# Attachment 5

# Westat and NCI IRB Approval's

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AN EMPLOYEE-OWNED
RESEARCH CORPORATION

MEMORANDUM

TO: Carolyn McLeod
Project Director

April 15, 2008

FROM: Kerry Levin
Acting Chair, Institutional Review Board

SUBJECT: Expedited Review and Approval for new activity
**Survey of Physicians Regarding the Care of Cancer Survivors (SPARCCS), Project 8137.06,**

As Acting Chair of the Westat Institutional Review Board (IRB), I have reviewed the materials submitted for the following: **Survey of Physicians Regarding the Care of Cancer Survivors (SPARCCS), Project 8137.06.** The IRB reviews all studies involving research on human subjects.

SPARCCS is sponsored by the National Cancer Institute (NCI) from the National Institutes of Health. Westat's role will be to identify the sampling frame, finalize the sample design, determine survey methods, develop survey materials, conduct the evaluation, enter and clean the data and conduct data linkages and analyses.

The IRB previously approved a Waiver of Standard Informed Consent and study instruments to conduct nine cognitive interviews among Primary Care Physicians and Medical Oncologists. The purpose of that testing was to examine how well question items measured knowledge, attitudes, and practices of primary care physicians and medical oncologists. This request is for approval to screen physicians in the sampling frame and to send a self-administered interview to approximately 4,400 physicians. The eligibility screener, mailings and follow up activities will be conducted from Westat's Rockville offices.

A random sample of primary care physicians belonging to primary care specialties (Family Practice, Obstetrics/Gynecology, General Internal Medicine, and Pediatrics) will be drawn from the Master File of the American Medical Association. Additionally, a second sample will be drawn from the Medical Oncology specialty category. Surveys will be sent via FedEx to physicians determined eligible at the screener with the hope that 1,100 completed surveys from Primary Care Physicians (PCPs) and 2,200 completed surveys from Medical Oncologists.

The physicians will be sampled from the American Medical Association Master File so that only non-Federal physicians currently practicing in office settings and belonging to the aforementioned specialties will be included. Because the sample frame includes outdated information, specialty and practice location will be verified along with address during verification calls conducted before the first mailing. Cases not meeting these criteria will be excluded. Separate screeners will be used for the primary care specialties. To participate, the oncologists must treat primarily breast and colon cancer patients.

Physicians will also have the choice to complete the questionnaire over the telephone. The time to complete the questionnaire is estimated at 20 minutes. Similar instruments will be used for primary care physicians and medical oncology physicians. Questionnaires will be shipped by Federal Express beginning in January 2009. The shipping envelope will have a return address label in the left hand corner of the envelope informing the recipient that the package is "From the National Institutes of Health". The package will contain a cover letter from NCI including a list of Frequently Asked Questions, the questionnaire, a check for $50 as incentive for participation, a postage paid, pre-addressed return envelope to Westat, a document describing background details about the study, and a letter of support from a specialty organization corresponding to the specialty of the physician respondent. There are no sensitive questions in the survey instruments. Questions about patient characteristics are of a general nature and information is collected in the aggregate rather than on specific individuals.

Completed questionnaires will be receipted and checked for completeness and legibility of answers. The questionnaires have been designed to be electronically scannable and as noted above, there is no identifying information in the questionnaires. Each will be identified by a unique identification number. Each participant's name and contact information will be stored in a secure database at the Westat offices in Rockville, Maryland. Information will be stored separately from information provided by the participant on the survey, and the only identifier on the survey will be a unique number. Only staff members from Westat who have signed confidentiality pledges will have access to the physician names and contact information. Very few staff will have access to files linking names/identifiers to survey responses. Names and contact information will be used only for follow-up purposes and purposes of payment by check. Linking information will be retained by Westat and NCI will receive only the data file with identification numbers. Identifiable data will be secure-shredded 6 months after the final report is submitted to NCI.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk. I am therefore approving the study under expedited authority.

A waiver of documentation of informed consent is also granted under 45 CFR 46.116 because the research involves no more than minimal risk to subjects and could not practicably be carried out without the waiver.

You obligation to submit the study for an annual review on or before January 17th, 2009 remains unchanged. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Jeanne Rosenthal

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

FAX: 301-435-3710 **Exempt: #:** 4146

To: Potosky, Arnold
NCI
EPN - Exec Plz North, 4005

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
The overall goal of the Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS) is to identify perceptions, knowledge, and practices of primary care and oncology specialist physicians regarding post-treatment follow up care of adult cancer survivors. There is little evidence regarding optimal follow up care practices as well as limited understanding of current practices. There is consensus, however, from IOM reports that the care of survivors is fragmented and poorly coordinated, and that considerable practice variation exists in survivorship care. Thus, the goal of the survey will be to obtain more information

Original Request Received in OHSR on: 4/18/2008

Responsible NIH Research Investigator(s): Arnold Potosky, NCI

OHSR review of your request dated Thu, Apr 17, 2008 has determined that:

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

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

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

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Note:

Office Person JS Admin Asst. CB

This research is exempt under 45 CFR 46 101 (b) (2).

for
Jerry Menikoff, MD, JD — Director, OHSR — 5/2/2008
Signature — Title — Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

#4146

**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: April 11, 2008

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

From: _____
(Signature)

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

**Name of NIH Principal Investigator(s):** Arnold L. Potosky

IC NCI Laboratory/Branch Health Services and Economics Branch
Building & Room No. EPN/Rm. 4110 Tel. No. 301-496-5662 FAX No.301-435-3710

**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 overall goal of the Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS) is to identify perceptions, knowledge, and practices of primary care and oncology specialist physicians regarding post-treatment follow-up care of adult cancer survivors. There is little evidence regarding optimal follow up care practices as well as limited understanding of current practices. There is consensus, however, from IOM reports that the care of survivors is fragmented and poorly coordinated, and that considerable practice variation exists in survivorship care. Thus, the goal of the survey will be to obtain more information concerning the reasons for this fragmentation in care by exploring limitations in knowledge, confusion about roles, and the key barriers to perceived "best practices" from the unique perspective of the practicing physicians. This is directly responsive to specific IOM and PCP report recommendations.

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

Name Institution Address Tel. # FAX #

Craig Earle
Dana Farber
44 Binney St.
Boston, MA 02115
Phone: 617-632-5564
Fax: 617-532-2270

Patti Ganz
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Los Angeles, CA 90095-6900
Phone: 310-206-1404
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Michael Stefanek
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250 Williams St.
Atlanta, GA 30303
Phone: 404-315-1123
Fax: 404-315-9348

Tenbroeck Smith
American Cancer Society
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John Ayanian
Harvard Medical School
180 Longwood Ave.
Boston, MA 02115
Phone: 617-432-3455
Fax: 616-432-0173

**3. Proposed start date of your research** January 3, 2009
**Proposed completion date** January 3, 2012

**4. Will you be _____these samples or data?**

Collecting **Yes**/No
Receiving **Yes**/No
Sending Yes/**No**

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

(b) Or are they being collected for the express purpose of this study? X Yes ____No
If "yes," please describe: This survey will be mailed to 2200 physicians.

(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)**

___ Analyze samples/data only.

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

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

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

___ You or NIH hold an IND for this research.

_X_ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain. I am the Task Order Monitor for this 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 will be recruited from physician offices and medical clinics across the United States.

**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 _X_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 _X_ No

(b) Pathological waste ___ Yes __X_No

(c) Autopsy material ___ Yes _X_ No

(d) Publicly available source ___Yes _X_ No

(e) Other_____

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

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

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

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

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

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

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

(c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.
If yes, does the provider intend to link your data to identifiable individuals?
_____Yes _____No

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

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

Westat — Name of institution that provided the review

1650 Research Blvd., Rockville, MD 20850 — Address of reviewing institution

Arnold L. Potosky — Name of PI for the IRB approved protocol

National Survey of Physician Attitudes Regarding the Care of Cancer Survivors Project#8137.06 — Title of IRB approved protocol and protocol #

FWAOOOO5551 — 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