

Retention of Informed Consent Records

Background

Regulations require retention of various records associated with the conduct of human subjects research. The Office of Research Ethics retains some records, including approved protocols, communication between the IRB and researchers, IRB meeting minutes, etc. Researchers are also required to retain records—primarily, those that relate to documenting participants' informed consent to participate in research (i.e., signed consent forms or parent consent forms, signed assent forms, signed HIPAA authorizations, etc.).

This document outlines Principal Investigator (PI) responsibilities for the retention of informed consent records, which refers to any record that documents participants' consent or assent to participate in research via signature (handwritten or electronic).

Although outside the scope of this document, researchers should also become familiar with *research data* retention requirements [at Iowa State](#) and within their disciplines and ensure that any information shared with research participants reflects those plans.

Retention of Informed Consent Records¹

Informed consent records must be retained for specified periods of time in relation to the conduct of the study (see Retention Timeline below). Researchers have flexibility in retention methods provided their plans align with the requirements outlined in this document. Storage methods must allow reasonable access for copying or inspection in the event of an audit or inspection.

Confidentiality

Informed consent records directly link an individual to a particular study. Therefore, retention plans and storage methods must assure confidentiality:

- Limit access to approved research team members who have been properly trained regarding their obligations to ensure participant confidentiality.
- In general, secure locations such as a locked file cabinet or lockbox or university-supported computers or cloud storage are appropriate. Be sure that permissions granting access are updated as study team members change.
- Avoid storage in a researcher's home or personal location; Supervising Investigators must provide secure storage options for any students who do not have adequate university-supported options.
- Do not keep informed consent records in unlocked cabinets in shared offices, on shared public computers, unencrypted portable devices, or other electronic settings that do not adequately restrict access.

¹ The Office of Research Ethics does not retain informed consent records for researchers. Retention is the responsibility of the Principal Investigator.

- Keep informed consent records separate from the research data files; doing so minimizes the likelihood that a person can be connected with their data in the event of a breach. Avoid documenting study ID codes or pseudonyms on informed consent records; instead, create a standalone “key” or “map.”
- Develop plans to transfer records and associated confidentiality responsibilities should the PI or Supervising Investigator leave Iowa State.

Electronic Records

Paper-based informed consent records can be scanned for electronic storage. Researchers must verify that complete consent forms (all pages—not just signature pages) are captured when scanned. Storage must meet the requirements outlined in this document (security, access only to approved individuals, etc.).

Electronic copies should be permanently deleted once the retention timeline has passed.

Retention Timeline

Informed consent records must be retained for at least 3 years following study closure. This basic time frame is required by regulation, but some disciplines, funding sources, or types of research have longer retention requirements. It is extremely important that each PI understand the specific requirements associated with the research.

If protected health information (PHI) that is covered under the Health Insurance Portability Accountability Act (HIPAA) policy is obtained for the research, HIPAA authorization forms must be retained for a minimum of 6 years after the close of the study.

Retention beyond the 3-year period may be important for a study that involves high risk to subjects or a high potential for long-term complications in case problems arise at a later date.

Secure and Effective Destruction

Destruction is the final step in retention process and must be carried out. Once the required retention timeline has passed, informed consent records must be effectively and securely destroyed. Destroying the forms can be achieved in a number of ways such as shredding, burning, etc. The documents cannot be recycled or simply thrown away as this does not protect confidentiality.

In cases where consent is captured by verbal response (audio or video recording) destruction must account for the unique methods necessary to effectively and securely destroy recordings to insure confidentiality. PIs should consult with Information Technology specialists for guidance.

Note

Some research, such as that regulated by the Food and Drug Administration (e.g., Investigational New Drugs, Investigational Device Exemptions, Food Additive Petitions, etc.)² may have additional recordkeeping requirements. PIs must ensure retention plans satisfy those requirements when applicable.

Document History

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² See Guidance on [Research Involving FDA-Regulated Investigational Articles](#) for information.