**\*NEW ORD Records Control Schedule RCS 10-1**

7.6 Research Investigator Files

Disposition Authority Number - DAA-0015-2015-0004-0032

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. Records include, but are not limited to: • research protocol and all amended versions of the protocol; grant application; review committee correspondence (e.g., Institutional Review Board, Institutional Animal Care and

Use Committee, Research & Development Committee) 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 research study; • data collected during the research including photos, video recordings, and voice recording, all derivative data, and derivative databases; • list of all subjects entered in the study and the cross-walk connecting the subjects 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, Office of Research Oversight (ORO), sponsor, or funding source; • correspondence and written agreements with the funding source or sponsor, ORD and applicable oversight entities such as IRB, Research and Development (R&D) Committee, VA Office of Research and Oversight (ORO), VA Office of Human Research Protections (OHRP) and FDA; • research study correspondence not involving ORD, Office of Research Oversight (ORO), sponsor, or funding source; • 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 Data Safety Monitoring Board Reports and audits by oversight entities; • documents related to budget and funding; • other forms required by policy and regulation; 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.

**\*Disposition Instruction:**

**Cutoff Instruction** = Cut off at the end of the fiscal year after completion of the research project.

**Retention Period** = Destroy 6 years after cutoff, may retain longer if required by other Federal regulations.

**\*Records may be disposed of 6 years after the end of the fiscal year in which the research study was terminated. A Guide for the disposal of research records follows:**

**Disposal of Research Records**

Research records that have met their Records Control Schedule (RCS), by the approved National Archives and Records Administration (NARA) schedule or other contractual obligation (whichever retention schedule is longest), may be disposed of. Any research records created as part of VA Ann Arbor Healthcare System (VAAAHS) approved research are subject to the approved NARA schedule for disposition, and must remain VAAAAHS property even if an investigator transfers to another facility. Inventory of destroyed records is required to be maintained by a Research Service Records Liaison (RL). Research records may not be disposed of until the retention period in the RCS has been met (6 years after the end of the fiscal year in which the research study was terminated).

**Paper Records.** Paper records may be destroyed using approved shred bins. Prior to destruction, the RL must complete VA Form 7468 (Request for Disposition of Records). This form is to be completed by the Research Service Records Liaison (Catherine Kaczmarek/Terry Robinson), signed by the Records Officer and a file copy is to be kept by both, the RL and the RO. Please contact the Research Office **BEFORE** the disposition of research records.

**Compact Discs/DVDs.** CD/DVD’s are collected and boxed by the Research Service RL, prior to having another contractor pick them up, taking them to their facility, shredding them, and providing us a certified copy of that destruction. A VA Form 7468 will need to be completed to prove that VA was the owner of those files. The current contractor we use to destroy CD/DVDs is: Rapid Shred, LLC. Please contact the Research Office if you have CD/DVDs that have past their retention period.

**Electronic records Stored on VA Servers.** At study completion, all investigator files should be transferred to a folder maintained by the research RL. The research RL utilizes a naming convention to track the study and disposition date for the files. Files stored on VA servers, when they have met their retention requirement, can be destroyed by deleting the file. It will be over-written and it will be no longer retrievable. The RL will maintain record of what was deleted and when.

**Electronic records Stored on Non-VA servers.**  The mechanism for storage and deletion of VA records stored on non-VA servers must be detailed in contractual agreement. Issues such as third-party back-up servers and encryption are typical issues dealt with in these arrangements; use of VA servers wherever possible is strongly preferred.

**Electronic Records Stored on Portable Media.**  Portable media used to store VA records, such as external hard-drives, or thumb-drives must be handled in accordance with current information security guidelines. The Information Security Officer must perform a sanitization of the portable media device and provide documentation of having completed the sanitization. A copy of that documentation must be provided to the Research Service RL for record keeping.