

Research Record Retention Requirements

Guidelines for VA research-related records retention are specified in the *National Archives and Records Administration Request for Records Disposition Authority DAA-0015-2015-0004*. Section 7.6 of the document addresses retention requirements for Research Investigator Files.

- These are the research records maintained by the investigator that span the entire lifecycle of the project and the records required by regulations such as the investigator's regulatory file.
- All records listed are now considered "Media Neutral", meaning paper copies can be converted to electronic copies at your discretion. Electronic records must be maintained on a VA server in a shared folder with access limited to the study team and the Research ADPACs.
- These records must be retained for 6 fiscal years, calculated from end of the fiscal year after final action, completion of study, or when expired/superseded (if applicable). Other Federal regulations or prior agreements and/or contracts with study sponsors may require a longer retention period.

Research Investigator Files include (but are not limited to) the following:

- Research protocol and all amended versions of the protocol
- Grant application
- Review committee correspondence (e.g., IRB, IACUC, RDC), including documents approved by the review committees
- Correspondence with ORD, regulatory entities, sponsor and/or funding source, correspondence
- Case report forms and supporting data (including, but not limited to, signed and dated informed consent forms and HIPAA authorization forms)
- Documentation on each subject including informed consent, interactions with subjects by telephone or in person, observations, interventions, and other data relevant to the study
- Data collected during the research including photos, video recordings, voice recording, all derivative data, and derivative databases
- List of all subjects entered in the study and the cross-walk connecting the subject's name with the code used for each subject
- Subject compensation records
- Reports of adverse events, complaints and deviations from IRB-approved protocol
- Data analyses
- Codes and keys used to de-identify and re-identify subjects' PHI
- Reports (including, but not limited to, abstracts and other publications)
- Research study correspondence not involving ORD, ORO, sponsor, or funding source
- Correspondence and written agreements with the funding source or sponsor, ORD and applicable oversight entities such as IRB, RDC, ORO, OHRP, and FDA
- Signed and dated forms submitted to regulatory agencies • investigator's brochure
- Records related to the investigational drugs such as drug accountability records
- Monitoring and audit reports such as DSMB reports and audits by oversight entities
- Documents related to budget and funding
- Other forms required by policy and regulation

Contact the IRB Office for specific instruction regarding archiving human subjects research records. The MVAHCS Records Manager will assist the Research Service in complying with these requirements.

Note: *If the investigator leaves VA, all research records are retained by the VA facility where the research was conducted. If the grant is ongoing and the investigator leaves one VA facility to go to another VA facility, the investigator must obtain approval for a copy of relevant materials to be provided to the new VA facility's research office. The investigator is not the grantee, nor does the investigator own the data.*