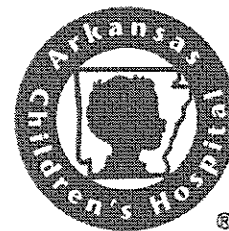


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Policy Date: 2/21/2008

Subject: Access to Protected Health Information for Research Purpose

Application: Hospital Wide

Distribution: All Holders of Administrative Policies and Procedures Manual

Approved By: Jonathan Bates *J Bates*
Chief Executive Officer

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PURPOSE

All staff, physicians, employees, students, contractors and/or agents performing research on human subjects (living or deceased), or conducting reviews of Protected Health Information preparatory to research on the ACH/ACHRI campus.

Quality Improvement/Assurance projects may be subject to HIPAA requirements and must always be submitted to the IRB.

DEFINITIONS

For purpose of this Policy, the following definitions apply:

Database means the completion of data in any form and maintained in any fashion, and includes, but is not limited to, spreadsheets, tables, or other data repositories maintained in any form. This list is not intended to be all inclusive but, rather, a guideline.

Data Use Agreement is a written agreement between ACH and the Limited Data Set recipient, which establishes the permitted uses and disclosures of such information and certain administrative safeguards to protect the information.

De-Identified Information means information which does not identify an individual and, with respect to which, there is no reasonable basis to believe that the information can be used to identify an individual. ACH may determine that health information is De-Identified if the following identifiers of the individual or of relatives, employers, or household members of the individual, are removed and ACH does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information:

Names;

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All geographic subdivisions smaller than a state, including street address, city, county, precinct, and ZIP Code;

All elements of dates (except year) directly related to an individual, including birth date, admission date, discharge date, date of death; all ages over 89, 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 address;

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.

Designated Record Set means, for purposes of Research, medical records about individuals used, in whole or in part, by or for ACH to make treatment decisions about individuals, including any treatment information generated in the research context.

Disclosure means the release, transfer, provision of access to, or divulging of information in any manner (verbally or in writing) to persons or entities OUTSIDE of ACH/ACHRI.

Limited Data means information that excludes the following direct identifiers of the individual and of relatives, employers, or household members of the individual:

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Names;

Street or Postal address information (other than town, city, State and zip code);

Telephone numbers;

Fax numbers;

Electronic mail address;

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.

If the information is necessary for the Research, the Limited Data Set can include:

Geographic identifiers, such as town, city, county, state, and five digit zip code (but not street name, street address, or post office box)

All elements of dates

Admission dates

Discharge dates

Service dates

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Date of birth and date of death

Age (including 90 or over)

Other unique codes or identifiers not listed above as a direct identifier

Pre-Research or Review Preparatory to Research means the review of information or records prior to obtaining patient authorization and consent or prior to obtaining an IRB Waiver of Authorization in which the review is solely to prepare a research protocol, to determine if a research project is feasible, or for similar purposes preparatory to research.

Principal Investigator (PI) or Investigator shall mean the ACH/ACHRI Principal Investigator, research or the research team or study coordinators collectively.

Protected Health Information (PHI) means information that is part of an individual's health information that identifies the individual or there is a reasonable basis to believe the information could be used to identify the individual, including demographic information, and that (i) relates to the past, present or future physical or mental health or condition of the individual; (ii) relates to the provision of health care services to the individual; or (iii) relates to the past, present, or future payment for the provision of health care services to an individual. This includes PHI which is recorded or transmitted in any form or medium (verbally, or in writing, or electronically). PHI excludes health information maintained in educational records covered by the federal Family Educational Rights Privacy Act and health information about ACH/ACHRI employees maintained by ACH/ACHRI in its role as an employer (but not kept by the ACH Health Plan).

Research shall mean any research or systematic investigation on living or deceased human subjects (retrospective or prospective) seeking the use of PHI, including research development, testing, and evaluation, designed to contribute to generalizable knowledge. This includes research that is consistent with what the IRB currently reviews under the Common Rule.

Workforce means ACH/ACHRI physicians, employees, trainees, students, volunteers, contractors, agents, and all other persons whose conduct, in the performance of work for ACH/ACHRI, is under direct control of ACH/ACHRI, whether or not they are paid by ACH/ACHRI.

POLICY

It is the policy of ACH/ACHRI to protect the privacy and confidentiality of medical records and information contained in the medical records of persons who are subject to ACH/ACHRI. Research projects, as required by law, including all Protected Health Information as defined by the HIPAA Privacy Regulations.

This HIPAA Research Policy is not intended to replace the applicable legal requirements or ACH/ACHRI policies concerning compliance with professional ethics, the Common Rule, FDA regulations, or other applicable laws and policies. The Principal Investigator (PI) or Project Director (PD) is responsible for obtaining IRB approval for all Research projects that use human subjects including Research projects that propose the use of an individual's or Research subject's PHI. The

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PI must secure an approval letter from the IRB before the project can begin. Please see IRB policies and procedures and the applicable regulations at <http://www.uams.edu/irb/IRB.asp> for the regulations and <https://aria.uams.edu> for submitting a human subjects protocol for review and approval by the IRB.

Anyone working with human subjects for Research purposes must complete the required Research Training found at www.citiprogram.org. This includes the Principal Investigator, co-investigators and research staff, including but not limited to, research associates, research assistants and study coordinators. See ACHRI Training in the Protection of Human Subjects in Research policy located on the ACHRI website.

RESEARCH COVERED BY THIS POLICY

1. This policy applies to all Research by ACH/ACHRI Workforce that involves the use or disclosure of Protected Health Information regardless 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 or treating an individual as well as Research that involves neither diagnosis or treatment. Quality Improvement/Assurance projects may be subject to HIPAA requirements and must always be submitted to the IRB.
3. This policy applies to all Research activities, including, but not limited to, the following:

The initial review of PHI for Pre-Research purposes such as to determine the feasibility of a study or to develop a research protocol;

Research projects that involve the creation of a Database containing PHI;

Research projects that involve the use of PHI from current Research Databases;

Research projects that involve the addition of PHI to existing Research Databases;

Research projects approved by the IRB that create PHI during the Research project;

Research projects approved by the IRB that use existing PHI stored in any form;

Recruiting patients to participate in a Research study;

Enrolling patients into a Research study;

Research projects with patient/subject authorization and consent;

Conducting a Research study

4. This policy applies to all research activities that use or seek to use human PHI, regardless of the

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form in which the PHI is maintained (e.g., hard copy or electronic format).

PROCEDURE

A. General: Protected Health Information can be used or disclosed for Research purposes under the following circumstances and only in accordance with this policy:

1. Authorization: The patient or the patient's Legal Representative has authorized the use or disclosure in accordance with this policy;
2. IRB/Privacy Board Review: An Institutional Review Board (IRB) has approved a Waiver of Authorization;
3. De-Identified Information: The PHI is De-Identified;
4. Limited Data Set: Only Limited Data Set information is used or disclosed, and ACH/ACHRI enters into a Data Use Agreement with the Limited Data Set recipient prior to disclosure;
5. Pre-Research: ACH/ACHRI 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. Deceased Individuals: ACH/ACHRI obtains from the researcher representations that the use or disclosure is sought solely for research utilizing the PHI of deceased individuals.

B. USES or DISCLOSURES OF PHI - IN GENERAL

1. General Requirements: ACH/ACHRI will protect the privacy of Research subjects and their PHI collected during a Research project. ACH/ACHRI will not use or disclose EXISTING PHI or PHI CREATED DURING A RESEARCH PROJECT, unless one of the following circumstances exist:

a. The subject signs both (1) a HIPAA Authorization for use and disclosure of PHI using the ACH/ACHRI HIPAA Research Authorization Form or other form containing all the elements of a legally effective HIPAA authorization; AND (2) the informed consent to participate in research form is approved by the IRB.

You must give a copy of the signed Authorization and Informed Consent Forms and the ACH Notice of Privacy Practices to the research subject. Ask the subject or parent to sign the Acknowledgement form; or

- b. The IRB grants a waiver to the requirement of obtaining a signed HIPAA Research Authorization Form, or
- c. The IRB approved protocol uses properly De-identified PHI, or
- d. The IRB approved protocol uses the Limited Data Set and the recipient signs a Data Use

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Agreement with ACH or falls under a statutory exception to this requirement.

2. Minimum Necessary Applies: PHI that is used or disclosed for Research purposes without a HIPAA -compliant Authorization should be limited to the minimum necessary to accomplish the purpose of the Research.

C. RESEARCH UTILIZING INFORMATION OF A DECEASED PERSON

1. General Requirements: A HIPAA Research Authorization Form is not required when conducting Research utilizing PHI of a deceased individual. The information requested, however, should be the minimum necessary to accomplish the purposes of the Research. The information requested must be solely for Research utilizing the PHI of decedents and not, for example, for Research concerning living relatives of decedents. Upon request of ACH/ACHRI, documentation of the deaths of study subjects will be provided. No authorization or alteration or waiver of Authorizations by an IRB or Privacy Board is needed for use or disclosure of PHI for Research utilizing only the PHI of deceased persons, if these conditions are met, and the Investigator completes a Certification as described below.

2. Certification by Investigator: A Certification by the Investigator is required in which Investigators must certify in writing the following when requesting PHI for deceased individuals: (1) The investigator seeks use and disclosure of PHI to conduct research concerning deceased individuals; (2) the investigator will provide proof of death if requested; and (3) the investigator seeks PHI solely for Research.

For these purposes, PIs will complete and sign a Certification for Use and Disclosure of Protected Health Information of Deceased Individuals Form and present it to the custodian of the records being requested before the custodian can release the PHI to the investigator.

D. REVIEW PREPARATORY TO RESEARCH

1. Pre-Research or Review Preparatory to Research means the review of information or records prior to obtaining authorization and consent or prior to obtaining an IRB Waiver of Authorization in which the review is solely to prepare a research protocol, to determine if a research project is feasible, or for similar purposes preparatory to research. For example, a review to design a research study, to formulate hypotheses, or to assess the feasibility of conducting a study.

NOTE: Preparatory to Research activities may include activities to identify prospective Research subjects, but it does not include contacting patients, contacting potential subjects, or recruitment of subjects in any manner.

2. Authorization: A HIPAA Authorization form is not required when conducting Pre-Research or Review Preparatory to Research.

3. Minimum Necessary: The information requested for review must be the minimum necessary to accomplish the purpose of the Pre-Research or Review Preparatory to Research. In addition, a Certification by the Researcher is required as described below.

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4. Certification by Researcher Required: When undertaking "Pre-Research" or a "Review Preparatory to Research," staff must have a current written certification on file signed by the staff member that includes the following representations:

- a. The Researcher seeks use or disclosure of PHI solely to review such information as necessary to prepare a Research protocol or similar purposes Preparatory to Research; and
- b. The Researcher shall not remove any PHI from ACH/ACHRI premises in the course of such review; and
- c. The use or disclosure of PHI is necessary for Research purposes.

For these purposes, Researchers must fill out a Reviews Preparatory to Research Form (<http://achri.archildren.org/resources/forms.htm>), submit it to The ACHRI Human Protections Administrator and to the database, medical record, or other custodian of records before the custodian can release the PHI to the investigator. Annual renewals are required. See #5 below.

5. Re-Certification Required: On an annual basis, Researchers must re-new their individual certifications regarding Reviews Preparatory to Research.

6. PHI May Not Leave ACH/ACHRI Premises: PHI that is being reviewed for Pre-Research purposes must not leave the premises in the course of such review.

E. IRB APPROVAL OF RESEARCH

The Principal Investigator (PI) or Project Director (PD) is responsible for obtaining IRB approval for all Research projects involving human subjects or which otherwise propose the use of an individual's PHI. The PI must have the approval letter from the IRB before the project can begin. Please see IRB policies and procedures for the regulations and visit <https://aria.uams.edu/> for submitting a human subjects protocol for review and approval by the IRB.

F. REQUIRED HIPAA RESEARCH AUTHORIZATION

1. HIPAA Research Authorization vs. Informed Consent for Research

All Research projects that use or create PHI must require subjects to sign an IRB-approved Informed Consent and a HIPAA Research Authorization form to participate in a Research project. The IRB will require the usual Informed Consent AND the additional HIPAA Research Authorization language as criteria for granting final approval for a Research project.

2. HIPAA Research Authorization Combined with Informed Consent for Research

a. Combination of HIPAA Research Authorization Form and Informed Consent Form:

The IRB prefers, but will not require, the HIPAA Research Authorization to be a form separate from the Informed Consent form. The HIPAA Research Authorization and the Informed Consent

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may be combined.

G. WAIVER OF HIPAA RESEARCH AUTHORIZATION

1. Waiver of HIPAA Research Authorization:

If it would be impractical to re-consent or obtain a HIPAA Research Authorization Form to do the research project, the PI can request a waiver of the additional HIPAA Research Authorization as described by this policy. PIs or PDs must submit their requests for waiver of authorization to the IRB in writing and must include the following explicit protocol elements for the waiver of authorization to be considered by the IRB:

- a. Provide a brief description of the Protected Health Information to be used.
- b. Use the following methods to provide minimal risk to privacy of individuals:
 - (i) Describe an adequate plan to protect the identifiers from improper use or disclosure.
 - (ii) Describe an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of Research, unless there is a health or research justification for retaining the identifiers if retention is required by law.
 - (iii) Assure the IRB in writing that the PHI will not be re-used or disclosed to any other person or entity, except as required by law, for authorized oversight of the Research project, or for other Research as permitted by the HIPAA regulations.
- c. Certify in writing that Research cannot practicably be carried out without the waiver.
- d. Certify in writing that Research cannot practicably be conducted without access or use of the PHI.
- e. The IRB approval letter **MUST** contain the following information if a waiver is granted by the IRB:
 - (i) Name of the IRB and the FWA assurance number.
 - (ii) Date of action
 - (iii) A statement that the IRB determined that the waiver satisfies all the criteria listed above.
 - (iv) A brief description of the PHI for which use and disclosure has been determined to be necessary for Research by the IRB. (Provided by the PI above).
 - (v) The type of review administered under the Common Rule.
 - (vi) Signature of the chair or chair's designee authorized to sign.

H. WHEN AUTHORIZATION IS NOT REQUIRED

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1. HIPAA Research Authorization is NOT Required When Information is De-Identified. (See definition of De-Identified Information in this Policy.)

a. Requirements for Use/Disclosure: Prior patient Authorization is not required for the use or disclosure of properly De-Identified information as defined in this Policy. If the PI or other researcher will receive PHI prior to it being De-Identified however, the PI/researcher must submit a research protocol to the IRB that includes a description of the health information sought and an explanation of how the information will be De-Identified.

b. Codes Used to Re-identify the Information. ACH/ACHRI may assign to, and retain with, the De-Identified, a code or other means of record re-identification as long as that code is not derived from or related to the information about the individual and is not otherwise capable of being translated to identify the individual. For example, a social security number would not be permissible "code". A randomly assigned re-identification code, however, is permissible because it would not be related to information about the individual. ACH may not disclose its method of re-identification or use or disclose its code for other purposes. Any codes used to render the information re-identifiable must be kept confidential and held to the same level of privacy as all other PHI pursuant to the policies and procedures of ACH and the HIPAA regulations.

2. HIPAA Research Authorization is NOT Required for Use/Disclosure of Limited Data Set Information and As Long As Recipient Signs a Limited Data Set Agreement Prior to Disclosure. (See definition of Limited Data Set in this Policy.)

a. Requirements for Use/Disclosure: Prior patient Authorization is not required for the use or disclosure of "Limited Data Set" information as defined in this Policy, as long as a Data Use Agreement is entered with the recipient of the information if the recipient is not a member of the ACH/ACHRI Workforce, and the use of disclosure is for one of the following purposes:

i. For the purposes of Research; or

ii. For the purposes of public health activities (not already allowed under HIPAA), such as disease registries maintained by ACH/ACHRI, private organizations, other universities, or other types of studies undertaken by the private sector or nonprofit organization for public health purposes; or

b. Data Use Agreement Required: If the Limited Data Set information is to be disclosed outside ACH/ACHRI, a Data Use Agreement must be entered with the recipient of the Limited Data Set information. Please contact the ACH/ACHRI Research Privacy Officer when a Data Use Agreement is needed. All Data Use Agreements require the signature of the ACH/ACHRI Research Privacy Officer and the authorized representative of the Limited Data Set recipient prior to disclosure.

c. Minimum Necessary Applies: The Limited Data Set information being used or disclosed must be the minimum necessary to accomplish the purpose of the Research.

I. USE of PHI in EXISTING DATABASES or CREATING A NEW DATABASE

1. Research Utilizing Existing Databases: For use or disclosure of PHI for Research purposes

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from an existing database maintained by ACH/ACHRI, ACH/ACHRI must have one of the following:

- a. a required HIPAA Research Authorization in accordance with this Policy; or
- b. an IRB Waiver of Authorization; or
- c. Use or disclosure PHI for Pre-Research purposes in accordance with this policy; or
- d. Use or disclose PHI for Research utilizing decedents' PHI in accordance with this Policy; or
- e. Use or disclose only the Limited Data Set Information and enter into a Data use Agreement with the recipient in accordance with this Policy; or
- f. Use or disclose PHI based on permission obtained prior to April 14, 2003 in accordance with the "Grandfathering" section of this policy.

2. Collecting PHI for Sole Purpose of Creating Research Database. Prior to creating a database containing PHI for the purpose of Research, the PI must seek the patient/subject HIPAA Authorization required under this policy, or seek a Waiver of Authorization from the IRB as described in this Policy.

J. RECRUITMENT:

The IRB must approve all recruitment plans prior to the recruiting activity taking place. The following are examples of recruiting activities.

1. Physicians or their clinical staff may identify potential Research subjects from their own patients and contact the patients directly regarding their own IRB approved Research study.
2. Clinical staff, directly involved in patient care, can inform their patients of Research studies and give the patients contact information about Research studies for which they may qualify.
3. A researcher can provide IRB approved flyers and handouts to other physicians or care providers for an IRB approved Research study. These providers can hand out the flyers and inform subjects to contact the researcher directly for information about the study.
4. IRB Approved Recruitment advertisements can be posted whereby potential subjects can initiate contact with the researcher.
5. Clinical care providers may send a letter or other type of mailing information their patients of a Research study and provide contact information for the researcher. Initial contact should always be made by a provider.
6. A researcher can ask providers to inform their patients of a potential Research study. The researcher should provide the provider with a Recruitment HIPAA Authorization form that the patient completes to give their permission for the Researcher to contact them regarding the study. The

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providers ask their patients if they would like to be contacted to learn more about the study, the patient completes the form if interested and the provider then forwards these forms to the researcher. The researcher may then contact the potential subject.

K. TREATMENT RECORDS AND THE DESIGNATED RECORD SET:

A Designated Record Set means, for purposes of Research, medical records about individual used, in whole or in part, by or for ACH/ACHRI to make treatment decisions about individuals, including any treatment information generated in the research context. Documents containing the subject's PHI in the course of Research and used in Research to make treatment decisions about the subject must be duplicated and the original record provided to the ACH Health Information Management (HIM)/Medical Records Department for inclusion in the subject's medical record unless the IRB approves a deviation from this requirement (example genetic information to only be recorded in the research file).

L. ACCOUNTING FOR DISCLOSURES - reference (ACH Accounting for Disclosure)

1. Accounting Required: An accounting for disclosures is a method of documenting and tracking disclosures (both oral and written) of PHI to non-ACH employees or other persons or entities outside ACH. An example is an oral or written disclosure of PHI to comply with reporting requirements to the Arkansas Department of Health.

ACH must account for "Disclosures" as defined herein for disclosures made without the individual's Authorization, such as:

- a. Disclosures of PHI made under an IRB waiver of authorization; and
- b. Disclosures of PHI for Research concerning deceased individuals.

2. Accounting Forms: All such disclosures must be documented and accounted for by the person who disclosed the PHI, or who is in charge of the project in which the PHI was disclosed. After documenting the disclosure, the Form or documentation must be provided to the ACH Medical Records Department. Copies may be maintained by the PI.

3. Multiple Disclosures to Same Person or Entity: When multiple disclosures of PHI are made to the same person or entity for a single purpose, the accounting for such disclosures may consist of the information required for an accounting for the first disclosure, plus the number of frequency of disclosures, and the date of the last disclosure during the time period covered by the request.

4. EXCEPTIONS - Accounting is NOT Required: ACH is NOT required to account for disclosures of the PHI of individual subjects only if the following can be documented:

- a. A valid HIPAA Research Authorization Form was signed by the individual who is the subject of the PHI being disclosed prior to the disclosure; or
- b. Only De-Identified Information is being disclosed pursuant to the ACH/ACHRI De-Identification

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Policy; or

c. Only Limited Data Set information is being disclosed and a Data Use Agreement was entered into with the recipient of the information, as described in this policy and the ACH/ACHRI De-Identification Policy.

GRANDFATHERING HIPAA RESEARCH AUTHORIZATION - Ongoing Research at Time of April 14, 2003

ACH/ACHRI may continue to use and disclose PHI created or received before and after April 14, 2003, for Research purposes if ACH/ACHRI obtained or received any one of the following prior to April 14, 2003:

- a. A HIPAA Research Authorization received prior to April 14, 2003, from the patient to use or disclose their PHI for Research purposes; or
- b. The informed consent of the patient received prior to April 14, 2003, to participate in the Research; or
- c. An IRB-approved waiver of informed consent for the Research in accordance with the Common Rule and received prior to April 14, 2003.

This includes permissions, consents or waivers that allowed future unspecified Research.

Exception to Grandfathering - When Authorization Required. If the protocol was approved by the IRB prior to April 14, 2003, but the protocol required that informed consent and subjects would be enrolled after April 14, 2003, a protocol revision must be submitted to the IRB adding a separate HIPAA-compliant Research Authorization or amending the informed consent to include the elements of a HIPAA-compliant Research Authorization for subjects enrolled after April 14, 2003.

Revised: March 2008