

NUMBER: 2.1.12**DATE: 04/01/2003****REVISION: 3/1/2004; 12/28/2010; 01/02/2013, 06/25/2025****PAGE: 1 of 12****SECTION: HIPAA****AREA: HIPAA PRIVACY/SECURITY POLICIES****SUBJECT: HIPAA RESEARCH POLICY****PURPOSE**

To set guidelines for the protection of patient privacy and the security of Protected Health Information (“PHI”) in the conduct of Research at the University of Arkansas for Medical Sciences (“UAMS”).

SCOPE

This policy applies to all UAMS physicians, faculty, employees, and students or other UAMS Workforce members performing Research or Reviews Preparatory to Research at UAMS which utilize PHI (of living or deceased subjects), all Research activities conducted by UAMS Workforce members that involves the use or Disclosure of PHI regardless of the Research funding’s source, and all UAMS Research activities that use or seek to use PHI about a subject, regardless of the form in which the PHI is maintained (*e.g.*, hard copy or electronic format).

For Research conducted on patients of another Covered Entity, such as Arkansas Children’s Covered Entities, the policies of that institution will apply, or the Office of General Counsel will determine if an agreement to share data is needed. For UAMS Research relying on an external IRB for review, the reliance agreement will describe which institution will make determinations regarding the need for a HIPAA authorization form or waiver.

DEFINITIONS

Database means the compilation 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 UAMS 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. UAMS 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 UAMS 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;

- all geographic subdivisions smaller than a state, including street address, city, county, precinct, and ZIP code, and their equivalent geocodes;
- 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 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 fingerprints; and
- full face photographic images and any comparable images;
- Any other unique identifying number, characteristic, or code, except as otherwise permitted.

Designated Record Set means, for purposes of Research, medical records about individuals used, in whole or in part, by or for UAMS 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) by UAMS to persons outside of UAMS or outside the covered components of the UAMS hybrid entity.

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

- names;
- street or postal address information, including geocodes (*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 fingerprints; and
- full face photographic images and any comparable images.

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

- geographic identifiers, such as town, city, county, state, and five-digit ZIP code (but not street name, street address, their equivalent geocodes, or post office box);
- all elements of dates, such as date of admission, date of discharge, date of service, date of birth, and date of death;
- age (including 90 or over); and
- other unique codes or identifiers not listed above as a direct identifier.

Pre-Research or Review(s) 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. (*e.g.*, a review to design a Research study, to formulate hypotheses, or to assess the feasibility of conducting a study.)

Principal Investigator (PI) or Investigator shall mean the UAMS Principal Investigator, researcher or the research team or study coordinators collectively.

Privacy Board is a review body that may be established to act upon requests for a waiver or an alteration of the Authorization requirement under the Privacy Rule for uses and disclosures of PHI for a particular research study. At UAMS, the Institutional Review Board (IRB) serves as the Privacy Board.

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 UAMS employees maintained by UAMS in its role as an employer and health information regarding a person who has been deceased for more than 50 years.

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

UAMS Workforce means physicians, employees, volunteers, residents/fellows, students, and other persons whose conduct, in the performance of work for UAMS, is under the direct control of UAMS, whether or not they are paid by UAMS.

To access any other terms or definitions referenced in this Policy, go to the UAMS HIPAA Office website at hipaa.uams.edu.

POLICY

UAMS will protect the privacy and confidentiality of medical records and information contained in the records of persons who are subjects of UAMS Research projects as required by law, including all Protected Health Information as defined by the HIPAA Privacy Regulations. The PHI of a Research subject, and the use or Disclosure of a Research subject's PHI, shall be governed by the UAMS Administrative Guide Policy 2.1.12, *HIPAA Research Policy*, and any other applicable UAMS policies.

The Principal Investigator is responsible for obtaining Institutional Review Board (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 PI must have the approval letter from the IRB before the project can begin.

Members of the UAMS Workforce working with human subjects for Research purposes must complete the required HIPAA Research Training included in the [required Human Subjects Training](#) accessible at citiprogram.org. This includes the PI, co-Investigators and Research staff including, but not limited to, Research Associates, Research Assistants and study coordinators.

This policy does not intend to replace the applicable legal requirements or UAMS policies concerning compliance with professional ethics, the Common Rule, FDA regulations, or other applicable laws and policies.

PROCEDURES

A. Use or Disclosure of PHI – In General

1. **General Requirements:** UAMS will protect the privacy of Research subjects and their PHI collected during a Research project. UAMS will not use or disclose existing PHI or PHI created or collected during a Research project, unless one of the following circumstances exist:
 - a. The subject signs a HIPAA-compliant Authorization for use and Disclosure of PHI containing all the elements of a legally effective HIPAA authorization. You must give a copy of the signed Authorization and the **UAMS Notice of Privacy Practices** to the Research subject. Ask subject to sign Acknowledgment form. Refer to Administrative Guide Policy 2.1.06, *Notice of Privacy Practices*.

- b. The IRB grants a Waiver to the requirement of obtaining a signed HIPAA Research Authorization.
- c. The protocol uses properly De-Identified Information.
- d. The protocol uses a Limited Data Set and the recipient (if recipient is not a member of the UAMS Workforce) signs a Data Use Agreement with UAMS (or the entity that maintains the Designated Record Set).
- e. **Review Preparatory to Research:** UAMS IRB obtains from the Investigator 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.
- f. **Deceased Person:** UAMS IRB obtains from the Investigator representations that the use or Disclosure is sought solely for Research on the PHI of the deceased person and a signed Certification for Use and Disclosure of Protected Health Information of Deceased Individual Form is signed by the PI.

- 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. Please refer to Administrative Guide 2.1.10, *Minimum Necessary Policy*.

B. Grandfathering HIPAA Research Authorization – Ongoing Research at Time of April 14, 2003

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

- 1. An authorization, consent, or similar document received prior to April 14, 2003, from the patient to use or disclose their PHI for Research purposes; or
- 2. The informed consent of the patient received prior to April 14, 2003, to participate in the Research; or
- 3. 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.

C. Research on Information of a Deceased Person

- 1. **General Requirements:** A UAMS HIPAA Research Authorization Form is not

required when conducting Research of PHI on the deceased person. The information requested, however, should be the minimum necessary to accomplish the purposes of the Research. Refer to Administrative Guide 2.1.10, *Minimum Necessary Policy*. The information requested must be solely for Research on the PHI of deceased person and not, for example, for Research of living relatives of deceased person. Upon request of UAMS, documentation of the deaths of the study subjects will be provided. No Authorization or alteration or Waiver of Authorization by an IRB or Privacy Board is needed for use or Disclosure of PHI for Research only on the PHI of the deceased person, if these conditions are met, and the Investigator completes a Certification as described below. An IRB or Privacy Board may grant an alteration or Waiver of Authorization for the use and Disclosure of PHI of deceased persons. If granted, the Investigator is not required to complete the Certification 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 on a project that includes only deceased individuals:
 - a. The Investigator seeks use and Disclosure of PHI for Research on deceased individuals.
 - b. The Investigator will provide proof of death if requested.
 - c. The Investigator seeks PHI solely for Research and nothing else.

For these purposes, PIs will complete and sign a **Certification for Use and Disclosure of Protected Health Information of Deceased Individuals Form** available in the IRB e-system and present it to the IRB.

D. Review Preparatory to Research

Note: Preparatory to Research activities may include activities to *identify* prospective Research subjects, but may not include contacting potential subjects, or recruitment of subjects in any manner prior to IRB approval of a Research protocol.

1. **Authorization Not Required:** A UAMS HIPAA Research Authorization is not required when conducting Review Preparatory to Research.
2. **Minimum Necessary:** The information requested for review must be the minimum necessary to accomplish the purpose of the Review Preparatory to Research. Refer to Administrative Guide 2.1.10, *Minimum Necessary Policy*. In addition, a Certification by the Investigator is required as described below.
3. **Certification by Investigator Required:** When undertaking a Review Preparatory to Research, Investigators must have a written certification on file with the Privacy Board, submitted through the UAMS IRB e-system, for the specific project of which the PHI is sought, signed by the Investigator, that includes the following representations:

- i. The PI 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
 - ii. PI shall not remove any PHI from UAMS premises in the course of such review; and
 - iii. the use of PHI is necessary for Research purposes.
 - iv. For these purposes, PIs must fill out and submit the above certification in the IRB's e-system.
4. **PHI May Not Leave UAMS Premises:** PHI that is being reviewed for Pre-Research purposes must not leave the UAMS premises in the course of such review.

E. Recruiting and Contacting Research Participants:

Under the "Preparatory to Research" provision, a Covered Entity may use and disclose PHI to researchers to aid in study recruitment. They may allow a researcher to identify, but not contact, potential study participants.

To contact potential study participants, a researcher must have obtained a partial HIPAA waiver for recruitment purposes only from the IRB.

The Recruitment Plan must be submitted and approved by the IRB prior to contacting potential Research participants.

F. Required HIPAA Research Authorizations

All Research projects, for which an Authorization is required, will have a HIPAA-compliant Research Authorization approved by the IRB. This Authorization form will be in addition to any Informed Consent required by the IRB.

1. **Combination of UAMS HIPAA Research Authorization Form and Informed Consent Form:** The HIPAA Research Authorization and the Informed Consent may be combined. Whether separate or combined, the Authorization or the Consent should be consistent.
2. **Elements of a Research Authorization:** For an Authorization from a patient or the patient's Legal Representative to be HIPAA-compliant, it must be written in plain language, and contain the following elements:
 - a. A specific description of the information to be used or disclosed;
 - b. the persons, or class of persons, authorized to make the requested use or Disclosure;
 - c. the name (or other specific identification) of the persons, or class of persons, to whom UAMS may disclose the records;
 - d. a description of each purpose of the requested use or Disclosure;

- e. an expiration date or expiration event or if the Authorization does not expire, that there is no expiration date or event, or that the Authorization continues until the “end of the research study”;
- f. a statement that the person can revoke the Authorization in writing, the process for revoking the authorization, and a statement that the person cannot revoke authorization for records already released in reliance upon the Authorization;
- g. a statement that UAMS will not condition treatment or payment on whether the individual signs the Authorization, except that UAMS may condition research-related treatment upon the signing of the Authorization;
- h. a statement that records or information in the records released might be redisclosed by the person receiving them and will not be covered under the federal privacy laws;
- i. signature of the patient and date; and
- j. if the Authorization is signed by a Legal Representative of the patient, a description of the Representative’s authority to act for the patient, (e.g., “parent of a minor”, “Court-appointed guardian”, “health care proxy”, or “pursuant to appointment under Power of Attorney”).

G. Waiver of HIPAA Research Authorization

If it would be impractical to obtain a UAMS HIPAA Research Authorization to do the Research project, then the PI can request a Waiver of the HIPAA Research Authorization as described below. PIs must submit their requests for a Waiver of Authorization to the IRB in writing and must include the following elements for the Waiver of Authorization to be considered by the IRB:

1. Provide a brief description of the PHI to be used.
2. Use the following methods to ensure minimal risk to privacy of subjects:
 - a. Describe an adequate plan to protect the identifiers from improper use or Disclosure.
 - b. 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 or retention is required by law.
 - c. 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 HIPAA regulations.
3. Certify in writing that Research cannot practicably be carried out without the Waiver.
4. Certify in writing that Research cannot practicably be conducted without access or use of the PHI.

5. The IRB approval letter **MUST** contain the following information if a Waiver is granted by the IRB:
 - a. Name of the IRB;
 - b. date of action;
 - c. a statement that the IRB determined that the Waiver satisfies all the criteria listed above;
 - d. 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);
 - e. the type of review administered under IRB policies;
 - f. signature of the chair or chair's designee authorized to sign; and
 - g. a reminder that other HIPAA requirements, such as the Minimum Necessary Rule, still apply.

H. When Authorization Is NOT Required

1. **HIPAA Research Authorization is NOT required when information is De-Identified.**
 - a. See definition of De-Identified Information for the list of identifiers that must be removed.
 - b. **Requirements for Use/Disclosure:** Authorization is not required for the use or Disclosure of properly De-Identified Information as defined in this Policy. Refer to Administrative Guide Policy 2.1.16, *De-Identification of PHI and Limited Data Set Information* to determine proper De-Identification methods. See Administrative Guide Policy 2.1.14, *Request for Data Extracts* and Administrative Guide Policy 16.1.23, *Data Sharing for Research Purposes* for additional requirements regarding the sharing of De-Identified Data. A data transfer agreement may be required for the sharing of De-Identified Data and/or coded data. Contract the General Counsels Office for further information.
 - c. **Codes Used to Re-identify the Information:** UAMS may assign to and retain 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 a permissible "code." A randomly assigned re-identification code, however, would be permissible because it would not be related to information about the subject. UAMS 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 UAMS and the HIPAA regulations.
2. **HIPAA Research Authorization is NOT Required for Use/Disclosure of Limited Data Set Information as Long as Recipient Signs a HIPAA Data Use Agreement Prior to Disclosure.**

- a. **If the information is necessary for the Research, the Limited Data Set can include:**
 - i. geographic identifiers, such as town, city, county, state, and five-digit ZIP code (but not street name, street address, or post office box);
 - ii. all elements of dates, such as date of admission, date of discharge, date of service, date of birth, and date of death;
 - iii. age (including 90 or over); and
 - iv. other unique codes or identifiers not listed above as a direct identifier.
- b. **Requirements for Use/Disclosure:** Authorization is not required for the use or disclosure of “Limited Data Set” information as defined in this Policy, as long as UAMS and the recipient has a Data Use Agreement in place to share the information if the recipient is not a member of the UAMS Workforce and the use or Disclosure is for the purposes of Research.
- c. **Data Use Agreement Required:** If the Limited Data Set information is to be Disclosed outside UAMS, a Data Use Agreement must be in place between UAMS and the recipient to share the Limited Data Set information. Contact the UAMS Office of General Counsel when a Data Use Agreement is needed. All Data Use Agreements require the signature of an authorized representative of UAMS with signature authority and the authorized representative of the Limited Data Set recipient *prior to Disclosure*. See Administrative Guide Policy 16.1.23, *Data Sharing for Research Purposes* for additional requirements regarding Data Use Agreements and Limited Data Sets.
- d. **Minimum Necessary Applies:** The Limited Data Set information being used or disclosed must be the minimum necessary to accomplish the purpose of the Research. Refer to Administrative Guide 2.1.10, *Minimum Necessary Policy*.

Refer to Administrative Guide Policy 2.1.16, *De-Identification of PHI and Limited Data Set Information* to determine proper use/Disclosure of Limited Data Set information. Also refer to Administrative Guide Policy 2.1.14, *Request for Data Extracts*.

I. Accounting Of Disclosures

1. **Accounting Required:** An accounting of Disclosures is a method of documenting and tracking Disclosures made (verbally or in writing) by UAMS to persons outside of UAMS or outside the covered components of the UAMS hybrid entity. See **APPENDIX A** for a list of covered components. An example is an oral or written Disclosure of PHI to comply with reporting requirements to the Arkansas Department of Health or regulatory Disclosures to agencies such as Office for Human Research Protections (OHRP) or FDA.

UAMS must account for “Disclosures” as defined herein and in the HIPAA Privacy Regulations 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 on the deceased.

See “Exceptions” below.

- 2. **Methods to Record Disclosures and Information that Must be Recorded:** All such Disclosures must be documented and accounted for by the PI who disclosed the PHI, or who is in charge of the project in which the PHI was disclosed. For methods to record Disclosures that are subject to an Accounting of Disclosures and for the information that must be recorded, refer to Administrative Guide Policy 2.1.11, *Accounting of Disclosures of PHI*.
- 3. **EXCEPTIONS – Accounting is Not Required:** UAMS 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 UAMS De-Identification 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 UAMS De-Identification Policy.

J. Investigators Leaving UAMS: Investigators leaving UAMS who wish to take Research data or PHI with them upon leaving UAMS must seek prior approval from the Vice Chancellor for Research and Innovation and the UAMS HIPAA Office. A data transfer or a Data Use Agreement may be required. Contact the General Counsel’s Office for further information.

SANCTIONS

Violation of this Policy will result in disciplinary action, in accordance with UAMS Administrative Guide Policy 4.4.02, *Employee Discipline* and UAMS Administrative Guide 2.1.42, *HIPAA Sanctions Policy*.

Signature:  _____

Date: June 25, 2025

APPENDIX A

UAMS COVERED COMPONENTS OF THE UofA HYBRID ENTITY

For the purposes of HIPAA, the following areas have been designated and treated as covered components of the University of Arkansas Hybrid Entity:

UAMS Medical Center Hospital and Clinics
UAMS College of Medicine (COM) and its Clinics
UAMS Area Health Education Centers (AHEC) Clinics
UALR Speech and Hearing Clinic
UAMS Outpatient Pharmacy
UAMS Optical Center
UAMS Myeloma Institute for Research and Therapy (MIRT)
UAMS Institute on Aging
UAMS Spine and Neurosciences Institute
UAMS Jones Eye Institute
UAMS Psychiatric Research Institute (PRI)
UAMS Cancer Institute
COM Faculty Group Practice Billing Offices
UAMS Patient Billing Services
UAMS Institutional Compliance
UAMS Information Technology (IT)
UAMS Campus Operations Clinical Engineering