The Office for Human Research Protections (OHRP) FAQ, “What records should investigators keep, and for how long?” addresses form of storage:

If investigators have been designated to retain certain records (e.g., informed consent documents signed by subjects) on behalf of the institution as required by the HHS regulations at 45 CFR 46.115(b), they must retain the records in some form. Such records may be preserved in hardcopy, electronic or other media form and must be accessible for inspection and copying by authorized representatives of HHS at reasonable times and in a reasonable manner (45 CFR 46.115(b)). Retention of multiple copies of each record is not required. Investigators should follow the institution’s policies and procedures for retaining records. If investigators who have been designated to retain records on behalf of the institution leave that institution, the investigators and the institution should identify the successor responsible for maintaining those institutional records, either at the original institution or wherever the records are relocated, for the period of time required under HHS regulations at 45 CFR 46.115(b).

The 2010 Food and Drug Administration (FDA) Info Sheet, FDA Inspections of Clinical Investigations, addresses records available for inspection:

The FDA investigator also may audit the study data by comparing the data filed with the agency or the sponsor, if available, with records related to the clinical investigation. Such records may include the case report forms and supporting source documentation including signed and dated consent forms and medical records including, for example, progress notes of the physician, the subject’s hospital chart(s), and the nurses’ notes. These records may be in hard copy and/or an electronic format. For electronic records and/or electronic signatures, the FDA investigator may gather information to determine whether 21 CFR Part 11 requirements have been met. See FDA Part 11 Guidance.

2013 FDA Final Electronic Source Data in Clinical Investigations

Includes a section on retention of records. When data elements are transcribed from paper into electronic case report forms, clinical investigator(s) must also retain the paper source or certified copies for FDA review.

2016 FDA Use of Electronic Health Record Data in Clinical Investigations

Outlines best practices when a healthcare facility’s EHR is identified as the source document. Also addresses utility of using EHRs that are interoperable with electronic systems that support clinical investigations such as sponsor’s data capture systems.
Regulatory References on Format of Investigator Research Record/Document Retention

The NIH Regulatory Binder Best Practices outlines tips for referencing electronic documents and document access for inspection or monitoring:

If you elect to use only electronic copies of particular documents, the following guidelines should be observed: Either

a) place a paper placeholder in the relevant location of the binder that directs an individual to the electronic location; or
b) place a paper placeholder in one location in the binder that includes a list of all documents that are stored only in electronic format, along with the specific electronic path for each item.

Electronic-only documents should be limited to documents that:

a) are easily accessible by site staff;
b) an inspector, auditor, or clinical monitor can be provided with easy access to the relevant electronic materials during a site visit; and
c) the electronic location is controlled, regularly backed up, and is not in danger of disappearing or changing in the foreseeable future. For e-mail correspondence, sites may want to include clarification in the binder that e-mail will be archived to a permanent storage medium on a particular schedule (specify in documentation) and the media will be stored in the binder or an easily accessible location.

University of Kentucky Healthcare Requirements and Security Resources

A13-010 Data Storage and Access for Mobile Devices

A13-050 Reuse and Disposal of Electronic Media

University of Kentucky Analytics & Technology Security Office, Policy, Tips, and Services

7/11/16
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