

## CHAPTER 8

## OFFICE OF RESEARCH AND DEVELOPMENT

8000-8999

The Veterans Health Administration's (VHA) research program is an intramural program administered by the VHA Office of Research and

Development (ORD) and conducted at Veterans Administration (VA) medical facilities nationwide under the authority of Title 38 United States Code (U.S.C), 7303. Federal records and copies of working documents are produced within ORD and by all VA medical facilities conducting research. These records relate to the administration of the research programs and the conduct of research.

8000General Program Records

This section covers records relating to ORD's general administration and operation of VA's intramural research programs and the conduct of research.

**8000.1. ORD Subject Files.**

Records generated by ORD related to management functions of organizational planning and structure, general policy and program matters, and informal discussions with Veterans Affairs (VA) officials on issues of concern or special interest. These records contain information on programs, activities, protocols, operations, budgets, position statements and related subject areas.

Temporary; cutoff at the end of the fiscal year after final action. Destroy no sooner than 3 years but no later than 6 years after cutoff. (DAA-0015-2015-0004, item 0001)

**8000.2. Program Management Files.**

Records generated by ORD services and programs in the course of ongoing program operations that are not covered elsewhere in the VHA Records Control Schedule. These files relate to program scope and responsibilities; program reviews and evaluations; extra-agency partnerships; scientific achievement award programs; infrastructure support activities; balancing research portfolios and budgets; establishing review boards; conducting staff meetings; and other program management activities.

[NOTE: Excluded are general administrative and routine housekeeping records, which are covered under the General Records Schedule and issued by NARA.]

Temporary; cutoff at the end of the fiscal year after final action. Destroy no sooner than 3 years but no later than 6 years after cutoff. (DAA-0015-2015-0004, item 0002)

**8000.3. Congressional Relations Files.**

Official reports prepared by ORD for Transmittal to members of Congress, Congressional Committees, or Congressional Staff.

PERMANENT. Cutoff at the end of the fiscal year after the material is presented to Congress. Transfer to NARA in 10 year blocks when youngest record is 20 years old. (DAA-0015-2015-0004, item 0003)

[NOTE: Transfer electronic records to the NARA for pre-accessioning 10 years after cutoff Transfer to the NARA for accessioning.]

**8000.4. Briefing Records.**

Materials prepared by ORD for the Under Secretary for Health, the Secretary of Veterans Affairs, or other VA officials to describe issues of concern or special interest, including materials for face-to-face briefings, presentations, activity reports, and issue briefs.

PERMANENT. Cutoff at the end of the fiscal year after the material is presented to the Under Secretary of Veterans Affairs or other VA officials. Transfer to NARA in 10 year blocks 20 years after youngest record closes. (DAA-0015-2015-0004, item 0004)

[NOTE: Transfer electronic records to the NARA for pre-accessioning 10 years after cutoff.]

**8000.5. Field Correspondence Files.**

Records documenting inquiries from medical field facility research offices, such as formal guidance related to interpretation of policy, required waivers for specific types of research and from specific policy requirements, review of policies or procedures being implemented by facilities, reports from the field on compliance matters that are duplicative of reports received by the Office of Research Oversight (ORO), and related matters.

Temporary; cutoff at the end of the fiscal year when superseded or obsolete. Destroy 1 year after cutoff or when no longer needed for administrative or reference purposes. (DAA-0015-2015-0004, item 0005)

**8000.6. Education, Training and Outreach Files.**

Materials developed by ORD to provide education, training, and information to specific audiences or the general public concerning ORD's areas of responsibility.

Temporary; cutoff at the end of the fiscal year when superseded or obsolete. Destroy 1 year after cutoff or when no longer needed for administrative or reference purposes. (DAA-0015-2015-0004, item 0006)

**8050****Technology Transfer**

**This section covers records relating to ORD's implementation and administration of the Federal Technology Transfer Act of 1986. ORD is responsible for translating the results of worthy discoveries made by employees of VA into practice.**

**8050.1. Invention Disclosure Case Files.**

Case files include a description of the invention, circumstances surrounding the invention, a certification form describing the use of Federal resources and related correspondence.

- a. Invention disclosure for which a patent application was filed and issued.

Temporary; cutoff at the end of the fiscal year upon expiration of the patent. Destroy 2 years after cutoff. (DAA-0015-2015-0004, item 0007)

- b. Invention disclosure for which no patent application was filed or no patent issued.

Temporary; cutoff at the end of the fiscal year upon expiration of the disclosure. Destroy 25 years after cutoff. (DAA-0015-2015-0004, item 0008)

**8050.2. Patent Case Files.**

Case files related to the application of a patent, patent prosecution, patent defense and patent infringement.

Temporary; cutoff at the end of the fiscal year upon expiration or abandonment of the patent. Destroy 5 years after all patents in that patent family expire. (DAA-0015-2015-0004, item 0009)

**8050.3. Cooperative Agreement Files.**

Agreements that address the management of jointly owned inventions, such as Cooperative Technology Administration Agreements and Inter-institutional Agreements, and related correspondence.

Temporary; cutoff at the end of the fiscal year after final action. Destroy 2 years after cutoff. (DAA-0015-2015-0004, item 0012)

**8050.4. VA Confidential Disclosure Agreements.**

These records consist of documents that address VA providing confidential information to another entity or receiving confidential information from another entity.

Temporary; cutoff at the end of the fiscal year upon expiration of the agreement. Destroy 5 years after cutoff. (DAA-0015-2015-0004, item 0011)

**8050.5. Technology Transfer Agreements.**

Agreements that transfer rights to intellectual property and/or materials to or from VA and to or from third parties, such as license agreements, material transfer agreements, government use licenses and related agreements.

Temporary; cutoff at the end of the fiscal year when the terms of the agreement expire. Destroy 2 years after cutoff. (DAA-0015-2015-0004, item 0012)

**8050.6. License Transmittal Files.**

Transmittals related to licenses including annual reports due under the license, royalty payments to VA, royalty distributions by VA to inventors and others, and all other correspondence connected to licenses.

Temporary; cutoff at the end of the fiscal year after final action. Destroy 2 years after cutoff. (DAA-0015-2015-0004, item 0013)

**8100****Non Profit Research and Education Corporations (NPC)**

**This section covers records relating to ORD's oversight and guidance of Non Profit Research and Education Corporations (NPC) established at VA medical centers. NPCs exist to provide VA medical centers with flexible funding mechanisms to support VA's research program. This funding mechanism is other than those funds received by VA from VA's Congressional appropriation. NPCs associated with the VA are non-**

government entities created pursuant to title 38 U.S.C. 7361-7366. NPC business records are not subject to disclosure under the Freedom of Information Act (FOIA).

#### **8100.1. Annual Reports from NPCs.**

NPCs are required to submit an annual report that details their operations, activities and accomplishments during the previous year. The annual report consists of, but is not limited to, signed certification, independent auditor's report, audited financial statements, IRS Form 990 or 990EZ with schedules, and related revenue and expense information.

Temporary; cutoff at the end of the fiscal year when all annual reports are received from NPCs. Destroy 6 years after cutoff. (DAA-0015-2015-0004, item 0014)

#### **8100.2. Audit Case Files.**

Files related to the audit of NPCs by independent auditors and government auditors to ensure internal controls are in place to protect its assets and operate in compliance with all applicable laws and regulations. Records include, but are not limited to: a final review report; on- and off- site reviews; questionnaires; reviews of board minutes, annual reports and any corrective action plans submitted by NPCs; documentation of reportable or significant adverse events; and related correspondence

Temporary; cutoff at the end of the fiscal year when report is completed. Destroy 6 years after cutoff. (DAA-0015-2015-0004, item 0015)

### 8150

#### Intramural Research Funding

**This section covers records relating to ORD's administration and management of VA appropriated funds to promote research, ensure adequate resources, and support other research-related activities connected to VA research programs that benefit Veterans. All requests for research-related awards are submitted by VA facilities to ORD for funding consideration.**

#### **8150.1. Requests or Solicitations for Research.**

Documents developed by ORD to request proposals or solicitations for scientific research and related program components.

Temporary; cutoff at the end of the fiscal year when the request or solicitation is superseded, obsolete, or withdrawn. Destroy 5 years after cutoff. (DAA-0015-2015-0004, item 0016)

#### **8150.2. Approved or Funded Case Files.**

All proposals, applications or nominations submitted by VA facilities that are approved and funded. Records include, but are not limited to: the original submission with funding requirement; recommendation by the Merit Review Board; approved plans and protocols; clearances and authorizations; progress reports and project modifications; committee reports and site visit reports; and related correspondence and documents as applicable to each funding program.

[NOTE: This schedule superseded the authority of NCI-15-82-7, Item No. 12 A-1]

Temporary; cutoff at the end of the fiscal year the proposed research project is completed. Destroy 6 years after cutoff, may retain longer if necessary. (DAA-0015-2015-0004, item 0017)

#### **8150.3. Not Approved, Withdrawn or Appealed Case Files.**

All proposals, applications or nominations submitted by VA facilities not approved for funding, withdrawn, or funding decision appealed. Records include, but are not limited to: the original submission, supporting documents, recommendation by the Merit Review Board, evaluation and decision connected to an appeal, and related correspondence with the VA facility.

Temporary; cutoff at the end of the fiscal year after final decision or action. Destroy no sooner than 3 years but no later than 5 years after cutoff. (DAA-0015-2015-0004, item 0018)

#### **8150.4. Merit Review Federal Advisory Committee Act (FACA) Committee Files.**

Records related to advisory committees established by agency authority and subject to the FACA that engage in scientific peer review of VA research-related activities. Records include, but are not limited to: Federal Register Notices, original and renewed committee charters, nomination packages, conflict of interest statements, membership rosters, meeting agendas and minutes, certificates of appreciation, and related documents. These records are maintained by the individual service areas and programs in ORD.

Temporary; cutoff at the end of the fiscal year when the original, renewed or amended committee charter expires. Destroy 10 years after cutoff. (DAA-0015-2015-0004, item 0019)

[NOTE 1: For advisory committees subject to FACA that do not engage in scientific peer review, please refer to the General Records Schedule issued by NARA.]

[NOTE 2: Request an exception to GRS 26 for the permanent portion of the FACA records.]

### 8200

#### VA Central Institutional Review Board (IRB) and VA Central Office (VACO) Human Research Protection Program (HRPP)

This section covers records relating to VA's adoption and implementation of the Federal Policy (Common Rule) for the Protection of Human Subjects (1991) that requires assurances and IRB approval of human subjects research conducted by VA to protect the rights and welfare of human research subjects. ORD is responsible for the review, management and oversight of the VA Central IRB and Human Research Protection Program (HRPP) for VA Central Office.

##### **8200.1. VA Central IRB Protocol Files.**

Files related to the review and oversight of human subjects research protocols submitted by VA investigators to the VA Central IRB. Records include, but are not limited to: the application to the VA Central IRB; research protocol and amendments; case report forms; informed consent template and HIPAA Authorization template; reports of adverse events, complaints and deviations from IRB-approved protocol; data and safety monitoring reports; research findings to date; and all relevant documents and related correspondence between the VA Central IRB and the investigators in the review of an associated protocol.

##### a. Protocols Approved by VA Central IRB.

Temporary; cutoff at the end of the fiscal year after the research project has been completed or terminated. Destroy 6 years after cutoff. (DAA-0015-2015-0004, item 0020)

##### b. Protocols Disapproved by VA Central IRB or Withdrawn by the Investigator.

Temporary; cutoff at the end of the fiscal year after the research project has been disapproved or withdrawn. Destroy 3 years after cutoff. (DAA-0015-2015-0004, item 0021)

##### **8200.2. VA Central IRB Operating Files.**

Files related to the ongoing operations of the VA Central IRB.

##### a. Implementation Records.

Records include, but are not limited to: agreements by VA facilities to use the VA Central IRB as the IRB of record; standard operating procedures, policies and educational materials; documents assessing the effectiveness of the IRB and compliance with all regulatory requirements; and related correspondence not specific to an individual protocol.

Temporary; cutoff at the end of the fiscal year after final action, expiration, or when superseded. Destroy 3 years after cutoff. (DAA-0015-2015-0004, item 0022)

##### b. Committee Records.

Records include, but are not limited to: VA Central IRB membership rosters, appointment letters, committee minutes, curricula vitae, training records and related documentation.

Temporary; cutoff at the end of the fiscal year after final action, expiration, or when superseded. Destroy 6 year(s) after cutoff. (DAA-0015-2015-0004, item 0023)

##### **8200.3. VACO Human Research Protection Program (HRPP) Files.**

Files related to the operations of the Human Research Protection Program (HRPP) for VA Central Office and its Federal-wide Assurance. Records include, but are not limited to: assurance application submitted to ORO and HHS Office of Human Research Protection (OHRP) for review and approval; documents related to the registration of the VA Central IRB; VACO HRPP site visit reports from entities such as the Food and Drug Administration (FDA), OHRP, Inspector General, and ORO; reports of remedial plans and corrective actions taken to address any deficiencies; and all related documentation that demonstrates efforts to come into compliance with applicable policy and regulations.

Temporary; cutoff at the end of the fiscal year after final action, expiration, or when superseded. Destroy 7 years after cutoff. (DAA-0015-2015-0004, item 0024)

### 8250

#### Human Research Protection Program (HRPP) Accreditation

This section covers records relating to ORD's oversight of HRPP accreditation activities in VA facilities. Accreditation of a HRPP is obtained through the Accrediting Organization, which is an independent body that has developed standards of performance to

**assess compliance with the prevailing ethical, professional, and regulatory guidelines for the conduct of human subjects research.**

#### **8250.1. Accreditation Application Case Files.**

Documents obtained or created by ORD, such as: initial and renewal applications; annual and interim reports; debriefing interview notes, agendas and minutes of meetings with the Accrediting Organization; tracking of accreditation visits and outcomes; and correspondence to/from the Accrediting Organization, HRPPs and affiliated institutions related to obtaining and maintaining HRPP accreditation.

Temporary; cutoff at the end of the fiscal year after accreditation cycle expires. Destroy 3 years after cutoff. (DAA-0015-2015-0004, item 0025)

#### **8250.2. Accrediting Organization Contract Files.**

Files related to management of the Accrediting Organization under contract with VA to administer HRPP accreditation in VA facilities. Records consist of, but are not limited to: evaluation of contract performance including deliverables, reports, and problems or issues conveyed to the Accrediting Organization regarding their assessment of individual field facility HRPP's; and other correspondence to/from the Accrediting Organization.

Temporary; cutoff at the end of the fiscal year when the contract expires. Destroy 7 years after cutoff. (DAA-0015-2015-0004 Item 0026)

### 8300

#### VA Field Facility Research Program

**This section covers records relating to the administration of intramural research programs and conduct of individual research projects at VA field facilities, some of which are funded by VA research appropriation. The research programs at each VA field facility are a decentralized program under the facility's direction. Policies for the administration of research programs and conduct of research are set by ORD.**

#### **8300.1. Documentation of Required Activities.**

These files include, but are not limited to: documentation of required education by research staff; protocol activities including documents created or used in submitting protocols for funding, approval status from required research review committees, status (e.g., active or completed) of protocols, and protocol funding source; and research related agreements, such as memorandums of

understanding and Cooperative Research and Development Agreements (CRADAs).

Temporary; cutoff at the end of the fiscal year after final action or when superseded. Destroy 6 years after cutoff. (DAA-0015-2015-0004 item 0027)

#### **8300.2. Research Accreditation.**

Records related to acquiring and maintaining accreditation for components of the facility's research program. The accreditations are for such components as the HRPP and the animal research program. Records include, but are not limited to: initial and renewal applications; annual and interim reports; tracking of accreditation visits and outcomes; and correspondence to/from the Accrediting Organization.

Temporary; cutoff at the end of the fiscal year after accreditation cycle ends. Destroy 2 years after cutoff. (DAA-0015-2015-0004, item 0028)

#### **8300.3. Research Publications.**

Copies of publications resulting from funded and approved research activities.

Temporary; cutoff at the end of the fiscal year after publication. Destroy 6 years after cutoff. (DAA-0015-2015-0004, item 0029)

#### **8300.4. Veterinarian Medical Unit Files.**

Records include, but are not limited to, sanitation records, daily room checks, feed/bedding invoices, temperature tapes (for the cage washes and autoclaves), health surveillance reports, HVAC performance data, cage cards, mortality reports, pest control reports, animal order invoices, quality assurance records (RODAC plates, ADP tests, etc.) and related documentation.

Temporary; cutoff at the end of the fiscal year after final action. Destroy 3 years after cutoff. (DAA-0015-2015-0004, item 0030)

#### **8300.5. Research Biosafety and Biosecurity Program Files.**

Records related to research laboratory inspections, emergency response planning, information on chemicals or other hazardous substances, inventory of chemicals and other agents in use in research laboratories, and laboratory safety and security policies.

Temporary; cutoff at the end of the fiscal year after final action. Destroy 3 year(s) after cutoff. (DAA-0015-2015-0004, item 0031)

#### 8300.6. Research Investigator Files.

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;
- Lists 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.

Temporary; cutoff at the end of the fiscal year after completion of the research project. Destroy 6 years after cutoff, may retain longer if required by other Federal regulations. (DAA-0015-2015-0004, item 0032)

[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.]

#### 8300.7. Research Review Committee and Subcommittee Protocol Files.

Committee and subcommittee files related to the review and oversight of research protocols submitted by VA investigators for research conducted at the field facility. The committees and subcommittees include, but are not limited to, the Research & Development (R&D) Committee, the Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), the Subcommittee on Research Safety, and the Institutional Biosafety Committee. Records include, but are not limited to, the application to the VA Central IRB; research protocol and amendments; case report forms; reports of adverse events, complaints and deviations from the approved protocol; data and safety monitoring reports; research findings to date; and all relevant documents and related correspondence between the committee and the investigators in the review of an associated protocol.

- a. Protocols Approved by the Committee or Subcommittee.

Temporary; cutoff at the end of the fiscal year after the research project has been completed or terminated. Destroy 6 years after cutoff. (DAA-0015-2015-0004, item 0033)

- b. Protocols Disapproved by the Committee or Subcommittee or Withdrawn by the Investigator.

Temporary; cutoff at the end of the fiscal year after the research project has been disapproved or withdrawn. Destroy 3 years after cutoff. (DAA-0015-2015-0004, item 0034)

**8300.8. Research Review Committee or Subcommittee Operating Files.**

Files related to the ongoing operations of the review committees or subcommittees.

- a. Implementation Records. Records include, but are not limited to: agreements by VA facilities to use a review committee or subcommittee from the affiliated university or other entity; standard operating procedures, policies and educational materials; documents assessing the effectiveness of the review committees or subcommittees and compliance with all regulatory requirements; and related correspondence not related to specific protocols received or created during the course of VA Central IRB operations.

Temporary; cutoff at the end of the fiscal year after final action, expiration, or when superseded. Destroy 3 years after cutoff. (DAA-0015-2015-0004, item 0035)

- b. Review Committee or Subcommittee Records. Records include, but are not limited to, membership rosters, appointment letters, curricula vitae, training records, meeting minutes and related documentation.

Temporary; cutoff at the end of the fiscal year after final action, expiration, or when superseded. Destroy 6 years after cutoff. (DAA-0015-2015-0004, item 0036)

**8500**

**Office of Research Oversight (ORO)**

Public Law 108-170, Veterans Health Care, Capital Asset, and Business Improvement Act of 2003 established by statute in the Veterans Health Administration an "Office of Research Oversight."

ORO serves as the primary advisor to the Under Secretary for Health on matters of compliance, assurance, and technical assistance in human subject protections, laboratory animal welfare, research safety, research laboratory security, research information security, facility research compliance officer education, research misconduct, and government suspension and debarment for

research impropriety. ORO conducts a variety of oversight activities to fulfill its mandate.

**8500.1. Case Records Containing Official Determinations.**

ORO records, including case reports and electronic databases containing official determinations (e.g., findings and required actions) related to ORO's compliance oversight, technical assistance, and quality assurance activities.

**PERMANENT.** Cutoff 7 years after relevant ORO actions are completed or 7 years after all relevant claims for or against VA are finalized, whichever is later. Transfer electronic records to NARA for pre-accessioning 5 year(s) after cutoff. Transfer to NARA 25 year(s) after cutoff. (DAA-0015-2015-0002, item 0001)

[NOTE: This schedule superseded the authority of XLVII-12, NARA job # (N1-0015-07-003, item 4)]

**8500.2. Evidential Records.**

Records that provide critical evidence in support of ORO determinations and/or actions that may be disputed or subjected to litigation.

Temporary; destroy 7 years after all relevant ORO actions are completed or 7 years after all relevant claims for or against VA are finalized, whichever is later. (DAA-0015-2015-0002 item 0002)

**8500.3. Policy and Guidance Records.**

Directives, handbooks, guidance, training materials, and standard operating procedures developed by ORO.

Temporary; destroy 7 years after documents are rescinded or superseded or 7 years after all relevant claims for or against VA are finalized, whichever is later. (DAA-0015-2015-0002 item 3)

[NOTE: This schedule superseded the authority of XLVII-13, NARA Job # (N1-015-07-3, item 11)]

**8500.4. Formal Briefing Records.**

Materials prepared by ORO for the Under Secretary for Health, the Secretary of Veterans Affairs, or other VA officials to describe issues of concern or special interest, including materials for formal face-to-face briefings, presentations, activity reports, and issue briefs.

**PERMANENT.** Cutoff at end of year in which documents are delivered to the relevant official or all relevant claims

for or against VA are finalized, whichever is later. Transfer electronic records to NARA for pre-accessioning 5 year(s) after cutoff. Transfer paper to NARA in 5 year blocks 25 year(s) after youngest record in block is 5 years old. (DAA-0015-2015-0002 item 004)

[NOTE: This schedule superseded the authority of XLVII-4 NARA Job# (N1-015-07-3, item 3)]

#### 8500.5. Congressional Relations Records.

Quarterly and annual reports to Congress as required by statute, special reports created at the request of Congress, written testimony, and supporting materials for face-to-face briefings of Members of Congress and Congressional staff.

**PERMANENT.** Cutoff annually after documents are delivered to Congress. Transfer to NARA in 5 year blocks 15 year(s) after closure of youngest record in block. (DAA-0015-2015-0002 item 0005)

[NOTE: This schedule superseded the authority of XLVII 8a/8b NARA Job # (N1-015-07-03, items 6a and 6b)]

#### 8500.6. Transitory Records with Limited Historical Value.

All records not specifically covered under other subsections of this manual.

Temporary; destroy when no longer needed. (DAA-0015-2015-0002 item 0006)

[NOTE: This schedule superseded the following schedule in the past RCS 10-1; XLVII-3a, XLVII-5a, XLVII-6, XLVII-7a, XLVII-10, XLVII-13a & 13b, XLVII-15a of NARA Job # (N1-15-07-3, items 1a, 3a, 4, 5a, 9, 12a & b and 14a)]

#### 8500.7. Duplicate Records.

Duplicate copies of records retained by ORO.

Temporary; destroy when no longer needed. (DAA-0015-2015-0002 item 0007)

[NOTE: Superseded authority XLVII-17 of old RCS 10-1]

#### 8500.8. Reference Documents.

Materials retained solely for reference or informational purposes.

Temporary; destroy when no longer needed. (DAA-0015-2015-0002 item 0008)

[NOTE: Superseded authority XLVII-14 of old RCS 10-1]

## 8600

### VHA Office of Research Oversight Research Case Files

**Public Law 108-170, Veterans Health Care, Capital Asset, and Business Improvement Act of 2003 established by statute in the Veterans Health Administration an "Office of Research Oversight." ORO serves as the primary advisor to the Under Secretary for Health on matters of compliance and assurance in human subject protections, laboratory animal welfare, research safety and security, and research impropriety and misconduct. ORO conducts a variety of oversight activities to fulfill its responsibilities and legislative mandate. ORO is organizationally structured under the Office of the Under Secretary for Health, Veterans Health Administration (VHA), VHA Central Office, Department of Veterans Affairs (VA). ORO provides program directions through its Central Office and strategically located Regional Offices. ORO oversees VHA's research misconduct program and is responsible for the oversight of suspensions and Government wide debarments for research impropriety.**

#### 8600.1. Research Misconduct Case Records Involving Allegations Referred for an Inquiry and/or Investigation. (see note below 1c)

- a. Research Misconduct Case Records with Significant Historical Value that are Maintained by ORO Involving Allegations that are Referred for an Inquiry or Investigation. Records with significant historical value that are maintained by ORO in the course of ORO's oversight of research misconduct cases, including, but not limited to, submitted written allegations, threshold determinations/preliminary assessments of allegations, final (issued) Inquiry and Investigation reports, Inquiry and Investigation report attachments and exhibits that are deemed significant by ORO, final (corrected) transcripts or recordings of interviews conducted during an Inquiry or Investigation, copies of research records or relevant sections thereof, final (issued) notifications and decisional letters, written appeals, and case information sheets (or equivalent case summary documents).

**PERMANENT.** Transfer to FRC 7 years after the case is closed or 7 years after all claims for or against VA related to the matter are finalized, whichever is later. Transfer to NARA in 5 year blocks 25 year(s) after case closure. (DAA-0015-2014-0001 item 0001)



- b. Research Misconduct Case Records with Minimal Historical Value that are Maintained by ORO Involving Allegations Referred for an Inquiry and/or Investigation. Records with minimal historical value that are maintained by ORO in the course of ORO's oversight of research misconduct cases, including, but not limited to, transitory or working papers such as draft versions of documents, e-mail correspondence, telephone logs, notes, and other records not specifically covered by Item XLVII-1a.

Temporary; destroy 7 year(s) after case is closed or after all claims for or against the VA related to this matter are finalized, whichever is later. (DAA-0015-2014-0001 item 0002)

- c. Research Misconduct Case Records Maintained by VA Medical Centers and VHA Offices Other than ORO Involving Allegations Referred for an Inquiry and/or Investigation. Records created and maintained in the course of responding to allegations of research misconduct, including, but not limited to, submitted written allegations, threshold determinations/preliminary assessments of allegations, Inquiry and Investigation reports, all Inquiry and Investigation report attachments and exhibits, transcripts or recordings of interviews conducted during an Inquiry or Investigation, case-related evidence, copies of research records, notifications and decisional letters, and written appeals.

Temporary; destroy 7 year(s) after the case is closed or after all claims for or against VA related to the matter are finalized, whichever is later (DAA-0015-2014-0001 item 0003)

[NOTE: This item has superseded item XLVII-1 in old RCS 10-1 manual, NARA Job # N1-015-06-1, Item 1.]

**8600.2. Research Misconduct Case Records Involving Allegations that are Not Referred for an Inquiry and/or Investigation.**

- a. Research Misconduct Case Records Maintained by ORO. Records maintained by ORO in the course of ORO's oversight of research misconduct cases, including, but not limited to, submitted written allegations, threshold determinations/preliminary assessments of allegations, copies of research records or relevant section thereof, final (issued) notifications and decisional letters, case information sheets (or equivalent case summary documents), draft versions of documents, e-mail

correspondence, telephone logs, notes, and other records.

Temporary; destroy 7 year(s) after case is closed or after all claims for or against VA related to the matter are finalized, whichever is later. (DAA-0015-2014-0001 item 0004)

- b. Research Misconduct Case Records Maintained by VA Medical Centers and VHA Offices Other than ORO. Records created and maintained in the course of responding to allegations of research misconduct, including, but not limited to, submitted written allegations, threshold determinations/preliminary assessments of allegations, case-related evidence, copies of research records, and notifications and decisional letters.

Temporary; destroy 7 year(s) after case is closed or after all claims for or against VA related to the matter are finalized, whichever is later. (DAA-0015-2014-0001 item 0005)

**8600.3. Case Records Maintained Throughout VHA for Government-wide Suspensions and Debarments Based on Research Impropriety.**

This item pertains to records that are created and/or used as a result of a recommendation to suspend or debar individuals from participating in Government-wide non-procurement activities based on research impropriety. The records are maintained by various VHA offices and at various locations, including VA medical facilities, VISN offices, ORO Central and Regional Offices, and VA Central Office.

[NOTE: Where applicable, the records are protected from disclosure by exemptions to the Freedom of Information Act (5 United States Code (U.S.C. 552(b)), the Privacy Act (5 U.S.C. 552a), 38 U.S.C. 5701, 5705, and 7332, and the HIPAA Privacy Rule (45 CFR Parts 160 and 164).]

- a. Suspension and Debarment Case Records with Significant Historical Value that are Maintained by ORO. Records with significant historical value that are created or maintained by ORO in the course of ORO's oversight or making of recommendations to institute a Government-wide suspension or debarment based on research impropriety, including, but not limited to, the underlying written recommendation for suspension Electronic Records or debarment, final (issued) reports and other documents resulting from a fact finding process that support the recommendations and decisions, transcripts or recordings of interviews and

proceedings; documentary evidence deemed significant for retention by ORO, final (issued) notifications and decisional letters, written requests for reconsideration of decisions, and case information sheets (or equivalent case summary documents).

**PERMANENT.** Transfer to FRC 7 years after the case is closed or 7 years after all claims for or against VA related to the matter are finalized, whichever is later. Transfer to the NARA in 5 year blocks 25 year(s) after case closure. (DAA-0015-2014-0001 item 0006)

- b. Suspension and Debarment Case Records with Minimal Historical Value that are Maintained by ORO. Records with minimal historical value that are maintained by ORO in the course of ORO's oversight or making of recommendations to institute a Government-wide suspension or debarment based on research impropriety, including, but not limited to, transitory or working papers such as draft versions of documents, e-mail correspondence, telephone logs, notes, and other records not specifically covered by Item XLVII-18a.

Temporary; destroy 7 year(s) after the case is closed or after all claims for or against VA related to the matter are finalized, whichever is later. (DAA-0015-2014-0001 item 0007) [NOTE: This item superseded item XLVII-18a.]

- c. Suspension and Debarment Case Records Maintained by VA Medical Centers and VHA Offices Other than ORO. Records created and maintained in the course of recommending or instituting a Government wide suspension or debarment based on research impropriety, including, but not limited to, the underlying written recommendation for suspension or debarment,
- d. Reports and other documents resulting from a fact-finding process that support the recommendations and decisions, transcripts or recordings of interviews and proceedings, documentary evidence, notifications and decisional letters, and written requests for reconsideration of decisions.

Temporary; destroy 7 year(s) after the case is closed or after all claims for or against VA related to the matter are finalized, whichever is later. (DAA-0015-2014-0001 item 0008)