UNM HEALTH SCIENCES CENTER

Research Data and Materials Retention Policy

Title: Research Data and Materials Retention Policy		
Doc Type: Policy-Procedure	**Policy-Procedure #:HSC-**R-801 PR.1	**Effective Date:** 02/18/2015
Owner(s) (Name and Title): Vice Chancellor for Research	**Revision Date:**	**Applies To:** All UNM Health Sciences Center components, as applicable.

DESCRIPTION/OVERVIEW

The University of New Mexico Health Sciences Center ("UNMHSC") has both rights and responsibilities toward scientific data generated by research on its campus.

This policy serves to:

1) ensure that Research Data and Materials are properly protected, archived, retained and available for review under the appropriate circumstances;
2) ensure compliance with local, state, and federal laws and regulations;
3) support matters of scientific integrity, human subjects, and animal use;
4) satisfy contractual obligations and sponsored project agreement requirements;
5) assure appropriate use of recombinant DNA, etiologic agents, radioactive materials, etc.; and
6) provide an overarching umbrella approach to research data and records management across UNMHSC since other division policies also exist and apply.

Additionally, the objective of this policy is to complement, and not supercede or conflict, other policies or Standard Operating Procedures ("SOP") of UNMHSC regarding records retention.

APPLICABILITY

This policy shall apply to all UNMHSC faculty, staff, postdoctoral fellows, students, and any other persons, including consultants, involved in the design, conduct or reporting of research performed at or under the auspices of UNMHSC, including all research projects on which those individuals work, regardless of funding source for the project.

DEFINITIONS

HRRC: Human Research Review Committee(s), which serve as the Institutional Review Board(s) relative to human subjects research conducted at or through the UNMHSC.

Human Subjects: a living individual whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual; or 2) identifiable private information.

IACUC: Institutional Animal Care and Use Committee

Principal Investigator: The individual who bears primary responsibility for technical, programmatic, fiscal, and administrative requirements of the project.

Research Data and Materials: Information recorded in physical form, regardless of form, or the media on which it may be recorded. For the purposes of this policy, Research Data and Materials is further defined as including any record that would be used for the reconstruction and evaluation of reported or otherwise published results. Research Data and Materials also include, but are not limited to: unmodified biological specimens, documentation of informed consent, original biological and environmental samples, equipment, laboratory notebooks, notes of any type, photographs, films, digital images, protocols,

numbers, graphs, charts, numerical raw experimental results, samples of chemicals and materials synthesized during research, vouchers, specimens, computer files, electronic data, electronically stored information, instrumental outputs from which Research Data and Materials can be derived and other deliverables under sponsored agreements.

Sponsor: Individual, company, institution, or organization taking responsibility for initiation, management, and financing of study.

POLICY

Retention Periods

Unless a different retention period is specified by the law, UNMHSC policy, UNMHSC SOP, sponsor, funding source, regulation, memorandum of understanding, agreement, or written exception by the Vice Chancellor for Research, the following retention periods shall be observed after the submission of the final report and close-out procedures on the research project for which the Research Data and Materials were prepared:

- Research Data and Materials are to be retained by UNMHSC for a period of at a minimum three (3) years. 45 CFR 46.115(b)
- Research Data and Materials involving Human Subjects are to be retained by UNMHSC for a period that is the greater of: (a) the retention period required by the sponsor in respect of a sponsored research project (as set forth in the definitive Clinical Trial Agreement with the sponsor), or (b) if no such agreement exists, then seven (7) years from and after the closure of the study in question.
- For Research Data and Materials involving Protected Health Information ("PHI"), the Principal Investigator must retain the signed consent forms that contain the permission to use the PHI for six (6) years beyond the expiration date of the authorization (i.e. the consent form or authorization). 45 CFR § 164.105
- Research Data and Materials involving minors aged eighteen (18) years of age and younger are to be retained by UNMHSC until the minor reaches the age of 22. NMAC 1.15.8.101.D(2)
- Research Data and Materials involving the research of drugs, devices, or biologics being tested in humans for FDA approval shall retain records for "a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified." 21 CFR § 312.62.c
- If there are two or more overlapping retention periods, then the applicable retention period is the longer (or longest) length of time between the two or more overlapping periods.

Responsibility

The collection, management, retention, and maintenance of the original Research Data and Materials in accordance with this policy and other applicable UNMHSC SOP shall be the responsibility of the Principal Investigator on behalf of UNM.

Ownership of Research Data

UNMHSC compensates researchers and allows students to produce work. Accordingly, UNMHSC owns all the Research Data and Materials generated by research projects conducted at or under the auspices of UNMHSC regardless of funding source, unless specific terms of sponsorships or other agreements

supersede these rights.

All researchers and students, including the Principal Investigator, may not copy, remove, or destroy data without explicit written permission from the Vice Chancellor of Research.

PROCEDURES

The following apply unless an explicit written exception to do otherwise has been given by the Vice Chancellor for Research.

Retention of Research Data and Materials.

- The Principal Investigator should adopt an organized system for Research Data and Materials retention and ensure compliance by all of his/her direct reports.
- The Principal Investigator is also responsible for providing responses to questions about accuracy, authenticity, primacy, and compliance with laws and regulations governing the conduct of research, and permit for a retrospective audit if necessary. He or she should also consult with UNMHSC officials regarding the development of any contingency plans.
- Research Data and Materials shall be maintained in the department or division in which they were produced; if they are in a shared, network-based electronic file, then access shall be limited to authorized personnel.
- Research Data and Materials must be retained on UNMHSC campus, campus affiliate, or an appropriate UNM-approved storage facility.
- In order to support the credibility of UNM's rights and ability to meet obligations related to the Research Data and Materials, should any revisions to the final Research Data and Materials be contemplated, the Principal Investigator must notify the appropriate offices at UNMHSC and the originator of the information.
- When research results in an invention assigned to UNMHSC, and made available for commercialization through STC.UNM, the original research lab log book that verifies the original discovery must be forwarded and stored with that respective department. The Principal Investigator may take a copy of the research lab log book with the approval of the Vice Chancellor for Research. This archive becomes the responsibility of that respective department.

Transfer of Research Data and Materials

- UNMHSC must retain all original Research Data and Materials. Any patient/subject records will require appropriate patient/subject authorization for use and disclosure to another entity.
- Before transferring the grant and a copy of the Research Data and Materials, the Principal Investigator must ensure that any special conditions stated in the grant, contract, or agreement are met.
- If a grant is being transferred to another institution with the Principal Investigator, then the Principal Investigator is responsible for leaving the original of all Research Data and Materials with UNM.
- The department is responsible for archiving the Research Data and Materials for at least six (6) years following the transfer of the Principal Investigator or the term of the grant or agreement, whichever is longer.
- Prior to the removal of any tangible research from UNMHSC, the recipient/institution must execute a Material Transfer Agreement with UNM.

Access to Research Data and Materials

- The Principal Investigator will have access to the Research Data and Materials generated by the project. Any other faculty, staff, student, or person involved in the creation of the Research Data and Materials may have the right to review that portion that he or she created.

UNM HEALTH SCIENCES CENTER

- UNMHSC will have access to the Research Data and Materials as necessary for technology transfer, compliance, and for any other purposes.
- UNMHSC will have the option to take custody of the Research Data and Materials, as determined by the Vice Chancellor for Research (or designee), but such shall not be invoked without cause and subsequent notification of the Principal Investigator.
- The Research Data and Materials shall be available to designated governmental officials or to a research sponsor, where such access is appropriate.
- Any disputes regarding requests for original Research Data and Materials, copies, or transfer of this data will be resolved by the Vice Chancellor for Research (or designee).

Destruction of Research Data and Materials

- Research Data and Materials must not be destroyed without prior approval of the Vice Chancellor for Research.
- Prior to any Research Data and Materials destruction, the following information shall be recorded in a log within that department or division: Principal Investigator name, protocol identifiers such as funding source or sponsor (when applicable), protocol number, HSC/IACUC or committee identifier, date of destruction, person destroying the documents, and a summary of the documents shredded.
- If the study is an industry-sponsored study, prior to destroying the documents or disposal of materials, the sponsor will be contacted and written permission obtained to destroy the documents.
- When the Research Data and Materials have met the applicable retention periods and all necessary information have been recorded, the destruction shall be as follows: the paper documents will be shredded, and the records stored on a computer hard drive should be erased using commercial software applications designed to remove all data from the storage device.

REFERENCES

- UNM Health Sciences Center Records Management, Retention, and Disposal Policy
- 21 CFR § 812.140
- 21 CFR § 56.11.5
- 21 CFR § 312.62
- 38 CFR § 16.115(b)
- 45 CFR § 46
- 45 CFR § 164.105
- NMAC 1.15.8.101.D(2)

DOCUMENT APPROVAL & TRACKING

Item	Contact	Date	Approval
Owner	UNM Health Sciences Center – Office of Research		
Consultant(s)			
Recommender(s)			[Y or N/A]
Committee(s)	Research Strategic Planning Committee		[Y or N/A]
HSC Legal Office	Rosalyn D. Nguyen, Esq., Associate University Counsel		[Y or N/A]
Official Approver	Richard S. Larson, MD, PhD, Executive Vice Chancellor, Vice Chancellor for Research		Yes

UNM HEALTH SCIENCES CENTER

Item	Contact	Date	Approval
Official Approver Signature		Date:	2/18/2015
2nd Approver			
2nd Approver Signature (Optional)		Date:	
Policy Origination Date:			