DUKE UNIVERSITY HEALTH SYSTEM
Human Research Protection Program

RETENTION OF IRB RECORDS AND OTHER DOCUMENTS

11/20/2023

IRB records document determinations required by laws, regulations, codes, and guidance, including documenting that the criteria for approval are met, and other required determinations, including whether noncompliance is serious or continuing, and whether a reported event is an unanticipated problem involving risks to subjects or others. 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.

In order to allow a reconstruction of a complete history of IRB actions related to the review and approval of a protocol, the IRB records include copies of such files and documents, which are not limited to:

- All IRB submission documents
- Research protocols
- Scientific evaluations
- DHHS-approved sample consent document and protocol, when they exist
- Progress reports of various kinds, such as IND progress reports, if submitted by investigators
- Reports of injuries to participants
- Unanticipated problems involving risks to subjects or others (UPIRTSOs)
- Documentation of noncompliance reviews and determinations
- Records of continuing review activities, including continuing review progress reports
- 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 people, fetuses, and neonates
    - Research involving imprisoned people
    - Research involving children
- For each protocol's initial and continuing review, the frequency for the next continuing review
- Membership rosters
- Minutes

When there are reliance agreements between the DUHS IRB and an external organization (or an external individual investigator), the IRB's records document and specify the responsibilities that a relying organization and an organization operating an IRB each will undertake to ensure compliance with the requirements of the Common Rule, when following DHHS requirements. Such records will be maintained per this policy.

All electronic or paper correspondence unrelated to a specific research protocol or study but of importance in documenting IRB policy development or the evolution of the IRB's assessment of a topic of importance is retained indefinitely.

All electronic or paper correspondence related to FDA or OHRP regulatory matters (even if not considered a study record required to be maintained by the IRB) will be brought by IRB staff to the attention of the IRB Executive Director and an IRB Chairperson for proper handling and disposition. A copy of all such correspondence will be retained by the IRB Executive Director or their designee indefinitely.

Paper minutes on site are maintained in a locked room within the main IRB Office and are available only to IRB staff. All paper records previously scanned and stored in Paperhost are accessible through the software program, SRAS 2000. The IRB staff have access to documents kept on the SRAS 2000.exe.

Paper files of studies are physically maintained in storage at a secure external site through a contract agreement with Iron Mountain, an information storage and management company. These paper files may be recalled, if needed, within three to five business days via notice to the company.

Electronic data in the IRB's electronic system iRIS are maintained by iMEDRIS and are backed up daily.

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.

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 minimum, 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 keeping it in the study's research files. A signed consent form can be sent to Duke's HIM to be stored in EPIC's MaestroCare electronic medical record.

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