4/13/11

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. 09-C-N190	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Frances E. Thompson, NCI/ARP, 301-435-4410, EPN 4095A, thompsof@mail.nih.gov

PROTOCOL TITLE:

24-Hour Dietary Recall Method Comparison Study

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	
		1080	Accrual ceiling by IRB
		0	New subjects accrued since last CR
		0	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: Stephanie George, Arthur Schatzkin per PC/PI
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: 1/26/11 Date cleared by IC DEC: 1/23/11

SIGNATURE	Frances E. Thompson (Principal Investigator)	Frances E. Thompson (Print/Type Name)	Date 1/31/11	Send to Accountable Investigator
RECOMMENDATION	Frances E. Thompson (Accountable Investigator)	Frances E. Thompson (Print/Type Name)	Date 1/31/11	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	(Br Chief/CC Dept. Head of Acct. Invest)	Susan M. Krebs-Smith (Print/Type Name)	Date 1/31/11	Send to Clinical Director
APPROVALS	(Clinical Director)	William D (Print/Type Name)	Date 3/11/11	Send to Chair, Institutional Review Board
EXPEDITED	(Chair, For Institutional Review Board)	[redacted] (Print/Type Name)	Date 3/7/11 Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Cherie Bonds-Beeken	Digitally signed by Cherie Bonds-Beeken DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, 0.9.2342.19200300.100.1.1=0014322567, cn=Cherie Bonds-Beeken Date: 2011.03.23 14:33:12 -04'00'	Date 03/23/11	

04/13/11

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. 09-C-N209	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Nancy Potischman, NCI/DDCPS/ARP EPN 4008 potischn@mail.nih.gov

PROTOCOL TITLE:

National Cancer Institute (NCI) Validation and Observational Feeding Study

PROTOCOL STATUS:

- ☒ Renew -Recruitment of participants has not yet begun.
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a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

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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)

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*If reporting more than one IND/IDE, list on attached sheet.

FDA No. _____
Name: _____
Sponsor: _____
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☒ 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: 1/7/11 Date cleared by IC DEC: 1/7/11

SIGNATURE	Nancy Potischman Principal Investigator	Nancy Potischman Print/Type Name	Date 1/21/11	Send to Accountable Investigator
RECOMMENDATION	Nancy Potischman Accountable Investigator	Nancy Potischman Print/Type Name	Date 1/21/11	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Rachel Ballard-Barbash Br Chief/CC Dept. Head of Acct. Invest	R Ballard-Barbash Print/Type Name	Date 1/21/11	Send to Clinical Director
APPROVALS	[signature] Clinical Director	William Print/Type Name	Date 3/9/11	Send to Chair, Institutional Review Board
EXPEDITED	Catherine Schairer Chair, For Institutional Review Board	Catherine Schairer Print/Type Name	Date 3/2/11 Protocol & Consent Approved Effective	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Sarita Thomas Protocol Specialist	Date 3-31-11		