ATTACHMENT 12

IRB Approvals for AHS Phase III

12A. Phase III NCI IRB (2009 approval attached. Application was re-submitted in March 2010. New approval will be attached upon receipt.)

12B. Phase III IRB Westat, the Coordinating Center for the Study

12C. Phase III IRB University of Iowa Field Station - Iowa (includes separate approvals for Main Study, Phase III, and Prostate Buccal Collection)

12D. Phase III IRB Batelle Centers for Public Health Research and Evaluation - North Carolina

5/7/09

CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION	PROTOCOL NO. OH93-NC-NO13	PRINCIPAL INVESTIGATOR (NIH Employee Name, Inst/Br, Address, Telephone and email): Michael Alavanja and Laura Beane Freeman, NCI/DCEG/OEEB301-435-4720

PROTOCOL TITLE:

A prospective study of cancer and other disease among men and women in agricultural (i.e., the Agricultural health Study)

PROTOCOL STATUS:
- ☐ Renew -Recruitment of participants has not yet begun.
- ☐ Renew -Participants are currently being recruited or enrolled.
- ☒ Renew -No longer recruiting or enrolling participants, subject follow-up only.
- ☐ Renew -Participants have completed study; study and data analyses ongoing.
- ☐ Renew -Clinical Hold/Recruitment or enrollment of participants suspended.
- ☐ Terminate -Study closed. Participants have completed study. Recruitment and data analysis complete.

SUMMARY OF PROTOCOL ENROLLMENT (Aggregate): Only when the NIH is the coordinating site, provide totals and enrollment table for other site.

NIH Site	Other Sites	Total	
0	90,500	90,500	Accrual ceiling by IRB
0	0	0	New subjects accrued since last CR
0	89,658	89,658	Aggregate total accrued

Are you currently recruiting healthy volunteers? ☒ No ☐ Yes
Will the protocol involve adults unable to give informed consent? ☒ No ☐ Yes

Have analyses by sex, racial/ethnic subgroups been conducted for Phase 3 Clinical Trials as required? ☐ No ☐ Yes (answer a and b) ☒ N/A
a. Have analyses been reported? ☐ No (explain in narrative) ☐ Yes
b. Have significant differences been found? ☐ No ☐ Yes

Have any non-NIH Investigators or sites been added since the last review?
☒ No
☐ Yes (Identify the persons or sites and describe the collaboration in the summary report)

WITH THIS REVIEW, I AM REQUESTING A CHANGE TO THE FOLLOWING:
*Include Name, Inst/Branch, Telephone, Address, e-mail. Check box if an NIH Employee and initial line. Attach sheet if necessary.

PRINCIPAL INVESTIGATOR:
Delete: Laura Beane Freeman
Add*: ☒ Co-principal investigator

EXTRAMURAL ADJUNCT PRINCIPAL INVESTIGATOR:
Delete: _____
Add: _____

MEDICAL ADVISORY INVESTIGATOR:
Delete: _____
Add*: _____

LEAD ASSOCIATE INVESTIGATOR:
Delete: _____
Add*: ☐ _____

RESEARCH CONTACT:
Delete: _____
Add*: ☐ _____

ASSOCIATE INVESTIGATOR(S):
Delete: _____
Add*: ☐ _____

IONIZING RADIATION USE (X-rays, e.g., CT; radioisotopes, e.g. PET, etc.) check all that apply:
- ☒ None
- ☐ Medically indicated
- ☐ Research indicated. Since the last review,
  - ☐ Research usage HAS NOT changed.
  - ☐ Research usage HAS changed. (Explain in summary report)

INVESTIGATIONAL NEW DRUG/DEVICE: ☒ None ☐ IND ☐ IDE
*If reporting more than one IND/IDE, list on attached sheet.

FDA No. _____
Name: _____
Sponsor: _____
Who is the manufacturer of the above entity? _____

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

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

Have there been any amendments since the last review?
☒ No
☐ Yes (Describe briefly in the attached narrative.)

Have there been any changes in the informed consent process or documentation since the last review?
☒ No
☐ Yes (Describe in Summary report)

Have there been any changes in the subject population, recruitment or selection criteria since the last review?
☒ No
☐ Yes (Explain changes in the attached narrative.)

Have any unexpected complications or side effects been noted since the last review?
☒ No
☐ Yes (Identify and explain in the attached narrative.)

Have any subjects withdrawn from this study since the last IRB approval?
☒ No
☐ Yes (Discuss in the attached narrative.)

Has any information appeared in the literature, or evolved from this or similar research, that might affect the IRB's evaluation of the risk/benefit analysis of human subjects involved in this protocol?
☒ No
☐ Yes (Discuss in the attached narrative.)

Has the NIH IRP COI Guide been distributed to new NIH investigators?
☐ No ☐ Yes ☒ N/A

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

CONFLICTS OF INTEREST REVIEW?
Date submitted to IC DEC: 3/6/09 Date cleared by IC DEC: 3/27/09

SIGNATURE	Principal Investigator	M Alavanja& L Beane Freeman Print/Type Name	Date 3/30/2009	Send to Accountable Investigator
RECOMMENDATION	Accountable Investigator	M. Alavanja Print/Type Name	Date 3/30/2009	Send to Branch Chief, or CC Dept. Head of Accountable Investigator
Expedited	Br Chief/CC Dept. Head of Acct. Invest.	Debra Silverman Print/Type Name	Date 3/31/2009	Send to Clinical Director
APPROVALS	Clinical Director	Print/Type Name	Date 5/4/09	Send to Chair, Institutional Review Board
	Chair, For Institutional Review Board	Nancy Potischman Print/Type Name	Date 4/29/09	Send to Office of Protocol Services, through IRB Protocol Coordinator
COMPLETION	Protocol Specialist	Date 5-7-09	Protocol & Consent Approved Effective	

From: Marsha Dunn
Sent: Tuesday, August 18, 2009 10:46 AM
To: Kate Torres
Subject: FW: IRB Continuing Approval Letter for Project #7874

fyi

From: Carol Dollarhide
Sent: Friday, August 14, 2009 4:29 PM
To: Marsha Dunn
Subject: FW: IRB Continuing Approval Letter for Project #7874

Westat | An Employee-Owned Research Corporation

1600 Research Boulevard
Rockville, MD 20850-3129
tel: 301-251-1500
fax: 301-294-2040
www.westat.com

DATE: August 14, 2009

TO: Marsha Dunn
Project Director

FROM: Kerry Levin
Chair, Institutional Review Board

SUBJECT: IRB Continuing Review and Approval
Agricultural Health Study (AHS)
Project #: 7874
FWA 5551

On August 12, 2009, the Westat Institutional Review Board conducted its continuing review of the following: Agricultural Health Study (AHS), Project #: 7874. 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 August 1, 2010. 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

Fb

THE UNIVERSITY OF IOWA

Human Subjects Office
340 Medicine Administration Building
Iowa City, Iowa 52242-1101
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 199206325

To: Charles Lynch

From: IRB-01 Univ of Iowa, DHHS Registration # IRB00000099, 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: 11/03/09

Next IRB Approval Due Before: 11/03/10

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:
William Hubbard, CIP, MA
11/03/09 1429

D153500

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.

199206325

1. Request Type
☐ ORIGINAL
☒ CONTINUATION
☐ EXEMPTION

2. Type of Mechanism
☐ GRANT ☒ CONTRACT ☐ FELLOWSHIP
☐ COOPERATIVE AGREEMENT
☐ OTHER:_____

3. Name of Federal Department or Agency, or organization, and, if known, Application or Proposal Identification No.
US Department of Health & Human Services, National Institutes of Health
HHSN261200455003C Mod. 16

4. Title of Application or Activity
A PROSPECTIVE COHORT STUDY OF CANCER AMONG MEN AND WOMEN IN AGRICULTURE (FIELD STATIONS)

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 01/26/2010 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: 11/03/09
Expiration Date: 11/03/10

☐ 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 - Iowa Field Station

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.

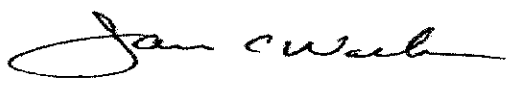
10. Name and Address of Institution
The University of Iowa
Human Subjects Office
Office of the Vice President for Research
340 Medicine Administration Bldg
The University of Iowa
Iowa City, IA 52242-1101

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



17. Date
11/03/09

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THE UNIVERSITY OF IOWA

Human Subjects Office
340 Medicine Administration Building
Iowa City, Iowa 52242-1101
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 200503790

To: Charles Lynch

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

Re: Phase III Main Study of the Agricultural Health Study

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

Approval Date: 12/01/09

Next IRB Approval Due Before: 12/01/10

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
US Department of Health & Human Services, Centers for Disease Control & Prevention

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:
William Hubbard, CIP, MA
12/01/09 0936

D153500

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.

200503790

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 HHSN261200455003C Mod. 16

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other
Phase III Main Study of the Agricultural Health Study	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 01/26/2010 IRB Registration No. IRB00000099

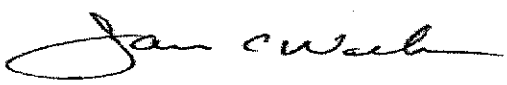
☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph .

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: 12/01/09
Expiration Date: 12/01/10

☐ 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 - Iowa Field Station

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
11. Phone No. *(with area code)* 319-335-6564 12. Fax No. *(with area code)* 319-335-7310 13. Email: James-walker@uiowa.edu	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
14. Name of Official James C Walker, PhD	15. Title Associate Vice President for Research - Regulatory Affairs
16. Signature 	17. Date 12/01/09

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THE UNIVERSITY OF IOWA

Human Subjects Office
340 Medicine Administration Building
Iowa City, Iowa 52242-1101
319-335-6564 *Fax* 319-335-7310
irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 200612708

To: Charles Lynch

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

Re: A NESTED CASE-CONTROL, MOLECULAR EPIDEMIOLOGY STUDY OF PROSTATE CANCER IN THE AGRICULTURAL HEALTH STUDY COHORT

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

Approval Date: 11/08/09

Next IRB Approval Due Before: 11/08/10

Type of Application:

☐ New Project
☒ Continuing Review
☒ Modification
Fetuses, Neonates

Type of Application Review:

☐ Full Board:
Meeting Date:

☐ Exempt

Approved for Populations:

☐ Children
☐ Prisoners
☒ Expedited
☐ Pregnant Women,

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:
William Hubbard, CIP, MA
11/08/09 2026

D153500

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.

200612708

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 HHSN261200455003C Mod. 16

4. Title of Application or Activity	5. Name of Principal Investigator, Program Director, Fellow, or Other
A NESTED CASE-CONTROL, MOLECULAR EPIDEMIOLOGY STUDY OF PROSTATE CANCER IN THE AGRICULTURAL HEALTH STUDY COHORT	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 01/26/2010 IRB Registration No. IRB00000099

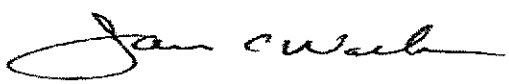
☐ Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph .

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: 11/08/09
Expiration Date: 11/08/10

☐ 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
Grant Title: The Agricultural Health Study - Iowa Field Station

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
11. Phone No. *(with area code)* 319-335-6564 12. Fax No. *(with area code)* 319-335-7310 13. Email: James-walker@uiowa.edu	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
14. Name of Official James C Walker, PhD	15. Title Associate Vice President for Research - Regulatory Affairs
16. Signature 	17. Date 11/08/09

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February 1, 2010

Charles E. Knott, MPA, PMP
Battelle CPHRE
100 Capitola Drive, Suite 200
Durham, NC 27713

Dear Mr. Knott:

As Chair of the Battelle/CPHRE Institutional Review Board (IRB) I have reviewed the continuing review submission dated 1/24/2010 for the study entitled "The Agricultural Health Study – Field Stations" (FG004905-Y102) and grant expedited approval to continue with this study. The study is minimal risk and no problems have been reported.

As with all Battelle/CPHRE studies, this study will be subject to continuing review again next year if it is still active. The current approval expires 1/31/2011. We will send you notification at the appropriate time. In the meantime, should any changes occur in your protocol or questionnaire, please inform the IRB and submit the changes for review. Similarly, the IRB needs to be notified in the event of any injury or unexpected outcome arising from this study.

Sincerely,

Margaret Penny Backer

Margaret R. Pennybacker, PhD
IRB Chair

cc: Brigette Brevard
Contracts
Jan Jaeger

Battelle/Centers for Public Health Research and Evaluation

100 Capitola Drive, Suite 200
Durham, NC 27713
Federal-wide Assurance No. FWA00004696 (IRB No. 284)

INSTITUTIONAL REVIEW BOARD NOTICE OF APPROVAL

PROJECT DIRECTOR: Charles Knott

PROJECT TITLE: The Agricultural Health Study – Field Stations

CLIENT: NCI

PROTOCOL DATE: 1/24/10

BATTELLE PROJECT CODE: FG004905-Y102

or PROPOSAL NUMBER: _ *(if preaward)*

NATURE OF REVIEW: *(check one)*

- [ ] FULL MEETING DATE: _____
- [X] EXPEDITED *(specify reason)*: no problems; minimal risk
- [ ] EXEMPT *(specify reason)*: _____

TYPE OF APPROVAL: *(check one)*

- [ ] PRELIMINARY. SCHEDULE NEXT REVIEW PRIOR TO INVOLVEMENT OF HUMAN SUBJECTS.
- [ ] PRETEST/PILOT TEST. SCHEDULE NEXT REVIEW PRIOR TO FULL IMPLEMENTATION.
- [ ] FULL IMPLEMENTATION.
- [X] RENEWAL/CONTINUING REVIEW.
- [ ] AMENDMENT DATED

Please note the following requirements:

PROBLEMS OR ADVERSE REACTIONS: If any problems in treatment of human subjects or unexpected adverse reactions occur as a result of this study, you must notify the IRB Chairperson immediately, then complete an Adverse Event/Incident Report and forward it to the CPHRE IRB Administrator.

CHANGES IN PROTOCOL: If there are any changes in procedures or study protocol, you must notify the IRB Chairperson and submit the revisions for review before they are implemented.

RENEWAL: You are required to apply for renewal of approval at least annually for as long as the study is active unless the Board finds it necessary to require more frequent reviews. Your next continuing review date should be on or before 1/31/11.

Margaret Pennybacker — 2/1/2010

IRB Chairperson — Date

Margaret R. Pennybacker, PhD
Print or Type Name

__X__ Copy of approved Informed Consent on file.

cc: Project Director
IRB Administrator