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DATE: March 16, 2010

TO: Kerry Grace Morrissey
Project Director

FROM: Kerry Levin
Chair, Institutional Review Board

SUBJECT: IRB Continuing Review and Approval
Multi-disciplinary Investigations of Nutrition and Cancer
Project #: 8472
FWA 5551

On March 9, 2010, the Westat Institutional Review Board conducted its continuing review of the following: Multi-disciplinary Investigations of Nutrition and Cancer, Project #: 8472, including:

8472.01.01 The NIH-AARP Diet and Health Study
8472.02.01 The India Diet and Health Study

Pursuant to 45 CFR pt 46.109(e), continuing review of research studies occurs at intervals appropriate to the degree of risk but not less frequently than once a year.

In accordance with 45 CFR pt 46, the Board approved the continuation of this study. The next continuing review will be due on or before March 31, 2011. In the interim, you are responsible for notifying the Institutional Review Board (IRB) Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to study design that relate to human subjects

cc: Institutional Review Board - Sharon Zack

3/15/10

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. 08-C-N152	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Arthur Schatzkin,MD, Dr.P.H. NEB/DCEG/NCI, 6120 Executive Blvd. Rockville, MD 20852;301-594-2931;schatzka@mail.nih.gov

PROTOCOL TITLE:

Feasibility study of a web-based automated self-administered 24-hour-dietary recall (ASA24) and a physical activity 24-hour recall (ACT24)

PROTOCOL STATUS:
- ☐ Renew -Recruitment of participants has not yet begun.
- ☒ Renew -Participants are currently being recruited or enrolled.
- ☐ Renew -No longer recruiting or enrolling participants, subject follow-up only.
- ☐ Renew -Participants have completed study; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): Only when the NIH is the coordinating site, provide totals and enrollment table for other site.

NIH Site	Other Sites	Total	
15,000	0	15,000	Accrual ceiling by IRB
251		251	New subjects accrued since last CR
562		562	Aggregate total accrued

Are you currently recruiting healthy volunteers? ☐ No ☒ Yes
Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex, racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A

a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

Have any non-NIH Investigators or sites been added since the last review?
- ☒ No
- ☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
*Include Name, Inst/Branch, Telephone, Address, e-mail. Check box if an NIH Employee and initial line. Attach sheet if necessary.

PRINCIPAL INVESTIGATOR:
Delete: _____
Add*: ☐ _____

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add*: _____

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add*: ☐ _____

RESEARCH CONTACT:
Delete: _____
Add*: ☐ _____

ASSOCIATE INVESTIGATOR(S):
Delete: _____
Add*: ☐ _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.) check all that apply:
- ☒ None
- ☐ Medically indicated
- ☐ Research indicated. Since the last review,
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.

FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above entity? _____

Does the protocol involve a Tech Transfer Agreement? ☒ No ☐ Yes

Does the protocol involve a drug/device/product that may lead to you or the NIH receiving payment and/or royalties?
- ☒ No
- ☐ Yes (Append a statement of disclosure)

Have there been any amendments since the last review?
- ☐ No
- ☒ Yes (Describe briefly in the attached narrative.)

Have there been any changes in the informed consent process or documentation since the last review?
- ☒ No
- ☐ Yes (Describe in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?
- ☒ No
- ☐ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?
- ☒ No
- ☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?
- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?
- ☒ No
- ☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☐ Yes ☒ N/A

Has the NIH IRP COI Guide been distributed to new Non-NIH investigators?
☐ No ☐ Yes ☒ N/A

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC: 1/4/10 Date cleared by IC DEC: 2/4/10

SIGNATURE	Principal Investigator	Arthur Schatzkin	Date 1-5-10	Send to Accountable Investigator	
RECOMMENDATION	Accountable Investigator	Arthur Schatzkin	Date 1-5-10	Send to Branch Chief, or CC Dept. Head of Accountable Investigator	
	Br Chief/CC Dept. Head of Acct. Invest	Robert N. Hoover	Date 1/5/10	Send to Clinical Director	
APPROVALS	Clinical Director	Wilson Durr	Date 3/23/10	Send to Chair, Institutional Review Board	
	Chair, For Institutional Review Board	Nancy Potischman	Date 3/16/10	Send to Office of Protocol Services, through IRB Protocol Coordinator	
COMPLETION	Protocol Specialist		Date 3/25/10	Protocol & Consent Approved Effective	