5917

CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):
Arthur Schatzkin, MD, Dr. P.H. NEB/DCEG, 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 (ASA 24) and a physical activity 24-hour recall

ABBREVIATED TITLE (30 characters or less): ASA24/ACT24 feasibility study

PROPOSED START DATE: 5/1/08 END DATE: 4/30/09 TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): 2,093

MULTI-SITE COLLABORATION:
Is this a multi-site collaboration? ☐ Yes (complete this section) ☒ No
Will subjects participate on the protocol at the NIH CC? ☐ Yes ☐ No
Will subjects participate on the protocol at other sites? ☐ Yes ☐ No
If yes, are the sites ☐ Domestic ☐ Foreign ☐ Both
Is NIH the coordinating site?
☐ Yes. For each participating site, provide: Institution name, address, investigator(s), indicate if subjects will be recruited and if they are, include a contact name on attached sheet/protocol face sheet.
☐ No. Coordinating Site is

REQUESTED ACCRUAL EXCLUSION (Check all that apply):
☐ None ☐ Asian
☐ Male ☐ Black or African American
☐ Female ☐ White
☒ Children <18 ☐ Hispanic or Latino
☐ American Indian/ Alaskan Native ☐ Native Hawaiian or Pacific Islander

SUBJECT ACCRUAL CHARACTERISTICS:
Minimum Age Permitted 50
Maximum Age Permitted none
Pediatric ☒ None ☐ <2 Yr. ☐ 2-6 Yrs. ☐ 7-17 Yrs.
Protocol involves healthy volunteers? ☒ Yes ☐ No
Are Healthy Volunteers NIH Employees? ☐ Yes ☒ No
Does the protocol permit self referral? ☐ Yes ☒ No
Will the protocol involve adults unable to give informed consent? ☐ Yes ☒ No

PROTOCOL TYPE: (Check one):
☐ Screening
☐ Training
☐ Natural History – Disease Progression/ Physiology
☐ Natural History – Sample/Data Collection or Analysis (Recruiting Patients)
☒ Natural History – Sample/Data Collection or Analysis (Not Recruiting Patients)
☐ Pharmacokinetics/Dynamics
☐ Clinical Trial: Identify Phase (Check one)
☐ Phase 0 ☐ Phase 1 ☐ Phase 1-2
☐ Phase 2 ☐ Phase 3 ☐ Phase 4

If a Phase 3 Clinical Trial, is analysis for sex, racial/ethnic subgroups required according to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research? ☐ Yes ☐ No ☐ N/A

KEY WORDS (Words or phrase that describe the protocol.)
1. web-based dietary assessment
2. web-based physical activity assessment
3. feasibility
4.
5.

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET; etc.): check all that apply
☒ None ☐ Medically indicated ☐ Research indicated*
*Complete NIH-88-23a, and attach to this application. Send a copy of entire protocol and NIH-88-23a to Chair, Radiation Safety for concurrent review).

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.
FDA No.
IND/IDE Name:
Sponsor:
Who is the manufacturer of the above entity:

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

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

Has the NIH IRP COI Guide been distributed to NIH Investigators?
☒ Yes ☐ No

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

CONFLICTS OF INTEREST REVIEW:
Date submitted to IC DEC: 2/6/08 Date cleared by IC DEC: 3/26/08

Is an Extramural Investigator an ADJUNCT PRINCIPAL INVESTIGATOR? ☐Yes ☒No

Name of Adjunct PI:

MEDICAL ADVISORY INVESTIGATOR (if necessary) Name, Inst/Branch, Telephone, Address, Email and initial line:
Arthur Schatzkin, MD, Dr.P.H. DCEG/NEB 301-594-2931, 6120 Executive blvd. Rockville MD 20852

LEAD ASSOCIATE INVESTIGATOR – Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☒ MB Michale Leitzmann, MD, Dr. P.H.DCEG/NEB 301-402-3491, 6120 Executive blvd. Rockville MD 20852

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☒ YP Yikyung Park, Sc.D. DCEG/NEB 301-594-6394, 6120 Executive blvd. Rockville MD 20852

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.
1. ☒ YP Yikyung Park, Sc.D. DCEG/NEB 301-594-6394, 6120 Executive blvd. Rockville MD 20852
2. ☒ SM Steven Moore, Ph.D. DCEG/NEB 301-594-2415, 6120 Executive blvd. Rockville MD 20852
3. ☒ AS Amy Subar, Ph. D. DCCPS 301-594-2931 6130 Executive blvd. Rockville MD 20852
4. ☒ FT Frances Thompson, Ph. D. DCCPS 301-594-2931 6130 Executive blvd. Rockville MD 20852
5. ☒ NP Nancy Potischman, Ph. D. DCCPS 301-594-2931 6130 Executive blvd. Rockville MD 20852

(Principal Investigator: Be sure to include PRECIS <=400 words as first section of protocol)

SIGNATURE	Principal Investigator	ARTHUR SCHATZKIN Print/Type Name	Date 3-3-08	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	ARTHUR SCHATZKIN Print/Type Name	Date 3-3-08	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
	Br. Chief/CC Dept. Head or Acct. Invest.	Robert N. Hoover Print/Type Name	Date 3/3/08	Send to Institute/Center Scientific Review Committee
APPROVALS	For Institute/Center Scientific Review Comm.	Sheila Zahm Print/Type Name	Date 5/20/08	Send to Clinical Director
	Clinical Director	F. Balis Print/Type Name	Date 5/23/08	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Maureen Hatch Print/Type Name	Date 5/20/08 Protocol & Consent Approval Completed	Send to Office of Protocol Services, through IRB Protocol Coordinator
PATIENT SAFETY/ RESOURCE REVIEW	Director, Clinical Center	G Allen Print/Type Name	Date 5/28/08	Return to Office of Protocol Services, (10/1S231B)
COMPLETION	Protocol Specialist	Date 5/30/08	PROTOCOL NO. 08-C-N152	

4/20/09

BD