

Office of Research Compliance (ORC) Guideline on Research Document Retention and Destruction for Human Subjects Research

Introduction

This guideline details the ORC recommendations for document retention and destruction. The University, its faculty, and its trainees have a common interest and a shared responsibility to ensure that research is appropriately recorded, shared, and retained. Consequently, researchers have a responsibility to retain original research results, in whatever form they may take, for a reasonable length of time to protect intellectual property rights, support scholarly collaboration and publication, and answer any questions that may arise about the conduct of the research. Likewise, the University has an interest in, and shared responsibility for, ensuring that research is appropriately recorded, archived, and available for review under appropriate circumstances.

Scope and Requirements

What do you do with your data and other research materials once the study has concluded? Different regulations apply to how long you are required to store records after the completion of research, and you must keep records for the longest applicable period of time. Federal regulations require research records to be retained for at least three (3) years after the completion of the research (45 CFR 46). Additional standards from your discipline may also be applicable to your data storage plan. For example, the Vice President for Research Unit has implemented a record retention schedule that requires the Office of Research Compliance to maintain IRB protocols that were approved or determined to be exempt for seven years beyond expiration date, date of exemption determination or close of the funded project (if applicable), whichever of these is longest. Research that involves identifiable health information is subject to Health Insurance Portability and Accountability Act (HIPAA) regulations, which require records to be retained for at least six (6) years after a participant has signed an authorization. Finally, research sponsors may require longer retention periods.

In summary, you may need to keep your research records for at least six (6) years and possibly longer, depending on the longest applicable standard. Another good practice is to retain data until there is no reasonable possibility

that you will be required to defend against an allegation of scientific misconduct.

Note that these regulations do not specify when you must destroy data, they only state the minimum amount of time you must retain it. As long as you can guarantee that your research records are secure, you can keep them indefinitely. Of course, practical considerations of storage space may make this impossible. Moreover, some participants may object to retention of their study records for an indefinite amount of time. Ideally, you should define your retention policy in your consent form, so that your participants can agree to it. Sometimes researchers wish to reuse data for subsequent studies. If you anticipate this situation, you should state in your consent form that data may be retained for use in future studies. In this case, you should destroy any identifying information and linking files once you have kept them for the longest applicable standard. If participants are unable to give consent to additional uses of their data then all records should be de-identified before use. Careful data storage for subsequent use prevents researchers from collecting the same data over and over again, protecting participants from inefficient research practices and exposing them to less risk.

When research records are to be destroyed instead of stored securely, you should remember to protect your participants' confidentiality throughout the process. Paper records should be shredded and recycled, instead of carelessly tossed in the garbage. Records stored on a computer hard drive should then be erased using commercial software applications designed to remove all data from the storage device. For data stored on USB drives or recorded data on tapes, CDs, or DVDs, the storage devices should be physically destroyed. You should keep records stating what documents / data were destroyed, and when and how you did so.

Recommendations

As described, 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? Unfortunately, there are several different regulations each of which has different requirements. As a result, researchers must comply with the longest applicable standard according to current institutional policies.

- **OHRP Requirements:** 45 CFR 46 requires research records to be retained for at least three years after the completion of the research.
- **HIPAA Requirements:** Any research that involved collecting identifiable health information is subject to HIPAA requirements. As a result records must be retained for a minimum of six years after each subject signed an authorization.
- **FDA Requirements:** Any research that involved drugs, devices, or biologics being tested in humans must have records retained for a period of two 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 two years after the investigation is discontinued and FDA is notified. Please note that it is recommended that you receive written confirmation from the sponsor and / or FDA granting permission to destroy the records. (21 CFR 312.62.c).
- **Ohio University Requirements – patents:** Any research data used to support a patent through OU must be retained for the life of the patent in accordance with OU's policy. Please direct any questions to the Office of Technology Transfer.
- **Sponsor Requirements – contract:** If your study is sponsored you must ensure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 20 years. Prior to agreeing to a contract that specifies how long records will be maintained you should ensure you will receive adequate funding to pay for the storage.
- **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.

In Summary:

- Research Records must be maintained a minimum of three years after the research is completed and the study closed with the IRB.
- Records may need to be kept longer if other requirements apply.
- Researchers must comply with the longest applicable standard as described above.

Documentation from the University of Virginia was used to help create parts of this guideline.