

## **06.3 HHS PIA Summary for Posting (Form) / NIH NCI Agricultural Health Study --Westat (AHSW)**

### **PIA SUMMARY AND APPROVAL COMBINED**

#### ***PIA Summary***

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 7/29/2011

**2. OPDIV Name:** NIH

**3. Unique Project Identifier (UPI) Number:** No

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-25-0200

**5. OMB Information Collection Approval Number:** 0925-0406

**6. Other Identifying Number(s):** AHSW

**7. System Name (Align with system Item name):** NIH NCI Agricultural Health Study - Westat (AHSW)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Michael Alavanja / Stanley Legum

**10. Provide an overview of the system:** The Agricultural Health Study is a collaborative effort involving the National Cancer Institute (NCI), the National Institute of Environmental Health Sciences (NIEHS), and the U.S. Environmental Protection Agency (EPA). The study has four major components:

1. The main prospective cohort study - cancer and non-cancer outcomes
  - a. linkage with cancer registries, vital statistics, United States Renal Data System (USRDS)
  - b. ongoing data collection (i.e., telephone interview, food frequency questionnaire and cheek cell collection)
2. Cross-sectional studies - including questionnaire data, functional measures, biomarkers, and GIS
3. Nested case-control studies
4. Exposure assessment and validation studies

The cohort includes 89,658 private pesticide applicators, spouses of private applicators, and commercial pesticide applicators recruited within Iowa and North Carolina. Phase I, initial cohort recruitment, began in 1993 and concluded in 1997. Phase II follow-up began in 1999 and concluded in 2003. The Phase III follow-up began in 2005 and concluded in February 2010. Phase I observation involved administration of a questionnaire to obtain information on pesticide use, other agricultural exposures, work practices that modify exposures, and other activities that

may affect either exposure or disease risks (e.g. diet, exercise, alcohol consumption, medical conditions, family history of cancer, other occupations, and smoking history). Phase II had three data collection components: a computer-assisted telephone interview (CATI), buccal cell collection, and a mailed dietary questionnaire. Phase II interviews are designed to record updated information on pesticide use since enrollment, current farming and work practices, and changes in health status. In addition, the Dietary Health Questionnaire in Phase II makes a detailed evaluation of subjects' cooking practices and dietary intake. The buccal cell collection of Phase II was implemented to assess the impact of genetic risk factors on epidemiologic outcomes. Phase III included two data collection components: a CATI interview and a buccal cell collection for selected members of the cohort. In addition to Phase II and Phase III data collection activities that include the whole cohort, a series of sub-studies involving a small number of study participants will directly measure applicator and family member exposures to selected pesticides and/or focus in greater detail on subgroups with specific diseases or exposures.

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):** Information Management Services (IMS - separately contracted by NCI - performs data analyses for NCI) National Death Index (NDI) - Annual match with NDI Plus files. Internal Revenue Service - to obtain updated address information. This system is also covered under the Privacy Act System of Records Notice 09-25-0200.

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** AHS analytic data files do not contain direct identifiers such as name, address, or SSNs. PII is shared with NDI and the IRS when we are performing matches to NDI and IRS files. Contact information (name, address, phone number) are stored in anticipation of use in future substudies, cohort maintenance purposes (e.g., possible mailings of study update newsletters), and matching with state and national vital statistics and health registries.

The AHS has four major components:

1. Main prospective cohort study - cancer and non-cancer outcomes
  - a. linkage with cancer registries, vital statistics, United States Renal Data System (USRDS)
  - b. data collection (i.e., telephone interview, food frequency questionnaire and cheek cell collection (no longer on-going))
2. Cross-sectional studies - including questionnaire data, functional measures, biomarkers, and GIS
3. Nested case-control studies
4. Exposure assessment and validation studies

There were also a series of sub-studies involving a small number of study participants that directly measured applicator and family member exposures to selected pesticides and/or focus in greater detail on subgroups with specific diseases or exposures. Additional substudies may be conducted in the future.

Participation is voluntary.

PII collected and maintained include name, date of birth, social security number, mailing address, phone number, and pesticide application certificate types.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

**(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]**) There have been no major changes in the system and none are contemplated. Our IRB would review any major changes prior to implementation and provide us with guidance on any needed notification and consent requirements.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:** No

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):** Yes

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Extensive safeguards are in place to ensure the confidentiality of each subject is protected. Each subject is assigned a six-digit number; these IDs are used for any references to subjects on an individual basis. Names and other identifying information are kept in a separate database from the analytic files. These data are joined only for performing linkages to the mortality and cancer incidences databases and for

direct contacts with cohort members to inform them of study progress or to request their participation in substudies. Several layers of passwords exist to ensure unauthorized access to electronically stored data is not permitted. Hard copies of questionnaires that contain any personal information have been shredded. Informed consent forms, which contain subjects' names and study IDs are stored in a secure facility separate from other study data. All personnel involved with the project have signed confidentiality agreements.

Files with PII are stored in a directory accessible only to the project's lead systems manager and one programmer. Data stored in the SQL Server contact database are protected with application level security and an additional password. Data stored in other file formats are encrypted when not in use and the encryption key is known only by the same two staff members. The files are never left in unencrypted form over night so that automatic backups contain only encrypted versions.

The system is protected by firewalls, intrusion detection systems, and passwords. There are comprehensive system security and contingency plans in place. An Incident Response capability is maintained.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Suzy Milliard

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Karen Plá

**Sign-off Date:** 9/30/2011

**Approved for Web Publishing:** Yes

**Date Published:** May 23, 2012

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### **06.3 HHS PIA Summary for Posting (Form) / NIH NIEHS NCI Agricultural Health Study (AHS)**

#### **PIA SUMMARY AND APPROVAL COMBINED**

##### ***PIA Summary***

**Is this a new PIA 2011?** No

**If this is an existing PIA, please provide a reason for revision:** PIA Validation

**1. Date of this Submission:** 9/22/2011

**2. OPDIV Name:** NIH

**3. Unique Project Identifier (UPI) Number:** N/A

**4. Privacy Act System of Records (SOR) Number (If response to Q.21 is Yes, a SORN number is required for Q.4):** 09-25-0200, Clinical, Epidemiologic, and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD

**5. OMB Information Collection Approval Number:** 0925-0406

**6. Other Identifying Number(s):** AHSW

**7. System Name (Align with system Item name):** NIH NIEHS NCI Agricultural Health Study (AHS)

**9. System Point of Contact (POC). The System POC is the person to whom questions about the system and the responses to this PIA may be addressed:** Novie Beth Ragan

**10. Provide an overview of the system:** The Agricultural Health Study system of records collects clinical and epidemiological data on health volunteer persons who are part of the Agricultural Health Study cohort, for the purpose of scientific analysis and publication of epidemiological research. AHS is a collaborative effort involving the National Cancer Institute (NCI), the National Institute of Environmental Health Sciences (NIEHS), and the U.S. Environmental Protection Agency (EPA).

**13. Indicate if the system is new or an existing one being modified:** Existing

**17. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system? (Note: This question seeks to identify any, and all, personal information associated with the system. This includes any PII, whether or not it is subject to the Privacy Act, whether the individuals are employees, the public, research subjects, or business partners, and whether provided voluntarily or collected by mandate. Later questions will try to understand the character of the data and its applicability to the requirements under the Privacy Act or other legislation. Does/Will the system collect, maintain (store), disseminate and/or pass through PII within any database(s), record(s), file(s) or website(s) hosted by this system?):**  
Yes

**21. Is the system subject to the Privacy Act? (If response to Q.19 is Yes, response to Q.21 must be Yes and a SORN number is required for Q.4):** Yes

**23. If the system shares or discloses IIF please specify with whom and for what purpose(s):**  
Disclosure of AHS PII:

National Death Index (NDI) - Annual match with NDI Plus files.

Internal Revenue Service - to obtain updated address information - now stored at Westat (for NCI); will be stored at coordinating center (TBA) for AHS Phase IV (for NCI).

Information Management Services - IMS - separately contracted by NCI - performs data analyses for NCI using analytic datasets. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NCI, NIEHS, EPA.

<Names, addresses and phone numbers of research subjects are not stored in analytic databases, records or files hosted at NIH, NIEHS, NCI or EPA. IIF information is not shared on research participants, except date of birth, which is used for scientific research analysis purposes only>

Westat – separately contracted by NCI – currently holds the full AHS participant contact database, including date of birth as well as other personal identifying information for all AHS participants – and handles all direct interactions with Iowa and North Carolina participants for NCI studies within the AHS.

Upon award of the AHS Phase IV Coordinating Center Contract, anticipated by September 30, 2011, the successful offeror will take over the AHS participant contact database.

Westat - separately contracted by NIEHS – performs data analyses for NIEHS. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NIEHS.

<Names, addresses and phone numbers of research subjects are not stored in analytic databases, records or files hosted at NIH, NIEHS, NCI or EPA. IIF information is not shared on research participants, except date of birth, which is used for scientific research analysis purposes only>

Social and Scientific Systems - SSS – separately contracted by NIEHS – handles all direct interactions with AHS participants in NIEHS substudies only: namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study.

Names, addresses and phone numbers of AHS NIEHS add-on research subjects are stored in secure and locked databases, records and / or files hosted at Social and Scientific Systems (SSS).

This system is also covered und the Privacy Act System of Records Notice 09-25-0200.

North Carolina Field Station - Battelle CPRHE, Durham, NC - separately contracted by NCI - handles all direct interactions with NC participants.

National Death Index (NDI) - Annual match with NDI Plus files.

Internal Revenue Service - to obtain updated address information which is stored at the field stations.

<Names, addresses and phone numbers of research subjects are not stored in analytic databases, records or files hosted at NIH, NIEHS, NCI or EPA. IIF information is not shared on research participants, except date of birth, which is used for scientific research analysis purposes only>

Information Management Services - IMS - separately contracted by NCI - performs data analyses for NCI using analytic datasets. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NCI, NIEHS, EPA.

Westat - separately contracted by NIEHS – performs data analyses for NIEHS. Analytic Data (including date of birth, but not including other personal information) are shared among members of the AHS research team at NIEHS.

Iowa Field Station - University of Iowa - separately contracted by NCI - handles all direct interactions with Iowa participants.

North Carolina Field Station - Battelle CPRHE, Durham, NC - separately contracted by NCI - handles all direct interactions with NC participants.

National Death Index (NDI) - Annual match with NDI Plus files.

Internal Revenue Service - to obtain updated address information which is stored at the field stations.

<Names, addresses and phone numbers of

**30. Please describe in detail: (1) the information the agency will collect, maintain, or disseminate; (2) why and for what purpose the agency will use the information; (3) in this description, explicitly indicate whether the information contains PII; and (4) whether submission of personal information is voluntary or mandatory:** AHS analytic data do not contain direct identifiers such as name, address, or SSNs.

The NCI shares PII with NDI and the IRS when performing matches to the NDI and IRS files. Contact information (name, address, phone number) for full cohort is stored at NCI contractor Westat in anticipation of use in future substudies, cohort maintenance purposes (e.g., possible mailings of study update newsletters), and matching with state and national vital statistics and health registries.

Upon award of AHS Phase 4 contract, AHS contact information for full cohort will be stored at the NCI Coordinating Center.

Participation is voluntary; full and open consent is required before information is collected.

The AHS system collects a wide variety of clinical information including pesticide application histories, medical histories, health information, exposure measurements from field instruments, and questionnaire data.

All IIF (except date of birth) on full cohort research subjects is kept at the Westat (NCI contractor) sites and are not available to investigators.

All IIF (except date of birth) on the sub-sets of AHS cohort research subjects who are participants in NIEHS sub-studies ( namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) are kept at SSS (NIEHS contractor) sites and are not available to investigators.

PII collected and maintained on all AHS participants includes name, date of birth, social security number, mailing address, phone number, and pesticide application certificate types.

PII collected, maintained, and updated for NIEHS sub-studies ( namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) for AHS participants includes name, date of birth, social security number, mailing address, phone number, and pesticide application certificate types.

Monthly updates to AHS addresses, phone numbers and other PII collected by SSS for NIEHS sub-studies ( namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) are sent via encrypted transmissions to Westat (NCI contractor) to update the full AHS cohort data on a monthly basis.

**31. Please describe in detail any processes in place to: (1) notify and obtain consent from the individuals whose PII is in the system when major changes occur to the system (e.g., disclosure and/or data uses have changed since the notice at the time of the original collection); (2) notify and obtain consent from individuals regarding what PII is being collected from them; and (3) how the information will be used or shared.**

(Note: Please describe in what format individuals will be given notice of consent [e.g., written notice, electronic notice, etc.]) There have been no major changes in the system and none are contemplated. NCI and NIEHS IRBs would review any major changes prior to implementation and provide us with guidance on any needed notification and consent requirements.

As part of the research protocol, all subjects are required to fill out consent documents which describe how their information will be used. If these change, participants will be contacted and informed.

**32. Does the system host a website? (Note: If the system hosts a website, the Website Hosting Practices section is required to be completed regardless of the presence of PII):** No

**37. Does the website have any information or pages directed at children under the age of thirteen?:**

**50. Are there policies or guidelines in place with regard to the retention and destruction of PII? (Refer to the C&A package and/or the Records Retention and Destruction section in SORN):**

**54. Briefly describe in detail how the IIF will be secured on the system using administrative, technical, and physical controls.:** Extensive safeguards are in place to ensure the confidentiality of each subject is protected.

TECHNICAL CONTROLS: Each AHS subject is assigned a six-digit ID number; these AHS IDs are used for any references to subjects on an individual basis. Names and other indentifying information for full AHS cohort are kept in separate databases maintained by Westat, and not comingled with the analytic data. These data files are joined only for performing linkages to the mortality and cancer incidences databases. Several layers of passwords exist to ensure



unauthorized access to electronically stored data is not permitted. The system is protected by firewalls, intrusion detection systems, and passwords. There are comprehensive system security and contingency plans in place. An Incident Response capability is maintained.

Similarly, names and other identifying information for NIEHS AHS sub-studies ( namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study) are kept in separate databases maintained by SSS, and not comingled with analytic data. Several layers of passwords exist to ensure unauthorized access to electronically stored data. The system is protected by firewalls, intrusion detection systems, and passwords. There are comprehensive system security and contingency plans in place and an incident response capability is maintained.

**PHYSICAL CONTROLS:** For NIEHS sub-studies ( namely AHS Lung Health Study, GAP Study, AHS Autoimmune Study, GENARM Study, SAFE Study and FAME Study), hard copies of questionnaires that contain any personal information are stored in locked rooms at SSS (NIEHS contractor). All personnel involved with the project have signed confidentiality agreements. Badged access is required for all server rooms, with badge lockdown policies in line with existing NIH procedures. Physical racks are key-locked. Data center is behind keycard access with 100% identification badge check by 24/7 security guard.

For the full AHS, PII data are stored at Westat (NCI contractor), where these files are stored in a directory accessible only to the project's lead systems manager and one programmer. They are also encrypted when not in use and the encryption key is known only by the same two staff members. The files are never left in unencrypted form over night so that automatic backups contain only encrypted versions. After the field stations confirm receipt of readable files, the copies at Westat are deleted.

**MANAGEMENT CONTROLS:** All PIs and investigators are approved by an AHS central board before gaining access to analytical data (including date of birth). Personal contact information for cohort is not available to NIH investigators.

***PIA Approval***

**PIA Reviewer Approval:** Promote

**PIA Reviewer Name:** Kim Minneman

**Sr. Official for Privacy Approval:** Promote

**Sr. Official for Privacy Name:** Karen Plá

**Sign-off Date:** 9/26/2011

**Approved for Web Publishing:** Yes

**Date Published:** May 23, 2012

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