Responsible Office:
Office of Research

Research Data Ownership, Retention, and Access

POLICY STATEMENT AND PURPOSE

This policy asserts and protects the rights of Virginia Commonwealth University (the University), and its Member researchers, in regard to ownership and retention of research data and related records.

WHO SHOULD READ THIS POLICY

All University Members involved in the conduct of research should read this policy.

RELATED DOCUMENTS

- Virginia Public Records Act, §§42.1-76 et.seq. of the Code of Virginia
- Commonwealth of Virginia Records Retention and Disposition Schedule No. 111
- VCU Records Management Procedure
- Intellectual Property Policy (link pending policy approval)
- Responsible Conduct in Research Policy (link pending policy approval)

CONTACTS

VCU Office of Research officially interprets this policy and will prepare revisions, as needed, to meet the changing needs of Virginia Commonwealth University. All revisions shall be subject to University Board of Visitors approval following review by university leadership (Vice Presidents, Council of Deans, University Council, and Faculty Senate).
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DEFINITIONS

Investigator means any University Member engaged in the conduct of research as either an employee or student of the University or any person using facilities owned or operated by, or resources administered by, the University.

Principal Investigator has primary stewardship of Research Data on behalf of the University. In this capacity the Principal Investigator (PI) is responsible for data collection, recording, storage, access, and retention in keeping with this policy and best practices in the PI’s discipline.

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

Research means a systematic investigation designed to develop or contribute to knowledge and may include the stages of development, testing, and evaluation.

Research Development Advisory Council (ReDAC): Inaugurated in 2006, its members are Associate/Assistant Deans for Research or individuals who hold comparable responsibilities for research development within their respective College/School. Council members represent the research interests of each of the Schools and Colleges at the University, and serve as a conduit of information from the Office of Research back to their constituencies. The
Council meets regularly with the Vice President for Research and the Associate Vice President for Research Development to address topics of specific interest to the University research enterprise, and to identify resources and supports necessary for increasing the strength and competitiveness of VCU as a research university.

**Research Data** means 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 these original data that are necessary for reconstruction 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 notebooks, printouts, worksheets, other media, survey, memoranda, evaluations, notes, databases, clinical case history records, study protocols, statistics, findings, conclusions, samples, physical collections, other supporting materials created or gathered in the course of the Research, Tangible Research Property, 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 preexisting materials in a unique way.

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

**Tangible Research Property** means products of research that include, but are not limited to, compositions, biologics, materials, illustrations and drawings, prototypes, devices, and equipment.

**University Member** means 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 the University, unless the activity results in a Report in which the individual is identified as having a University affiliation.

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**POLICY**

**Acquisition and Use of Research Data**

Investigators shall record original observations in accordance with the standards of their respective disciplines and the University Responsible Conduct of Research Policy. The Investigator who gathers or creates Research
Data may use the information as he/she deems appropriate and may authorize others to make appropriate use thereof, subject to University and personal contractual commitments and University policies. The use of Research Data gathered or created within a group of Investigators is subject to the reasonable control of the Principal Investigator.

**Custody of Research Data**

All Research Data shall be preserved in the custody of, or as arranged by, the Principal Investigator on behalf of the University.

The Principal Investigator is charged with the integrity, preservation and security of Research Data, appropriate marking and reporting of all University intellectual property that may be included in, or derived from, the Research Data. In the case of incapacity of the Principal Investigator, that individual’s supervisor will take custody of that individual’s Research Data until other appropriate arrangements are made for alternative custody.

Investigators on Research teams have obligations to discuss responsibilities of data acquisition, use, management, access and retention with other members of a Research team. This especially includes the further access and use of de-identified human subjects data that is acquired via student research projects.

Preservation and security of Research Data is typically an allowable direct cost of conducting research and can be a budgeted item in many sponsored program agreements.

In cases involving misconduct in research and scholarly activities, the threat of imminent loss of data custody, maintenance of intellectual property records, or for other justifiable causes, the University, acting through the Vice President for Research or designee, may take immediate custody of Research Data.

**Retention of Research Data**

The Principal Investigator of each Research program must ensure that Research Data documenting the methods and accuracy of data collection and interpretation is retained. Research Data disclosed or referenced in publications, including the primary experimental results, must be retained for a minimum of five (5) years (or as otherwise defined by state regulations or agreement) to allow analysis and replication by others. Research Data resulting from sponsored programs are to be retained for a minimum of five (5) years after submission of the final Report on the Research project, unless a longer retention period is specified by the sponsor. 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.
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 5 year 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. Research Data should be kept for as long as may be required to protect any patents or other intellectual properties resulting from this work.

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 University intellectual property, or involves the use of animal or human subjects.

**Access to Research Data**

The University has the right to access Research Data for all Research that is either performed at the University, supported by University administered funds, or conducted using University facilities, provided such access shall be for reasonable cause, at reasonable times and after reasonable notice, except in the event of a bona fide emergency. The University’s right of access shall continue regardless of the location of the Principal Investigator 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. The University and appropriate external officials shall have access to Research Data concerning matters of compliance with human or animal research subject 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 the University 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 the University, 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 the University to be a tenet of the scientific community. Standards of data sharing have been published by national scientific organizations and by federal funding agencies:

- **Sharing Publication-Related Data and Materials: Responsibilities of Authorship in the Life Sciences** *(The National Academies Press)*
- **NIH Data Sharing Policy** *(National Institutes of Health)*
- **NSF General Grant Conditions** *(National Science Foundation)*

Scientific and scholarly publications increasingly include statements that promote data sharing in their instructions to authors. This language may indicate that such sharing be a condition of publication (Piwowar, H. and W. Chapman. 2008). 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. 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 University-approved Materials Transfer Agreement. Shared data resulting from human subjects research shall be de-identified, with the linkage code residing in the custody of the University Principal Investigator.

**Transfer of Research Data**

When an Investigator separates from the University, a written Agreement on Disposition of Research Data shall be negotiated between the Investigator and the Investigator’s department chair or dean. In most cases, this agreement shall allow the Investigator's Research Data (other than personally identifiable clinical Research records) to be transferred with the Investigator. These agreements will serve to ensure appropriate access to the transferred Research Data in fulfillment of the University'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 the University. See **Appendix I** for a template *Written Agreement on Disposition of Research Data*.

In some cases (e.g., Research Data supporting a patent application, Research Data generated and/or used by other University 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 the University. 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 study director shall be

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responsible for arranging appropriate access to, use of, and retention of Research Data.

When required by law, regulation or contract, or to fulfill other obligations, the University may transfer title or custody of Research Data and records at its discretion. In such cases, the University, insofar as possible, will ensure access by Principal Investigators, Investigators and other appropriate individuals to that Research Data.

**Ownership of Research Data and University Disposition**

Consistent with federal policy and prevailing higher education practice, Research Data belong to the University. In the event that Investigator data retention and maintenance practices are found to be contrary to this Policy, the University 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, the VCU Intellectual Property Policy and the VCU Policy and Procedure for Misconduct in Research and Scholarly Activities.

**Research Data Policy Oversight and Dispute Resolution**

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

Approved Board of Visitors 5-15-09
APPENDIX I: TEMPLATE

Written Agreement on Disposition of Research Data

Research Data pertaining to this agreement: Original research data from [Investigator’s name; name of study(ies); and funding source(s)].

In order to remain in accordance with the University’s policies on the transfer of research data, [Investigator] and [name of Chairperson; Department name] agree that the following original items will be transferred with the Investigator, [name], to [name of institution].

- [List all completed instruments, signed consent forms, other sources of data, etc.]

All copies of the data will remain in the [indicate location within Department or School] at Virginia Commonwealth University. [Name of faculty] will have access to the copies in the event such copies are needed in the future. The original data and copies have been de-identified, as applicable, in accordance with University data policy.

Signed copies of this agreement will be provide to [Dept.], to the Investigator, and to the Chair.

_____________________________  _________
Signature of Chairperson                Date

_____________________________  _________
Signature of Investigator                 Date

Enclosure: Transfer of Research Data excerpt from Data Ownership, Retention, and Access Policy