From the VCU Security Standard for Research Data policy

**Data Maintenance and Destruction Regulations**

See below (the table) for more information on special circumstances and resources.

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| Regulatory Body | Link | Regulation or Policy | Materials | Retention Period | After Retention Period | Special Note |
| Code of VA | http://sacs.wm.edu/archives/2006\_decennial/accdoc/3/4/11/documents/Library\_of\_VirginiaRecordsManagement.pdf | Library of VA No. 101171 | Research notes, work papers and technical data - college or  university sponsored | retained for  3 years after the end of research or in accordance with  college or university intellectual property or retention policy,  whichever is greater, then offered to archives, special  collections or the library. | Archives, special collections or the  library may selectively retain all or part of the records for  their collections; the balance is to be destroyed. |  |
| VCU Policy | http://www.policy.vcu.edu/sites/default/files/Research%20Data%20Ownership%2C%20Retention%2C%20Access%20and%20Securty.pdf  <http://www.assurance.vcu.edu/Policy%20Library/Research%20Data%20Ownership,%20Retention%20&%20Access.pdf> | Research Data Ownership, Retention, & Access | Research Data disclosed or referenced in publications, including 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 | See VCU Destruction of Records Policy  <http://www.ts.vcu.edu/askit/policies-and-publications/records-management/destruction-of-records/> |  |
| VCU Policy | <http://www.assurance.vcu.edu/Policy%20Library/Research%20Data%20Ownership,%20Retention%20&%20Access.pdf> | Research Data Ownership, Retention, & Access | 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. See FDA below AND review your signed Agreement | See VCU Destruction of Records Policy  <http://www.ts.vcu.edu/askit/policies-and-publications/records-management/destruction-of-records/> |  |

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| Regulatory Body | Link | Regulation or Policy | Materials | Retention Period | After Retention Period | Special Note |
| FDA | <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm073122.pdf> | GCP Guidance | 4.9.5 Essential documents Page 21  Records Handling Page 25 | retained until at least 2 years after the last  approval of a marketing application in an ICH region and until there are no  pending or contemplated marketing applications in an ICH region or at least 2  years have elapsed since the formal discontinuation of clinical development of the  investigational product. These documents should be retained for a longer period,  however, if required by the applicable regulatory requirements or by an agreement  with the sponsor. | See VCU Destruction of Records Policy  <http://www.ts.vcu.edu/askit/policies-and-publications/records-management/destruction-of-records/> | It is the responsibility of the sponsor to inform the  investigator/institution as to when these documents no longer need to be retained  (See section 5.5.12).  5.5.12 The sponsor should inform the investigator(s)/institution(s) in writing of  the need for record retention and should notify the investigator(s)/institution(s) in  writing when the trial-related records are no longer needed (see section 4.9.5). |
| FDA | <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=812&showfr=1> | Sec. 812.140 Records | Maintain the records required by this subpart during the investigation and for a period of 2 years after the latter of the following two dates: | The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. | See VCU Destruction of Records Policy  <http://www.ts.vcu.edu/askit/policies-and-publications/records-management/destruction-of-records/> | (e)Records custody. An investigator or sponsor may withdraw from the responsibility to maintain records for the period required in paragraph (d) of this section and transfer custody of the records to any other person who will accept responsibility for them under this part, including the requirements of 812.145. Notice of a transfer shall be given to FDA not later than 10 working days after transfer occurs. |
| FDA | http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62 | Record keeping and retention 21 CFR 312.62 | Research Records | 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated  2 years after the investigation is discontinued and FDA is notified if no application is to be filed or if the application has not been approved for such indication | See VCU Destruction of Records Policy  <http://www.ts.vcu.edu/askit/policies-and-publications/records-management/destruction-of-records/> |  |

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| Regulatory Body | Link | Regulation or Policy | Materials | Retention Period | After Retention Period | Special Note |
| NIH | http://silk.nih.gov/silk/silkpdf/media.degauss/form.pdf | Media Sanitation Service (for NIH customers) | CDs, DVDs, tapes, and disk media | Meets Federal Information Security Management Act (FISMA ) and DOD requirements |  |  |
| NIH | http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap\_2b\_security\_procedures.pdf | NIH Security Best Practices for Controlled-Access Data Subject to the NIH Genomic Data Sharing (GDS) Policy | NIH’s expectations for the management and protection of NIH controlled access data transferred to and maintained by institutions whether in their own institutional data storage systems or in cloud computing systems |  |  |  |
| NIH | http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/documents/recordretentionfaq.pdf | NIH  FAQs Clinical Record Retention | Essential and source documents found on the list in  the DAIDS Policy on Essential Documents (not conducted under an IND) Appendix 11  ; and records, in any form (including, but  not limited to, written, electronic, magnetic, and optical records; and scans, x-rays, and  electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, and the  actions taken2 | All records relating to research that is conducted must be retained for at least three years after  completion of the research4  . The three-year time period begins when the individual institution’s  engagement in the human subjects’ research activity ends. |  | See link for more information |
| NIH | http://www.fic.nih.gov/Grants/Pages/records.aspx | **Reporting and Record Retention Guidance for NIH Grantees** |  | **Grantees generally must retain financial and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of three years from the date the annual FFR is submitted.** |  | See link for more information |

**Special Circumstances**

Reference: VCU Policy on Research Data Ownership, Retention, & Access

http://www.policy.vcu.edu/sites/default/files/Research%20Data%20Ownership%2C%20Retention%2C%20Access%20and%20Securty.pdf

<http://www.assurance.vcu.edu/Policy%20Library/Research%20Data%20Ownership,%20Retention%20&%20Access.pdf>

• 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, 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.

**Resource for Information on Data Destruction**

VCU Destruction of Records Policy

<http://www.ts.vcu.edu/askit/policies-and-publications/records-management/destruction-of-records/>

**How do I get permission to destroy records once they have exceeded their retention period in the records schedules?**For official records you need to complete a [Certificate of Records Destruction](http://www.lva.virginia.gov/agencies/records/forms.asp" \t "_self) (RM-3 Form), have it approved by an administrator in your office and by the University Records Officer. Complete instructions and downloadable forms are located the Library of Virginia's [Records Management Forms](http://www.lva.virginia.gov/agencies/records/forms.asp" \t "_self) page. If you have questions while completing the form, please contact the University Records Manager ([rsdavis@vcu.edu](mailto:rsdavis@vcu.edu) or 8-2103) for assistance before sending, as most questions can be answered before a form is submitted. Once you receive the approved form back, you may destroy the records. Please note you need to send the original RM-3 to the Library of Virginia upon destruction of the records–including a signature and destruction date.

FDA Resource for Investigator Responsibilities Control of investigational drug (312.61)

FDA http://www.fda.gov/training/clinicalinvestigatortrainingcourse/default.htm