

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.
- Below are examples of regulations that might apply to your research:
 - Office for Human Research Protections (OHRP) Regulations
 - The Health Insurance Portability and Accountability Act (HIPAA)
 - Food and Drug Administration (FDA) Regulations
 - Department of Veterans Affairs (VA) 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.

- To determine how long you should retain your research you should look to the specific language of the regulation. Some examples of record retention are the following:
 - **(1) Office for Human Research Protections (OHRP):** Research records must 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. <http://answers.hhs.gov/ohrp/categories/1567>
 - **(2) Health Insurance Portability and Accountability Act (HIPAA):** Any research that involves collecting identifiable health information is subject to HIPAA requirements. These records must be retained for at least 6 years after the personal health information was disclosed. <http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveridentities/research.html>
 - **(3) Food and Drug Administration (FDA):** Research records must be retained for 2 years after either (1) the date a marketing application is approved or (2) the investigation is discontinued and the FDA is notified. <http://www.accessdata.fda.gov/SCRIPTS/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=312&showFR=1&subpartNode=21:5.0.1.1.3.4>
 - **(4) Department of Veterans Affairs (VA):** Research Records must be retained indefinitely. http://www.va.gov/ORO/Research_Information_Protection.asp
- **Questions of Data Validity:** If there are questions or allegations about the validity of the data or appropriate conduct of the research, you must retain all of the original research data until such questions or allegations have been completely resolved.

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

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.**

Note: The information above was adapted from the University of Florida, Institutional Review Board.