

National Archives and Records Administration
REQUEST FOR DISPOSITION AUTHORITY

Records Schedule Number: DAA-0088-2024-0001

Status: APPROVED
Date Approved: 05/09/2024

General Information

Agency or Establishment	Food and Drug Administration
Record/Scheduling Group	0088 - Records of the Food and Drug Administration
Records Schedule Applies To	Agency-wide
Schedule Subject	Technology Transfer Records
Additional Schedule Information	Technology Transfer Records include: Employee Invention Reports (EIRs), Patent Applications, Cooperative Research and Development Agreements (CRADA), and other records developed and/or supported by the Food and Drug Administration (FDA) for the implementation of the Federal Technology Transfer Act, the Bayh-Dole Act, the Stevenson-Wydler Act and other statutes and regulations that may govern technology transfer.
Is There a Classified Version of This Schedule?	No
Is consultation and coordination with Tribal Governments required?	No - the records covered by this schedule do not implicate Tribal interests

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Item Count

Total number of disposition items: 5

Number of Temporary disposition items: 5

Number of Permanent disposition items: 0

Number of Items with Disposition Not Approved: 0

Number of Inactive disposition items: 0

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Outline of Records Schedule Items for DAA-0088-2024-0001

Item #	Title	Disposition
0001	Employee Invention Reports (EIRs) and Patent Applications Case Files	Temporary
0002	License Agreements, CRADA, and Other Technology Transfer Agreement Records : Executed Agreements and Amendments with Financial Terms	Temporary
0003	License Agreements, CRADA, and Other Technology Transfer Agreement Records : Denied License Applications That are Under Appeal	Temporary
0004	License Agreements, CRADA, and Other Technology Transfer Agreement Records : All Other Agreements and Amendments without Financial Terms, No Term, and All Other Cancelled or Non-executed Agreement Applications	Temporary
0005	Technology Transfer Consultation Records	Temporary

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Records Schedule Items

DAA-0088-2024-0001-0001		STATUS: Active
ITEM GENERAL INFORMATION		
Item Title	Employee Invention Reports (EIRs) and Patent Applications Case Files	
Item Description	These records consist of invention descriptions and associated documents submitted by scientists to the FDA Technology Transfer Program (TTP) for review to determine means of transfer, which may require patenting; U.S. Patent Cooperation Treaty (PCT) and foreign patent applications and related documents including evaluations, law firm correspondence, patentability correspondence (from the USPTO or foreign counterparts), and work orders; and Cooperative Research and Development Agreements (CRADA) with a CRADA Subject Invention reported through an EIR. These records include information housed in the technology transfer database.	
Is this item media neutral?	Yes	
Is this item a Big Bucket?	No	
MANUAL CITATION		
Agency Code	0088	
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS		
Does this item supersede existing disposition authorities?	No	
Is this item a deviation from the GRS?	No	
DISPOSITION INSTRUCTION		
Final Disposition	Temporary	
Cutoff Instructions	Other: Cut off at end of fiscal year following expiration, lapsing, withdrawal or abandonment of patent application, issued patents, or associated patent family, whichever occurs later; or when unpatented invention is not associated with available licensable or licensed research material.	
Retention Period	Other: Destroy/delete 10 years after cutoff	
ADDITIONAL INFORMATION		
Are any of the records covered by this item national security classified?	No	
GAO Approval Required	No	

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Group Title	License Agreements, CRADA, and Other Technology Transfer Agreement Records
Group Description	<p>These records include license agreements, Cooperative Research and Development Agreements (CRADAs), and other Technology Transfer Agreements.</p> <p>License Agreements: Includes domestic and foreign, exclusive and nonexclusive, invention and biological material license agreements, Inter-Institutional Agreements (IIAs), and Inter-Agency Letter Agreements (LTRs- for co-development of shared inventions);</p>
	Cooperative Research and Development Agreements (CRADAs): Between or among FDA/Centers/Offices and private industry, nonprofit organizations, academia, or other government agencies;
	Other Technology Transfer Agreements: Includes Material Transfer Agreements (MTAs) or equivalent, agreements associated with incoming Research Grant/SubAward, Confidential Disclosure Agreements (CDAs), CRADA Letters of Intent, Letters of Interest, Clinical Trial Agreements (CTAs), Data Transfer (or Use) Agreements, and Research Collaboration Agreements (RCAs).
	Associated records may include: Amendments, clearance forms, progress reports, sales reports, fees handling paired with a Technology Transfer Agreement record, inventorship determinations, Royalty Distribution Forms, and technology marketing and commercialization assessments.
DAA-0088-2024-0001-0002	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Executed Agreements and Amendments with Financial Terms
Item Description	Records include CRADAs, MCRADAs, IIAs, LTRs, MTAs with handling fee or equivalent, agreements associated with incoming Research Grant/Sub-Award, and Licenses.
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	

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Final Disposition	Temporary
Cutoff Instructions	Other: Cutoff at end of fiscal year of expiration or termination of the License, CRADA, or other Technology Transfer Agreement.
Retention Period	Other: Destroy 7 years after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No
DAA-0088-2024-0001-0003 STATUS: Active	
ITEM GENERAL INFORMATION	
Item Title	Denied License Applications That are Under Appeal
Item Description	Records include non-executed license application that are under appeal.
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cut off at end of fiscal year of the date of resolution of the appeal.
Retention Period	Other: Destroy 7 years after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No
DAA-0088-2024-0001-0004 STATUS: Active	
ITEM GENERAL INFORMATION	
Item Title	All Other Agreements and Amendments without Financial Terms, No Term, and All Other Cancelled or Non-executed Agreement Applications
Item Description	Records include all other agreements without financial terms, no term, and all other non-executed Agreement Applications including cancelled or withdrawn records.
Is this item media neutral?	Yes

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Is this item a Big Bucket?	No
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	
Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cut off at end of fiscal year of 1) expiration, completion, withdrawal of the Agreement or confidentiality term; or 2) when Agreement negotiations are terminated, or the license application is denied and there is no appeal and there is confirmation that the activities under the Agreement are no longer continuing; or 3) when the Agreement is withdrawn, the negotiations are terminated, or the license application is denied and there is no appeal.
Retention Period	Other: Destroy 3 years after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

DAA-0088-2024-0001-0005	STATUS: Active
ITEM GENERAL INFORMATION	
Item Title	Technology Transfer Consultation Records
Item Description	These records include information related to research analysis and guidance provided for technology transfer, intellectual property, and partnership activities. Includes records for projects that were initiated and that did not result in an invention, patent application, or agreement. This series covers records not accounted for in Employee Invention Reports (EIRs) and Patent Applications Case Files, License Agreement, CRADA, and Other Technology Transfer Agreement Records and Memoranda of Understanding.
Is this item media neutral?	Yes
Is this item a Big Bucket?	No
MANUAL CITATION	
Agency Code	0088
SUPERSEDED AGENCY DISPOSITION AUTHORITIES AND GRS DEVIATIONS	

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Does this item supersede existing disposition authorities?	No
Is this item a deviation from the GRS?	No
DISPOSITION INSTRUCTION	
Final Disposition	Temporary
Cutoff Instructions	Other: Cutoff should align with cutoff of the record series for which the database record was created. For consultation records that are not linked to Employee Invention Reports (EIRs) and Patent Applications Case Files, License Agreement, CRADA, and Other Technology Transfer Agreement Records, cutoff records at end of fiscal year that consultation is completed.
Retention Period	Other: Destroy 7 years after cutoff.
ADDITIONAL INFORMATION	
Are any of the records covered by this item national security classified?	No
GAO Approval Required	No

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Signatory Information

Action	User	Date
Accept	Bethany Reiswig	11/27/2023
Approve	Colleen Shogan	05/09/2024