

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

FAX: 301 435-3710
To: Smith, Ashley
NCI
EPN 4090

Exempt #: 3827

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The National Physician Survey on Diet, Physical Activity, and Weight Control is a mail survey to be sent to a national sample of 2,000 primary care physicians and their administrators. The purpose of this survey is to obtain current, national data on physician knowledge, attitudes, recommendations, and practices related to diet, physical activity and weight among patient populations from infants to older adults. The survey will identify factors that aid or hinder the dissemination of information about diet, physical activity, and weight

Original Request Received in OHSR on: 8/1/2007

Responsible NIH Research Investigator(s): Ashley Smith, NCI

OHSR review of your request dated Tue, Jul 31, 2007 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. No further action is necessary.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Confidentiality Agreement
- Reliance
- Amendment
- Other

Note:

Office Person Admin Asst.

Jerry Menikoff, MD, JD

Director, OHSR

Signature

Title

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

**REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN
SUBJECTS**

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

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

Date: July 31, 2007

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

From: Ashley W. Smith (ASHLEY W. SMITH)
(Signature)

FOR STEVE CLAUSER (BRANCH CHIEF, ORB)

Through: Bryce B. Reeve (BRYCE B. REEVE)
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Name of NIH Principal Investigator(s): Ashley Wilder Smith
IC: NCI Laboratory/Branch: Outcomes Research Branch
Building & Room: EPN 4090 Tel: (301-451-1843)
FAX: (301-435-3710)

Is the Principal investigator an NIH employee? 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 National Physician Survey on Diet, Physical Activity, and Weight Control is a mail survey to be sent to a national sample of 2,000 primary care physicians and their administrators. The purpose of this survey is to obtain current, national data on physician knowledge, attitudes, recommendations, and practices related to diet, physical activity and weight among patient populations from infants to older adults. The survey will identify factors that aid or hinder the dissemination of information about diet, physical activity, and weight through physicians' offices to the general patient population.

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

Name	Institution	Address	Tel. #	FAX #
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1. Deborah Galuska	CDC	Centers for Disease Control and Prevention 4770 Buford Highway NE MS 24	Phone: 770-488-6017	Fax: 770-488-6500
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2. Caroline McLeod, PhD	Westat	1650 Research Blvd. Rockville, MD 20850	Phone: (240) 453-2786	Fax: (301) 610-5140
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3. Proposed start date of your research: November 2007**Proposed completion date:** August 2008**4. Will you be _____ these samples or data?**

Collecting	Yes / <u>No</u>
Receiving	<u>Yes</u> / No
Sending	Yes / <u>No</u>

A contractor will be collecting and receiving survey data, and will send us data files without subject identifiers.

5. Do the samples or data:(a) Already exist? ___ Yes x No(b) Or are they being collected for the express purpose of this study? x Yes ___ No
If "yes," please describe: This is a mailed survey to 2,000 physicians and their administrators.(c) Or a combination of (a) and (b)? ___ Yes x No**6. What role will you have in this research project? (Check all that apply)**x Analyze samples/data only.

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.

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

I am the Task Order Monitor for this Westat-conducted project.

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

7. Where are the subjects of this research activity located?

Participants are located in physician offices and medical clinics across the country.

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?) Yes No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?

Responses to questionnaire items

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

(a) Repository Yes No

(b) Pathological waste Yes No

(c) Autopsy material Yes No

(d) Publicly available source Yes No

(e) Other _____

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) 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) 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 that you are proposing in this form been approved by an Institutional Review Board (IRB) elsewhere?

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

<u>Westat</u>	Name of institution that provided the review
<u>1650 Research Blvd.</u> <u>Rockville, MD 20850</u>	Address of reviewing institution
<u>Ashley Wilder Smith</u>	Name of PI for the IRB approved protocol
<u>National Survey of Energy Balance Related Care Among Primary Care Physicians Project #8357.05</u>	Title of IRB approved protocol and protocol #
<u>FWA 5551</u>	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?**

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

Robinson, Kimberley (NIH/OD) [?]

From: Robinson, Kimberley (NIH/OD) [?]
Sent: Tuesday, August 07, 2007 2:13 PM
To: Smith, Ashley (CDC)
Subject: RESPONSE TO REQUEST FOR REVIEW # 3827
Attachments: SmithA_NCI_Exempt_3827_CY2007.pdf

Good afternoon:

Attached please find the Response to Request for Review of Research Activity Involving Human Subjects dated 07/31/07.

Any questions, feel free to contact OHSR.

Best Regards,

Kimberley V. Robinson

Kimberley V. Robinson
Administrative Assistant
OD/OHSR/NIH
10 Center Drive, Rm. 2C-146
Bethesda, MD 20892
301-402-8631 (Direct)
301-402-3443 (Fax)

8/7/2007