

<b>REQUEST FOR RECORDS DISPOSITION AUTHORITY</b>		JOB NUMBER <i>71-015-07-3</i>	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		DATE RECEIVED <i>1-4-2007</i>	
1. FROM (Agency or establishment) Department of Veterans Affairs (VA)		NOTIFICATION TO AGENCY In accordance with the provisions of 44 U.S.C. 3303a the disposition request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
2. MAJOR SUBDIVISION Veterans Health Administration (VHA)			
3. MINOR SUBDIVISION			
4. NAME OF PERSON WITH WHOM TO CONFER Sherwin Lynch (lynsher@mail.va.gov)	5. TELEPHONE 202-273-8312	DATE <i>3/17/02</i>	ARCHIVIST OF THE UNITED STATES <i>Allen W...</i>
6. 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 on the attached ___ page(s) are not now needed for the business of this agency or will not be needed after the retention periods specified; and that written concurrence from the General Accounting Office, under the provisions of Title 8 of the GAO manual for Guidance of Federal Agencies,  <input type="checkbox"/> is not required; <input type="checkbox"/> is attached; or <input type="checkbox"/> has been requested.			
DATE <i>4/22/06</i>	SIGNATURE OF AGENCY REPRESENTATIVE <i>Loise A. Russell</i> Loise A. Russell		TITLE Director, Records Management Service
7. Item No.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)

**OFFICE OF RESEARCH OVERSIGHT (ORO)  
RECORDS**

The Office of Research Oversight (ORO) provides advice to the Under Secretary for Health, Department of Veterans Affairs (VA) on matters of compliance and assurance in human subject protections, laboratory animal welfare, research safety and security, and research impropriety and misconduct.

This SF 115 covers records created and maintained by ORO and its regional offices. The records are temporary and can be destroyed after expiration of their respective retention periods.

*SA 8/23/07 copies sent to Agency, NARA, NWCT, NR*

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Assurance Files and Related Records. Temporary. Records obtained or created by ORO concerning Research Assurances filed by VA facilities and/or affiliated institutions. These records may include VA or other Federal Department or Agency Assurance Documents; Federal-wide Assurances (FWAs); Memoranda of Understanding (MOUs); Membership Rosters; Work Papers, and other documents obtained or created by ORO in the course of its Assurance Oversight activities. Assurance records may be categorized as Critical or Supplemental.

(a) Critical Assurance Records. Signed copies of MOUs and Assurances and their attachments, including Membership Rosters, which are critical to documenting the assurance status of a VA facility or its affiliates.

Disposition. Destroy 7 years after the Assurance has expired or been superseded.

(b) Supplemental Assurance Records. Work papers and other documents related to ORO's Assurance activities.

Disposition. Destroy after the Assurance has expired or been superseded.

2.

Briefing Records. ~~Temporary~~ Materials created by ORO for internal use in briefing the Secretary of Veterans Affairs, the Under Secretary for Health, the Principal Deputy Under Secretary for Health, and/or other VA or Executive Branch officials or offices.

Disposition: PERMANENT. Transfer to the National Archives in 5-year blocks when 30 years old.

REQUEST FOR RECORDS DISPOSITION AUTHORITY - CONTINUATION

7. ITEM NO.	8. DESCRIPTION OF ITEM <i>(With Inclusive Dates or Retention Periods)</i>	9. GRS OR SUPERSEDED JOB CITATION	PAGE OF 10. ACTION TAKEN <i>(NARS USE ONLY)</i>
3.	<p>Case Files. Temporary. Documents obtained or created by ORO in the course of individual For-Cause Compliance Evaluations, Routine Reviews, Compliance Monitoring, Adverse Event Monitoring, or other ORO Compliance Oversight activities related to human research protections, laboratory animal welfare, or research safety and security. Case Files may include Compliance Decision Documents, Compliance Support Documents, Work Papers, or other documents obtained or created in the course of such ORO Compliance Oversight activity. Documents in case files may be categorized as Critical or Supplemental.</p> <p>(a) Critical Case Records. Compliance Decision Documents, Critical Compliance Support Documents, Critical Work Papers and other critical documents (as defined elsewhere in this schedule) obtained or created in the course of ORO Compliance Oversight activity.</p> <p>Disposition. Destroy 7 years after resolution of the case.</p> <p>(b) Supplemental Case Records. Supplemental Compliance Support Documents, Supplemental Work Papers, and other supplemental documents (as defined elsewhere in this schedule) in the course of ORO Compliance Oversight activity.</p> <p>Disposition. Destroy after final resolution of the case.</p>		
4.	<p>Compliance Decision Documents. Temporary. Reports, letters, and memoranda (including attachments) that convey interim or final findings, decisions, or determinations related to For-Cause Compliance Evaluations, Routine Reviews, Compliance Monitoring, Adverse Event Monitoring, or other ORO Compliance Oversight activities concerning human research protections, laboratory animal welfare, or research safety and security.</p> <p>Disposition. Destroy 7 years after resolution of case.</p>		

**REQUEST FOR RECORDS DISPOSITION AUTHORITY - CONTINUATION**

7. ITEM NO.	8. DESCRIPTION OF ITEM <i>(With Inclusive Dates or Retention Periods)</i>	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN <i>(NARS USE ONLY)</i>
5.	<p>Compliance Support Documents. Temporary Documents providing support for ORO findings, decisions, or determinations related to For-Cause Compliance Evaluations, Routine Reviews, Compliance Monitoring, Adverse Event Monitoring, or other ORO Compliance Oversight activity concerning human research protections, laboratory animal welfare, or research safety and security. Compliance Support Documents may include Work Papers; correspondence to or from complainants, VA facilities or personnel, and other parties; adverse event, noncompliance, suspension, or termination reports; copies of medical or research records; copies of relevant facility policies and procedures, research protocols, and informed consent documents; corrective action plans and progress reports; or other documents created or obtained in the course of ORO's oversight activities. Decision support documents may be categorized as Critical or Supplemental.</p> <p>(a) Critical Compliance Support Documents. Documents providing substantive direct evidence in support of ORO findings, decisions, or determinations that are likely to require justification or be questioned, disputed, or subjected to litigation.</p> <p>Disposition. Destroy 7 years after final resolution of case.</p> <p>(b) Supplemental Compliance Support Documents. Documents not providing direct substantive evidence in support of ORO findings, decisions, or determinations that are likely to require justification or be questioned, disputed, or subjected to litigation.</p> <p>Disposition: Destroy after final resolution of the case.</p>		

ITEM NO.	8. DESCRIPTION OF ITEM <i>(With Inclusive Dates or Retention Periods)</i>	SUPERSEDED JOB CITATION	NOT TAKEN (NARS USE ONLY)
6.	<p>Congressional Relations Records. Reports prepared by ORO for transmittal to members of Congress, Congressional Committees, or Congressional staff.</p> <p>a. Quarterly Reports. Disposition: TEMPORARY. Destroy 2 years after the material is presented.</p> <p>b. Annual Reports. Disposition: PERMANENT. Transfer to the National Archives in 4-year blocks when 20 years old.</p>		
7.	<p>Correspondence. Temporary. Letters and memoranda of a general nature that do not establish a policy or precedent and are not retained elsewhere by ORO. Correspondence includes letters and memoranda responding to requests for information or clarification regarding established policies or precedents.</p> <p>Disposition. Destroy 2 years after date of issuance.</p>		
<del>8.</del>	<p><del>Duplicate Records. Copies of organized records maintained elsewhere by ORO.</del></p> <p><del>Disposition. Destroy when no longer needed.</del></p>		
9.	<p>Information and Outreach Materials. Temporary. Documents developed by ORO to provide information to specific audiences or the general public concerning matters within ORO's areas of responsibility. Information and outreach materials include papers and presentations describing or clarifying established ORO activities, functions, or responsibilities.</p> <p>Disposition. Destroy 1 year after presentation or publication or thereafter when no longer needed for reference.</p>		
10.	<p>Office of Research Compliance and Assurance (ORCA) Records. Temporary. Documents and materials related to the creation of ORCA; the transition of ORCA to ORO; and ORCA activities not carried over to ORO.</p> <p>Disposition. Destroy 7 years after no longer needed.</p>		

11.

Policy Precedent Records. ~~Temporary~~ Standard operating procedures, or other documents originating in ORO, or developed at the request of ORO, that provide clarification or precedent upon which ORO takes action, makes determinations, or provides recommendations.

Disposition: PERMANENT. Transfer to the National Archives in 5-year blocks when 30 years old.

12.

Quality Assurance (QA) Records. Temporary. Materials related to ORO's Quality Assurance (QA) activities. QA Records may be categorized as Critical or Supplemental.

(a) Critical QA Records. Reports and accompanying data tables providing the outcome of ORO quality assurance activities.

Disposition. Destroy 7 years after the report is finalized.

(b) Supplemental QA Records. Work Papers, data tables, and source documents created or obtained by ORO Central Office or Regional Offices in support of ORO's QA activities.

Disposition. Destroy 1 year after report is finalized.

13.

Reference Documents. Temporary. Materials retained solely for reference and information purposes. Reference documents may include materials developed by ORO that are not required to be retained by other items in this schedule, or materials originating outside ORO and of interest to ORO, including (but not limited to):

14.

- (a) Publications, periodicals, books.
- (b) Journal articles and news clippings.
- (c) Materials from conferences and workshops.
- (d) Informational materials about events or activities.
- (e) Other items of interest to ORO.

Disposition. Review annually and destroy when no longer needed.

Work Papers. Temporary. Staff notes and analyses, printed e-mail messages, telephone notes, interview notes, meeting agendas and notes, meeting handouts, logs, calendars, diaries, and other materials created by ORO staff while serving in an official capacity as follows. Work Papers may be retained as created or may be incorporated into summary documents. Work papers that are incorporated into summary documents may be destroyed provided that the summary documents are retained as follows. Work Papers may be categorized as Critical or Supplemental.

(a) Critical Work Papers. Work Papers that constitute Critical Compliance Support Documents, Critical QA Records, or Critical Assurance Records. Printed E-mail messages that are categorized as Critical Work Papers must be retained in hard copy.

Disposition. Relate Work Papers to the appropriate official file and destroy when the official file is destroyed.

(b) Supplemental Work Papers. Work papers that do not constitute Critical Compliance Support Documents, Critical QA Records, or Critical Assurance Records.

Disposition. Relate work papers to the appropriate official file and destroy when the case has been resolved or the relevant matter has been completed.

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15.	<p>Work Status Records. Temporary. Reports or records that summarize the status of ORO Assurance, Compliance, or other activities.</p> <p>Disposition. Destroy 2 years after the records are no longer current.</p>		

Note: VHA will submit an SF 115 for the temporary records that rise to the level of permanency.