AHS Guideline

Use and Disclosure of Protected Health Information (PHI) for Research Purposes

Effective Date: July 6, 2004

I. PURPOSE

This policy has been established to protect confidentiality of the recipients of AHS services by providing guidelines in regard to disclosing and using Protected Health Information (PHI) for research purposes.

II. CONTEXT

Protected health information can be used or disclosed for research purposes under the following circumstances:

1. The study participant or his/her authorized representative has authorized the use or disclosure;
2. An Institutional Review Board (IRB) has approved a waiver of authorization;
3. The researcher is requesting the use of de-identified information;
4. The researcher requests a limited data set and when necessary, AHS enters into a data use agreement with the limited data set recipient;
5. AHS obtains from the researcher representations that the use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
6. AHS obtains from the researcher representations that the use or disclosure is sought solely for research on the PHI of deceased individuals.

DEFINITIONS:

Protected Health Information means:
Information, including demographic information, that relates to the past, present, or future physical or mental health or condition of a consumer, or the provision of health care to a consumer that identifies the consumer; or with respect to which there is a reasonable basis to believe the information can be used to identify the consumer.

Research means:
A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge as defined by the Common Rule.

Generalizable Knowledge means:
Knowledge that can be applied to populations outside of those served by Agency of Human Services.

Institutional Review Board (IRB) means:
A committee whose primary purpose is to protect the rights and safety of human subjects by reviewing and approving research protocols involving human subjects.

De-identified information means:
Protected Health Information in which the following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

- Names;
- All geographic subdivisions smaller than a state;
- All elements of dates (except year) for dates directly related to an individual including birth date, admission date, discharge date, date of death, and all ages over 89 years and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social Security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators;
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including voice and finger prints;
- Full face photographic images and any comparable images;
- Any other unique identifying number, characteristic or code, and AHS does not have actual knowledge that the information could be used alone or in coordination with other information to identify an individual who is the subject of the information

Limited Data Set means:
Protected Health Information **that excludes** the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

- Names;
- Postal address information, other than town and city, state, and zip code;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social Security numbers;
- Medical Record numbers;
- Health Plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including voice and finger prints; and
- Full face photographic images and any comparable images.

Limited Data Set or Data Use Agreement means:
An agreement between AHS and the limited data set recipient that establishes the permitted uses and disclosures of such information by the limited data set recipient; establishes who is permitted to use or receive the limited data set; and establishes certain administrative safeguards. The standard AHS Data Use Agreement can be obtained through the AAG's office and/or the AHS Privacy Officer.

Designated Record Set means:
A group of records maintained by or for the AHS that is:

- The medical records and billing records about individuals maintained by or for AHS departments or divisions that provide health care;
- The enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for the AHS departments or divisions that are health plans; or
- Used, in whole or in part, by or for AHS to make decisions about individuals.

Note: "Records" include any item, collection, or grouping of information that includes PHI and is maintained, collected, used or disseminated by or for the AHS

SCOPE OF COVERAGE

1. This policy applies to all research at AHS, or elsewhere that requires the use or disclosure of protected health information maintained by AHS irregardless of the source of funding of the research.
2. This policy applies to clinical trials, chart reviews, epidemiological studies, behavioral and social science studies, basic science research studies, and research that involves diagnosing and/or treating an individual as well as research that does not involve either diagnosis or treatment.
3. This policy applies to all research activities, including but not limited to the following:
   - The initial review of clinical information, whether in hard copy or electronic format, to develop a research protocol;
   - The creation of a research database;
   - The addition of PHI to an existing research database;
   - Recruiting consumers to participate in a research study;
   - Enrolling consumers into a research study; and
   - Conducting a research study.
4. This policy applies to all protected health information, regardless of the form in which the PHI
   is maintained (e.g., hard copy or electronic format/computer database).

GUIDELINES

I. *Use and Disclosure of PHI with Consumer Authorization*

AHS may use or disclose PHI for a research purpose if the subject of the PHI or their authorized representative has signed an authorization form approved by the AHS Institutional Review Board (IRB).

II. *Use and Disclosure of PHI without Consumer Authorization*

Unless the PHI is de-identified or in a limited data set, protected health information can only be used or disclosed without authorization by the participant in the following three situations:

- An alteration to or waiver, in whole or in part, of the participants' authorization for the use or disclosure of information about them for research purposes has been approved by an Institutional Review Board;
- When the use or disclosure of the information is for a review preparatory to research; or
- When the use or disclosure of information being sought is solely for research on decedents.

III. *Use and Disclosure of PHI with a Waiver of Authorization or Alteration*

AHS may use or disclose PHI for research purposes without consumer authorization if an IRB has approved a "Waiver of Authorization."In order to use or disclose PHI with a waiver of authorization, an IRB must find:

(a) The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following criteria:

(1) An adequate plan to protect the identifiers from improper use and disclosure;

(2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law;

(3) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted under the HIPAA privacy rule.

(b) The research could not practicably be conducted without the alteration or waiver; and

(c) The research could not practicably be conducted without access to and use of the protected health information.

To apply to the AHS IRB for a waiver of authorization for research purposes, the Principal Investigator must complete a Waiver of Authorization form and submit it to the IRB with all other documents related to the protocol. The IRB will evaluate the request to ensure that the waiver criteria set forth above are met. If the waiver is granted, a waiver approval signed by the IRB chair/co-chair or designee shall be forwarded to the Principal Investigator. The approval form will include:

- The date on which the waiver or alteration of authorization was approved;
- A statement that the IRB Board has determined that the waiver or alteration satisfies the mandated criteria;
- A brief description of the PHI for which use or access has been determined to be necessary; and
- A statement that the waiver or alteration has been reviewed and approved under either normal or expedited review procedures.

IV. *Use and Disclosure of PHI for Research on Deceased Individuals*

AHS may use or disclose the PHI of deceased individuals for research purposes, without authorization or an IRB waiver of authorization, if;

- The use or disclosure sought is solely for research on the PHI of decedents;
- The PHI for which use or disclosure is sought is necessary for the research purposes.
- The researcher provides documentation, if requested by AHS, of the death of the individuals.

V. *Use and Disclosure of PHI for Review Preparatory to Research*

AHS may use and disclose PHI in connection with a review preparatory to research (e.g., reviewing consumer records to develop a research hypothesis or to determine the number of subjects that might be eligible to participate in a research study). AHS may use and disclose PHI for these review activities without individual authorization and without documentation that the IRB has altered or waived individual authorization if;

- The use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
- No PHI is to be removed from AHS designated record sets or AHS offices by the researcher in the course of the review; and
- The PHI for which access is sought is necessary for the research purposes.

VI. *Use and Disclosure of De-identified PHI*

AHS may use and disclose de-identified PHI (as defined in the Definitions Section of this Policy) for research purposes without consumer authorization or an IRB waiver of authorization.

VII. *Use and Disclosure of Limited Data Sets*

AHS may use and disclose a Limited Data Set (as defined in the Definitions Section of this Policy) for research purposes without authorization or an IRB waiver of authorization if the limited data set recipient has entered into a Limited Data set/Data Use Agreement. Researchers who wish access to a Limited Data Set must execute a Limited Data Set/Data Use Agreement prior to the creation of the Limited Data Set.

VIII. *Recruitment of Research Subjects*

Recruitment of potential research subjects at AHS offices or by affiliated staff is a regulated research activity. AHS may use or disclose PHI for the recruitment of AHS consumers into a research study ***without*** authorization or an IRB waiver of authorization only if such recruitment is performed by a full or part time member of the AHS workforce.

A member of the AHS workforce may without consumer authorization or an IRB waiver of authorization review the records of consumers with whom he or she has a service relationship to determine whether they meet the eligibility criteria for enrollment into a research study. He or She may contact prospective subjects directly or by letter and explain the research study and request a decision concerning the individual's interest in the study.

In all other cases AHS may only use or disclose PHI for recruitment purposes if the use or disclosure has been authorized by the consumer or the researcher has obtained an IRB waiver of authorization.

IX. Minimum Necessary

AHS may use or disclose only the PHI necessary to conduct research activities.

- For research conducted pursuant to the participant's authorization, the authorization will define the PHI to be used or disclosed.
- For research conducted pursuant to a waiver of authorization, the principal investigator must specify in the waiver request the PHI to be used and represent that it is the minimum necessary to conduct the research study.
- For telephone screenings of prospective subjects, the individual conducting the screening must limit the questions to those related to the inclusion/exclusion criteria of the specified protocol.

X. Consumer Access to Research Records

Generally, consumers have a right to access PHI maintained by AHS as part of their "designated record set" (as defined in the Definitions section of this policy). However, the individual's right to access their PHI in a designated record set may be suspended for as long as the research is in progress provided that:

- The individual has agreed to the denial of access when consenting to participate in the research study; and
- The individual has been informed that the right of access will be reinstated upon completion of the research.

XI. Accounting for Disclosures

A. Individuals have a right to receive an accounting of disclosures of PHI made by AHS for research purposes in the six years prior to the date on which the accounting is requested. The following types of research disclosures do not require an accounting:
   - Disclosures made pursuant to an authorization,
   - Disclosures of de-identified information, and
   - Disclosures of Limited Data Sets.

B. All other research-related disclosures must be included in the accounting with the following limited exception: If during the period covered by the accounting AHS has made disclosures of PHI for a particular research purpose for 50 or more individuals, the accounting may provide:
   - The name of the protocol or other research activity;
   - A description of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
   - A brief description of the type of PHI that was disclosed;
   - The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure during the accounting period;
   - The name, address, and telephone number of the entity that sponsored the research and the researcher to whom the information was disclosed; and
   - A statement that the PHI of the individual may or may not have been disclosed for a particular protocol or other research activity.

XII. Research Databases

New Research Databases

Currently no research data bases exist at the AHS. At such a time that a research database is contemplated, AHS may use or disclose PHI to create a new research database (or add cases to a new database) if:

- The consumer has authorized the use or disclosure,
- An IRB has approved a waiver of authorization,
- The PHI is de-identified, or
- The PHI only includes a Limited Data Set provided under a Data Use Agreement.

XIII. Transition Provisions

AHS may continue to use and disclose PHI created or received before and after April 14, 2003 for research purposes if AHS has obtained or received any of the following prior to April 14, 2003:

- An authorization or other express legal permission from the consumer to use or disclose their PHI for research purposes;
- The informed consent of the consumer to participate in the research; or
- A waiver or alteration by an IRB of informed consent for the research in accordance with the Common Rule.