



I. Policy

A. Introduction

Each department chairman or center director is ultimately responsible for the review and scientific integrity of any proposal that will be sent to the IRB. In the case of most centers, such as the Hollings Cancer Center, there are standing committees of scientists, physicians, statisticians, and other health professionals that review protocols for scientific integrity prior to review by the director or chairman's office.

B. Federal Regulations

Federal Regulations for record retention and access to records for awards to recipients are set forth in OMB Circular A-110, (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations), and specifies that financial records, supporting documents, statistical records and all other pertinent records shall be retained by the institution. Research records are pertinent to the award and therefore, must be retained. In addition, 42 Code of Federal Regulations (CFR) Part 93 (Public Health Service Policies on Research Misconduct) specifies evidentiary retention requirements for research records.

C. MUSC Agents and Affiliates

The record retention and access to records requirements specified in this policy apply to research conducted by the Medical University of South Carolina, its agents or affiliates.

II. Procedures

A. Record Retention

1. Research records should be retained for a sufficient minimum period to allow evaluation and repetition by others of the results and to investigate an allegation of research misconduct. Usually [unless granted an exception by the Department of Health and Human

Services (HHS) or the Office of Research Integrity (ORI)], this minimum period is six years.

2. For research involving children, this minimum period for research to keep research records is six years or until the child reaches the age of eighteen, whichever is later.

B. Definition of Research Record

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, clinical trial records, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to the Department of Health and Human Services (HHS) or an institutional official by a respondent in the course of a research misconduct proceeding

C. Ownership

1. MUSC assumes legal and financial accountability for awarded funds and owns the rights in data resulting from a grant-supported project. Therefore, MUSC retains ownership rights to research records generated by MUSC faculty, scholars, staff, post-doctoral fellows, students and visiting scientists whether generated during scholarly activities or in conducting sponsored activities funded by external agencies.
2. MUSC may choose not to claim ownership rights if there is a term or condition of the award, an agreement or in law or regulation. In addition, MUSC supports the National Institutes of Health (NIH) Data Sharing Policy as defined in NIH Notice: NOT-OD-03-032. However, MUSC retains the right to use research records for its own educational, research and non-commercial purposes

D. Management of Data

1. Data management, including the decision to publish, is the responsibility of the principal investigator. Research data, including detailed experimental protocols, all primary data, and procedures of reduction and analysis are the essential components of scientific progress. Scientific integrity is inseparable from meticulous attention to the acquisition and maintenance of these research data.
2. The results of research should be carefully recorded in a form that will allow continuous access for analysis and review. Attention should be given to annotating and indexing notebooks and documenting computerized information to facilitate detailed review of data. All data, even from observations and experiments not directly

leading to publication, should be treated comparably. Investigators should be aware that research data are legal documents for purposes such as establishing patient rights or when the veracity of published results is challenged and the data are subject to subpoena by congressional committees and the courts.

E. Access to Research Records

1. Since MUSC is responsible for managing and monitoring each project, program, sub award, function or activity for awarded research, MUSC retains the right of access and to make copies of records for all research performed at MUSC or supported by MUSC sponsored funds. Where feasible, appropriate notice will be given of the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going work. Examples of MUSC's right of access are to conduct compliance audits, investigate allegations of research misconduct, etc.
2. All research data should be available to scientific collaborators and supervisors for immediate review, consistent with requirements of confidentiality.
3. Either before or when MUSC notifies the respondent of an allegation, inquiry or investigation, MUSC shall promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
4. The PI maintains the right to either retain or obtain copies of research records to use for their defense.

F. Health Insurance Portability and Accountability Act (HIPAA)

HIPAA prohibits removing research-related identifiable protected health information (PHI) from MUSC unless:

1. The removal is authorized by the patient/research subject;
2. The PHI is de-identified;
3. The PHI is part of a Limited Data Set with an approved Data Use Agreement;

4. The Institutional Review Board (IRB) grants a waiver of authorization; or
5. The removal is required by law.

G. Transfer of Research Records

1. In the event the Principal Investigator (PI) transfers or leaves MUSC, the PI and the Vice President for Research will negotiate an agreement on the disposition of research records. This agreement will specify MUSC's right of access to research records for reasonable cause after reasonable notice regardless of the location of the records.
2. The HIPAA Privacy Rule does not permit a PI to transfer control of subject identifiable research records to another institution unless the original permission under which the PI obtained or created the data in the record (such as the individual's authorization or approved by the Institutional Review Board) was granted explicitly for the PI, rather than solely for MUSC. Otherwise, any transfer of PHI from MUSC to another institution for research purposes must be done according to a new permission (authorization, waiver, etc.).
3. As authorized by the PI, when individuals (i.e. students, post-doc fellows, etc.) involved in a research project leave MUSC, they may take copies of research records which they generated unless restricted by the terms of the applicable contract, other contractual agreements, and/or law (i.e. HIPAA) or regulations.

H. Resolution of Disputes Involving Research Records

1. The Provost or designee shall arbitrate all disputes involving the ownership, retention and access to research records.