



VCU

Research Data Ownership, Retention, Access, and Security

Policy Type: Administrative

Responsible Office: Office of the Vice President for Research and Innovation

Initial Policy Approved: 05/15/2009

Current Revision Approved: 05/13/2021

Policy Statement and Purpose

This policy aims to establish a consistent and efficient management of university research data that complies with applicable federal regulations and with the Library of Virginia Public Records Act. VCU is ultimately responsible for compliance with state and federal regulations, as well as, sponsor grant and contractual requirements. Therefore, VCU asserts ownership over research data for projects conducted at the university, under an award made to the university, or created using university resources. This policy also outlines the university's treatment of research data security that includes stipulations on access to university research data.

In cases involving allegations of misconduct in research and scholarly activities, the threat of imminent loss of data custody, maintenance of intellectual property records, incapacity of the principal investigator (PI) or for other justifiable causes, the university, acting through the vice president for research and innovation or designee, may take immediate custody of research data in its entirety or by allowing investigator access after a forensically sound copy is made.

In cases where this policy conflicts with VCU's *Intellectual Property Policy*, the *Intellectual Property Policy* supersedes this policy.

Noncompliance with this policy may result in disciplinary action up to and including termination. VCU supports an environment free from retaliation. Retaliation against any employee who brings forth a good faith concern, asks a clarifying question, or participates in an investigation is prohibited.

Principal Investigator's General Responsibilities:

The use of research data gathered or created within a group of investigators is subject to the reasonable control of the PI. PIs are subject to university commitments and university policies when using information or data gathered or created through research. Investigators must be aware of, and comply with, sponsor requirements for data management plans, data sharing, and data preservation. Investigators are obligated to discuss and be aware of responsible data handling, university policies, and university commitments with other members of their research team.

Custody of Research Data:

The PI is considered to be a data custodian under the VCU Information Technology Policy Framework, Data Classification Standard and is therefore charged with the creation, integrity, preservation and security

of research data, as well as appropriate marking and reporting of all university intellectual property that may be included in, or derived from, the research data.

Retention of Research Data:

The PI of each research program must ensure that research data documentation is retained according to the standards of the Virginia Public Records Act, the requirements of the sponsor, and according to VCU policies.

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.

Research data must be kept for as long as may be required to protect any patents or other intellectual properties.

If a student or trainee is involved in research, that 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.

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 party, 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 is 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 continues regardless of the location of the PI or of the research data.

The university and appropriate external officials will 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 them but not to access research data pertaining to others.

When an investigator separates from the university, all data must remain at the university and should be delivered to the chair of the investigator's department. For Category III data, the investigator is then authorized to transfer a copy of their data to their new institution if desired. For Category I data, a written data use agreement must be negotiated between VCU and the investigator's new institution before data is transferred. For Category II data, a written data use agreement may be required and the investigator must submit a request to the Division of Sponsored Programs for evaluation. These agreements will serve to ensure appropriate access to the research data in fulfillment of the university's obligations to funding sources and other supporting entities, and for research compliance purposes. In all circumstances of data transfer, the investigator or the investigator's department chair has the obligation to hold the data in trust for the university. 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.

Sponsor requirements for public access and/or data sharing must be met.

Security Requirements for Stored Research Data:

The VCU Information Technology Policy Framework contains VCU Information Technology policies, standards and baseline requirements that must be followed in conjunction with this policy in addition to abiding by all grant related regulations.

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Who Should Know This Policy _____

All university parties involved in the conduct of research are responsible for knowing this policy and familiarizing themselves with its contents and provisions.

Definitions _____

Availability

“Ensuring timely and reliable access to and use of information...” [44 U.S.C., SEC. 3542] A loss of availability is the disruption of access to or use of information or an information system.

Confidentiality

“Preserving authorized restrictions on information access and disclosure, including means for protecting personal privacy and proprietary information...” [44 U.S.C., Sec. 3542] A loss of confidentiality is the unauthorized disclosure of information.

Database

A database is an organization or collection of data. The definition is intentionally broad, and is intended to include but is not limited to spreadsheets or Word documents used to store data and saved on a laptop or desktop, space partitioned on VCU owned servers for data storage, and any data stored on third party or “cloud” servers owned by an entity other than VCU. (Examples of third party or “cloud” storage: Dropbox, VCU Wiki, or other web based file repositories.) The degree of data sensitivity may determine whether use of third party storage entities is permitted.

Data Custodian

The data custodians can have both a business and/or technical role, though it is typically considered a business role. The data custodians are responsible for entering, modifying and maintaining data in the enterprise databases and information systems.

Digital Data

The digital recorded factual material commonly accepted in the scientific community as necessary to validate research findings including data sets used to support scholarly publications.

HIPAA Data

HIPAA (Health Insurance Portability and Accountability Act) data is data that contains individually identifiable health information. Some examples are: names, social security numbers, birth dates, and other identifiers. HIPAA data is required by the federal government to be retained for six years.

Integrity

“Guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity...” [44 U.S.C., Sec. 3542] A loss of integrity is the unauthorized modification or destruction of information.

Investigator

A university party who uses university facilities or resources to conduct research or a sponsored project. See Principal Investigator.

Original Copy

The top copy or document having the actual typed, handwritten, or computer generated print or signature on it. In cases where the original copy has been sent outside of the university, the institutional copy that resides in the originating office is to be treated as the original copy. The requirement for records retention and disposition schedules relates specifically to original/institutional copies.

Principal Investigator (PI)

For the purpose of this policy, the individual with overall responsibility for the conduct of research or other activity described in a proposal, protocol, or an award, and/or the individual with fiduciary responsibility for award management

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 party.

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Research may be defined in additional detail in certain contexts.

Research Data

Recorded information, regardless of form or the media on 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.

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 VCU for their constituencies, and serve as a conduit of information from, and resource asset to, the Office of the Vice President for Research and Innovation (OVPRI). The council meets regularly with the vice president for research and innovation and the associate vice president for research development to address topics of specific interest to the VCU research enterprise and to identify resources and supports necessary for increasing the strength and competitiveness of VCU as a research university.

Tangible Research Property

Products of research that include, but are not limited to, compositions, biologics, materials, illustrations and drawings, prototypes, devices, and equipment.

University Party

Any person engaged, participating in, or directly or indirectly supervising a university research-related activity, including but not limited to a full- or part-time faculty or staff member; VCU official; students assistant, student, fellow, or trainee; visiting faculty member or researcher; volunteer; agent of VCU or the VCU Health System; or, when covered by a sponsored program agreement or other contractual arrangement, a contractor, subcontractor, subawardee, or their respective employees.

University Records

University records are public records as defined by Code of Virginia § 42.1-77. University records are recorded information that document a transaction or activity by or with any appointed board member, officer, or employee of the university. Regardless of physical form or characteristic, the recorded information is a university record if it is produced, collected, received or retained in pursuance of university business or in compliance with federal and state statutes and regulations. University records include but are not limited to: publications, personnel records, student records, research records, financial records, patient records and administrative records. Record formats/media include but are not limited to: email, electronic databases, electronic files, paper, audio, video and photographs.

VCU Technology Services Data Security Classifications:

Category I - Highly Sensitive Records

Records containing personal information that can lead to identity theft if exposed, health information that reveals an individual's health condition and/or history of health services use, export controlled data, and proprietary data.

Category II - Moderately Sensitive Records

Physical records containing data that is not explicitly defined as highly sensitive information or is not intended to be made publicly available.

Category III - Public Information (not sensitive) Records

Information that is intentionally made available to the public.

Contacts

The Office of the Vice President for Research and Innovation officially interprets this policy. The Office of the Vice President for Research and Innovation is responsible for obtaining approval for any revisions as required by the policy *Creating and Maintaining Policies and Procedures* through the appropriate governance structures. Please direct policy questions to the Office of the Vice President for Research and Innovation at rescomply@vcu.edu.

Policy Specifics and Procedure

1. Acquisition and Use of Research Data:

Investigators must record original observations in accordance with the standards of their respective disciplines and [responsible conduct of research](#) best practices.

The investigator who gathers or creates research data can use the information as they deem appropriate and can authorize others to make appropriate use thereof, subject to university contractual commitments and university policies.

2. Custody of Research Data:

All research data must be preserved in the custody of the PI who is responsible for treating such data in accordance with this policy

In the case of incapacity of the PI, that individual's supervisor will take custody of that individual's research data until other appropriate arrangements are made for alternative custody.

As required by this policy, investigators on research teams are obligated to discuss with other members of a research team the responsibilities of data:

- Acquisition
- Use
- Management
- Access
- Retention
- Security
- Further access and use of de-identified human subjects data that is acquired via student research projects

- Dissemination of data and research findings in presentations and manuscripts submitted for publication.

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.

3. Retention of Research Data:

Research data must be retained in compliance with the Virginia Records Retention and Disposition Schedule, federal law, sponsor requirements, and other VCU policies.

The most common exception to the five year period required by the Virginia Code is the six year retention required by HIPAA if any personally identifiable health information is included in the data.

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. In addition to the five 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.

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.

4. Access to Research Data:

University parties 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.

Research team members are encouraged to practice post-study data sharing within the boundaries of ethical practice, in accordance with relevant regulations and current recommendations in the scientific community. Standards of data sharing have been published by national scientific organizations and by federal funding agencies:

- [NIH Data Sharing Policy and Implementation Guidance](#) (National Institutes of Health)
- [Dissemination and Sharing of Research Results](#) (National Science Foundation)
- [NIH Strategic Plan for Data Science](#), including the FAIR principles (National Institutes of Health)
- [Enabling FAIR Data Project](#) (The Coalition for Publishing Data in the Earth and Space Sciences)
- [Sharing and Retention of Research Data: Rights and Responsibilities](#) (Council on Government Relations)
- [Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk](#)

- (The National Academies Press)
[Summary of ICMJE requirement of data sharing statement for clinical trials](#)
(International Committee of Medical Journal Editors)

University parties are expected to share their published data upon request.

In the case of requests that have commercial implication or those that involve tangible research property that may represent potential or protected intellectual property such materials may be shared under the terms of a university-approved [material transfer agreement](#).

Shared data resulting from human subjects research can be shared in accordance with approved VCU Institutional Review Board (IRB) protocols and consent forms. At minimum, shared data from human subjects research must be de-identified, with the linkage code residing in the custody of the university PI, unless otherwise approved by the IRB.

VCU Libraries research data management services can assist in developing and implementing data management plans, complying with data sharing regulations for awards, training research teams in data practices for ethical and replicable research, and finding appropriate data repositories.

University parties must request preparation of a data use agreement prior to providing research data to a third party.

Sponsor Requirements for Public Accessibility

Some sponsors mandate specific methods for long-term preservation and analysis for digital data. Research data resulting from sponsored programs must comply with all sponsor-mandated preservation requirements. Long-term preservation methods include deposit of data in the sponsor's repository, the [Open Science Framework](#), a publicly accessible sponsor-approved subject repository that supports the FAIR (Findable, Accessible, Interoperable, and Reusable) data principles, or the VCU institutional repository, [Scholars Compass](#), managed by VCU Libraries.

Sharing of data as required by sponsors, including the primary data, samples, physical collections and other supporting materials, must occur in a timely manner and involve only necessary costs.

5. Transfer of Research Data:

In general, research data is owned by the university (award recipient), but the PI can retain a copy of the data for future use. The PI must meet with their department chair before departure to ensure they understand VCU's requirements regarding the transfer of data and request a data use agreement through RAMS-SPOT, if required. VCU and the investigator's new institution must enter into a data use agreement describing the disposition and permissible use(s) of research data for Category I data. A data use agreement may be required for Category II data. Category III data needs to remain in the custody of the PI's department chair; however, the PI can retain a copy of Category III data for future use with no other written agreement.

In some cases (e.g., research data supporting a patent application, research data generated and/or used by other VCU investigators, some tangible research property, or as required by the terms of

extramural funding agreements), the data use agreement will allow the investigator only access to the research data. In order to ensure the university and appropriate external officials have access to research data concerning matters of compliance with human or animal subjects research laws, regulations and policies, original data will remain in the appropriate school or department at VCU.

In cases of multi-institutional studies, the institution of the primary study director will be responsible for arranging appropriate access to, use of, and retention of research data.

If VCU transfers title or custody of research data and records as required by law, regulation, contract, or to fulfill other obligations, VCU, insofar as possible, will ensure access by PIs, investigators and other appropriate individuals to that research data.

6. Security Requirements for Digitally Stored Research Data:

All sponsored projects and/or IRB protocols involving Category I data must go through an assessment process – the VCU Data Management System (DMS). Individuals must use the DMS as their main tool for assessing storage requirements.

This policy is designed to address research projects with standard data security needs that focus on the integrity and availability aspects of data/information security. Reference the *Export Compliance and Research Security* policy for data/information security issues focusing on confidentiality and other highly restricted data/information.

7. Research Data Policy Oversight and Dispute Resolution:

The vice president for research and innovation 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 and innovation, the investigator may file a written appeal to be reviewed by a committee of researchers, appointed by the VCU Research Development Advisory Council.

Forms

1. [To Request a Data Use Agreement](#)

Related Documents

1. Virginia Public Records Act: <https://law.lis.virginia.gov/vacodepopularnames/virginia-public-records-act/>
2. VCU Policy: [Intellectual Property](#)
3. [Information Technology Policies, Standards, Baselines and Guidelines](#)
4. [Responsible Conduct of Research](#)
5. Records Retention and Disposition Schedule, GS-111
https://www.lva.virginia.gov/agencies/records/sched_state/
6. [VCU Libraries Research Guide Research Data Management](#)
7. [VCU Data Management System](#)

8. VCU Policy: [Export Compliance and Research Security](#)
9. VCU Policy: [Records Management](#)
10. [VCU Data Classifications Tool](#)
11. [VCU Research data privacy webpage](#)
12. Expanding Public Access to the Results of Federally Funded Research
<https://obamawhitehouse.archives.gov/blog/2013/02/22/expanding-public-access-results-federally-funded-research>
13. FIPS Publication 199, Standards for Security Categorization of Federal Information and Information Systems - <http://nvlpubs.nist.gov/nistpubs/FIPS/NIST.FIPS.199.pdf>

Revision History

This policy supersedes the following archived policies:

November 16, 2017	<i>Research Data Ownership, Retention, Access, and Security</i>
November 05, 2015	<i>Research Data Ownership, Retention, Access, and Security</i>
May 15, 2009	<i>Research Data Ownership, Retention and Access</i>

FAQ

1. Why may VCU take immediate custody of research data in cases of research misconduct?

VCU is legally required to do so under 42 CFR § 93.305 - Responsibility for maintenance and custody of research records and evidence.

2. What if the records I have are not listed in an approved records schedule?

Not all records fit neatly into the categories given in the examples. If you have records that are unique and you cannot locate a time table for retention either in university policy or in the Library of Virginia approved Records Retention and Disposition Schedules, contact the university records officer for assistance. The VCU Records Management webpage can be found here: <https://ts.vcu.edu/askit/policies-and-publications/records-management/>.

3. If I am in possession of or have created an electronic version of a document do I have to keep the paper copy?

No. The Library of Virginia Records Retention and Disposition Schedule, General Schedule No. GS-111 requires simply that, "All records must be accessible throughout their retention period in analog or digital format. Whether the required preservation is through prolongation of appropriate hardware and/or software, reformatting, or migration, it is the obligation of the agency or locality to do so."

4. What should I do if I receive a Freedom of Information Act (FOIA) request for documents?

If you receive a FOIA request for documents, do not respond to the requester directly. Promptly visit the [VCU News Center FOIA requests](#) page for more information.

5. What is the VCU Data Management System (DMS) and how can I get more information about it?

The DMS is designed to provide VCU personnel with guidance on the handling, transmission and storage of information, including specific requirements related to the handling of various types of information, IT resources and services offered by the university that can assist in handling of such information, and specific precautions one must take in handling various types of information. Additionally, this system provides a platform for requesters of data and information to interact with designated data stewards. The features of this system are designed to help requesters in constructing formal data security plans that can be used as an addendum to project proposals, to help the data stewards in communicating expectations, and to provide an understanding for users on how data and information must be properly handled. You can access the VCU Data Management System at <https://ts.vcu.edu/about-us/information-security/data-management-system/>.