

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 Male Female Children <18 American Indian/ Alaskan Native Asian Black or African American White Hispanic or Latino 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

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: Michale Leitmann, 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: 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. Yikyung Park, Sc.D. DCEG/NEB 301-594-6394, 6120 Executive blvd. Rockville MD 20852 2. Steven Moore, Ph.D. DCEG/NEB 301-594-2415, 6120 Executive blvd. Rockville MD 20852 3. Amy Subar, Ph. D. DCCPS 301-594-2931 6130 Executive blvd. Rockville MD 20852 4. Frances Thompson, Ph. D. DCCPS 301-594-2931 6130 Executive blvd. Rockville MD 20852 5. 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: Arthur Schatzkin (Principal Investigator) Date 3-3-08 Send to Accountable Investigator RECOMMENDATION: Arthur Schatzkin (Accountable Investigator) Date 3-3-08 Send to Branch Chief, or CC Dept. Head of Accountable Investigator APPROVALS: Robert N. Hoell (Bk. Chief/CC Dept. Head of Acct. Invest.) Date 3/13/08 Send to Institute/Center Scientific Review Committee Sherita Zahm (For Institute/Center Scientific Review Comm.) Date 5/20/08 Send to Clinical Director F. Balis (Clinical Director) Date 5/23/08 Send to Chair, Institutional Review Board Maureen Hatch (Chair, For Institutional Review Board) Date 5/20/08 Protocol & Consent Approval Completed Send to Office of Protocol Services, through IRB Protocol Coordinator PATIENT SAFETY/ RESOURCE REVIEW: G. Garcia (Director, Clinical Center) Date 5/28/08 Return to Office of Protocol Services, (10/1S231B) COMPLETION: Josiana Briggs (Protocol Specialist) Date 5/30/08

PROTOCOL NO. 08C-N152