

5/25/07

CLINICAL RESEARCH PROTOCOL CONTINUING REVIEW APPLICATION	PROTOCOL NO. OH95-C-NO25	PRINCIPAL INVESTIGATOR (NIH Employee Name, Ins/Br, Address, Telephone and email) Arthur Schatzkin, M.D., Dr. P.H.
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PROTOCOL TITLE:  
NIH-AARP Diet and Health 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
540,833		Accrual ceiling by IRB
0		New subjects accrued since last CR
540,833		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, Ins/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: 3/5/07 Date cleared by IC DEC: 3/14/07

**Expedited**  
APPROVALS

SIGNATURE	<u>Arthur Schatzkin</u> Principal Investigator	<u>Arthur Schatzkin</u> Print/Type Name	Date	4-12-07	Send to Accountable Investigator
RECOMMENDATION	<u>Arthur Schatzkin</u> Accountable Investigator	<u>Arthur Schatzkin</u> Print/Type Name	Date	4-12-07	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	<u>Robert N. Hoover</u> Branch/CC Dept. Head of Acct. Invest	<u>Robert N. Hoover</u> Print/Type Name	Date	4/12/07	Send to Clinical Director
	<u>F Balis</u> Clinical Director	<u>F Balis</u> Print/Type Name	Date	5/25/07	Send to Chair, Institutional Review Board
	<u>Mauveen Hatch</u> Chair, For Institutional Review Board	<u>Mauveen Hatch</u> Print/Type Name	Date	5/23/07	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	<u>Patricia Jeffers</u> Protocol Specialist	Date	5/25/07		