


<b>REQUEST FOR RECORDS DISPOSITION AUTHORITY</b> <i>(See Instructions on reverse)</i>		<b>LEAVE BLANK (NARA use only)</b>	
TO: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		JOB NUMBER <div style="text-align: right; font-size: 1.2em;">N1-442-06-1</div>	
		DATE RECEIVED <div style="text-align: right; font-size: 1.2em;">7/5/06</div>	
1. FROM (Agency or establishment) <i>Department of Health and Human Services</i> 2. MAJOR SUBDIVISION Centers for Disease Control and Prevention - COTPER 3. MINOR SUBDIVISION Division of Select Agents and Toxins (DSAT)		<b>NOTIFICATION TO AGENCY</b>	
		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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	
		DATE <div style="font-size: 1.2em;">7/2/07</div>	ARCHIVIST OF THE UNITED STATES <div style="font-size: 1.2em;">Albin Lindner</div>
4. NAME OF PERSON WITH WHOM TO CONFER  Jimmy Harrison		5. TELEPHONE  (404) 498-1509	
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 <u>23</u> 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 checked="" type="checkbox"/> is not required; <input type="checkbox"/> is attached; or <input type="checkbox"/> has been requested.			
DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE	
6/14/06		Director, Office of Resources Management DHHS Records Management Officer	
7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
7.	This schedule covers the records generated by the Centers for Disease Control and Prevention, Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER), Division of Select Agents and Toxins, Select Agent Program. (See Attachment to SF115 for details.)  Page 2 of this document provides a listing of the record items.		

**REQUEST FOR RECORDS DISPOSITION AUTHORITY — CONTINUATION**

JOB NUMBER  
N1-442-06-01

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7. ITEM NO.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
1.	Applic. for Lab Regis. for Posses., Use, & Trans. of Select Agents & Toxins		
2.	Select Agent Entity Inspection Reports	unscheduled	
3.	Security Risk Assessment	unscheduled	
4.	Request to Transfer Select Agents & Toxins	unscheduled	
5.	Import Form/Importation Permits	unscheduled	
6.	Report of Theft, Loss or Release of Select Agents & Toxins	unscheduled	
7.	Report of Ident. of a Select Agent or Toxin in a Clinical or Diag. Lab	unscheduled	
8.	Req. for Exem. of Select Agents & Toxins for Pub. Health or Agric. Emer.	unscheduled	
9.	Conflict of Interest Forms	unscheduled	
10.	Notice of Destruction Records	unscheduled, non-recur.	
11.	Training Records (CDC required training)	B-321, Part 3, 3-11	
12.	Select Agent Program - Controlled Correspondence	B-321, Part 1, 1-7 a/b	
13.	Web Page Documents	unscheduled	
14.	Select Agent Program Reports	unscheduled	
15.	Director's Report - Division Select Agents & Toxins	unscheduled	
16.	Continuation of Operations Plans (COOP)	GRS 24, Item 5a	
17.	Select Agent Possessor/Non Possessor Survey Records	unscheduled, non-recur.	
18.	Software Development Records	GRS 24, Item 11b	
19.	Request for Information	unscheduled	
20.	Non-Registered Entities	unscheduled	
21.	Compliance Files	unscheduled	
22.	OIG/FBI Referral Documentation	unscheduled	
23.	Rules of Behavior Forms/Network Permissions/User Role Documentation	GRS 24, Item 6a	

**Request for Records Disposition Authority – SF115**  
**Centers for Disease Control – Division of Select Agents and Toxins (DSAT)**

**Unless otherwise stated, this schedule covers records in any and all media, in any and all formats, and produced using any and all tools. Records may include, but are not limited to, word-processing documents, presentation materials, statistical data, test data, spreadsheets, databases, email, e-messages, photographic materials, audio materials, audio materials, film and video materials, drawings, and artwork.**

**Item 1: Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents and Toxins – APHIS/CDC Form 1 (Formerly 2040/0.1319)**

Original applications, confirmation receipts, amendments and related correspondence that may include approval letters, acknowledgement letters, registration certificates material, withdrawals, suspensions, inventories of biological agents or toxins used at a specified location, agent quantities, biosafety and laboratory data, lists of authorized personnel at the entity location, facility floor plans, clinical/diagnostic forms, possession forms, exemption requests, security risk assessments, reports of theft/loss/release, transfer reports, possession reports activity logs, routing forms, attachments, mailing receipts, general and special communications, and other related records of the DSAT select agent program registration.

**Authorized Disposition:**

Cut off files when entity registration expires. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 2: Select Agent Entity Inspection Reports**

Notices of Inspection (NOI), inspection checklists, facility inspection reports, site visit personnel attendance lists, laboratory inspection/certification reports, entity emergency response checklists, emergency protocol, emergency response procedures, security plans, general site procedures, facility site plans, FedEx tracking forms, correspondence (e.g., responses from entity to CDC/HHS or from CDC/APHIS to entity) and other related records.

**Authorized Disposition:**

Cut off files when entity registration expires. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 3: Security Risk Assessments**

Approval/denial letters, appeals and related correspondence which includes FD-961 forms and fingerprint cards.

Authorized Disposition:

Cut off files when entity registration expires. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 4: Request to Transfer Select Agents and Toxins - APHIS/CDC Form 2 (Formerly 2041/EA-101)**

Reports of Transfer of Select Agents and Toxins (APHIS/CDC Form 2), approval/disapproval notices from the CDC, and related correspondence.

Authorized Disposition:

Cut off files when transfers are complete. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 5: Import Form/Importation Permits- Etiologic Agents - Form CDC 0.753 Live Bats - Form CDC 0.1345**

Applications for permit to import or transport etiologic agents, hosts, or vectors of human disease; applications for permit to import or transport live bats, CDC approval permits, import program phone reports, confirmations of import applications, veterinarian certificates, information letters and other related records.

Authorized Disposition:

Cut off files when permit expires. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 6: Report of Theft Loss, or Release of Select Agents and Toxins - APHIS/CDC Form 3 (Formerly 2043/0.1316)**

Reports of theft, loss, or release of select biological agent forms, incident reports, inspector notes, copies of registration and application forms, correspondence, and other related records.

Authorized Disposition:

Cut off files when case is closed. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 7: Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory—APHIS/CDC Form 4 (Formerly 2044/0.1318)**

These records may include Report of Identification of a Select Agent or Toxin in a Clinical or Diagnostic Laboratory forms and any related documentation and correspondence.

**Authorized Disposition:**

Cut off files at the end of the calendar year in which the report was completed. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 8: Request for Exemption of Select Agents and Toxins for Public Health or Agricultural Emergency or Investigational/Experimental Products - APHIS/CDC Form 5 (Formerly 2042/0.1317).**

Requests for exemption of select agents and toxins for public health or agricultural emergency or investigational/experimental products, forms, and approval/denial information and related correspondence.

**Authorized Disposition:**

Cut off files at end of calendar year in which completed. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 9: Conflict of Interest Forms**

Includes annual list documentation and financial disclosure statement

**Authorized Disposition:**

Cut off files at end of calendar year. Maintain forms onsite. Destroy/delete records six years after cutoff.

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**Item 10: Notice of Destruction Records**

Destruction notices generated prior to 3/18/05 to comply with requirements specified in the interim rule for 42 CFR 73.

Authorized Disposition:

Cut off files when entity registration expires. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 11: Training Records (CDC-required training)**

Records maintained for the purpose of providing documentation of CDC-required training for specified DSAT personnel (e.g., contract inspectors). These records may include respirator training and other applicable training records.

Authorized Disposition:

Cut off files upon employee termination from DSAT. Transfer to FRC 2 years after employee terminates/separates from DSAT. Destroy records 5 years after employee termination/separation from DSAT.

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**Item 12: DSAT/Select Agent Program – General/Controlled Correspondence**

DSAT/Select Agent Program correspondence, including email communications, as applicable, Standard Operating Procedures (SOP's) and associated comments, and email responses related to public inquiries received through the Lab Registration Select Agent Transfer [Lrsat@cdc.gov](mailto:Lrsat@cdc.gov) web address.

Authorized Disposition:

- a. Office of record: Cut off files at end of calendar year. Transfer hardcopy records to the FRC when 5 years old. Destroy/delete all records when 10 years old.
  - b. All other offices: Cut off files at end of calendar year. Transfer hardcopy records to the FRC when 2 years old. Destroy/delete all records when 7 years old.
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**Item 13: Web Page Documents**

Records generated by CDC DSAT and maintained on the CDC Select Agent Program web site and other related sites with information generated by the CDC. (e.g. OHS/CDC – Import Permits). This record series includes web page information and supporting documentation generated by the CDC that is not elsewhere protected and where DSAT is the record owner.

May include Notifications of Excluded Attenuated Strains, Maximum Toxin Amounts Excluded from Regulation, Frequently Asked Questions (FAQ's) and responses posted

on the CDC website with regard to regulation 42 CFR Part 73 and the Select Agent Program, and the Import Permit process.

Authorized Disposition:

Cut off files after substantive revisions to content. Transfer hardcopy record to the FRC 2 years after cutoff. Destroy/delete all records 10 years after cutoff.

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**Item 14: Select Agent Program Reports**

Includes the annual report, and various routine monthly/weekly activity status reports and performance metrics.

Authorized Disposition:

Cut off files at the end of the calendar year. Transfer hard copy records to the FRC when 1 year old. Destroy/delete all records when 5 years old.

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**Item 15: Director's Report – Division of Select Agents and Toxins**

Programmatic files of the Office of the Director possess inherent evidential and informational values vital for the primary use in developing an agency history. These records include such documents as correspondence, transcripts of speeches and meetings, and memoranda. These records furnish the researcher with the insight, planning, organizational structure, functions, and overall direction of CDC units. Many of these units have a direct impact on public health efforts in the United States and across the world. These records contain information on the programs, activities, decisions and functions of CDC.

Authorized Disposition:

**PERMANENT.** Cut off files at the end of the calendar year. Transfer hardcopy (paper) records to the FRC 4 years after cut off or when no longer needed to conduct current operations. **Transfer all records to the National Archives when 10 years old.**

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**Item 16: Continuity of Operations Plan for DSAT – Select Agent Program Software**

Includes the Continuation of Operations Plan (Data Recovery Plan/Business Continuity Plan) and associated documentation.

Authorized Disposition:

Maintain COOP and associated documentation in file until superseded, then destroy.

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**Item 17: Select Agent Possessor/Non-Possessor Survey Records**

These records consist of a one-time survey that was sent to entities that may collect, use, maintain, possess, store or transfer select agents and toxins requesting declaration information. This record collection was transferred to the FRC in October, 2003 and stored under CDC RCS B-321, 1-34, Federal Register Notices--Public Comments, (N1-442-93-2, Item 1), Control No. T5727, Accession No. 442-04-0053. Records exist to capture declaration information received from the initial survey sent to entities that may collect, use, maintain, possess, store, or transfer select agents and toxins.

**Authorized Disposition:**

Cut off files at the end of the calendar year in which survey is completed. Transfer to the FRC one year after survey completion. Destroy when 10 years old.

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**Item 18: Software Development Records – Select Agent Program**

This record series may include the following: Biosecurity Plan template, (Incl. Policies/procedures for entities for implementation), Operational Concept Description, Detailed Requirements Document (hard copy/electronic media), System/Subsystem Specifications, Software Requirement Specification, Interface Requirement Specification, Database Design Description, Software Development Plan, Business Case, Project Plan, Statement of Work, BETA test results, Release of Data Approval Documentation, Various Reports (Including Monthly status activity), Certification and Accreditation/Authority to Operate documentation, and Transmittals for systems such as SAP72.6, SAP73, TRIM, SQL, Select Agent Registration Information System (SATERIS), National Select Agent Registry (NSAR).

**Authorized Disposition:**

Cut off files upon project termination. Destroy/delete 5 years after project termination.

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**Item 19: Request for Information**

Records may include original requests from Federal agencies/departments and correspondence generated by CDC responses; may also include information copies of various entity files, and inspection reports.

**Authorized Disposition:**



Cut off files when investigation is closed. Transfer hardcopy records to the FRC 2 yrs. after investigation is closed. Destroy/delete all records 10 years after cutoff.

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**Item 20: Non-Registered Entities**

These files primarily consist of information copies of records that are otherwise protected as a record such as Report of Theft, Loss or Release of Select Agents and Toxins. Non-registered entity files are segregated into two types: Non-Registered Entities and Non-Registered Entities – Notice of Destruction. Note: These are only tracked in TRIM (legacy system) and not entered into the SQL database. Registered entities were entered in the SQL database (legacy system) and forward fit entered into SATERIS.

**Authorized Disposition:**

Cut off files at end of calendar year. Transfer hardcopy records to the FRC 2 years after cutoff. Destroy/delete all records when 10 years old.

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**Item 21: Compliance Files**

This records series includes related emails, phone logs, contact information, and Request for Information Letter and responses. (Note: This category *does not* include Office of Inspector General (OIG) documents. OIG files are compiled of copies of various entity files, inspection reports, and general correspondence. The documents contained in these files are *reference copies only*. The official record copy is protected in record categories already specified for entity files and inspection reports including related correspondence.)

**Authorized Disposition:**

Cut off files at end of calendar year. Maintain hardcopy records onsite for 5 years and then transfer to FRC. Destroy/delete all records when 10 years old.

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**Item 22: OIG/FBI Referral Documentation**

Records include correspondence generated by CDC DSAT to the entity, the Office of Inspector General (OIG), or the Federal Bureau of Investigation (FBI), as applicable, regarding violations to the regulations that may result in a litigation case.

**Authorized Disposition:**

Cut off files when case is closed. Maintain hardcopy records onsite for 2 years after case is closed and then transfer to FRC. Destroy/delete all records 10 years after cutoff/closing.

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**Item 23: Rules of Behavior Forms/Network Permissions/User Roles Documentation**

Documentation maintained to comply with regulatory requirements for the protection of information resources pertaining to DSAT Select Agent Program, specific laboratories, select agent transfer records, the DBMS, and other sensitive, confidential and proprietary information used for oversight and monitoring activities. This record series includes Rules of Behavior forms and associated network permission/user role documentation that may be required for audit purposes.

**Authorized Disposition:**

Destroy/delete 6 years after user account is terminated or password is altered, or when no longer needed for investigative or security purposes, whichever is later.