

<b>REQUEST FOR RECORDS DISPOSITION AUTHORITY</b>		JOB NUMBER <i>N1-443-10-1</i>	
To: NATIONAL ARCHIVES & RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-6001		Date received <i>11/27/09</i>	
1 FROM (Agency or establishment) Department of Health and Human Services		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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10	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 National Institutes of Health			
3 MINOR SUBDIVISION Agency Wide			
4 NAME OF PERSON WITH WHOM TO CONFER Nyja DeFrank	5 TELEPHONE NUMBER 301-496-2463	DATE <i>7/15/2009</i> <i>3 Aug 10</i>	ARCHIVIST OF THE UNITED STATES <i>[Signature]</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 <u>11</u> page(s) are not needed now for the business for 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 <i>11/24/09</i>	SIGNATURE OF AGENCY REPRESENTATIVE <i>Yvonne Z. Wilson</i>		TITLE <i>HHS Records Officer</i>
7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)
1100-L-2-a	Approval is requested to revise and update the NIH Manual Chapter 1743 – Keeping and Destroying Records (NIH Records Control Schedule), Section 1100 - General Administration, 1100 - L Patents, Inventions and Licensing  Attached is the final version that will be posted to the NIH website after approvals are obtained  Nyja DeFrank, NIH RMO	NCI-443-94-1	
1100-L-3-a-1		NCI-443-94-1	
1100-L-3-c		NCI-443-94-1	
1100-L-4-a-1		NCI-443-94-1	
1100-L-4-2		NCI-443-94-1	
1100-L-4-2-b		NCI-443-94-1	
1100-L-4-b		NCI-443-94-1	
1100-L-5-a-1		N1-443-07-3	
1100-L-5-a-2		N1-443-07-3	
<b>NEW!</b> Please schedule			
1100-L-2-c			
1100-L-9-1			
1100-L-9-2			

Clearances:

Nyja DeFrank:

*Nyja DeFrank*  
NIH Records Officer,  
NIH/OD/OM/OMA/DMS/Records Management Program

11-9-2009  
Date

Ekaterini (Katy) Perry:

*Ekaterini Perry*  
Director,  
NIH/OD/OM/OMA/Division of Management Support

11/9/09  
Date

Susan Bruff.

*Susan Bruff*  
NIH OD/OTT Records Liaison

11/09/2009  
Date

Mark Rohrbaugh:

*Mark Rohrbaugh*  
NIH/OD/OIR/Office of Technology Transfer

11/9/09  
Date

**DALE BERKLEY**

~~Karen Nemes:~~

*Dale Berkley*  
NIH/Office of the General Counsel

11-2-2009  
Date

Yvonne Wilson:

*Yvonne K. Wilson*  
Department of Health and Human Services,  
Sr. Records Management Officer,  
DHHS/OCIO/ASRT

11/24/09  
Date

NOTES:

Please note that this router has already been approved by Nyja DeFrank, Katy Perry, Susan Bruff, Mark Rohrbaugh and by Yvonne Wilson (via email); as well as reviewed by the appointed National Archives and Records Administration (NARA) Archivist, Andrea Loiselle (via email). I will obtain original signatures again, after you return it with your original signatures. Copies will be sent to all parties

Thank you in advance for your review.

Nyja

## L. Patents, Inventions and Licensing

This section covers records developed and/or supported by NIH involved in the implementation of the Federal Technology Transfer Act.

NOTE: Patents, Inventions and Licensing records retrieved by individual identifiers are part of Privacy Act system of records 09-25-0168, "Inventions, Patent and Licensing Documents Submitted to the Public Health Service by its Employees, Grantees, Fellowship Recipients and Contractors, DHHS/NIH/OTT."

**1100-L-1** Records of experimental and statistical data: logs or notebooks used to record observations and data which contain evidence for establishing patents or inventions rights.

Located in intramural program files.

*Disposition*: TEMPORARY. Cut off at end of fiscal year after issuance of patent. Destroy 30 years after cutoff. (*Supersedes N1-443-94-1, Item 1100-L-1*)

**1100-L-2** Employee Invention Reports (EIRs) invention description, Confidential Disclosure Agreements (CDAs), and associated documents submitted by scientists via Technology Development Coordinators to OTT for review of patentability or transfer by other means.

a. ~~EIRs on which a Patent or Patent Cooperation Treaty (PCT) application(s) has been filed.~~

~~*Disposition*: Incorporate into the first filed application file. (*Filing Instruction only*)~~

b. ~~EIRs on which a Patent or PCT application will not be filed but has been licensed.~~

~~*Disposition*: TEMPORARY. Cut off at the end of the fiscal year after expiration of last active license. Destroy 10 years after cutoff. (*Supersedes N1-443-94-1, Item 1100-L-2-b.*)~~

*See next page*

c. ~~EIRs on which a Patent or PCT application will not be filed and for which no license has been executed.~~

~~*Disposition*: TEMPORARY. Cut off at the end of the fiscal year after docketed by OTT. Destroy 10 years after cutoff. (*Supersedes N1-443-94-1, Item 1100-L-2-b.*)~~

*See next page*

~~**1100-L-3** Patent Application Files, including U.S., PCT and foreign applications, containing copies of patent applications, drawings, evaluations, Summary of Invention Data, published articles, progress/utilization reports, work orders, Cooperative Research and Development Agreement (CRADA) with a reported CRADA Subject Invention, and related correspondence.~~

~~a. Located in the NIH Office of Technology Transfer.~~

~~1. Issued Patent Files~~

~~*Disposition*: TEMPORARY. Cut off at the end of the fiscal year after expiration or lapse of the patent. Destroy 10 years after cutoff. (*Supersedes N1-443-94-1, Item 1100-L-3-a-1 and N1-443-94-1, Item 1100-L-4-a-1*)~~

*See next page*

1100-L-2

a.

b.

c.

1100-L-3

a.

1.

Superseded by Job / Item number:

DAA-0443-2016-0002-0001

Date (MM/DD/YYYY):

5/16/2017

2. Inactive Patent Application Files (i.e., Abandoned, Withdrawn, Expired). Patent application files where no patent has been issued.

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after the last application in the family becomes inactive. Destroy 7 years after cutoff.

*(Supersedes N1-443-94-1, Item 1100-L-3-a-2 and N1-443-94-1, Item 1100-L-4-a-2)*

b. Located in Division of Extramural Invention Reports.

1. Official File (except abandoned cases and cases that involve a Publication Bar)

*Disposition:* TEMPORARY. Place in inactive file upon issuance of patent. Cut off at the end of the fiscal year after expiration of patent. Transfer files to the FRC 1 year after cutoff or when no longer needed for administrative purposes, whichever is later. Destroy 10 years after cutoff. *(Supersedes N1-443-94-1, item 1100-L-3-b)*

2. Abandoned cases and cases involving a Publication Bar

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year following receipt of notice from Contractor/Grantee. Destroy 1 year after cutoff. *(Supersedes N1-443-94-1, item 1100-L-3-b)*

c. Located in IC Technology Transfer Office

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year when case is abandoned, withdrawn, or expires. Destroy 1 year after cutoff. *(Supersedes N1-443-94-1, Item 1100-L-4-b)*

See next page

**1100-L-4 License Agreement Files.**

Located in the NIH Office of Technology Transfer

a. Executed agreements and associated amendments.

1. Official File. Domestic and foreign, exclusive and non-exclusive, invention and biological material license agreements, Inter-Institutional Agreements (IIAs), Inter-Agency Agreements (IAAs) executed either by NTIS or OTT, and related correspondence, including progress reports, royalty reports, transmittal documents and inquiries.

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after the expiration or termination of the license agreement or amendment. Destroy 10 years after cutoff. *(Supersedes N1-443-94-1, Item 1100-L-5-a and N1-443-94-1, Item 1100-L-5-b)*

2. Copies of documents used for convenience of reference, working drafts and correspondence requesting pen and ink type changes (e.g., grammatical, style, etc.), duplicate copies of comments.

See next page

2.

b

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Superseded by job / item number:

DAA-0443-2016-0002-0001

Date (MM/DD/YYYY):

5/16/2017

1100-L-4

a.

1.

2.

Superseded by job / item number:

DAA-0443-2016-0002-0002+0004

Date (MM/DD/YYYY):

5/16/2017

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after the agreement or amendment is executed. Destroy immediately after cutoff. (*Supersedes N1-443-94-1, Item 1100-L-5-c*)

b. ~~Non-executed license agreement and amendments. The application and all other related record material, including correspondence, documents, drafts, and logs.~~

1. ~~Applications that are withdrawn, terminated, or denied and there is no appeal.~~

~~Disposition: TEMPORARY. Cut off at the end of the fiscal year when the application is withdrawn, negotiations are terminated, or the application is denied and there is no appeal. Destroy 3 years after cutoff.~~

*See next page*

2. ~~Applications that are appealed~~

~~Disposition: TEMPORARY. Cut off at the end of the fiscal year after resolution of the appeal. Destroy 7 years after cutoff.~~

*See next page*

~~**1100-L-5 Cooperative Research and Development Agreement (CRADA)** between or among ICs and private industry, non-profit organizations, academia, or other government agencies. Documents include: original signature page, clearance forms and appendices; correspondence including progress reports, financial reports, negotiations, and inquiries.~~

~~A. Executed Agreements~~

~~1. Located in the NIH Office of Technology Transfer~~

~~*Disposition:* TEMPORARY. Cut off at the end of the fiscal year following termination or expiration of the CRADA. Destroy 3 years after cutoff. (*Apply N1-443-07-3, Item 1100-L-6-A-2*)~~

~~2. Located in IC Technology Transfer Office.~~

~~*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after termination or expiration of the CRADA. Transfer to the Federal Records Center 1 year after cutoff. Destroy 10 years after cutoff. (*Apply N1-443-07-3, Item 1100-L-6-A-1*)~~

~~B. Non-executed Agreements~~

~~Located in IC Technology Transfer Office.~~

~~*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after it is determined that the agreement will not be executed. Destroy 1 year after cutoff. (*Apply N1-443-07-3, Item 1100-L-6-B*)~~

~~**1100-L-6 Staff Working Paper Files:** technical reference materials, publications, convenience copies of documents, drafts and other working papers maintained for convenience of office operations by staff members.~~

b.

1.

Superseded by job / item number:

DAA-0443-2016-0002-0004

Date (MM/DD/YYYY):

5/16/2017

2.

Superseded by job / item number:

DAA-0443-2016-0002-0003

Date (MM/DD/YYYY):

5/16/2017



~~*Disposition:* TEMPORARY. All copies—Destroy when no longer needed. (Apply NI-443-94-1, item 1100-L-7.)~~

~~**1100-L-7 Chronological File** consisting of copies of documents signed or prepared in the office, and maintained by date.~~

~~*Disposition:* TEMPORARY. Cut off at the end of the fiscal year in which signed or prepared. Destroy 5 years after cutoff. (Apply NI-443-94-1, item 1100-L-8.)~~

~~**1100-L-8 Data Files** containing statistical information about the Technology Transfer Program used for support of administration functions.~~

~~*Disposition:* TEMPORARY. All copies—Destroy when no longer needed for reference. (Apply NI-443-94-1, item 1100-L-9 or GRS 20, item 5 as appropriate.)~~

**1100-L-9 Technology Transfer Marketing Files** containing marketing research, communications with inventor(s), Notice of Availability for Publication and Licensing, publications describing the invention, mass mailing/emailing contact list(s), summaries of marketing, incoming licensing inquiries, outgoing targeted marketing, communications regarding Confidential Disclosure Agreements (CDAs), signed CDAs, communications regarding sending non-confidential and confidential information to prospective licensees, communications regarding sending a license application.

- a. If associated with an executed license.

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after expiration of last active license or after the report was docketed by OTT, whichever is later. Destroy 10 years after cutoff.

- b. If no license is executed.

*Disposition:* TEMPORARY. Cut off at the end of the fiscal year after docketed by OTT. Destroy 10 years after cutoff.

**1100-L-10 Technology Transfer Agreements** Technology transfer agreements not covered in another section. The agreements include, but are not limited to, Material Transfer Agreements (MTAs), Simple Letter Agreements (SLAs), IC Confidential Disclosure Agreements (CDAs), Clinical Trial Agreements (CTAs), Letters of Collection (LOCs), and Memoranda of Understanding (MOU).

**NOTE: Disposition schedules for technology transfer agreements negotiated on behalf of contractors are covered in Section 2600-A.**

- a. Executed Agreements:

1. Pre-executed Agreement File: The request letter, initial boiler plate PHS and/or NIH version, outside party's agreement (if used), marked-up versions of the agreement documenting substantive changes, telephone logs documenting negotiated points, correspondence, and any NIH or company papers documenting STRONG controversy between the two versions, maintained prior to the approval of the Agreement.

*Disposition* TEMPORARY. Cut off at the end of the fiscal year following the date of execution. Destroy 1 year after cutoff. **(Supersedes N1-443-01-1, item 1100-L-11-A-1)**

2. Final Executed Agreement File: The final executed Agreement and post execution correspondence and documents.

a) For Agreements with a fixed expiration date:

*Disposition* TEMPORARY. Cut off at the end of the fiscal year after expiration or termination of the agreement. Destroy 1 year after cutoff. **(Supersedes N1-443-01-1, item 1100-L-11-A-2-a)**

b) For Agreements *without* a fixed expiration date:

1) If notification of termination is received:

*Disposition* TEMPORARY. Cut off at the end of the fiscal year after notification by either party of termination. Destroy 1 year after cutoff. **(Supersedes N1-443-01-1, item 1100-L-11-A-2-b)**

2) If notification of termination is not received:

*Disposition* TEMPORARY. Cut off at the end of the fiscal year after execution. Destroy 8 years after cutoff. **(Supersedes N1-443-01-1, item 1100-L-11-A-2-b)**

b. Non-executed Agreements: The request letter and all other related record material including correspondence, documents, drafts and logs created.

*Disposition* TEMPORARY. Cut off at the end of the fiscal year after it is determined the Agreement will not be executed and the file is closed. Destroy 1 year after cutoff. **(Supersedes N1-443-01-1, item 1100-L-11-B-1)**

c. Copies of documents used for convenience of reference, working drafts and correspondence requesting pen and ink type (e.g., grammatical, style, etc) changes, duplicate copies of documents.

*Disposition* TEMPORARY. Destroy when the Agreement is closed. **(Supersedes N1-443-01-1, item 1100-L-11-A-3 and N1-443-01-1, item 1100-L-11-B-2)**