Attachment 3

Documentation of IRB Approval

WESTAT
AN EMPLOYEE-OWNED
RESEARCH CORPORATION

MEMORANDUM

TO: Caroline McLeod
Project Director, Westat

June 8, 2007

FROM: Thomas W. McKenna
Chairman, Institutional Review Board

SUBJECT: IRB Review and Approval
National Survey of Energy Balance Related Care Among Primary Care Physicians
Contract No. N02-PC-61301308
Project 8357.05
FWA 5551

As Chairman of the Westat Institutional Review Board (IRB), I have reviewed the materials submitted for the following: **National Survey of Energy Balance Related Care Among Primary Care Physicians**, Contract No. N02-PC-61301308, Project 8357.05. Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. This survey is sponsored by the National Cancer Institute (NCI). Co-funding is provided by the National Institute for Child Health and Human Development (NICHD), and the Office of Behavioral and Social Sciences Research in the Office of the Director at the National Institutes of Health (NIH).

The survey of primary care physicians will obtain data on physicians' knowledge, attitudes, and activities related to diet, physical activity, and weight control in adults and children (two separate paper-and-pencil questionnaires). An additional survey, sent to the administrators of physicians returning a survey, will focus on the administrative structures within the office and the medical practice in which the physician works. The introduction to the questionnaires contains an assurance of confidentiality, and a statement that the respondents' answers will be aggregated with those of other respondents in reports to NCI and any other parties. Further, respondents are assured that participation is voluntary and there are no penalties for not responding, though non-response may seriously affect the final results. 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. Westat's role includes identifying the sampling frame, finalizing the sample design, determining survey methods, developing survey materials, fielding the survey, computerizing and cleaning the data, and conducting data linkages and analyses.

Follow-up of non-responding physicians will be conducted 14 days about after the initial mailing. At this time, physicians will be offered the option of completing the questionnaire over the phone. An additional survey and replacement honorarium check will be sent if necessary. An additional follow-up call will be made to the physicians who agree to fill out the survey but from whom no survey has been received within two weeks after the physician has agreed. A third physician survey will be sent to physicians who say they have lost the second package and to physicians who have not responded approximately 10 weeks after the initial mailing. Mailing to administrators will begin one month after receipt of the completed physician survey. The same follow-up procedures will be used for the administrators as for the physicians.

Participant name and contact information will be stored in a secure database at the Westat offices in Rockville, Maryland. This 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. Names and contact information will be used only for follow-up purposes and purposes of payment by checks. The file linking names and contact information with study identifiers will be retained by Westat in a secure data file, and will be destroyed after five years. NCI will receive only the data file with identification numbers. If the client chooses to use the linking file within the five year window as the basis for another study, additional IRB approval will be need to be obtained for that study.

IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b)(1)], and this study can be considered minimal risk. I am therefore approving this study under expedited authority. I am also granting a waiver of documentation of informed consent, since this survey presents no greater than minimal risk and is being conducted by mail (and possibly telephone).

You are required to submit the project for an annual review on or before June 8, 2008. 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
Miriam Aiken