UNC-CH DAHS Data Retention Policy

Purpose

The purpose of this policy is to provide guidance to departmental researchers on regulatory guidelines associated with the retention of research data and materials.

Ownership and Overview of Responsibilities

The Principal Investigator (PI) of a research study is the primary custodian/steward of Research Data and Materials generated in the context of that study. The PI provides scholarly leadership and bears primary responsibility for technical, programmatic, fiscal, and administrative requirements of the project, working in partnership with the department, division, and University administration to manage and protect the Research Data and Materials produced at the University.
https://policy.uncg.edu/university-policies/research_data/

Investigator Requirements for Retaining Research Data

Regulations require each investigator to retain research data not only while the research is being conducted but also after the research is completed. *How long do you have to keep the records after the completion of the research?* There are several regulations that you may need to be aware of, each of which has different requirements. As a result, **researchers must determine and comply with the longest applicable standard according to current institutional policies**.
http://irb.ufl.edu/index/data/investigator-requirements-for-retaining-research-data.html

How Long should I Retain my Research Data?

Step 1: Determine which regulation applies to your research.

- It is important to determine which regulation applies to your research, because different regulations have different timelines. It is also important to keep in mind that multiple regulations may apply to the research. If multiple regulations apply, the investigator should keep the data for the **longest** required amount of time.

- Examples of regulations that might apply to your research:

    - UNC IRB Regulations
    - The Health Insurance Portability and Accountability Act (HIPAA)
    - Food and Drug Administration (FDA) Regulations
    - Department of Veterans Affairs (VA) Regulations
    - Department of Defense (DoD) Regulations
    - Department of Education (DoE) Regulations
    - Health and Human Services (HHS) Regulations

- In addition to the above regulations, if your study is under a sponsored project (grant or contract) **you must comply with any terms for record retention detailed in the award from the sponsor.**

Step 2: After determining which regulation applies, determine the time requirement.

- Office for Human Research Protections (OHRP): 45 CFR 46.115 requires research records to be retained for at least 3 years after the completion of the research. Research is completed when all research-related interventions/interactions with human subjects have been completed and all data collection and analysis of identifiable private information described in the IRB-approved research plan have been finished.
  https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html

- UNC IRB records must be retained for at least 3 years after the completion of the research.
  https://research.unc.edu/files/2017/05/SOP-June-2-2017-bookmarked-and-TOC-links.pdf

- Health Insurance Portability and Accountability Act (HIPAA): Any research that involves collecting identifiable health information is subject to HIPAA requirements. As a result, all relevant documentation must be retained for 6 years from the date of its creation or the date when it last was in effect, whichever is later.
  https://www.hhs.gov/sites/default/files/hipaa-simplification-201303.pdf

- Food and Drug Administration (FDA) Regulations: (21 CFR 56.115). Data must be retained for 3 years post study. Any research that involves drugs, devices, or biologics being tested in humans must 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. Please note – this length of time can be much greater than 2 years. You should receive written confirmation from the sponsor and/or FDA granting permission to destroy the records.
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=312.62

- Department of Veterans Affairs (VA) Regulations: At present, records for any research that involves the VA must be retained for 6 years beginning at the end of the fiscal year after the completion of the research project. Other Federal regulations may require that the data be kept longer (DAA-0015-2015-0004, item 0032 – See chapter 8 of the PDF referenced below).
  https://www.va.gov/vhapublications/RCS10/rcs10-1.pdf

- Department of Defense (DoD): 32 CFR 219 requires all institutions, including investigators, engaged in DoD-conducted or -supported research involving human subjects to retain records for at least 3 years after the completion of the research. This requirement includes documentation of all regulatory study documents, investigator training and qualifications to conduct the study, communications between the Human Protections Administrator/PI/IRB, and other actions relevant to the Human Research Protection Program. (See p. 9 of the document below.)
  http://usacac.army.mil/sites/default/files/documents/cace/CGSC/CAC-E DoD Unique Requirements 20150905.pdf

- Department of Education (DoE): Almost all of the DoE's programs fall under the record retention provisions of the General Education Provisions Act (GEPA) and 2 CFR part 200. Grant records must be maintained for 3 years after the submission of all required reports, unless this time period is extended due to audit or legal matters.
  https://www2.ed.gov/fund/grant/about/grantmaking/grantmaking.pdf
  https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=89550025cad94848c15837428eee500a&mc=true&n=pt2.1.200&r=PART&ty=HTML - se2.1.200_1333

- Health and Human Services (HHS): The USDHHS requires that research data be retained for a period of 3 years after the project ends. (See p. 17 of the file below.)
  https://ori.hhs.gov/images/ddblock/data.pdf

Step 3: Determine what information to keep.

- To determine what information you should keep, you should look to the specific language of the applicable regulation above. As a general rule you should keep the following:
  - Signed participant informed consent/assent documents
  - Signed parental/guardian informed consent documents
  - Written research summary

- Hard copies can be scanned into digital data and discarded appropriately.

IN SUMMARY:

(1) Determine which regulation applies to your research.
(2) Determine the time requirement (minimum of 3 years).
(3) Determine what information to keep.
(4) Researchers must comply with the longest applicable standard as described above.

https://www.uwyo.edu/research/_files/docs/investigator requirements for retaining research data.pdf

Data Archiving

There are situations where long-term archival of Research Data and Materials may be needed. Some funding agencies require that a copy of research data is made publically accessible in de-identified form; these requirements are typically specified in the sponsor agreement and should be planned for accordingly. The decision to archive data when it is not mandated by University policy, the funding agency, or sponsor rests with the PI, and should be made in accordance with specifications about data access and use stipulated in participant consent forms, data management plans, departmental / division-specific policies, and other appropriate agreements. UNC-CH provides two places for all UNC researchers to store their data long-term for free and have it available for dissemination. Both the Carolina Digital Repository (CDR) and Odum Institute can archive research data. The CDR can even allow researchers to protect some or all of the data from general view. The Odum Institute can be contracted to "clean up" the data for archiving and dissemination.

Adapted from https://policy.uncg.edu/university-policies/research_data/

Specific to DAHS:

As UNC-CH moves toward a new funding model for the university, the Department will incur costs for space, including digital space on the School of Medicine's or other University servers. To be proactive, the DAHS has developed some guidelines for researchers to consider as they are planning their next research projects.

If you anticipate your project will need to use a large amount of server space (e.g., collecting videos on a large sample size), we recommend the following steps:

1. Prior to submitting the grant, consult with John Bulluck (john_bulluck@med.unc) or SOM IT to determine how much server space your project will likely use, obtain an estimate, and factor those costs into your proposed budget.
2. For unfunded research projects or small grants where the funds may not be available to pay for digital space, meet with Val Tan and/or Dr. Stephen Hooper about your space needs prior to initiating the project or submitting the grant to discuss funding options for digital space.
3. Once projects (funded or unfunded) that are using large amounts of server space have ended, meet with Dr. Stephen Hooper and/or the Associate Chair for Research to discuss your options for continued data retention (if needed to meet regulatory requirements). Options could include, but are not limited to, (a) maintaining the data on the current server, (b) removing the data from the server and copying it onto a DVD or some other medium for the PI, or (c) destroying the data.

We, in the DAHS, want to work with you to meet your data storage and retention needs.