SECTION: RESEARCH
AREA: RESEARCH ADMINISTRATION
SUBJECT: DATA SHARING FOR RESEARCH PURPOSES

PURPOSE

To establish the procedures necessary to ensure that scientific data sharing is responsible and in accordance with all applicable federal regulations.

SCOPE

This policy applies to all UAMS physicians, faculty, employees and students or other UAMS Workforce members and all prospective and retrospective research (*i.e.*, not just clinical trials) conducted using UAMS data regardless of the source of funding.

DEFINITIONS

For the purposes of this Policy, terms are defined as follows:

Controlled Access: Physical and logical controls implemented by UAMS or a Repository in order to (1) safeguard the confidentiality, integrity, and availability of Scientific Data, (2) limit access to Scientific Data to those persons or entities approved by UAMS pursuant to this policy.

Data Management: The process of validating, organizing, securing, maintaining, and processing scientific data, and of determining which scientific data to preserve.

Data Management and Sharing Plan: A plan describing how scientific data will be managed, preserved, and shared with others (*e.g.*, researchers, institutions, the broader public), as appropriate.

De-identified Data: Data created by removing all 18 elements that could be used to identify the individual or the individual's relatives, employers, or household members; these elements are enumerated in the HIPAA. UAMS also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information.

HIPAA: Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. Parts 160 & 164, and all applicable regulations promulgated from time to time thereunder.

Institutional Certification: An assurance provided to NIH that a submission of human genomic data meets the expectations of NIH's Genomic Data Sharing Policy, or other similar assurance requested by or imposed by the terms of service of a relevant funding agency or Repository concerning the provenance of data being submitted by UAMS.

Limited Data Set: Protected Health Information ("PHI") that excludes 16 categories of direct identifiers under HIPAA and may be used or disclosed, for purposes of research, public health, or health care operations, without obtaining either an individual's authorization or a waiver or an alteration of authorization for its use and disclosure, with a data use agreement. A Limited Data Set may include city; state; ZIP Code; elements of date; and other numbers.

Repository: Enterprise data storage that has been specifically partitioned for scientific, research, or analytic purposes; such purposes may be domain-specific or generalist.

Scientific Data: The recorded factual material commonly accepted in the scientific community as necessary to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.

Sharing: The distribution of data outside the original study team including, but not limited to, uploading to a publicly-available Repository or sharing with non-UAMS investigators for research projects not described in the original protocol under which the data were collected or created.

POLICY

Sharing UAMS scientific data must comply with legal, regulatory, and ethical constraints. In particular, for human subject research, UAMS has an obligation to protect the rights and privacy of research subjects whose data is shared.

Data sharing will only be for the purpose of research and, when applicable, shall be completed within the constraints of the consent under which the data was originally gathered. The UAMS Data Use Committee may review requests for data sharing to ensure adherence to the constraints under which the data were originally gathered.

Data will be considered Controlled Access unless it has been uploaded to an unrestricted access Repository. Requests may be received from outside of UAMS for Controlled Access data. In such cases, the following guidelines should be considered:

- Requestors need to demonstrate, through their peer review publications in the area of interest, their ability to carry out the proposed research on the requested dataset
- Requestors must not have a conflict of interest that may potentially influence their analyses

Requests will be reviewed by the UAMS Office of General Counsel to assess the need for a data transfer or use agreement. The data must only be used for the purpose described in the proposal and may not be transferred to any third party without permission. Unless (1) specifically authorized in a subject's HIPAA authorization for research, or (2) the requirement for a HIPAA research authorization has been waived by the IRB, all human subjects data must be de-identified, coded, or a Limited Data Set, and neither key codes nor direct identifiers (*i.e.*, the 16 categories of identifiers excluded from a Limited Data Set) will be made available to the requestor. The process for de-identification, coding, or the creation of a Limited Data Set found in UAMS Administrative Guide 2.1.16 must be followed. The requestor must not attempt to identify any individual from the

data provided. The requestor must agree not to link the data provided with any other dataset without permission. The requestor must limit distribution of the data on a need-to-know basis and must report any unauthorized access or use of the data to UAMS.

The UAMS investigator who originally collected the requested data should ordinarily be listed as a collaborator on a collaboration project with the option of authorship if the criteria for such as recommended by the International Committee of Medical Journal Editors (ICMJE) are met. In all instances, the requestor will agree to acknowledge the UAMS investigator and UAMS as the source of the data for the research.

PROCEDURES

1. Investigators shall:

    A. Design research projects with the expectations that data will be shared
    B. Design a data management and sharing plan
    C. Share data as required by legal, regulatory, ethical, and commercial guidelines
    D. Should follow NIH or other applicable guidelines in selecting an appropriate Repository
    E. Abide by the International Committee of Medical Journal Editors (ICMJE) requirements:
        a. Manuscripts submitted to ICMJE journals that report the results of clinical trials must contain a data sharing statement as per the ICMJE recommendations.
        b. For clinical trials that begin enrolling participants after January 1, 2019, the clinical trial's registration must have a data sharing plan

2. Data Sharing Eligibility and Limits:

    A. Data derived from human specimens collected prior to January 25, 2015 that did not have specific language in the informed consent consistent with the NIH genomic guidelines will require an IRB determination that data sharing was not inconsistent with the consent signed for that project. Data should be de-identified and have Controlled Access.
    B. Data derived from human specimens collected after January 25, 2015 should have language in the informed consent (even if de-identified) about the type of research, data sharing, and secondary research associated with that project. Additionally, the consent should address whether the data will be shared through Controlled Access or unrestricted access. These guidelines are inclusive of cell lines and clinical specimens that are de-identified. If a specimen was collected after January 25, 2015 and consent did not have the appropriate language, the investigator will have to justify the use of those samples to the IRB, the Data Use Committee, the Office of General Counsel, and/or other appropriate institutional officials.
    C. Data derived from grants, subawards, or other sponsored research may be subject to additional limitations imposed by funding agencies or industry sponsors.
    D. The above eligibility limits will apply to all scientific data subject to data sharing regardless of funding source.

3. Data Management and Sharing Plan:

For each project conducted at UAMS where a proposal involves the generation of datasets for wider research use, investigators should have in place a data management and sharing plan. This plan should be in place before the project becomes active. The plan should address the following questions:

A. What data will your project generate and what value will it have to other researchers?
B. Where will you store the data?
C. Who will control the key linking coded data to identifiers?
D. Where do you plan to publish the data?
E. What documentation will you provide?
F. How will people access the data?
G. Are there any limits to the data?
H. How will the data be preserved?

4. Institutional Certification:

Institutional Certification may be required for public data sharing, including the upload of data to an unrestricted access Repository or to a Controlled Access Repository. All human subject data projects must have IRB approval or an IRB determination before a request for Institutional Certification can be completed. Requests for Institutional Certification should also be submitted to the Office of General Counsel via researchcontracts@uams.edu. This request should state whether the data will be submitted to an unrestricted access Repository or to a Controlled Access Repository, and will be reviewed to confirm the following:

A. Data submission is consistent with applicable national, tribal, state laws and institutional regulations.
B. The sharing and subsequent use of the data are not inconsistent with the informed consent under which they were originally collected or created.
C. Identities of subjects will not be disclosed.
D. An IRB has reviewed the proposal for data sharing and assures that the project is consistent with 45 CFR Part 46, as follows:
    a. Data submission and subsequent sharing are consistent with the informed consent of the study participants from whom the data were obtained.
    b. Risks to subjects and their family relating to sharing were considered and mitigated to the extent possible.
    c. Risks to groups or populations related to data sharing was considered and mitigated to the extent possible.
    d. Plans for de-identifying datasets is consistent with the known NIH standards and HIPAA standards.

REFERENCES

- Draft NIH Policy for Data Management and Sharing https://osp.od.nih.gov/wp-content/uploads/Draft_NIH_Policy_Data_Management_and_Sharing.pdf

- Institutional Certifications https://osp.od.nih.gov/scientific-sharing/institutional-certifications/

- UAMS Administrative Guide Policy 2.1.16, De-Identification of Protected Health Information and Limited Data Set Information

- Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. Part 160 https://www.ecfr.gov/cgi-bin/text-idx?SID=5bc548c93d58e6f5a1790ff054e8d5ae&mc=true&node=sp45.2.160.a&rgn=div6

- Health Insurance Portability and Accountability Act of 1996, 45 C.F.R. Part 164 https://www.ecfr.gov/cgi-bin/text-idx?SID=5bc548c93d58e6f5a1790ff054e8d5ae&mc=true&node=pt45.2.164&rgn=div5

- International Committee of Medical Journal Editors (ICMJE) requirements http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Signature:  **Date:** **July 8, 2020**