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SECTION: HIPAA

AREA: HIPAA PRIVACY/SECURITY POLICIES

SUBJECT: HIPAA RESEARCH POLICY

PURPOSE

This policy is established to set guidelines for the protection of patient privacy and the security of protected health information in the conduct of research at UAMS.

SCOPE

All UAMS physicians, faculty, employees and students or other UAMS Workforce members performing research or reviews preparatory to research utilizing Protected Health Information (of living or deceased subjects). For research conducted on patients of another Covered Entity, such as Arkansas Children's Hospital, the policies of that institution will apply.

DEFINITIONS

For purposes of this Policy, the following definitions apply:

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;
- 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 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 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 (*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.

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 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 IRB serves at 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.

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.

UAMS Workforce means for the purpose of this Policy, physicians, employees, volunteers, trainees, 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:

<http://hipaa.uams.edu/DEFINITIONS%20-%20HIPAA.pdf>

POLICY

It is the policy of UAMS to 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 any and all Protected Health Information as defined by the HIPAA Privacy Regulations. Protected Health Information of a Research subject, and the use or disclosure of such information, shall be governed by the UAMS Research Policy and any other applicable UAMS policies.

This HIPAA Research Policy is not intended 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. The Principal Investigator (PI) 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 PI must have the approval letter from the IRB before the project can begin. Please see IRB policies and procedures and the applicable regulations at <http://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.

UAMS Workforce working with human subjects for Research purposes must complete the required HIPAA Research Training included in the IRB Human Subjects Training <http://www.uams.edu/irb/submissions.asp>. This includes the Principal Investigator, co-investigators and research staff including, but not limited, to research associates, research assistants and study coordinators.

PROCEDURES

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 subject or the subject'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 granted 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 UAMS enters into a Data Use Agreement with the Limited Data Set recipient prior to disclosure;
5. **Pre-Research:** UAMS 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:** UAMS obtains from the researcher representations that the use or disclosure is sought solely for research on the PHI of deceased individuals.

B. RESEARCH COVERED BY THIS POLICY

This policy applies to all Research by UAMS Workforce that involves the use or disclosure of Protected Health Information regardless of the source of funding of the Research. This policy applies to 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).

Examples include 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.

C. USES or DISCLOSURES 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. See *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, 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 (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). See [APPENDIX A](#).

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. *Administrative Guide Policy 2.1.10, Minimum Necessary Policy*.

D. 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:

- A HIPAA Research Authorization received prior to April 14, 2003, from the patient to use or disclose their PHI for Research purposes; or
- The informed consent of the patient received prior to April 14, 2003, to participate in the Research; or
- 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.

E. 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. The information requested, however, should be the minimum necessary to accomplish the purposes of the Research. *Administrative Guide Policy 2.1.10, Minimum Necessary Policy*. The information requested must be solely for Research on the PHI of decedents and not, for example, for Research of living relatives of decedents. 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 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 on deceased individuals: (1) The investigator seeks use and disclosure of PHI for research on deceased individuals; (2) the investigator will provide proof of death if requested; and (3) 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** (see [APPENDIX B](#)) and present it to the UAMS Privacy Board.

F. REVIEW PREPARATORY TO RESEARCH:

- 1. 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. 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 potential subjects, or recruitment of subjects in any manner prior to IRB approval.

- 2. Authorization Not Required:** A UAMS HIPAA Research Authorization is not required when conducting Review Preparatory to Research.
- 3. Minimum Necessary:** The information requested for review must be the minimum necessary to accomplish the purpose of the Review Preparatory to Research.

Administrative Guide Policy 2.1.10, Minimum Necessary Policy. In addition, a Certification by the Investigator is required as described below.

4. **Certification by Investigator Required:** When undertaking a “Review Preparatory to Research,” investigators must have a written certification on file with the Privacy Board for the specific project for which the PHI is sought, signed by the investigator, that includes the following representations:
 - a. 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
 - b. PI shall not remove any PHI from UAMS premises in the course of such review; and
 - c. The use or disclosure of PHI is necessary for Research purposes.

For these purposes, PIs must fill out a **Reviews Preparatory to Research Form**, (see [APPENDIX C](#)) and submit it to the Privacy Board.

5. **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.

G. REQUIRED HIPAA RESEARCH AUTHORIZATION

1. HIPAA Research Authorization

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

- a. **Combination of UAMS HIPAA Research Authorization Form and Informed Consent Form:** UAMS 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 may be combined. Whether separate or combined, the Authorization or the Consent should be consistent.
- b. **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:

 - (i) A specific description of the information to be used or disclosed.
 - (ii) The persons, or class of persons, authorized to make the requested use or disclosure.
 - (iii) The name (or other specific identification) of the persons, or class of persons, to whom UAMS may disclose the records.
 - (iv) A description of each purpose of the requested use or disclosure.

- (v) 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”.
- (vi) 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.
- (vii) 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.
- (viii) 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.
- (ix) Signature of the patient and date; and
- (x) 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,” “pursuant to appointment under Power of Attorney.”)

H. WAIVER OF HIPAA RESEARCH AUTHORIZATION

1. 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 Privacy Board in writing and must include the following elements for the waiver of authorization to be considered by the Privacy Board:

- a. Provide a brief description of the Protected Health Information to be used.
- b. Use the following methods to ensure minimal risk to privacy of subjects:
 - (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 or retentions is required by law.
 - (iii) Assure the Privacy Board 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 Privacy Board approval letter **MUST** contain the following information if a waiver is granted by the Privacy Board:
- (i) Name of the Privacy Board.
 - (ii) Date of action.
 - (iii) A statement that the Privacy Board 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 Privacy Board. (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.
 - (vii) A reminder that other HIPAA requirements, such as the Minimum Necessary Rule, still apply.

I. WHEN AUTHORIZATION IS NOT REQUIRED

1. HIPAA Research Authorization is NOT Required When Information is De-Identified.

- a. **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 and 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;
- 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 finger prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic or code.

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 Protected Health Information and Limited Data Set Information* to determine proper de-identification methods. Also refer to *Administrative Guide Policy 2.1.14, Request for Data Extracts*.

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 Limited Data Set Agreement Prior to Disclosure.

a. 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 (*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
 - Date of birth and date of death
 - Age (including 90 or over)
 - 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 a Data Use Agreement is entered with the recipient of 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 entered with the recipient of the Limited Data Set information. Please contact the UAMS Research Support Center 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*.
- 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. *Administrative Guide Policy 2.1.10, Minimum Necessary Policy.*
- e.** Refer to *Administrative Guide Policy 2.1.16, De-Identification of Protected Health Information and Limited Data Set Information* to determine proper use/disclosure of Limited Data Set information, and also refer to the *Administrative Guide Policy 2.1.14, Request for Data Extracts*.
- J. RECRUITMENT:** The IRB must approve all recruitment plans prior to any recruiting activity taking place. UAMS prefers that patients be contacted for recruitment purposes in the following way, in order of preference:
1. Patients are provided with information about studies via handouts, in the waiting room, posters in the exam room, etc. and then self-refer.
 2. The patients’ physicians and physicians’ clinical staff identify studies for which the patients may qualify and ask the patient whether they are interested. If the patient indicates they are interested in study, have research staff come speak with the patient about the study and possibly screen the patient for inclusion in the study.

3. Patients sign a recruitment authorization (with all of the required elements of a HIPAA-compliant authorization), which says they are interested in possibly participating in clinical trials and are willing to have their PHI shared with researchers at UAMS. Research staff may then review the patient's record and contact the patient about studies for which they may qualify.
4. Research staff working for any physician in the department may review the records of any patients in that department to identify potential subjects, and then have the patient's physician contact the patient to see whether they are interested in participating in the study.

K. ACCOUNTING FOR DISCLOSURES

1. **Accounting Required:** An accounting for 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. 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.

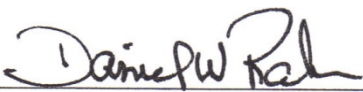
See "Exceptions" below.

2. **Accounting Form:** 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, using the **Accounting For Disclosures Form** attached to the *Administrative Guide Policy 2.1.11, Accounting of Disclosures of PHI*. After completing the Form or documenting the disclosure, the Form or documentation must be provided to the UAMS Health Information Management Department (a/k/a UAMS Medical Records Department), Slot #524. Copies may be maintained by the PI.
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.
- L. Researchers 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 the UAMS HIPAA Office.

SANCTIONS

Violation of this Policy will result in disciplinary action, in accordance with *Administrative Guide Policy 4.4.02, Employee Discipline*.

Signature: 

Date: January 2, 2013

APPENDIX A
UAMS DATA USE AGREEMENT FOR THE LIMITED DATA SET

This Data Use Agreement (“DUA”) is made effective this ____ day of _____, 20__, (“Effective Date”) by and between The Board of Trustees of the University of Arkansas acting for and on behalf of the University of Arkansas For Medical Sciences (“Covered Entity”) with offices at _____, and _____ (“RECIPIENT”), with offices at _____; individually, a “Party” and collectively, the “Parties”.

UAMS is a Covered Entity as defined in the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”); and

UAMS is providing RECIPIENT with a Limited Data Set of Protected Health Information (“PHI”) as defined in HIPAA, thus rendering RECIPIENT a “Limited Data Set Recipient” as defined in HIPAA;

The Parties agree to the provisions of this DUA in order to address the requirements of HIPAA and to protect the interest of both Parties.

1. **DEFINITIONS:** Except as otherwise defined, any terms in this DUA shall have the definitions set forth in HIPAA. In the event of any inconsistency between the provisions of this DUA and mandatory provisions of HIPAA, as amended, the HIPAA definition shall control. Where provisions of this DUA are different than those mandated in HIPAA, but are nonetheless permitted by HIPAA, the provisions of this DUA shall control.
2. **USE OR DISCLOSURE:** RECIPIENT shall have the right to use all PHI provided to it by UAMS for the Research, Public Health or Health Care Operations purposes of:

INSERT THE “USES OF THE DATA” TO BE PROVIDED BY UAMS TO RECIPIENT.

and any other purpose in satisfaction of a judgment of a court of law or pursuant to any Federal or State law or regulation applicable to such PHI.

3. **RESTRICTIONS ON USE:** RECIPIENT agrees to not use or further disclose the PHI other than is permitted by this DUA, or as otherwise required by law. RECIPIENT shall use appropriate safeguards to protect the PHI from misuse or inappropriate disclosure and shall prevent any use or disclosure of the PHI other than as provided in this DUA. RECIPIENT shall not attempt to identify the individuals to whom the PHI pertains, or attempt to contact such individuals.

4. **REPORTING:** RECIPIENT shall report to UAMS any use or disclosure of the PHI not provided for in this DUA of which RECIPIENT is or becomes aware. RECIPIENT will take reasonable steps to limit any further such use or disclosure.

5. **TERMINATION:** This Agreement and all obligations hereunder, shall be effective on the Effective Date first set forth above and shall continue as long as RECIPIENT retains the data, unless otherwise terminated by applicable law or regulation. RECIPIENT may terminate this Agreement by returning or destroying the PHI. Should RECIPIENT commit a material breach of this Agreement, which breach is not cured within thirty (30) days after RECIPIENT receives notice of such breach from the Covered Entity, then the Covered Entity may discontinue disclosure of PHI and report the breach to the appropriate Privacy Officer at UAMS.

6. **RECIPIENT AS A COVERED ENTITY:** RECIPIENT acknowledges that if it is, itself, a covered entity as defined in HIPAA, then breach of this DUA will be treated as noncompliance with 45 CFR 164.514(e).

IN WITNESS WHEREOF, the Parties have executed this Data Use Agreement as of the day and year first set forth above.

Covered Entity (Covered Entity)

Limited Data Set Recipient

Signature

Signature

Name

Name

Title

Title

APPENDIX B
UAMS CERTIFICATION FOR USE OR DISCLOSURE OF
PROTECTED HEALTH INFORMATION OF DECEASED INDIVIDUALS
(45 CFR 164.512(i)(1)(iii))

Names and Addresses of Investigators:

Description of the project for which the PHI is requested:

In accordance with 45 CFR 164.512(i)(1)(iii), the undersigned investigators hereby certify that:

1. Said investigators seek the use or disclosure of Protected Health Information (as defined in 45 CFR 164.501) located at UAMS, as defined in 45 CFR 160.102, solely for research on the Protected Health Information of decedents;
2. Said investigators shall, if requested, provide UAMS with documentation of the death of the individuals for whose Protected Health Information said investigators seek use or disclosure; and
3. The Protected Health Information of decedents located at UAMS is necessary for the research purposes of said investigators.

Signature of Principal Investigator:

Name

Signature

Date

**APPENDIX C
UAMS CERTIFICATION
FOR USE OR DISCLOSURE OF PROTECTED
HEALTH INFORMATION FOR THE PURPOSE OF REVIEW
PREPARATORY TO RESEARCH (45 CFR 164.512(i)(1)(ii))**

Names and Addresses of Investigators:

Source of Data:

Description of the PHI requested:

Description of the specific project for which the PHI is requested:

In accordance with 45 CFR 164.512(i)(1)(ii), the undersigned investigators hereby certify that:

1. Said investigator()seek the use or disclosure of Protected Health Information (as defined in 45 CFR 164.501) located at UAMS, as defined in 45 CFR 160.102, named above solely to review such information as necessary to prepare a research protocol or for similar purposes preparatory to research;
2. Said investigators shall not remove any Protected Health Information from UAMS named above in the course of the review (and shall record only de-identified Protected Health Information); and
3. The Protected Health Information located at UAMS is necessary for the research purposes of said investigators.

Signature of Principal Investigator:

Name

Signature

Date

**APPENDIX D
RECRUITMENT HIPAA AUTHORIZATION**

I authorize the use/disclosure of my health and contact information as described below:

1. Who is authorized to use/disclose the information: **<Insert description of individual/group collecting the info, ex. treating physician>**
2. Who is authorized to receive the information: **<Insert description of individual/group receiving information, ex. research team>**
3. The specific information to be requested or released: **<Insert specific elements of PHI that will be shared>**
4. This information is needed to determine whether you qualify for a research project studying:
<Insert description of research project>

Someone from the research project will discuss the project in detail with you. There is no obligation to enter into the research project.

5. I understand that if the person or entity that receives the information is not a health care provider or health plan covered by federal privacy regulations, the information described above may be redisclosed and no longer protected by these regulations.

6. I understand that I may refuse to sign this authorization and that my refusal to sign will not affect my ability to obtain treatment or payment or my eligibility for benefits

7. I understand that I will be given a signed copy of this authorization form.

8. I understand that I may revoke this authorization in writing at any time by delivering a copy of my revocation to **<insert name and address of person to receive revocations>** except to the extent that action has been taken in reliance on this authorization.

9. This authorization expires on **<insert expiration date or event>**.

Name: _____

Signature of Patient
Or Legal Representative _____ Date/Time _____

If Legal Representative, authority of Legal Representative _____
(such as parent of minor, court-appointed guardian, administrator of estate of deceased, attorney-in-fact appointed with power of attorney, or healthcare proxy)