

Requirements for Retention of Signed Consent Forms

Background

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

This document outlines Principal Investigator’s responsibilities for record retention as it specifically relates these documents. Although outside the scope of this document, researchers should also become familiar with the requirements for research data retention within their disciplines and ensure that any information shared with research subjects reflects these plans.

Retention of Signed Informed Consent Forms¹

When signed informed consent is required, by handwritten or electronic signature, as part of the IRB-approved protocol, researchers must retain signed consent documents for specified periods of time (normally, three-years after study closure). Researchers have flexibility in how these records are maintained, but the following criteria must be met:

- a) the confidentiality of the subject must be maintained;
- b) records must be stored appropriately, locked, and accessible to only those listed in the approved study;
- c) records must be kept for the required time periods:
 - Signed informed consent documents -- at least 3 years
 - Signed HIPAA Authorizations -- at least 6 years
- d) at the end of the required retention period, documents identifying subjects (e.g., signed informed consent forms) should be effectively and securely destroyed;
- e) in the event a principal investigator leaves ISU, provisions must be made for record retention as needed given the status of the project (e.g., transferred to a new PI at ISU who will assume responsibility for the project, transferred with the PI to the new institution, etc.).

Confidentiality

The confidentiality of research subjects is of the utmost importance when handling and receiving the signed informed consent forms. Signed consent forms should only be accessible only by individuals who are approved to be on the study team and who have been properly trained regarding their obligations to ensure participant confidentiality.

¹ The Office for Responsible Research does not retain signed informed consent forms or HIPAA authorizations for investigators. These requirements are the responsibility of the principal investigator.

Storage

Signed informed consent forms must be stored in a manner that assures confidentiality and that limits access to approved members of the research team (e.g., locked file cabinet, secure electronic files, etc.). Copies should not be kept in unlocked cabinets in shared offices, on shared public computers, unencrypted portable devices, or other electronic settings that do not adequately restrict access. Further, consent forms should be stored in a manner that prevents connection of individuals with their research data.

Retention Timeline

Signed informed consent forms are to be retained for at least 3 years following the close of the study, and must be kept in a manner that allows reasonable access for copying or inspection in the event of an audit, inspection, etc. 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 investigator understand the specific requirements associated with his or her research.

Further, for a study that involves high risk to subjects, or a high potential for long-term complications, it may be important to retain the forms longer than 3 years in case any problems arise at a later date.

If a research study accesses protected health information (PHI) and is covered under the Health Insurance Portability and Accountability Act (HIPAA) policy, consent/HIPAA authorization forms are to be retained for a minimum of 6 years after the close of the study.

Secure and Effective Destruction

Once the required retention timeline has passed, the signed informed consent forms must be effectively and securely destroyed. Destroying the records can be achieved in a number of ways including shredding, burning, etc. The documents cannot be recycled or simply thrown away as this does not maintain confidentiality.

Destruction is the final step in retention process, and must be carried out. In cases where consent is documented by audio or video recording, destruction must account for the unique methods necessary to effectively and securely destroy recordings to insure confidentiality. Investigators may need to consult with Information Technology specialists for guidance.

Note

Some types of research, such as that operating under requirements for Investigational New Drugs, Investigational Device Exemptions, Clinical Trials, Food Additive Petitions, etc. may have other recordkeeping requirements. Investigators are also responsible for ensuring those requirements are met in a manner that aligns with the applicable criteria noted above.

Document History

Created/Approved: 4/12/2017

Revised: 12/18/2018 (effective 1/21/2019)
