

Policy on Research Data Retention

I. Purpose: Adequate preparation and retention of records is essential to any research endeavor. Sponsors, federal and state agencies, or journals and other colleagues in the field may need or be legally entitled to review research data well after study activities have been concluded. The University must retain research data in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy and maintain compliance with laws and regulations governing the conduct of the research. It is the purpose of this policy to ensure that research data are recorded and used properly, are retained under responsible custody for a reasonable length of time, and are made available for review under appropriate circumstances

II. Applicability

This policy applies to all University of Mississippi Medical Center (UMMC) faculty, staff, and students involved in the design, conduct, or reporting of research at or under the auspices of UMMC, or with the use of UMMC resources or facilities. It shall apply to all research projects on which those individuals work, regardless of the source of funding for each project.

III. Definition of Research Data

Research data are defined as the material, originally recorded by or for the investigator, commonly accepted in the scientific community as necessary to validate research findings. Research data include, but are not limited to, laboratory notebooks, as well as any other records that are necessary for the reconstruction and evaluation of reported results of research and the events and processes leading to those results, regardless of the form or the media on which they are recorded. Included in this term are unique research resources such as novel compounds synthesized by the investigator, organisms, cell lines, viruses, cell products, cloned DNA as well as genetic sequences and mapping information, crystallographic coordinates, plants, animals and spectroscopic data. For this policy, information incidental to administration (for which other UMMC policies may apply), such as financial, administrative, cost or pricing, or management information are not included.

IV. Policy

UMMC is responsible for the proper maintenance and accountability of data created or collected by University faculty, staff, students and trainees. The Principal Investigator (PI) is responsible for integrity, preservation and security of research data. Faculty members are responsible for the retention of records created by students, trainees, or staff whom they sponsor/mentor/supervise.

Original scholarly/research records shall remain upon the premises of UMMC unless otherwise authorized by UMMC. All research data shall be preserved in the custody of, or as arranged by, the PI on behalf of UMMC. In order to comply with this policy, it is the responsibility of the PI to put into place a system of data organization and communicate that system to all members of the research group and to the appropriate administrative personnel, where applicable, to ensure orderly collection and proper maintenance of research data. Particularly for long-term research projects, the PI should establish and maintain procedures for the protection of essential records.

Collection and Retention of Research Data

Research data shall be recorded in accordance with the accepted standards of the particular academic field or discipline. Accurate and appropriate research records are essential to research. It is important that investigators have the ability to document the results of research, both for the sake of meeting legal requirements as well as for more traditional reasons of establishing priority for patentable items, publishing manuscripts, and the like.

Research data shall be retained for a period of no less than six (6) years after approval of the final report or publication, unless a longer retention period is specified by the sponsor. If any of the following circumstances should arise during the retention period, additional retention time or special considerations may be required:

- Data must be kept for as long as may be necessary to protect any intellectual property resulting from the research activity.
- If any charges regarding the research arise, such as allegations of misconduct in research or financial conflict of interest, data must be retained until such charges are fully resolved.
- If a student is involved and the data constitutes part of the student's work toward a degree, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.
- Beyond the period of retention specified here, the destruction of the research record is at the discretion of the PI and his or her department or laboratory.

Clinical Research Data

Research data collected during the course of clinical research involving human research participants shall be collected and retained in accordance with this policy, applicable regulations and the requirements of the clinical trial agreement with the sponsor or agency, whichever document specifies a longer period. Additionally, the PI must ensure that the procedures for retention and/or destruction of participants' research data are carried out in accordance with the provisions of the written informed consent document signed by the research participant, as well as this policy, applicable regulations and the clinical trial agreement. If the study includes medical treatment, the PI must ensure that the medical records are retained in compliance with state law and UMMC policy for medical record retention.

Access

To enable the University to meet its responsibilities related to custody of research data, the PI is obligated, upon request by the Vice Chancellor of Health Affairs or his/her designee, to make all data available for review by the University, its officials or the external funding agency or journals, or other external regulatory agencies. This obligation continues even after the PI leaves the University.

In group research projects, the PI is obligated to give co-investigators access to the research data or copies thereof for review and/or use in follow-on research, with proper acknowledgement. Data sharing and custody arrangements by co-investigators or group projects should be determined by the investigator when joining the project and preferably defined in a data use agreement.

Research data will normally be retained in the unit/laboratory/department where they are produced. Research data must be retained in such a manner that they are readily accessible for inspection and copying by authorized representatives of UMMC. To assure accessibility, data archival systems must be compatible with existing technology.

To assure needed and appropriate access, if the PI is transferring to a new institution, the original data shall remain with UMMC, in the custody of either a newly assigned PI, a designated department official

or with the Office of Sponsored Programs. The PI may take copies of research data, provided confidentiality and contractual agreements allow.

Ownership

The terms of research data ownership shall be addressed in the research agreement with the sponsor or funding agency. The research agreement shall be reviewed and approved by the Office of Sponsored Programs and by UMMC legal staff. Unless otherwise authorized, UMMC shall retain ownership and custody of research data for projects conducted at UMMC, under the auspices of the University, or with University resources is based on both regulation and sound management principles.

UMMC responsibilities in this regard include, but are not limited to:

- Complying with terms of sponsored project agreements;
- Ensuring the appropriate use of animals, human subjects, recombinant DNA, etiological agents, radioactive materials, and the like;
- Protecting the rights of faculty, students, postdoctoral scholars, and staff, including, but not limited to, their rights to access data from research in which they participated;
- Securing intellectual property rights;
- Facilitating the investigation of charges, such as misconduct in research or financial conflict of interest;
- Responding to legal actions involving the University related to research carried out under its auspices.

When a PI is leaving UMMC and a project is to be moved to another institution, ownership of the data may be transferred with the approval of the Associate Vice Chancellor for Research and with written agreement from the PI's new institution that guarantees 1) its acceptance of custodial responsibilities for the data and 2) UMMC's access to the data should that become necessary. The Office of Sponsored Programs must be contacted to complete the necessary forms.

When a PI retires or departs from UMMC, a written request to take the research data may be made to the Associate Vice Chancellor of Research. If the PI does not wish to take the data, the PI's department chair shall appoint a designee to assume custody of the research data. It is the responsibility of the PI to make appropriate arrangements for the transfer of research data prior to their planned departure from UMMC. In those cases when a PI leaves the University without fulfilling this responsibility, or in the case of death of the PI, the PI's department chair shall appoint a designee to assume custody of the research data.

Freedom of Information Act

Federal regulations require that research data relating to published research findings first produced in whole or in part under a federal award and that were used by the federal government in developing an agency action that has the force and effect of law be made available to the public through the procedures established under the Freedom of Information Act (FOIA). The following are excluded from the federal FOIA requirement:

- Preliminary analyses
- Drafts of scientific papers
- Plans for future research
- Peer reviews
- Communications with colleagues
- Physical objects (e.g., laboratory samples, audio tapes, video tapes)
- Trade secrets

- Commercial information
- Materials necessary to be held confidential by a researcher until publication in a peer-reviewed journal
- Information which is protected under the law (e.g., intellectual property)
- Personnel and medical files and similar files, the disclosure of which would constitute unwarranted invasion of personal privacy
- Information that could be used to identify a particular person in a research study

Request for research data under the FOIA are to be directed to the federal sponsoring agency. The sponsoring agency, in turn, requests the data from the grant recipient institution. Research investigators who receive requests for research data directly from a federal agency sponsor or from a third party under the FOIA are responsible for referring such requests to the Office of Integrity and Compliance.

Questions

For additional information regarding retention, access or requests for original or copied research data, contact the Office of Integrity and Compliance.