



RETENTION OF IRB RECORDS

03/24/2008

All IRB files and documents that relate to the protection of human research participants are retained for at least six years following completion of the study. Study records involving pediatric research participants must be maintained until the youngest child on study is 21 years old, or for six years following completion of the study, whichever is longer. If a protocol is cancelled without participant enrollment, IRB records are maintained for at least six years after cancellation.

Such files and documents include, but are not limited to:

- IRB submission documents
- Research protocols
- Scientific evaluations
- DHHS-approved sample consent document and protocol, when they exist
- Progress reports submitted by investigators
- Reports of injuries to participants
- Records of continuing review activities
- Correspondence between the IRB and the investigator
- Statements of significant new findings provided to participants
- For initial and continuing review of research using the expedited procedure:
 - The specific permissible category
 - Description of action taken by the reviewer
 - Any findings required under the regulations
- For exemption determinations the specific category of exemption
- Unless documented in the IRB minutes, determinations required by the regulations and protocol-specific findings supporting those determinations for:
 - Waiver or alteration of the consent process
 - Research involving pregnant women, fetuses, and neonates
 - Research involving prisoners
 - Research involving children
- For each protocol's initial and continuing review, the frequency for the next continuing review
- Membership rosters
- Minutes
- Other correspondence not related to a specific research study.

Paper records on site are maintained in a locked file room or locked offices within the main IRB Office and are available only to IRB staff. Paper files of studies that have been officially closed via IRB approval of the Final Progress Report are maintained in storage at a secure external site through a contract agreement with Recall, an information management company. These paper files may be

recalled, if needed, within three to five business days via notice to the company. Electronic files through our eIRB are maintained on secure servers by Duke Health Technology Solutions (DHTS). These files are backed up approximately 3 times per hour.

All records are accessible for inspection by authorized representatives of the OHRP, FDA, sponsors, and other authorized entities at reasonable times and in a reasonable manner.

When the retention period for a paper record expires, and a decision is made by the IRB Executive Director or designee in conjunction with the Institutional Official to no longer retain the record, the record will be shredded or otherwise destroyed. In such an instance the IRB staff member who works with the Principal Investigator's department or division will advise the Principal Investigator to inform the sponsor that study records will be destroyed on a specific date so that the sponsor may discuss any concerns with the IRB before the action is taken. The IRB anticipates maintaining its electronic records indefinitely.

A signed and dated consent form (on paper with original signature) must be maintained by the investigator at DUHS for as long as the research records are retained --- at least 6 years after the study is completed, or if the subject is a child, until the youngest child on study reaches the age of 21, whichever is longer. This can be satisfied by placing the consent form in the medical record or by keeping it in the study's research files.