

HAC Policies and Procedures for HAC Members and OHRP Staff

HAC Record Storage

How Does the HAC Limit Access to their Records?

HAC file access is limited to the OHRP staff, HAC members, and advisors. Research team members and others who submit a request in writing to the HAC may be allowed to view their own records in the presence of an OHRP staff member.

How Does the HAC Store all Active Research Protocols?

All active research protocols are maintained in a keypad protected room in storage and in individual locked offices while in use. In/Out cards are used, as well as a file log in the HAC office of the OHRP suite.

How Does the HAC Store Research Protocols that are no Longer Active?

All research protocol files that are no longer active such as those protocols whose approval expired, or was cancelled without subject enrollment, or were terminated (within the past year) are maintained in a locked storage space in the OHRP suite and as space permits. All files that are no longer active (with expiration dates greater than one year ago) are maintained at a local secure data storage facility with limited access.

How Does the HAC Store HAC Records that are not Related to a Specific Research Study?

These are maintained in a locked storage space in the OHRP suite and as space permits. All files that are no longer active (with expiration dates greater than one year ago) are maintained at a local secure data storage facility with limited access.

How Long does the HAC Maintain these Records?

The HAC has a letter of agreement with the FDA that records will be maintained for 25 years. FDA 21 CFR 56.115 b. The records required by this regulation shall be retained for at least 25 years after completion of the research.

HHS regulations at 45 CFR 46.115(b) require that 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. However, the HAC record will be maintained for 25 years.

Who can Access the HAC Records for Inspection and Copying?

Authorized representatives of federal agencies or departments including but not limited to, the Research and Development Committee of the Charlie Norwood VA Medical Center, United States Food and Drug Administration, and Department of Health and Human Services, can access the HAC records for inspection and copying at reasonable times and in a reasonable manner.