportunities presented by a national shift in communication context, and by so doing, improve the Nation's ability to reduce the national cancer burden.

(c) Or a combination of (a) and (b)? 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.

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

___ 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. Dr. Hesse was hired by NCI to supervise administration of the Health Information Trends Survey. Consequently, he has direct program responsibility over all major facets of the survey.

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

_____

_____

**7. Where are the subjects of this research activity located?** The HINTS target population is all adults aged 18 or older in the civilian non-institutionalized population of the United States. The sample design for HINTS 4 will consist of a series of four single stage stratified samples of addresses selected from a file of residential addresses based on the United States Postal Service (USPS) Computerized Delivery Sequence File (CDSF). Each sample will be selected just prior to the data collection cycle in which it is to be used. The frame will cover addresses from all zip codes in the 50 states and the *District of* Columbia. Addresses in the frame will be grouped into two strata: one containing a high

concentration of minority adults and the other containing a low concentration. The number of addresses to be sampled at each cycle is 6,150 for the first two cycles and 6,121 for the last two cycles. The total number of addresses sampled over all four cycles is 24,602. The samples from each stratum will be selected independently and addresses within each stratum will be selected with equal probability. The expected number of completed questionnaires for each cycle is 3,533 for the first two cycles and 3,500 for the last two cycles. The number of completed questionnaires expected over the four cycles is 14,066. The difference in the sample sizes among the cycles is due to a modest oversample planned for Central Appalachia in cycles 1 and 2 described in the next section. The expected overall response rate for the HINTS 4 sample is 40 percent.

**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?) 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?**
CONFIDENTIALITY

No names will be used in the main data collection. At the close of each field period, address information will be destroyed.

DATA OWNERSHIP
The data will be owned by NCI but NCI will not receive the data until it has been de-identified.

DATA SECURITY
Paper forms will be processed in a locked field room and stored in a locked file cabinet.

DATA DESTRUCTION
All address information will be destroyed at the end of each field period.

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

(a) Repository No

(b) Pathological waste No

(c) Autopsy material No

(d) Publicly available source No

(e) Other_ Samples will be drawn from addresses selected from a file of residential addresses based on the United States Postal Service (USPS) Computerized Delivery Sequence File (CDSF).

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

(a) ____ 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) **X** 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):

__Westat_____ Name of institution that provided the review

1650 Research Boulevard
Rockville, MD 20850_____ Address of reviewing institution

David Cantor_____ Name of PI for the IRB approved protocol

*"Health Information National Trends Survey 4 (HINTS 4)*
( Project # 8861.01.04) Title of IRB approved protocol and protocol #

_____5551_____ 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

## OHSR (NIH/DDIR)

**From:** Finney Rutten, Lila (NIH/NCI) [C]
**Sent:** Thursday, June 09, 2011 8:53 AM
**To:** OHSR (NIH/DDIR)
**Cc:** Hesse, Bradford (NIH/NCI) [E]; Blake, Kelly (NIH/NCI) [E]
**Subject:** requestforReview HINTS4_Main Study_6_1_11.doc
**Attachments:** requestforReview HINTS4_Main Study_6_1_11.doc

**Follow Up Flag:** Follow up
**Flag Status:** Flagged

Please find the attached request for review for the HINTS 4 data collection. Please let us know if you require additional documentation for this request.

Lila Rutten on behalf of
Bradford Hesse, PhD, Chief, Health Informatics Research Branch

**Lila J. Rutten, PhD, MPH [Contractor]**
Behavioral Scientist
Clinical Monitoring Research Program
SAIC-Frederick, Inc.
National Cancer Institute at Frederick
5705 Industry Lane
Frederick, MD 21702
Phone: 301-947-4912
finneyl@mail.nih.gov



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**From:** Alston, Monique (NIH/OD) [E]
**Sent:** Thursday, June 09, 2011 8:33 AM
**To:** Finney Rutten, Lila (NIH/NCI) [C]
**Cc:** Klein, William (NIH/NCI) [E]
**Subject:** requestforReview HINTS4_Main Study_6_1_11.doc

Signed copy per Bill's request. If you have any questions please feel free to contact.

**Monique Alston**
**Task Leader, Hub D (NCI & OGA)**
**6130 Executive Plaza, Room 4057A**
**Bethesda, MD 20892**
**(301) 496-2242**
**(301) 435-7547 (f)**
**alstonm@od.nih.gov**

## OHSR (NIH/DDIR)

**From:** Hesse, Bradford (NIH/NCI) [E]
**Sent:** Wednesday, June 15, 2011 7:25 AM
**To:** OHSR (NIH/DDIR)
**Cc:** Terisa Davis - Health Studies; Finney Rutten, Lila (NIH/NCI) [C]; Moser, Richard (NIH/NCI) [E]; Blake, Kelly (NIH/NCI) [E]
**Subject:** RE: HesseB_NCI_5810_CY2011

This correspondence is to confirm the fact that all activities related to the Health Information National Trends Survey (HINTS) will conform to existing collaborative protocol. Moreover, I offer confirmation that no one from the National Cancer Institute will be in a position to seek the identity of the subjects from whom we have collected data in the HINTS program. All of the original data files, including data files with anything resembling personal identifiable information, while be kept in a highly secure data location housed by our contractor Westat. Westat will maintain its usual high level of data security as specified in its data security plan submitted to the NCI. Staff within the NCI have been briefed, and have exercised their customarily high levels of protection for participant anonymity over the past ten years in which the HINTS program has been collecting data.

To verify our mutual understanding, I will cc Terisa Davis, who is the Project Director at Westat. Ms. Davis will respond with an email confirm Westat's adherence to privacy protocols as requested in your memorandum.

Thank you very much for your prompt review and concise request. If there is anything else I can do please do not hesitate to ask.

-Brad Hesse

Bradford W. Hesse, Ph.D.
Chief, Health Comm & Informatics Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
Executive Plaza North, Room 4068
6130 Executive Blvd., MSC 7365
Bethesda, MD 20892-7365

> {for express mail, use: Rockville, MD 20852}
Phone: 301-594-9904
Email: hesseb@mail.nih.gov

---

**From:** OHSR (NIH/DDIR)
**Sent:** Tuesday, June 14, 2011 3:17 PM
**To:** Hesse, Bradford (NIH/NCI) [E]
**Subject:** HesseB_NCI_5810_CY2011

Good Afternoon Dr. Hesse:

Thank you for the opportunity to review your research project entitled "Health Information National Trends Survey 4 (HINTS 4)." Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

1. Confirm that the work you are doing is consistent with the existing collaborative protocol.
2. Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive.
3. Ask your collaborator to provide documentation that the identity of the subjects who have provided the samples you will receive will not be released to you.

An e-mail from you and from the investigator(s) holding the key to the code is sufficient documentation.

*This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.*

Best regards,

Office of Human Subjects Research
Office of Intramural Research
National Institutes of Health
Bldg 10 Room 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

## OHSR (NIH/DDIR)

**From:** Terisa Davis - Health Studies [TerisaDavis@westat.com]
**Sent:** Wednesday, June 15, 2011 8:35 AM
**To:** Hesse, Bradford (NIH/NCI) [E]; OHSR (NIH/DDIR)
**Cc:** Finney Rutten, Lila (NIH/NCI) [C]; Moser, Richard (NIH/NCI) [E]; Blake, Kelly (NIH/NCI) [E]
**Subject:** RE: HesseB_NCI_5810_CY2011

This email is to confirm that identifying information of respondents participating in the Health Information National Trends Survey 4 (HINTS 4) will not be released to NCI at any time. The names, addresses and other identifying information of the survey respondents will not be included in any data provided to NCI. Individual survey responses will be identified by an assigned ID number only. Access to the code linking the ID numbers and the personal information will be restricted to only a few Westat staff members. Once the study is complete, the personal information will be destroyed.

If you have additional questions about the protection of HINTS subjects, please don't hesitate to contact me.

Thank you,

Terisa Davis, MPH
Project Director, HINTS
Westat
1600 Research Boulevard
Rockville, MD 20850
Tel: 301-294-2864
terisadavis@westat.com

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Thank you very much for your prompt review and concise request. If there is anything else I can do please do not hesitate to ask.

-Brad Hesse

Bradford W. Hesse, Ph.D.
Chief, Health Comm & Informatics Research Branch
Behavioral Research Program
Division of Cancer Control and Population Sciences
National Cancer Institute
Executive Plaza North, Room 4068
6130 Executive Blvd., MSC 7365
Bethesda, MD 20892-7365

> {for express mail, use: Rockville, MD 20852}
Phone: 301-594-9904
Email: hesseb@mail.nih.gov

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**To:** Hesse, Bradford (NIH/NCI) [E]
**Subject:** HesseB_NCI_5810_CY2011

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Best regards,

Office of Human Subjects Research
Office of Intramural Research
National Institutes of Health
Bldg 10 Room 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

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**Subject:** HesseB_NCI_5810_CY2011

Good Afternoon Dr. Hesse:

Thank you for the opportunity to review your research project entitled "Health Information National Trends Survey 4 (HINTS 4)." Since the work you are doing at the NIH provides little or no risk to human subjects off-site, OHSR has decided the appropriate action for you to take is the following:

1. Confirm that the work you are doing is consistent with the existing collaborative protocol.
2. Provide documentation that you will not seek the identity of the subjects who have provided the samples you will receive.
3. Ask your collaborator to provide documentation that the identity of the subjects who have provided the samples you will receive will not be released to you.

An e-mail from you and from the investigator(s) holding the key to the code is sufficient documentation.

*This action is based on guidance issued on Aug. 10, 2004 by the HHS Office of Human Research Protections, the regulatory office for the protection of human subjects.*

Best regards,

Office of Human Subjects Research
Office of Intramural Research
National Institutes of Health
Bldg 10 Room 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

## OHSR (NIH/DDIR)

**From:** OHSR (NIH/DDIR)
**Sent:** Monday, June 13, 2011 4:14 PM
**To:** Hesse, Bradford (NIH/NCI) [E]
**Cc:** Finney Rutten, Lila (NIH/NCI) [C]
**Subject:** Request for Review Rec'd-OHSRP 5810

Good afternoon Dr. Hesse,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as **OHSRP #5810.** Please use this number in any future correspondence regarding this study. 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.

**Protocol Title:** Health Information National Trends Survey 4 (HINTS 4)

Thank you.

Sincerely,
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

***The NIH is committed to maintaining the highest standards for the protection of human subjects.***


Please consider the environment before printing this e-mail

## OHSR (NIH/DDIR)

**From:** OHSR (NIH/DDIR)
**Sent:** Thursday, June 23, 2011 10:45 AM
**To:** Hesse, Bradford (NIH/NCI) [E]
**Cc:** Finney Rutten, Lila (NIH/NCI) [C]; Grant, Nicole (NIH/NCI) [E]
**Subject:** Request for Review Determination_OHSRP # 5810
**Attachments:** HesseB_NCI_5810_CY2011.pdf

Good morning Dr. Hesse,

Attached, please find OHSRP's determination of your Request for Review of Research, OHSRP # 5810. Please contact OHSRP with any questions.

Sincerely,
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

***The NIH is committed to maintaining the highest standards for the protection of human subjects.***


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