Attachment 12: Phase IV Buccal Cell IRB Approval Signature Pages

12.1). Phase IV IRB NCI

12.2). Phase IV IRB Westat

12.3). Phase IV IRB University of Iowa

Department of Health & Human Services

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

iRIS Reference Number ***320597***

Amendment Letter: B
IRB Number: OH93NCN013
Version Date: 02/15/2012

06/07/2012

TO: Michael Alavanja
NCI - Occupational and Environmental Epidemiology Branch

FROM: Chairperson, Special Studies Institutional Review Board, NCI

SUBJECT: Action on Clinical Research Protocol Amendment

Your amendment to protocol, "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.

The SSIRB has taken the following action:

X	Approved as written. Forwarded to the CC OPS for administrative processing.
	Approved with stipulations pending re-review by SSIRB Chair. See review comments.
	Deferred pending response to stipulations and re-review by a subcommittee of the Board. See review comments.
	Tabled pending response to stipulations and re-review by the full SSIRB. See review comments.

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AMENDMENT REVIEW FORM

(TO ADD OR CHANGE PREVIOUSLY APPROVED RESEARCH)

All changes or new activities for previously approved studies require submission, review and approval of an Amendment Request. Please complete and submit this form to irb@westat.com and attach all necessary materials to be reviewed. Once reviewed, you will be contacted. If this change or new activity requires a full Board review, those meetings occur on the second Tuesday of every month. To check the date of meetings, please see the meeting schedule under IRB in WesInfo. Thank you for your cooperation.

1. **Today's Date:** 03 / 26 / 2012

Date of Original Approval: 00 / 00 / 2008

Project Name: The Agricultural Health Study

Westat Project Number: 8970. .

Agency Grant or Contract Number: HHSN261201100017C

Project Director: Marsha Dunn **Ext.** 3557

Unit Ops Number/Study Area: 1.21.72

Area IRB Rep: Nancy Weinfield

2. **Indicate the type of addition or change being requested to a previously approved study.**
(SELECT ALL THAT APPLY.)

- ☐ Name (s) of investigators
- ☐ Project Number
- ☐ Introduction of a new IRB or request for Westat to serve as the IRB
- ☐ Study design, survey questionnaire or procedure (s)
- ☒ Informed consent process, consent form (s), parent permission (s), or assent form (s)
- ☒ Recruitment materials or strategies
- ☐ Incentives
- ☐ Survey instruments
- ☐ Number or type of populations studied
- ☐ Review of final instrument such as interview questions or data collection sites for a previously approved study
- ☐ Mode of administration of instruments in your study (e.g., from mail or telephone to web or Internet access)
- ☐ Data access rights
- ☐ Any other change in protocol that affects treatment of human subjects:
(PLEASE SPECIFY)

IRB Office Only

APPROVED – NEXT CONTINUING REVIEW DATE: _____

CONDITIONAL APPROVAL (PLEASE SEE ATTACHED LETTER)

DID NOT QUALIFY FOR EXPEDITED REVIEW

3. **Please provide a brief summary of your change or addition to previously approved research.**

In Phase IV we will continue the Phase III buccal collection protocol, which requests buccal specimens from selected cancer cases. Westat will contact the North Carolina cohort and the University of Iowa (subcontractor), the Iowa cohort. Westat will coordinate. See also attached.

4. **How does each change or addition affect the risks to participants in your study?** ***(PLEASE SELECT ONLY ONE.)***

a. (No change)

b. N/A – no risks

c. Decreases the risk (***SPECIFY):***

d. Increases the risk (***SPECIFY):***

e. Adds a new risk (***SPECIFY):***

SIGNATURE – Sign here or deliver through electronic email from your computer.

The information provided in this request form is complete and correct.

Project Director/Principal Investigator: Marsha Rosa **Date:** 3/26/2012

Please attach:

- One document that clearly identifies (through track changes, highlights, or italics) the revision in the previously approved submission.
- Another document labeled "corrected version."

If you have any questions, feel free to contact Sharon Zack, IRB Administrator, at ext. 8828.

IRB Administration Use Only

Expedited review and approval for the modification(s) on this form:

IRB Chair / Associate Chair / Designee Date

IRB Office Only

APPROVED – NEXT CONTINUING REVIEW DATE: _____

CONDITIONAL APPROVAL (PLEASE SEE ATTACHED LETTER)

DID NOT QUALIFY FOR EXPEDITED REVIEW

D858900

OMB No. 0990-0263

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

201202812

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency, or organization, and, if known, Application or Proposal Identification No.
☒ ORIGINAL ☐ CONTINUATION ☐ EXEMPTION	☐ GRANT ☒ CONTRACT ☐ FELLOWSHIP ☐ COOPERATIVE AGREEMENT ☐ OTHER:_____	US Department of Health & Human Services, National Institutes of Health//Westat, Inc. 8970-S01
4. Title of Application or Activity AHS Phase IV Buccal Cell Collection		5. Name of Principal Investigator, Program Director, Fellow, or Other Charles Lynch

6. Assurance Status of this Project *(Respond to one of the following)*

☒ This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. FWA00003007, the expiration date 11/08/2013 IRB Registration No. IRB00000099

☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph .

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

☒ This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: ☐ Full IRB Review -- date of IRB meeting: or ☒ Expedited Review
Approval Date: 03/28/12
Expiration Date: 03/28/13

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

Contract Title: The Agricultural Health Study (AHS) Phase IV

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution The University of Iowa Human Subjects Office Office of the Vice President for Research 340 Medicine Administration Bldg The University of Iowa Iowa City, IA 52242-1101
11. Phone No. *(with area code)* 319-335-6564 12. Fax No. *(with area code)* 319-335-7310 13. Email: James-walker@uiowa.edu	
14. Name of Official James C Walker, PhD	15. Title Associate Vice President for Research - Regulatory Affairs
16. Signature James C Walker	17. Date 03/28/12

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