

Request for Records Disposition Authority

Records Schedule Number **DAA-0015-2015-0004**
 Schedule Status **Approved**

Agency or Establishment **Department of Veterans Affairs**
 Record Group / Scheduling Group **Records of the Department of Veterans Affairs**
 Records Schedule applies to **Major Subdivision**
 Major Subdivision **Veterans Health Administration**
 Schedule Subject **Office of Research and Development**
 Internal agency concurrences will be provided **No**

Background Information **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.**

Analysis: This appraisal and related SF 115 covers records created by the Office of Research and Development or other designees. The records contain information on patients, VA health care providers, VA employees, community members, vendors and other individuals.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
36	2	34	0

GAO Approval

Outline of Records Schedule Items for DAA-0015-2015-0004

Sequence Number	
1	General Program Records
1.1	ORD Subject Files Disposition Authority Number: DAA-0015-2015-0004-0001
1.2	Program Management Files Disposition Authority Number: DAA-0015-2015-0004-0002
1.3	Congressional Relations Files Disposition Authority Number: DAA-0015-2015-0004-0003
1.4	Briefing Records Disposition Authority Number: DAA-0015-2015-0004-0004
1.5	Field Correspondence Files Disposition Authority Number: DAA-0015-2015-0004-0005
1.6	Education, Training and Outreach Files Disposition Authority Number: DAA-0015-2015-0004-0006
2	Technology Transfer
2.1	Invention Disclosure Case Files
2.1.1	Invention Disclosure for which a patent application was filed and issued Disposition Authority Number: DAA-0015-2015-0004-0007
2.1.2	Invention Disclosure for which no patent application was filed or no patent issued Disposition Authority Number: DAA-0015-2015-0004-0008
2.2	Patent Case Files Disposition Authority Number: DAA-0015-2015-0004-0009
2.3	Cooperative Agreement Files Disposition Authority Number: DAA-0015-2015-0004-0010
2.4	VA Confidential Disclosure Agreements Disposition Authority Number: DAA-0015-2015-0004-0011
2.5	Technology Transfer Agreements Disposition Authority Number: DAA-0015-2015-0004-0012
2.6	License Transmittal Files Disposition Authority Number: DAA-0015-2015-0004-0013
3	Non Profit Research and Education Corporations (NPC)
3.1	Annual Reports from NPCs Disposition Authority Number: DAA-0015-2015-0004-0014
3.2	Audit Case Files Disposition Authority Number: DAA-0015-2015-0004-0015

4	Intramural Research Funding
4.1	Requests or Solicitations for Research Disposition Authority Number: DAA-0015-2015-0004-0016
4.2	Approved or Funded Case Files Disposition Authority Number: DAA-0015-2015-0004-0017
4.3	Not Approved, Withdrawn or Appealed Case Files Disposition Authority Number: DAA-0015-2015-0004-0018
4.4	Merit Review FACA Committee Files Disposition Authority Number: DAA-0015-2015-0004-0019
5	VA Central Institutional Review Board (IRB) and VA Central Office (VACO) Human Research Protection Program (HRPP)
5.1	VA Central IRB Protocol Files
5.1.1	Protocols Approved by VA Central IRB Disposition Authority Number: DAA-0015-2015-0004-0020
5.1.2	Protocols Disapproved by VA Central IRB or Withdrawn by the Investigator Disposition Authority Number: DAA-0015-2015-0004-0021
5.2	VA Central IRB Operating Files
5.2.1	Implementation Records Disposition Authority Number: DAA-0015-2015-0004-0022
5.2.2	Committee Records Disposition Authority Number: DAA-0015-2015-0004-0023
5.3	VACO Human Research Protection Program (HRPP) Files Disposition Authority Number: DAA-0015-2015-0004-0024
6	Human Research Protection Program (HRPP) Accreditation
6.1	Accreditation Application Case Files Disposition Authority Number: DAA-0015-2015-0004-0025
6.2	Accrediting Organization Contract Files Disposition Authority Number: DAA-0015-2015-0004-0026
7	VA Field Facility Research Program
7.1	Documentation of Required Activities Disposition Authority Number: DAA-0015-2015-0004-0027
7.2	Research Accreditation Disposition Authority Number: DAA-0015-2015-0004-0028
7.3	Research Publications Disposition Authority Number: DAA-0015-2015-0004-0029
7.4	Veterinarian Medical Unit Files Disposition Authority Number: DAA-0015-2015-0004-0030

7.5	Research Biosafety and Biosecurity Program Files Disposition Authority Number: DAA-0015-2015-0004-0031
7.6	Research Investigator Files Disposition Authority Number: DAA-0015-2015-0004-0032
7.7	Research Review Committee and Subcommittee Protocol Files
7.7.1	Protocols Approved by the Committee or Subcommittee Disposition Authority Number: DAA-0015-2015-0004-0033
7.7.2	Protocols Disapproved by the Committee or Subcommittee or Withdrawn by the Investigator Disposition Authority Number: DAA-0015-2015-0004-0034
7.8	Research Review Committee or Subcommittee Operating Files
7.8.1	Implementation Records Disposition Authority Number: DAA-0015-2015-0004-0035
7.8.2	Review Committee or Subcommittee Records Disposition Authority Number: DAA-0015-2015-0004-0036

Records Schedule Items

Sequence Number					
1	<p>General 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.</p>				
1.1	<p>ORD Subject Files Disposition Authority Number DAA-0015-2015-0004-0001</p> <p>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.</p> <p>Final Disposition Temporary Item Status Active Is this item media neutral? Yes Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No</p> <table border="1" style="width: 100%;"> <tr> <td>Manual Citation</td> <td>Manual Title</td> </tr> <tr> <td>New</td> <td>RCS 10-1</td> </tr> </table> <p>Disposition Instruction Cutoff Instruction Cut off at the end of the fiscal year after final action. Retention Period Destroy no sooner than 3 years but no later than 6 years after cutoff.</p> <p>Additional Information GAO Approval Not Required</p>	Manual Citation	Manual Title	New	RCS 10-1
Manual Citation	Manual Title				
New	RCS 10-1				
1.2	<p>Program Management Files Disposition Authority Number DAA-0015-2015-0004-0002</p> <p>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</p>				

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.

Final Disposition Temporary
Item Status Active
Is this item media neutral? Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action.
Retention Period Destroy no sooner than 3 years but no later than 6 years after cutoff.

Additional Information

GAO Approval Not Required

Congressional Relations Files

Disposition Authority Number DAA-0015-2015-0004-0003

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

Final Disposition Permanent
Item Status Active
Is this item media neutral? Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

1.3

Electronic Records

If this item has multiple sections, indicate here records to which this section apply

Cutoff Instruction: Cut off at the end of the fiscal year after the material is presented to Congress.

Transfer Electronic Records to the National Archives for Pre-Accessioning: Transfer electronic records to the National Archives for pre-accessioning 10 year(s) after cutoff

Transfer to the National Archives for Accessioning: Transfer to National Archives in 10 year blocks when youngest record is 20 years old.

Additional Information

First year of records accumulation: 1997

What will be the date span of the initial transfer of records to the National Archives?: From 1997 To 2006

How frequently will your agency transfer these records to the National Archives?: Every 10 Years

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	10 GB	2 MB
Paper		
Microform		
Hardcopy or Analog Special Media		

Disposition Instruction

Non-electronic Textual Records

If this item has multiple sections, indicate here records to which this section apply

Cutoff Instruction: Cut off at end of the fiscal year after the material is presented to Congress

Transfer to the National Archives for Accessioning: Transfer to the National Archives immediately after 20 years

Additional Information

First year of records accumulation **1994**
 End year of records accumulation **1996**
 What will be the date span of the initial transfer of records to the National Archives? **From 1994 To 1996**
 How frequently will your agency transfer these records to the National Archives? **Unknown**
This is a one time transfer. Records are electronic beginning in 1997.

	Estimated Current Volume	Annual Accumulation
Electronic/Digital		
Paper	3 Cubic feet	
Microform		
Hardcopy or Analog Special Media		

1.4

Briefing Records

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

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.

Final Disposition **Permanent**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

If this item has multiple sections, indicate here records to which this section apply **Electronic Records**

Cutoff Instruction **Cut off at the end of the fiscal year after the material is presented to the Under Secretary of Veterans Affairs or other VA officials.**

Transfer Electronic Records to the National Archives for Pre-Accessioning **Transfer electronic records to the National Archives for pre-accessioning 10 year(s) after cutoff**

Transfer to the National Archives for Accessioning **Transfer to the National Archives in 10 year blocks 20 year(s) after youngest record closes**

Additional Information

First year of records accumulation **2014**

What will be the date span of the initial transfer of records to the National Archives? **From 2014 To 2024**

How frequently will your agency transfer these records to the National Archives? **Every 10 Years**

	Estimated Current Volume	Annual Accumulation
Electronic/Digital	1 MB	1 MB
Paper		
Microform		
Hardcopy or Analog Special Media		

1.5

Field Correspondence Files

Disposition Authority Number **DAA-0015-2015-0004-0005**

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.

Final Disposition **Temporary**

Item Status **Active**
 Is this item media neutral? **Yes**
 Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction **Cut off at end of the fiscal year after final action.**
 Retention Period **Destroy 1 year(s) after cutoff.**

Additional Information

GAO Approval **Not Required**

Education, Training and Outreach Files

Disposition Authority Number **DAA-0015-2015-0004-0006**

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

Final Disposition **Temporary**
 Item Status **Active**
 Is this item media neutral? **Yes**
 Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction **Cut off at the end of the fiscal year when superseded or obsolete.**
 Retention Period **Destroy 1 year(s) after cutoff or when no longer needed for administrative or reference purposes.**

Additional Information

1.6

2	GAO Approval Not Required				
	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.				
2.1	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.				
2.1.1	Invention Disclosure for which a patent application was filed and issued Disposition Authority Number DAA-0015-2015-0004-0007 Final Disposition Temporary Item Status Active Is this item media neutral? Yes Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No				
	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%;">Manual Citation</td> <td style="width: 50%;">Manual Title</td> </tr> <tr> <td>New</td> <td>RCS 10-1</td> </tr> </table>	Manual Citation	Manual Title	New	RCS 10-1
Manual Citation	Manual Title				
New	RCS 10-1				
	Disposition Instruction Cutoff Instruction Cut off at the end of the fiscal year upon expiration of the patent. Retention Period Destroy 2 year(s) after cutoff.				
2.1.2	Additional Information GAO Approval Not Required Invention Disclosure for which no patent application was filed or no patent issued Disposition Authority Number DAA-0015-2015-0004-0008 Final Disposition Temporary Item Status Active Is this item media neutral? Yes Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No				

2.2

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year upon expiration of the disclosure.

Retention Period Destroy 25 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Patent Case Files

Disposition Authority Number DAA-0015-2015-0004-0009

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

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year upon expiration or abandonment of the patent.

Retention Period Destroy 5 year(s) after all patents in that patent family expire.

Additional Information

GAO Approval Not Required

2.3

Cooperative Agreement Files

Disposition Authority Number DAA-0015-2015-0004-0010

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

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action.

Retention Period Destroy 2 year(s) after cutoff.

Additional Information

GAO Approval Not Required

VA Confidential Disclosure Agreements

Disposition Authority Number DAA-0015-2015-0004-0011

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

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

2.4

2.5

Cutoff Instruction Cut off at the end of the fiscal year upon expiration of the agreement.

Retention Period Destroy 5 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Technology Transfer Agreements

Disposition Authority Number DAA-0015-2015-0004-0012

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

2.6

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year when the terms of the agreement expire.

Retention Period Destroy 2 year(s) after cutoff.

Additional Information

GAO Approval Not Required

License Transmittal Files

Disposition Authority Number DAA-0015-2015-0004-0013

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction **Cut off at the end of the fiscal year after final action.**
Retention Period **Destroy 2 year(s) after cutoff.**

Additional Information

GAO Approval **Not Required**

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).

Annual Reports from NPCs

Disposition Authority Number **DAA-0015-2015-0004-0014**

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.

Final Disposition **Temporary**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

3

3.1

3.2

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year when all annual reports are received from NPCs.
Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Audit Case Files

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

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.

Final Disposition Temporary
Item Status Active
Is this item media neutral? Yes
Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year when report is completed.
Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

4

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

4.1

benefit Veterans. All requests for research-related awards are submitted by VA facilities to ORD for funding consideration.

Requests or Solicitations for Research

Disposition Authority Number **DAA-0015-2015-0004-0016**

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

Final Disposition **Temporary**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction **Cut off at the end of the fiscal year when the request or solicitation is superseded, obsolete, or withdrawn.**

Retention Period **Destroy 5 year(s) after cutoff.**

Additional Information

GAO Approval **Not Required**

4.2

Approved or Funded Case Files

Disposition Authority Number **DAA-0015-2015-0004-0017**

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.

Final Disposition **Temporary**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

4.3

Manual Citation	Manual Title
New	RCS 10-1

GRS or Superseded Authority Citation National Archives Job No. NCI-15-82-7, Item No. 12 A-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year the proposed research project is completed.

Retention Period Destroy 6 years after cutoff, may retain longer if necessary.

Additional Information

GAO Approval Not Required

Not Approved, Withdrawn or Appealed Case Files

Disposition Authority Number DAA-0015-2015-0004-0018

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final decision or action.

Retention Period Destroy no sooner than 3 years but no later than 5 years after cutoff.

Additional Information

4.4

GAO Approval Not Required

Merit Review FACA Committee Files

Disposition Authority Number DAA-0015-2015-0004-0019

Records related to advisory committees established by agency authority and subject to the Federal Advisory Committee Act (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. 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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year when the original, renewed or amended committee charter expires.

Retention Period Destroy 10 year(s) after cutoff.

Additional Information

GAO Approval Not Required

5

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.

5.1

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.

5.1.1

Protocols Approved by VA Central IRB

Disposition Authority Number DAA-0015-2015-0004-0020

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered
by this item currently exist in
electronic format(s) other than e-
mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after the research project has been completed or terminated.

Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

5.1.2

Protocols Disapproved by VA Central IRB or Withdrawn by the Investigator

Disposition Authority Number DAA-0015-2015-0004-0021

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered
by this item currently exist in
electronic format(s) other than e-
mail and word processing? No

Manual Citation	Manual Title

New	RCS 10-1
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Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after the research project has been disapproved or withdrawn.

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

5.2

VA Central IRB Operating Files

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

5.2.1

Implementation Records

Disposition Authority Number DAA-0015-2015-0004-0022

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action, expiration, or when superseded.

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

5.2.2

Committee Records

Disposition Authority Number DAA-0015-2015-0004-0023

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

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action, expiration, or when superseded.

Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

5.3

VACO Human Research Protection Program (HRPP) Files

Disposition Authority Number DAA-0015-2015-0004-0024

Files related to the operations of the Human Research Protection Program (HRPP) for VA Central Office and its Federalwide 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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action, expiration, or when superseded.

Retention Period Destroy 7 year(s) after cutoff.

Additional Information

GAO Approval Not Required

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.

Accreditation Application Case Files

Disposition Authority Number DAA-0015-2015-0004-0025

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after accreditation cycle expires.

6

6.1

6.2

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Accrediting Organization Contract Files

Disposition Authority Number DAA-0015-2015-0004-0026

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 HRPPs; and other correspondence to/from the Accrediting Organization.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year when the contract expires.

Retention Period Destroy 7 year(s) after cutoff.

Additional Information

GAO Approval Not Required

7

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.

7.1

Documentation of Required Activities

Disposition Authority Number DAA-0015-2015-0004-0027

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).

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action or when superseded.

Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Research Accreditation

Disposition Authority Number DAA-0015-2015-0004-0028

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

7.2

7.3

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after accreditation cycle ends.

Retention Period Destroy 2 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Research Publications

Disposition Authority Number DAA-0015-2015-0004-0029

Copies of publications resulting from funded and approved research activities.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after publication.

Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

7.4

Veterinarian Medical Unit Files

Disposition Authority Number DAA-0015-2015-0004-0030

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.

Final Disposition Temporary
 Item Status Active
 Is this item media neutral? Yes
 Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action.
 Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Research Biosafety and Biosecurity Program Files

Disposition Authority Number DAA-0015-2015-0004-0031

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.

Final Disposition Temporary
 Item Status Active
 Is this item media neutral? Yes
 Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action.
 Retention Period Destroy 3 year(s) after cutoff.

7.5

7.6

Additional Information

GAO Approval Not Required

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
New	RCS 10-1

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.**

Additional Information

GAO Approval **Not Required**

7.7

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.

7.7.1

Protocols Approved by the Committee or Subcommittee

Disposition Authority Number **DAA-0015-2015-0004-0033**

Final Disposition **Temporary**

Item Status **Active**

Is this item media neutral? **Yes**

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? **No**

Manual Citation	Manual Title
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New	RCS 10-1
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Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after the research project has been completed or terminated.

Retention Period Destroy 6 year(s) after cutoff.

Additional Information

GAO Approval Not Required

7.7.2

Protocols Disapproved by the Committee or Subcommittee or Withdrawn by the Investigator

Disposition Authority Number DAA-0015-2015-0004-0034

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after the research project has been disapproved or withdrawn.

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

7.8

Research Review Committee or Subcommittee Operating Files
Files related to the ongoing operations of the review committees or subcommittees.

7.8.1

Implementation Records

Disposition Authority Number DAA-0015-2015-0004-0035

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.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action, expiration, or when superseded.

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Review Committee or Subcommittee Records

Disposition Authority Number DAA-0015-2015-0004-0036

Records include, but are not limited to, membership rosters, appointment letters, curricula vitae, training records, meeting minutes and related documentation.

Final Disposition Temporary

Item Status Active

Is this item media neutral? Yes

Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? No

Manual Citation	Manual Title
New	RCS 10-1

Disposition Instruction

Cutoff Instruction Cut off at the end of the fiscal year after final action, expiration, or when superseded.

7.8.2

Retention Period	Destroy 6 year(s) after cutoff.
Additional Information	
GAO Approval	Not Required

Agency Certification

I hereby certify that I am authorized to act for this agency in matters pertaining to the disposition of its records and that the records proposed for disposal in this schedule are not now needed for the business of the agency or will not be needed after the retention periods specified.

Signatory Information

Date	Action	By	Title	Organization
02/09/2015	Certify	Martin Hill	Program Management Office	Office of Information and Technology - Enterprise Records Service
06/30/2015	Submit for Concurrence	David Weber	for	National Archives and Records Administration - Records Management Services
07/09/2015	Concur	Laurence Brewer	Director, National Records Management Program	National Archives and Records Administration - National Records Management Program
07/09/2015	Concur	Laurence Brewer	Director, National Records Management Program	National Archives and Records Administration - National Records Management Program
07/10/2015	Approve	David Ferriero	Archivist of the United States	Office of the Archivist - Office of the Archivist