

# Office of Research Compliance (ORC) Guidance on Retention and Destruction for Human Subjects Research Documents and Data

## **Introduction**

This guidance details recommendations for document retention and destruction. Ohio University, its faculty, staff, and students have a common interest and a shared responsibility to ensure that research is appropriately recorded, protected, retained, and available for review under appropriate circumstances. Researchers, and the Principal Investigator (PI) in particular, have a responsibility to retain original research results, in whatever form they may take, for a reasonable length of time to protect human subjects, protect intellectual property rights, support scholarly collaboration and publication, and answer any questions that may arise about the conduct of the research. Study sponsors may also have specific requirements that researchers must follow, particularly federal funding agencies.

## **Scope**

This guidance applies to research data as well as materials documenting the ethical conduct of the research. Research data are primary materials (such as lab notebooks, interview transcripts, raw survey data, etc.) and methodologies for collection and analysis, which are necessary to evaluate or replicate the research findings. Additional relevant materials include a record of informed consent and, when applicable, signed informed consent forms.

## **Guidance on Retention**

What do you do with your data and other research materials once the study has concluded? There are several sets of regulations that may determine how long you are required to retain records after the completion of research, and you must keep records for the longest applicable period of time. Federal regulations require that IRB records be retained for at least three (3) years after the completion of the research (45 CFR 46.115). Following this timeline, best practice in human subjects research calls for the PI to maintain the original research data, signed informed consent forms, and other materials related to the conduct of the research in a secure and confidential setting for a minimum of three (3) years after the study is closed with the IRB. Additional standards from your discipline, or sponsor, may also be applicable to your data storage plan.

Research that involves protected health information (PHI) is subject to Health Insurance Portability and Accountability Act (HIPAA) regulations, which require records to be retained for at least six (6) years after the last use of a participant's PHI.

Food and Drug Administration (FDA) regulations require specific retention periods for drug and device studies, with records retained for a period of two (2) years following the date a marketing application is approved for the drug or device 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.

Research sponsors may require longer retention periods than what is outlined above; this will be described in your study contract. For example, Public Health Service policies on research misconduct require that research records be retained for at least six (6) years after completion of the project (e.g., publication of the final results) or until they are no longer needed for scientific reference, whichever is longer.

In summary, you should keep your research records for at least three (3) years after your study ends and possibly longer, depending on the longest applicable standard.

It is good practice to retain data until there is no reasonable possibility that you will be required to defend against an allegation of scientific misconduct. 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.

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 ensure that your research records are secure, you can keep them indefinitely. Keep in mind that retention of data containing identifying information requires current IRB approval. All identifiers in the data must be destroyed before you close the study with the IRB.

For additional information about appropriate storage of identifiable human subjects research data, please see Ohio University's Office of Information Technology [website](#).

### **Guidance on Destruction**

When research records are to be destroyed, you should remember to protect your participants' confidentiality throughout the process, paying special attention to any research records that contain direct or indirect identifiers. Paper records should be shredded or placed in a secure shredding bin instead of tossed in the garbage. Records stored on a computer hard drive should be erased using commercial software

applications designed to remove all data from the storage device. For data stored on devices such as USB drives, laptops, or cell phones, the appropriate method of destruction will depend on the level of data sensitivity. See guidance on clearing, purging, and destroying digital media on Ohio University's Office of Information Technology [website](#). You should keep records stating what documents / data were destroyed, and when and how you did so.

## **Summary**

Regulations require each investigator to retain research data not only while the research is being conducted but also after the research is completed.

At Ohio University, researchers should plan to retain their de-identified, original human subjects research data and documentation of informed consent for a minimum of three (3) years after they close the study with the IRB. You may need to retain your records longer if HIPAA or FDA regulations apply, or as described in your funding award or contract. Student researchers and their faculty advisors should ensure that this data will be accessible after the student graduates and departs Ohio University.