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Memo

Date: May 13, 2011

To: Kerry Grace Morrissey, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Initial Approval of AARP Biomarker Validation, Project Number 8855.03 FWA 05551**

As Chair of the Westat Institutional Review Board (IRB), I reviewed the materials submitted for the following: **AARP Biomarker Validation, Project Number 8855.03.** The Westat IRB reviews all studies involving research on human subjects. This study is being conducted by the National Cancer Institute.

This study, designed to validate the accuracy of web-based instruments that collect information on 24-hour diet recall (ASA24) and 24-hour activity recall (ACT24) against objectively measured biomarkers, will be conducted within the existing NIH-AARP Diet and Health Study. The sample will include 1,200 men and 1,200 women age 50-74 years living in the Pittsburgh area.

Eligible participants will provide documented informed consent.

University of Wisconsin (UW), Westat's subcontractor, will perform the analysis on the water samples. These specimens will include a unique specimen identification number. Further, UW will not have the link to the study identification number.

The following is a list of questions from the primary reviewer assigned to this project as well as the research team's responses.

1. Under Data analysis, the protocol states, "DNA may also be extracted from biospecimens." There is no mention of this in the consent form. There is a section that asks if future studies using the collected blood, urine, and saliva samples would be permitted, but doesn't mention DNA. If they really plan to extract, store, and study DNA, the standard DNA consent wording for study or biorepository probably should be added up front. I'd guess that the future DNA testing depends on later funding availability, but worry that the blanket permission for future biospecimen use could be interpreted to include DNA studies, unbeknownst to the research subjects.

PD Response: This sentence will be deleted, as DNA will not be extracted.

2. The protocol notes that "metabolic profiles" will be evaluated for each subject. Does this include genetic information?

PD Response: Metabolic profiles will not include genetic information since DNA is not being extracted.

3. Are they able to determine if the biosamples will be destroyed (and if so, when) or archived indefinitely?

PD Response: The biospecimens will be stored until they have all been used.

4. Please replace "any" for "nay" on page 3 of the informed consent form, 5th line from the bottom.

PD Response: Done

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 and is approved under expedited authority.

As the Project Director you are responsible for the following:

- You are required to submit this study for a continuing review on or before May 13, 2012.
- 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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Date: April 20, 2011

From: Dr. Catherine Schairer
Chair, NCI Special Studies Institutional Review Board

Subject: Approval of Initial Review to Protocol Entitled "Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker based validation study of internet-based and conventional self-report instruments for assessing diet and physical activity within AARP"

To: Drs. Heather Bowls and Yikyung Park
Principal Investigator, IIB, DCEG, NCI

Your responses to the IRB stipulations from the above-mentioned study were given expedited review by the NCI IRB Chair and are now approved.

The subcommittee does recommend that the introductory letters could be toned down by changing the sentence, "This research is so important and your contribution so valuable...you will receive $450.00..." The reason they receive $450.00 is because the research is burdensome to the participant. The subcommittee recommends starting the sentence with "If you are eligible...you will receive $450.00..." and leave it at that.

Please provide the brochure for SSIRB review when it becomes available.

You may now go forward and implement your study. Thank you for your cooperation in this matter.

Approved: Catherine Schairer 4/20/11

Catherine Schairer, Ph.D. Date
Chair, NCI SSIRB