Attachment 12: Phase IV Buccal Cell IRB Approval Signature Pages

12.1) Phase IV IRB NCI

12.2) Phase IV Westat

12.3) Phase IV University of Iowa (Phase IV Cohort)

Department of Health & Human Services

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

iRIS Reference Number 354519

IRB Number: OH93NCN013
Study Status: Open - No Longer Recruiting - Follow-up Only
Expiration Date: 02/06/2017

01/14/2016

TO: Laura Beane Freeman
NCI - Occupational and Environmental Epidemiology Branch

FROM: Chairperson, Special Studies Institutional Review Board, NCI

SUBJECT: Action on Clinical Research Protocol

Your Continuing Review of, "The Main Agricultural Health Study - A Prospective Study of Cancer and Other Diseases among Men and Women in Agriculture," was reviewed by the National Cancer Institute Special Studies Institutional Review Board (NCI-SSIRB) by expedited review and approved on 01/14/2016.

The SSIRB has taken the following action:

X	Approved. Forwarded for administrative processing by OPS, Clinical Center.
	Approved with stipulations pending re-review by SSIRB Chair. See review.
	Deferred pending response to stipulations and re-review by the full SSIRB. See review.
	Disapproved. See review.

Kate Torres

From: Marsha Dunn
Sent: Wednesday, January 06, 2016 12:59 PM
To: Kate Torres; Amy Miller
Subject: FW: IRB Continuing Approval Letter for Project 8970

From: Institutional Review Board
Sent: Wednesday, January 06, 2016 11:46 AM
To: Marsha Dunn
Cc: Doris Ryba; Institutional Review Board; Alicia Sutherland
Subject: IRB Continuing Approval Letter for Project 8970

Westat | An Employee-Owned Research Corporation

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Rockville, MD 20850-3129
tel: 301-251-1500
fax: 301-294-2040
www.westat.com

DATE: January 6, 2016

TO: Marsha Dunn

FROM: Kerry Levin
Chair, Institutional Review Board

SUBJECT: IRB Continuing Review and Approval
Project Name: AGR HEALTH STUDY PHASE iV
Project: 8970
FWA 00005551

On January 5, 2016, the Westat IRB Continuing Review Committee conducted its continuing review of the following: AGR HEALTH STUDY PHASE iV, Project # 8970. Pursuant to 45 CFR pt 46.109(e), continuing review of research studies occurs at intervals appropriate to the degree of risk but not less frequently than once a year.

In accordance with 45 CFR pt 46, the Board approved the continuation of this study. The next continuing review will be due on or before January 5, 2017. In the interim, you are responsible for notifying the Institutional Review Board (IRB) Office as soon as possible if there are any injuries to the subjects, problems with the study, or changes to study design that relate to human subjects.

cc: Institutional Review Board - Sharon Zack

THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
105 Hardin Library for the Health Sciences
600 Newton Road
Iowa City, Iowa 52242-1098
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 199206325

To: Charles Lynch

From: IRB-01 DHHS Registration # IRB00000099,
Univ of Iowa, DHHS Federalwide Assurance # FWA00003007

Re: A PROSPECTIVE COHORT STUDY OF CANCER AMONG MEN AND WOMEN IN AGRICULTURE (FIELD STATIONS)

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 01/07/16

Next IRB Approval Due Before: 01/06/17

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
☐ New Project	☐ Full Board:	☐ Children
☒ Continuing Review	Meeting Date:	☐ Prisoners
☐ Modification	☒ Expedited	☐ Pregnant Women, Fetuses, Neonates
	☐ Exempt	

Source of Support: US Department of Health & Human Services, National Institutes of Health

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

This approval has been electronically signed by IRB Chair:
Brian Bishop, CIP, MA
01/07/16 1523

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.) If hospital/clinic patients are being enrolled, a copy of the IRB approved Record of Consent form should be placed in the subject's electronic medical record.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.