Attachment 17 – ASA24 Dietary Recall Comparison and Feeding Studies

IRB Approvals

NCI IRB – Dietary Recall Comparison Study (TO BE ATTACHED)
NCI IRB – Feeding Study

Westat IRB - Dietary Recall Comparison Study – Page 2-3
Westat IRB - Feeding Study – Page 4

Henry Ford IRB – Page 5-6

Kaiser IRB - (TO BE ATTACHED)

NCI Feeding Study IRB Approval

CLINICAL RESEARCH PROTOCOL
INITIAL REVIEW APPLICATION

PRINCIPAL INVESTIGATOR (Name of NIH Employee, Institute/Branch, Address, Telephone and email):
N. Potischman, NCI/ARP,(301.594.6573),EPN 4008, potischn@mail.nih.gov

PROTOCOL TITLE: National Cancer Institute (NCI) Validation and Observational Feeding Study

ABBREVIATED TITLE (30 characters or less): Observational Feeding Study

PROPOSED START DATE: Sep 30, 2009 END DATE: Sep 29, 2011 TOTAL SUBJECTS TO BE ACCRUED (Attach target table for Phase 3-4): 80

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: Westat

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 20
Maximum Age Permitted 70
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

KEYWORDS (Words or phrase that describe the protocol.)
1. Dietary assessment methods
2. Measurement of diet
3. 24-hour diet recall
4. feeding study
5. validation

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: Apr 15, 2009 Date cleared by IC DEC: Apr 29, 2009

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:

LEAD ASSOCIATE INVESTIGATOR - Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☒ N. Potischman, NCI/ARP,(301.594.6573), EPN 4008, potischn@mail.nih.gov

RESEARCH CONTACT: Name, Inst/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line:
☒ N. Potischman, NCI/ARP,(301.594.6573), EPN 4008, potischn@mail.nih.gov

ASSOCIATE INVESTIGATOR(S): Name, Institute/Branch, Telephone, Address, Email. Check box if an NIH employee and initial line. Attach list if necessary.
1. ☐ See Attached List.
2. ☐
3. ☐
4. ☐
5. ☐

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

SIGNATURE _____ Principal Investigator — Nancy Potischman Print/Type Name — Date 7/28/09 — Send to Accountable Investigator

RECOMMENDATION _____ Accountable Investigator — Print/Type Name — Date — Send to Branch Chief, or CC Dept. Head of Accountable Investigator

Br. Chief/CC Dept. Head of Acct. Invest. Print/Type Name — See attached — Date — Send to Institute/Center Scientific Review Committee

APPROVALS
For Institute/Center Scientific Review Comm. — Print/Type Name — Date — Send to Clinical Director

Clinical Director — Print/Type Name — Date — Send to Chair, Institutional Review Board

Vice Chair, For Institutional Review Board — James Goedert Print/Type Name — Date 7/29/09 — Protocol & Consent Approval Completed — Send to Office of Protocol Services, through IRB Protocol Coordinator

PATIENT SAFETY/ RESOURCE REVIEW Director, Clinical Center — Print/Type Name (10/1S231B) — Date — Return to Office of Protocol Services,

COMPLETION _____ Protocol Specialist — Date _____ PROTOCOL NO. _____

Clinical Research Protocol Initial Review Application
NIH-1195 (9-06)

Westat® | An Employee-Owned Research Corporation

Memo

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Initial Approval of ASA24 Comparison Study, Project 8372.02.22**
FWA 5551

As Chair of the Westat Institutional Review Board (IRB), I have reviewed the materials submitted for the following**: ASA24 Comparison Study, Project 8372.02.22.** Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. This project is sponsored by The National Cancer Institute (NCI). The IRB overseeing protections of human subjects for this project is the Marshfield Clinic Research Foundation.

The 24 hour dietary recall comparison study is designed to compare self-reported dietary intake data using the newly developed web-based Automated Self Administered 24-hour Recall (ASA24) to the current standard of interview-administered 24-hour recall, the Automated Multiple Pass Method (AMPM).

The sample will be drawn from three health maintenance organizations (HMO) ---Security Health Plan (using the Marshfield Clinic), Wisconsin; Henry Ford Health System, Michigan; and Northern California Kaiser-Permanente, California, all participants of NCI's Cancer Research Network. Interested participants from each center will be directed to a study website where they will provide their contact information through a secure on-line consent form.

Westat's role will include monitoring and tracking consents from the initial contact and provide the centers with a list of those who do not respond within 10 days of mail out. Each center will follow-up with these non-responders and send a second mailing. Westat will continue to track consents until the quota for each stratum is met. Westat will follow-up with individuals who have consented to participate and administer, by telephone, a screening questionnaire to ascertain eligibility for the study. Following, Westat will conduct cognitive interviews in order to test questions for a survey about late life disability trends and dynamics in individuals over 65 years.

Electronic data will be password protected and stored by the data management contractor, and also will be destroyed after a year.

The IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk. I am therefore approving this study under expedited authority. Per 45 CFR 46 117, your request for a waiver of documentation of informed consent is also approved.

If activities change, please contact the IRB Office to ensure that the status is accurately reflected in our records. You are only required to submit the study for a continuing review on or before June 10, 2010 if activities change for this project. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Susan Crystal Mansour

Westat® | An Employee-Owned Research Corporation

Memo

To: Susie McNutt, Project Director

From: Kerry Levin, Chair Westat IRB Kerry Levin

Subject: **Initial Approval of ASA24 Feeding Study, Project 8372.02.23**
FWA 5551

As Chair of the Westat Institutional Review Board (IRB), I have reviewed the materials submitted for the following**: ASA24 Feeding Study, Project 8372.02.23.** Pursuant to 45 CFR pt. 46, the IRB reviews all studies involving research on human subjects. This project is sponsored by The National Cancer Institute (NCI).

The NCI ASA24 Feeding Study is designed to assess the validity and reliability of the ASA24 by comparing results of a 24-hour dietary recall collected using a telephone-administered AMPM interview with results obtained from the ASA24.

Westat will enroll 100 participants from a list generated by a well known recruitment firm. Participants will be invited to Westat for two consecutive days, the first day to eat 3 meals and the second day to try to recall what they consumed the day before while at the study site. Researchers will observe and weigh the food intake of the participants, and then compare the observed intake to later self-reported intake using either one of two methods being compared. Standard informed consent will be collected from all participants.

Security protocols will be implemented to ensure that all data are recorded and stored in such a manner that individual research subjects cannot be identified directly or through identifiers. No identifying information will be recorded in the data file and there will be no way to detect the identification of any respondent. After the data collection is completed, Westat will store the paper informed consent forms and paper questionnaires in a locked, secure facility for a year, and then they will be shredded. Electronic data will be password protected and stored by the data management contractor, and also will be destroyed after a year.

The IRB regulations permit expedited review of certain activities involving minimal risk [45 CFR pt. 46.110 (b) (1)]. This study can be considered minimal risk. I am therefore approving this study under expedited authority. If activities

change, please contact the IRB Office to ensure that the status is accurately reflected in our records. You are only required to submit the study for a continuing review on or before June 10, 2010 if activities change for this project. In the interim, you are responsible for notifying the Office of Research Administration as soon as possible if there are any injuries to the subjects, problems with the study, or changes to the study design that relate to human subjects.

cc: Institutional Review Board
Susan Crystal Mansour

RESEARCH ADMINISTRATION

June 5, 2009

Research Administration
CFP-Basement 046
2799 West Grand Boulevard
Detroit, MI 48202-2689
(313) 916-2024 Office
(313) 916-2018 Fax

To: Gwen Alexander, Ph.D.
Biostatistics and Research Epidemiology

Fm: Timothy Roehrs, Ph.D., Chair
Jonathan Ehrman, Ph.D., Vice Chair
Adrian Ormsby, M.D., Vice Chair
Institutional Review Board (IRB)

Re: **Automated Self-Administered 24-Hour Recall Comparison Study**
(IRB No. 5623)

Period of IRB Approval: **June 5, 2009 – June 4, 2010**

This is to apprise you that the above-named project was reviewed through the expedited procedure on **June 5, 2009**. The human rights aspects of the above-referenced protocol were reviewed and approved. This approval is based on Title 45, Section 46.110 of the HHS Code of Federal Regulations related to no more than minimal risk to the subject. The approval of this project will be presented as an informational item at a subsequent IRB meeting.

The Institutional Review Board and Federal Regulations require that each research proposal involving human subjects be reviewed at intervals appropriate to the degree of risk but not less than once per year and that a final report is submitted at the termination of the project. ***Therefore, a continuation or final report for this proposal is due in one year. The report must be submitted to and approved by the IRB by June 4, 2010 to avoid a lapse in your approval. As the Principal Investigator, you are ultimately responsible for timely submissions of continuation and final reports. You are encouraged to create a tracking mechanism to ensure timely submissions.***

Revisions to the protocol must be approved by the IRB prior to implementation. In addition, our IRB is expected to review all documents and activities that bear directly on the rights and welfare of participants of research. A copy of the signed and stamped application, indicating approval by the Institutional Review Board, is enclosed for your files.

Forms for progress reports, final reports, modification and adverse/unexpected event are available on the IRB website or in the Research Office (CFP-Bsmt). Please contact the Research Office at 916-2024 if you have questions regarding these matters.

New Protocol Application

Institutional Review Board

All submissions must be complete and typewritten.
Investigators are responsible for utilizing the most current versions of IRB forms and the IRB has the authority to refuse out of date forms.

RECEIVED
APR 17 2009
RESEARCH ADMINISTRATION

Section 1: GENERAL INFORMATION

HFHS Principal Investigator (PI): **Gwen Alexander** Department (select from drop downs): **BRE** Division:
Phone or pager: **873-6737** PI E-mail address:**galexan2@hfhs.org**
Are you employed by HFHS or a HFH Medical Group physician?
☒ Yes ☐ No (if not, you will need to contact Research Administration for assistance)
Entire Project Title (no acronyms): **Automated Self-Administered 24-hour Recall Comparison Study**
Contact Person: **Gwen Alexander** Contact phone #: **874-6737** Contact E-mail address:**galexan2@hfhs.org**
Location to send correspondence or pick-up (required):**OFP, 5C**
Grant title & Project Director (if different):
Sponsor/Funding source (name of agency, company, NIH or internal committee): **National Cancer Institute**
Is this study PI initiated (the original idea of the HFHS PI)? ☐ Yes ☒ No
Is this study federally funded (if so, attach grant proposal)? ☒ Yes ☐ No Date submitted to funding agency: **Not yet submitted, awaiting funding commitment within NCI**
If sponsor's grant number known, please supply: Unknown; will be a contract Multi-center study? ☒ Yes ☐ No
Performance Sites:☐Cottage ☐Detroit/Main ☐Macomb ☐W. Bloomfield ☐Wyandotte ☒All ☐ Other:
Research conducted:☐ Inpatient ☐ Outpatient ☐ In & Outpatient ☐ No direct patient contact ☒ Other: **Three sites, Kaiser Permanente NW, Marshfield Clinic in Danville, PA, and HFMG/HAP members**
What is submitted with this application?: ☒ Protocol (version # **1**) ☐ Investigator Brochure (version #) ☒ Consent Form (version) Other documents: **study protocol, screening questionnaire, preference questionnaire, demographic questionnaire, recruitment letter, website welcome/agreement page**

THE REST OF THIS PAGE IS FOR IRB USE ONLY

IRB #:5623

Review Type:
☐ Full Board
☒ Expedited: meets category/s [45 CFR 46.110(a)(b)]: 7
  ☒ Approve
  ☐ Withheld pending response:
    ☐ member review ☐ administrative review
  ☐ Expedited approval denied (requires full board review)
☐ Exempt: meets category/s [45 CFR 46.101(b)]:

Consent/patient authorization:
☒ Required ☐ Waived

APPROVAL STAMP
APPROVAL PERIOD
JUN 05 '09 JUN 04 '10
Institutional Review Board

The HFHS IRB has read & reviewed this protocol & finds this research is appropriate in design and meets the requirements of the Federal Guidelines, 45 CFR Part 46 and 21 CFR Part 50.

_____ Date: 6/5/2009