

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 <input type="checkbox"/> ORIGINAL <input checked="" type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input checked="" type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> 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
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: 12/18/07
 Expiration Date: 12/17/08
- 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: Agricultural Health Study Field Station - 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. (<i>with area code</i>)	319-335-6564	
12. Fax No. (<i>with area code</i>)	319-335-7310	
13. Email:	richard-hichwa@uiowa.edu	
14. Name of Official Richard D. Hichwa, PhD		15. Title Associate Vice President for Research
16. Signature 		17. Date 12/18/07

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Human Subjects Office

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Iowa City, Iowa 52242-1101
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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: 12/18/07

Next IRB Approval Due Before: 12/17/08

Type of Application:

- New Project
- Continuing Review
- Modification

Type of Application Review:

- Full Board:
Meeting Date:
- Expedited
- Exempt

Approved for Populations:

- Children
- Prisoners
- Pregnant Women, Fetuses, Neonates

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:
Martha Jones, CIP, MA
12/18/07 0821