**Children’s Hospital and Health System**

**Administrative Policy and Procedure**

This policy applies to the following entity

[x]  Children’s Hospital and Health System

**SUBJECT: Research Records - Record Retention for Human Subjects**

**POLICY**

To provide guidelines for retention, preservation, and responsible disposal of the Children’s Hospital and Health System, Inc. and its Affiliates (CHHS) human subject research records, to:

* Promote compliance with federal requirements for human subject research record retention. Effectively utilize storage space.
* Ensure the retained records can be retrieved in a timely manner.
* Ensure the appropriate and approved method of destruction of records.

**Background**

The principal investigator of an application approved by a CHW IRB (or where CHW chooses to rely on another IRB) is required to retain records associated with a human subject research project. All research data and materials must be retained for a period of at least 10 years from the date of the last entry in the record of the last subject enrolled in the study.

Investigators may be required to retain research subject records for a longer period of time as required by investigator agreements, sponsors, pursuant to terms of a grant, a federal agency, or agreements with the institution at which the study is conducted.

**PROCEDURE**

1. **Maintenance of Records**
2. Principal Investigators/research teams must retain the original copies of all records pertaining to research studies.
3. Principal Investigators/research teams are responsible for implementing a process to ensure that all records are retained in accordance with this policy, consistent with IRB documents, and for maintaining and safeguarding records applicable to research subjects. During the retention period the records must be protected from alteration, tampering, loss, and physical damage.
4. Access to research related data is limited to specific individuals listed as members of the research team with the CHW IRB or IRB of record.
5. Electronic records must be protected by the use of encryption.
6. If permitted by sponsor/grant, paper records may be scanned and retained on/in an encrypted device.
7. Each principal investigator shall assess the status of retained records and either retain on-site, store off-site or destroy records when appropriate.
8. Off-site storage must utilize a contracted record retention facility (Iron Mountain), which agrees to control, protect, and maintain the confidentiality of the records.
9. **Record Destruction**

Research records and files must be disposed of in a manner that ensures research subject information cannot be recovered or reconstructed.

1. The suggested method for destruction of paper research records is shredding.
2. An IronKey encrypted flash drive, provided by CHHS, can be securely erased and prepared for re-use by the CHW IS Service Center.
3. Media requiring disposal can be turned in to the CHW IS Service Center for secure disposal.
4. **Retention logs**

It is suggested that Principal Investigators/research teams maintain a log of record retention dates of storage, location of storage, and dates of record destruction per research protocol.

**Related regulations**

**21 CFR 312.62** [**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.62)

**21 CFR 812.140(a)**

[**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=812.140)

**OHRP FAQ** [**http://www.hhs.gov/ohrp/policy/faq/investigator-responsibilities/records-should-investigators-keep.html**](http://www.hhs.gov/ohrp/policy/faq/investigator-responsibilities/records-should-investigators-keep.html)

**ICH E6- Good Clinical Practice** [**http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf**](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf)[45 CFR 164.530(j) (1)](http://www.gpo.gov/fdsys/pkg/CFR-2011-title45-vol1/pdf/CFR-2011-title45-vol1-sec164-530.pdf) HIPAA requires a **6 year retention period**

[45 CFR 46.115(b)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.115) and [21 CFR 56.115(b))](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.115) require that all IRB records be retained for at least 3 years, and records relating to research which is conducted be retained for at least 3 years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of HHS or the FDA at reasonable times and in a reasonable manner.

Federal Regulatory Requirements for Recipients of Grants: OMB Circular A-110, and in various regulations including 45 CFR 74 and 45 CFR 92. Other records pertinent to an award includes all research-related study records.The minimum retention period is 3 years but individual granting agencies can require longer periods of up to 7 years. Investigators must comply with the requirements of the granting agency.

[42 CFR 93](http://www.ecfr.gov/cgi-bin/text-idx?SID=b615e4bc107c324567541fbc36022291&node=42:1.0.1.8.74.3.29.6&rgn=div8)(Public Health Service Policies on Research Misconduct) specifies evidentiary retention requirements for research records that are part of a research misconduct investigation.

 Approved by:

 

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 Peggy Troy, President & CEO

 Children’s Hospital and Health System

January 19, 2022