

**OFFICE OF RESEARCH AND DEVELOPMENT (ORD)
VETERANS HEALTH ADMINISTRATION (VHA)**

Guidance on ORD's New Record Control Schedule

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SCOPE: The Federal Records Act (FRA) requires that all Federal agencies make and preserve records that pertain to the functions, decisions, and other actions of the agency. The National Archives and Records Administration (NARA) is the Federal agency responsible for maintain and preserving Federal records; appraising records to determine if the records are worth preserving permanently or if they are temporary records; approving agency record control schedules and the disposition of records; and operating Federal Records Centers. The Archivist of the United States who is the senior civilian at NARA has approved a Records Control Schedule (RCS) for ORD. Below is information related to the ORD RCS and will cover the following areas:

1. What records and documents must be maintained by VA research programs under the FRA and in accordance with the RCS?
2. Are all records or documents that are created or used by researchers or research administration covered under the ORD RCS?
3. What is meant by record cutoff and a record disposition?
4. What is media neutrality?
5. How long must the records be kept?
6. How is ORD's RCS arranged?
7. What special issues related to the RCS must be addressed?
8. Are there any other miscellaneous issues?

1. What records and documents must be maintained by VA research programs under the FFRA and in accordance with the RCS?

As applied to VA research records, the FRA defines Federal records as all documentary material, regardless of physical form, or characteristics made or received by a VA research program or in connection with the transaction of the Agency's business, (i.e., the conduct of VA's research programs and VA research) and that are preserved or are appropriate for preservation as evidence of VA's activities or because of their informational value of data in them.

- The term "made" means: The act of creating and recording information by Agency personnel in the course of their official duties.
- The term "receive" means: The acceptance or collection of documentary materials by Agency personnel in the course of their official duties regardless of the material's origin (for example, other units of their agency, private citizens,

public officials, other agencies, contractors, Government grantees) and regardless of how transmitted (in person, by messenger, mail, electronic means, or by any other method).

Note: *Federal records may be paper, electronic (including e-mail), pictures, film or other types of media.*

Examples of Federal records include such documents as policies and procedure; statistical data; reports; legal opinions and decisions; research data and studies; research records; letters and memoranda; completed forms (if they document the conduct of business); photographs; audio and video recordings; posters and graphics; architectural and engineering documents. E-mails may also be considered Federal records depending on their content and if the content represents decisions and the conduct of business. See: <http://www.archives.gov/records-mgmt/email-mgmt.html>

Working files may also be considered Federal records. Working files are defined as rough notes, drafts, or calculations developed and used to prepare or analyze other documents. They are not personal papers, personal files, or copies of Federal records.

Note: *Not all drafts or notes would be considered Federal records. The determination of their status is dependent on the circumstances, the impact of the drafts or notes, and the final decision of the Agency's designated office or privacy official. The VHA Privacy Officer or VHA Records Manager will be able to assist in this determination and in determining who is the Agency's designated official.*

Non-record materials. Non-record materials are U.S. Government owned records/documentary materials that do not meet the conditions of records status (see 36 CFR §1222.12(b)) or that are excluded from the legal definition of records (44U.S.C. 3301). This would include such items as copies of documents preserved only for convenience or reference, copies of publications, reference materials. Non-records should be destroyed when no longer needed. Non-records should only be removed from U.S. government custody with the Agency's approval or as per Agency policies. Non-records must be secured, used, transmitted, and destroyed according to all applicable VA policies including VA Handbook 6500 if they contain any sensitive information as defined by Handbook 6500. **Note:** *To ensure there is no confusion over what is the Federal record and what is the copy; all copies should be clearly labeled as copies.*

2. Are all records or documents that are created or used by researchers or research administration covered under the ORD RCS?

No. Some records are covered by other Record Control Schedules. Some examples, 1) when a researcher uses the VA's Computerized Patient Record System (CPRS) or

makes an entry in the medical record for research purposes the medical record is still covered under the schedule for Health Information Management Service (see VHA RCS 10-1, Section XLIII. (<http://vaww.va.gov/vhapublications/rcs10/rcs10-1.pdf>). 2)

Pharmacy records including those related to the investigational pharmacy are found in VHA RCS 10-1 Section XV. **Note:** *All RCS specific to VHA are found in RCS 10-1.* For records that are common to all Agencies, a General Records Schedule (GRS) (<http://www.archives.gov/records-mgmt/grs.html>) may be applicable including:

- Financial Records are covered under GRS 1.0
- Human Resource Management Records are covered under GRS 2.0
- General Operations Support are covered under GRS 5

3. What is meant by record “cutoff” and a record “disposition”?

Cutoff. File cutoffs or file breaks are convenient points within a filing plan/system at which files are separated for purposes of storage and/or disposition. The record cutoff serves as the starting point from which you determine if the record has been retained a length of time equivalent to the disposition instructions. The cutoff is usually a calendar reference point (e.g., end of calendar year, end of fiscal year, or end of a quarter) or it can be an event such as when a research study is closed/completed or at the end of a review cycle. It is important to remember that retention periods begin with the cutoff and not when the record is first created. Non-records do not have a cutoff or a retention period.

Disposition. The record disposition defines how long the record must be stored and retained after the cutoff if the record is a temporary record. For permanent records it defines when the records must be sent to NARA for permanent storage at the archives.

Disposal of temporary records. These records have been approved by NARA for destruction after they have been retained for the amount of time specified in the RCS. Once this time requirement has been met, the records must be disposed of promptly. **Note:** *This disposition is for the record itself and not copies of the record.* The destruction of the records must follow NARA required procedures. The VHA Records Manager at each facility can assist the research office in complying with these requirements. Temporary records cannot be disposed of at any arbitrary time or by any arbitrary method.

Temporary records must not be disposed of prior to the time mandated in the RCS unless there is applicable authority to do so. Regulations allowing emergency destruction of Federal records are found in 36 CFR §1228 Subpart F. Reasons for emergency destruction may include “menaces to human life or health or to property” per the regulations. This emergency destruction may cover such records as those that become wet and moldy, those that are infested by vermin, or those that cannot be used

or repaired. NARA must be contacted and concur before the records are destroyed except for records stored on nitrate film. If they are on nitrate film and they pose a threat to life or property the VA may destroy them before reporting it to NARA.

Transfer of Permanent Records. Records determined to be permanent records by NARA must be transferred to NARA archives per the specified timeframe in the RCS. The Records Manager at each facility will assist the research office in complying with these requirements.

4. What is media neutrality?

This term “media neutrality” refers to the Federal regulations that allow Federal records to be in any form (paper, electronic, etc.) and for the Agency to transfer the record from one medium to another unless the record control schedule identifies a specific medium for a specific series of records. (See 36 CFR §1225.12). The phrase “regardless of physical form or characteristics” is frequently used in relationship to the concept of media neutrality. This phrase means that the Federal record medium may be paper, film, disk, or another physical type or form. It also means that the method of recording may be manual, mechanical, photographic, electronic, or any combination of these or other technologies.

For ORD’s RCS, all paper records can be digitalized with the resulting digitalized document constituting the Federal record, unless the RCS clearly indicates it cannot be transferred to another medium. In addition, the digitalization must follow all applicable policies including the NARA policies on the quality and accuracy of the digitalized document. The storage of the digitalized document must also follow applicable policies. For example: If a research document is from a Food and Drug Administration(FDA) regulated study, the Information Technology (IT) system that stores the digitalized document must be compliant with 21 CFR Part 11.

5. How long must Federal records be kept?

The RCS specifies how long records must be kept and when they must be destroyed. As indicated above, the “Disposition” indicates the record retention time. Copies of Federal records that were made as a convenience or as working copies do not have a disposition and may be retained until they are no longer needed.

6. How is ORD’s RCS arranged?

There are 7 main sections in the RCS. The first 6 sections apply to records created, used, or received by ORD in Central Office. Section 7 applies to records created, used, or received by the research offices in field facilities.

Section 7 is broken down into eight (8) subsections. The subsections were developed and written sufficiently broad to allow for all current and new types of Federal records to fall into one of the subsections.

7. What special issues related to the RCS must be addressed?

Research data repositories. Because research data repositories must be covered under an active repository protocol the data and documents related to the research data repository do not have a cutoff , therefore, they do not have a specific time for disposition unless the repository protocol is closed and the content of the repository will no longer be used. If the repository is closed then the repository records and all files will fall under the ORD RCS Section 7.6.

Digitalizing files from FDA regulated studies.

For FDA regulated studies some of the investigator's paper records when digitalized, will fall under the scope of 21 CFR Part 11. For those electronic records that fall under Part 11, if the FDA required retention period has not been met, then the records can only be digitalized and stored in compliance with Part 11. VISTA/CPRS is Part 11 compliant but other IT systems within VA may not be Part 11 compliant. If the FDA required retention period has passed when VHA digitalize the records then the Part 11 requirements are no longer applicable.

The basic requirements for retention of investigator files under FDA regulations are as follows:

- The retention requirements for investigator files from clinical investigations involving investigational drugs are found at 21 CFR §312.62. Investigator files from clinical investigations subject to 21 CFR §312 must be kept 2 years after the 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.
- The retention requirements for investigator files from clinical investigations involving medical devices with investigational device exemptions are found in 21 CFR §12.140(d). Investigator files from clinical investigations subject to 21 CFR §812 must be maintained during the investigation and for a period of 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
- Care must be taken with research records that have been maintained in off-site storage; commercial, federal records centers, and VA records storage in Meosho, MO. Many of these records were placed in storage as unscheduled records or under prior record disposition schedules. Care must be taken by the

Facility Records Manager and the Facility Research Office to ensure that the proper schedule is attached to the records in storage. This may be done by reviewing the inventory attached to the SF-135 or VA form 0244 if the inventory provides enough information to make a determination. If not, the records may have to be physically reviewed to ensure proper classification.

All digitalized records must meet all applicable privacy and security requirements including those found in VA Handbook 6500. **Note:** *Currently the Office of Human Research Protections (OHRP) does not have any guidance or regulations related to digitalizing paper records.*

Data Availability for Public Access. VHA has developed a proposed policy and an action plan for the Department of Veterans Affairs (VA) to implement the February 22, 2013, memorandum from the White House Office of Science and Technology Policy (OSTP) directing Federal agencies to support increased public access to the results of Federally-funded research. This proposed policy and action plan have not yet been finalized.

There are many issues within the proposed policy that have not been fully addressed including an effective date. In addition, such issues as informed consent agreements, HIPAA authorizations, and other documents (such as Data Use agreements (DUAs), contracts, and memoranda of understanding) associated with currently existing research data have typically included restrictions on use of the data outside VA and/or beyond the study for which the data were collected. For this reason, VA's public access requirement relative to research data will not be applied retrospectively to previously initiated research. VHA contemplates that its proposed "public access to research data" policy will not be applied to studies initiated prior to promulgation of the policy. The current RCS disposition requirements must be applied at least to all VA research data from studies initiated prior to promulgation of VA's forthcoming "public access to research data" policy except for data placed in a research data repository for future reuse.

Research Consents signed by subjects to allow data to be in a repository for reuse of data and/or biological specimens. If subjects sign a consent and authorization to allow their data and/or biological specimen to be placed in a research repository, the original consents and authorizations or a copy of these documents must be retained by the repository for the timeframe that the repository is active and has a current protocol. The consents/authorizations may be from a study that has already been closed.

8. Are there any other miscellaneous issues?

The following are miscellaneous issues that are important for compliance with all applicable regulations and policies:

- Records currently in storage at a facility or off-site. For records that are currently being stored, prior to destroying any of the records it may be necessary to ensure that the records are categorized by the RCS Section and subsection that is applicable. For example: investigator files fall under Section 7.6. In addition, VHA must insure that there are no stored records that belong to the VA non-profit research and education corporation established at VA Medical centers or from other non-VA entities.
- For any records that are maintained beyond the disposition timeframe in the RCS permission must be obtained in writing from NARA via the VHA Records Officer. The facility Records Manager can assist in applying for this permission. Records subject to a record hold/freeze or to a litigation hold must not be destroyed until that hold/freeze is lifted regardless of the disposition schedule in the RCS.
- Records that are being stored because the time period listed for their disposition has not been met or are records subject to a hold/freeze are discoverable under Federal Law, including the Freedom of Information Act. Failure to produce these records in a litigation matter may place VA in contempt of court and allow court sanctions to be made against VA and VA legal counsel. The facility Records Manager or Privacy Officer must be contacted if a research office or research personnel receive such a request for records to be produced.
- Inventories of all records must be maintained per the FRA and NARA law and regulations. Your facility Records Manager will assist you in creating a record inventory but it is the responsibility of the research office to conduct the inventory and maintain it as current.