



7.10.1 Research Data Ownership, Retention and Access

Chapter 7 - Research and Sponsored Programs	Original Effective Date: August 2017
Section: 7.10 Research Administration	Date Last Reviewed: June 2023
Responsible Entity: Vice President for Research	Date Last Revised: July 2018

I. Purpose

This policy asserts and protects the rights of the UT Health San Antonio and its Member Researchers, regarding ownership and retention of research data and related records.

II. Scope

This policy applies to UT Health San Antonio full or part-time faculty members, classified employees, administrative staff members, paid student assistants, student, volunteers, fellows, or trainees, visiting faculty members or researchers involved in Research.

III. Policy

It is the policy of UT Health San Antonio (UTHSA) that research investigators, faculty, staff, trainees, and students all share in the obligation to retain research data in appropriate form, archive it for a reasonable length of time and make the data available for collaborative research and for review under the appropriate circumstances.

A. Acquisition and the Use of Research Data

Investigators shall record original observations in accordance with the standards of their respective disciplines and in accordance to UTHSA's policies in the Handbook of Operating Policies (HOP). The Investigator who gathers or creates Research Data may use the information as they deem appropriate and may authorize others to make appropriate use thereof, subject to UTHSA and personal contractual commitments and UTHSA policies. The use of Research Data gathered within a group of Investigators is subject to the reasonable control of the Principal Investigator (PI). In the event Research Data is acquired via Sponsored Research, the restrictions imposed by the agreement associated with such sponsorship shall control any uses of Research Data.

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B. Custody of Research Data

All Research Data shall be preserved in the custody of, or as arranged by, the PI. The PI is charged with the integrity, preservation and security of Research Data and the appropriate marking and reporting of all UTHSA intellectual property that may be included in, or derived from, the Research Data. In the case where the PI is unable to perform these functions, the PI's supervisor will take custody of the Research Data until arrangements are made for alternative custody. The PI shall ensure the availability of digital Research Data, including, but not limited to, archiving or escrowing any system-specific access codes, encryption keys, or passwords not related to the Investigator's personal credentials.

Principal Investigators leading Research teams have obligations to discuss responsibilities of data acquisition, use, management, security, access, and retention with other members of a Research team. This may also include access and use of de-identified human subject's data that is acquired via student research projects.

In cases involving allegations of research misconduct, the threat of imminent loss of data or records, or for other justifiable causes, the UTHSA, acting through the Vice President for Research (VPR) or designee, may take immediate custody of Research Data (see HOP [7.6.1, Research Misconduct](#)).

C. Retention of Research Data

The PI must ensure that the data collection and its interpretation methods are documented and retained. Research Data disclosed or referenced in publications, including the primary experimental results, must be retained per HOP [2.2.1 Records Management](#), HOP [5.8.21 Data Classification](#), and the State of Texas Record Retention Schedule (Medical Services/Research and Development 130 Department; After Closed + 15 years) or as otherwise defined by state regulations, internal agreement, or Sponsored Research agreement to allow analysis and replication by others. Retention of Research Data resulting from sponsored programs or commercial agreements are subject to additional policies or contract obligations. Consult with the Office of Sponsored Programs (OSP) for specific federal, state, and local regulations, sponsor requirements, and organizational policies and procedures. Consult with the Office of Technology Commercialization (OTC) for specific commercial agreement requirements and obligations. Research Data collected for product application to the Food & Drug Administration (FDA) may be subject to additional data retention requirements as specified by the sponsor and/or the FDA.

Appropriate measures to protect confidential information must be taken. For data stored on electronic media, protect research data using appropriate administrative, physical and technical controls in accordance with HOP [5.8.22](#)

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Data Protection. In addition, any of the following circumstances may warrant longer periods of retention;

1. Data pertaining to patient rights that involve Protected Health Information (PHI) or other pertinent information such as medical records, protocols, case history forms, clinical trial agreements, as well as progress reports and final reports.
2. Principal Investigators who maintain research databases for which a waiver of patient authorization was granted have additional record maintenance responsibilities related to HIPAA.

Additionally, record retention considerations should include record retention regulations and guidance which are dependent on funding source for all applicable parties (i.e. DHHS, FDA, IRB, private sponsors).

If an investigation, legal action, or official inquiry concerning a Research activity is ongoing; all Research Data related to the project must be retained and made accessible until all issues are resolved.

In addition to the record retention requirement above, if a student or trainee is involved, Research Data must be retained at least until the degree is awarded to the student, the training period is complete, or it is clear that the student has abandoned the work.

In addition to other requirements and obligations in this Chapter, Research Data should be kept for at least as long as may be required to determine if the Research involves patentable subject matter or other intellectual property and until the Office of Technology Commercialization (OTC) has made a final decision on whether to file a patent application. If UTHSA or any other entity files a patent application related to Research Data, all Research Data containing evidence of contribution to inventorship by a University Member should be kept until all related patent applications are finally abandoned, or in the case of issued patents, for the life of the patent. Consult with the OTC to determine if your research involves patentable subject matter or for questions regarding inventorship.

This policy does not create an obligation to retain Research Data ensuing from an abandoned or unfunded project, unless it results in a Report in which the investigator is identified as a University Member, constitutes a record of UTHSA intellectual property, or involves the use of animal or human subjects.

D. Access to Research Data

UTHSA has the right to access Research Data for all Research that is either performed at UTHSA, supported by UTHSA administered funds, or conducted using UTHSA facilities, provided such access shall be for reasonable cause, at

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reasonable times and after reasonable notice, except in the event of a bona fide emergency. UTHSA's right of access shall continue regardless of the location of the PI or of the Research Data.

Information or data that would violate the confidentiality of sources or subjects involved in the Research shall not be disclosed except in accordance with law or regulation. UTHSA and appropriate external officials shall have access to Research Data concerning matters of compliance with human or animal research subject to applicable laws, regulations, and policies. Subject to provisions of law, individual human research participants may be allowed to access Research Data that pertains to themselves, but not to access Research Data pertaining to others.

Extramural sponsors providing support to UTHSA or appropriate governmental officials also may have the right to review the Research Data resulting from that extramural support.

University Members who are an integral part of a Research project have the right and responsibility to review all Research Data that they gathered or created, or which support publications for which they are named authors, even after departure from UTHSA, to the extent that such Research Data continues to exist and can be identified.

Sharing of Research Data (that has been published) is held by UTHSA to be a tenet of the scientific community. Standards of data sharing have been published by national scientific organizations and by federal funding agencies such as:

1. Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences (The National Academies Press)
2. NIH Data Sharing Policy (National Institutes of Health)
3. NSF General Grant Conditions (National Science Foundation)
4. International Committee of Medical Journal Editors

Scientific and scholarly publications increasingly include statements that promote data sharing in their instructions to authors. University Members are expected to share their published data upon request. Sharing of data should occur in a timely manner and involve only necessary costs. Data are to be shared in reasonable but limited quantities with members of the research community for non-commercial purposes and in compliance with any restrictions that may have been agreed to with the entity funding the research. In the case of requests that have commercial implication or those that involve Tangible Research Property which may represent potential or protected intellectual property such materials may be shared under the terms of a UTHSA-approved Materials Transfer Agreement which may be obtained through the Office of Sponsored Programs, or in some cases, the Office of Technology Commercialization. Shared

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data resulting from human subjects research shall be stripped of all direct identifiers and coded, with the linkage key to the code residing in the custody of the UTHSA PI.

E. Transfer of Research Data

The transfer of Research Data is managed through the Office of the VPR. When a PI separates from UTHSA (i.e., no longer a compensated or adjoint appointed employee), the Research Data shall remain the property of and in the possession of UTHSA, unless a written agreement on Disposition of Research Data is reached between the PI and the PI's department chair or Dean and the Chief Information Security Officer or designee and is then memorialized in an appropriate agreement between UTHSA and the PI's new employer processed through the Office of Sponsored Programs. In most cases, this agreement may allow the original Research Data to be transferred with the PI. These agreements will serve to ensure appropriate access to the transferred Research Data in fulfillment of UTHSA's obligations to funding sources and other supporting entities, and for research compliance purposes. Under the terms of the agreement, the Investigator shall have the obligation to hold these Research Data in trust for UTHSA. Requests to transfer Research Data or Tangible Research Property when a University Member leaves UTHSA are coordinated by the Office of the VPR. Completed request forms will be maintained by the Office of the VPR according to UTHSA's retention schedule. Questions regarding the transfer process may be addressed to the Office of the VPR at vpr@uthscsa.edu.

In general, Investigators other than the PI may request copies of the Research Data but are not authorized to transfer original data. Investigator requests are approved by the PI. Certain federal and state laws and policies, including federal export control regulations, are applicable to certain types of research material and data, regardless of whether the Research Material is a copy or original. It is the investigator's responsibility to comply with all applicable laws, regulations, and policies.

In some cases (e.g. Research Data containing patentable subject matter, Research Data generated and/or used by other UTHSA Investigators, some Tangible Research Property, or as required by the terms of extramural funding agreements), it may be necessary for original Research Data to be retained at UTHSA. In such cases, this agreement shall allow the Investigator to access and, where practical, to copy Research Data. In cases of multi-institutional studies, the institution of the primary PI shall be responsible for arranging access to, use of, and retention of Research Data.

When required by law, regulation, or contract, or to fulfill other obligations, UTHSA may transfer title or custody of Research Data and records at its

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discretion. In such cases, UTHSA, to the extent as possible, will ensure access by Principal Investigators, Investigators, and other appropriate individuals to that Research Data.

In all cases where sensitive information leaves UTHSA systems, security precautions will be taken, and best practices adhered to ensure the confidentiality, integrity, and availability of the Data until it reaches its destination.

F. Ownership of Research Data and UTHSA Disposition

Consistent with federal policy and prevailing higher education practice, Research Data is owned by the Board of Regents. Sponsored Research Data ownership is subject to the agreement between UTHSA and the extramural sponsor. In the event that Investigator data retention and maintenance practices are found to be contrary to this Policy, UTHSA may make disposition of these Research Data and related property rights in a manner that is consistent with law and policy, including, but not limited to, UTHSA's HOP [12.1.1 Intellectual Property Policy](#) and HOP [7.6.1 Research Misconduct](#).

Students own Research Data that they generate or acquire in their academic work, unless the Research Data are:

1. generated or acquired within the scope of their employment at UTHSA;
2. generated or acquired through use of substantial UTHSA resources; or
3. subject to other agreements that supersede this right (e.g., Research Data Ownership Acknowledgment form signed by student and PI).

Research data generated or acquired by students outside of their academic work or by volunteers through research projects conducted at or under the auspices of UTHSA, regardless of funding source, are owned by UTHSA unless superseded by specific terms of sponsorship or other agreements.

G. Research Data Policy Oversight and Dispute Resolution

The VPR has responsibility for oversight of, and resolution of, disputes resulting from this policy. If an Investigator desires to contest the decision of the VPR, the Investigator may file a written appeal to be reviewed by a committee of researchers, appointed by VPR.

IV. Definitions

When used in this document with initial capital letter(s), the following words have the meaning set forth below unless a different meaning is required by context.

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University Member – any full or part-time faculty member, classified employee, administrative staff member, paid student assistant, student, volunteer, fellow or trainee, visiting faculty member or researcher. One is not a University Member when acting in a purely private role that in no way or manner implicates UTHSA, unless that activity results in a Report in which the individual is identified as having a UTHSA affiliation.

Investigator – a University Member engaged in the conduct of Research or any person using facilities owned or operated by, or using resources administered by UTHSA.

Principal Investigator (PI) – the Investigator who, acting on behalf of UTHSA, has primary stewardship of Research and or Research Data. In this capacity the PI is responsible for the collection, recording, storage, access, and retention of Research Data in keeping with this policy's best practices.

Report – a summary, statement or description of research activities published in the open literature or provided to the public, UTHSA, a sponsor, or other researchers by a University Member.

Research – a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research includes investigation of a test article (i.e. a drug or device).

Research Data – recorded information, regardless of form or the media in which it may be recorded, which constitute the original observations and methods of a study and the analyses of the original data that are necessary for reconstructions and evaluation of the Report(s) of a study made by one or more Investigators.

Research Data also includes all such recorded information gathered in anticipation of a Report.

Research Data differ among disciplines. The term may include but is not limited to technical information, computer software, laboratory and other protocols, statistics, findings, conclusions, samples, physical collections, other supporting materials created or gathered in the course of the Research, Tangible Research Property (i.e., products of research that include, but are not limited to compositions, biologics, materials, illustrations and drawings, prototypes, devices and equipment), unique Research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA as well as genetic sequences and mapping information, crystallographic coordinates, plants, animals and spectroscopic data, and other compilations formed by selecting and assembling pre-existing materials in a unique way.

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The term does not include information incidental to research administration such as financial, administrative, cost or pricing, or management information.

Sponsored Research – Research which is funded or otherwise supported by extramural sources.

V. Related References

[Summary Table of Common Record Retention Rules](#)

[Office of the Vice President for Research \(VPR\)](#)

[Office of Sponsored Programs \(OSP\)](#)

[Office of Technology Commercialization \(OTC\)](#)

VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
08/2017	Policy Origination		
07/2018	Policy Review		
06/2023	Policy Review		