

HAC Policies and Procedures

Why Do I Have To Keep The Information?

You are required to keep the information for several reasons including federal regulations, state law, Board of Regents' policies, institutional policies and good clinical practice.

What Do I Do With All The Documents And Records?

If your department has storage space you can store them on site. You may also arrange for long-term storage off site.

What Do I Do If I Need Access To A Terminated HAC File?

Each request must go through the OHRP staff to gain access to those records.

How Long Do Study Records Need To Be Stored Following Study Closure? Our Study Has Been Over For About Three Years. How Long Do We Have To Store This Stuff?

Per FDA 21 CFR312.62 Investigator record keeping and record retention:

- a. Disposition of drug. An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59.
- b. Case histories. An investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the investigational drug or employed as a control in the investigation.
- c. Record retention. An investigator shall retain records required to be maintained under this part for a period of 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified.

Per ICH Guidelines 4.9 Records and Reports, Section 4.9.5:

Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing application in an ICH region at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained (see section 5.5.12).

HAC Policies and Procedures

For studies that are conducted at the Augusta VAMC, please refer to the VA section.

Can We Ask The Sponsor to Provide for Long-Term Storage?

Absolutely! Contact the sponsor and ask if they can store the documents after the two-year obligation is met. Some will store the information or they will provide written documentation to destroy the records.

Is There A Current Institution SOP For Research Record Storage?

The institution currently has no policy on record retention, other than the FDA regulation. The institution is in the process of preparing a SOP for this. As far as budgetary information, this is an investigator decision.

The CFR regulations only apply to those studies under FDA jurisdiction.