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NATIONAL ARCHIVES AND RECORDS ADMINISTRATION
Request for Records Disposition Authority

Records Schedule: DAA-0443-2012-0006

Request for Records Disposition Authority

Records Schedule Number DAA-0443-2012-0006

Schedule Status Returned Without Action

Agency or Establishment National Institutes of Health

Record Group / Scheduling Group Records of the National Institutes of Health

Records Schedule applies to Agency-wide

Schedule Subject
Item 1.1: Intramural research records related to planning, development, oversight and execution of biomedical research projects and programs performed by NIH investigators, contractors and/or under collaborative research and development agreements (CRADAs). These records span the project life cycle and include, but are not limited to, final plans and protocols, clearances and authorizations, experimental, observational and control data generated in such research; including laboratory notebooks, paper records and electronic records; and the products of research such as articles, reports and data sets required to:

- Facilitate data analysis, publication, collaboration, and peer review.
- Demonstrate compliance with accepted policies and standards for the conduct of good science.
- Validate and reproduce research outcomes.
- Support intellectual property claims.
- Defend against allegations of research misconduct and malpractice.

All records covered under this schedule must be evaluated and assigned one of the following three disposition levels. At the termination of the project or research program, the Institute or Center (IC) that sponsored the research shall assess the ongoing scientific, research and intellectual property value of the project records.

Internal agency concurrences will be provided No

Background Information The NIH intramural research records retention schedules were updated to reflect the needs of the scientific community, reduce the administrative burden associated with managing research records, and achieve compliance with NARA mandates and guidelines.

Item Count

Number of Total Disposition Items	Number of Permanent Disposition Items	Number of Temporary Disposition Items	Number of Withdrawn Disposition Items
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GAO Approval

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Outline of Records Schedule Items for DAA-0443-2012-0006

Sequence Number	
1	Item 1.1a: Records of intramural research projects of historical significance to the country and/or the scientific community Disposition Authority Number: DAA-0443-2012-0006-0001
2	Item 1.1b: Intellectual property records consisting of project documentation supporting patents or inventions rights not included under item 1.1a. Disposition Authority Number: DAA-0443-2012-0006-0002
3	Item 1.1c: Records of all other intramural research projects not included under items 1.1a and 1.1b. Disposition Authority Number: DAA-0443-2012-0006-0003
4	Item 1.2: Registries and data sharing systems Disposition Authority Number: DAA-0443-2012-0006-0004
5	Item 1.3: FDA regulated research records Disposition Authority Number: DAA-0443-2012-0006-0005
6	Item 1.4: Institutional Review Board (IRB) records Disposition Authority Number: DAA-0443-2012-0006-0006
7	Item 1.5: Clinical care services records Disposition Authority Number: DAA-0443-2012-0006-0007
8	Item 1.6: Radiology and imaging records Disposition Authority Number: DAA-0443-2012-0006-0008
9	Item 1.7: Blood donor and receiving records Disposition Authority Number: DAA-0443-2012-0006-0009
10	Item 1.8: Blood product manufacture, storage and distribution records Disposition Authority Number: DAA-0443-2012-0006-0010
11	Item 1.9: Patient medical records Disposition Authority Number: DAA-0443-2012-0006-0011
12	Item 1.10: Medical Staff credentialing records Disposition Authority Number: DAA-0443-2012-0006-0012
13	Item 1.11: Pathology test records Disposition Authority Number: DAA-0443-2012-0006-0013

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Records Schedule Items

Sequence Number	
1	<p data-bbox="358 406 1455 476">Item 1.1a: Records of intramural research projects of historical significance to the country and/or the scientific community</p> <p data-bbox="358 495 1130 527">Disposition Authority Number DAA-0443-2012-0006-0001</p> <p data-bbox="358 549 1474 874">These records span the project life cycle and include, but are not limited to records which Received national or international awards of distinction; Resulted in a significant improvement in public health, safety, or other vital national interest; Drew widespread national or international media attention and/or extensive congressional, NIH or other government agency investigation; â€¢ Showed the development of new and nationally or internationally significant techniques which are critical for future scientific endeavors; â€¢ Made a significant impact on the development of national or international scientific, political, economic, or social priorities.</p> <p data-bbox="358 895 911 927">Final Disposition Permanent</p> <p data-bbox="358 949 902 981">Item Status Withdrawn</p> <p data-bbox="358 1002 813 1034">Is this item media neutral? Yes</p> <p data-bbox="358 1055 813 1172">Do any of the records covered by this item currently exist in electronic format(s) other than e-mail and word processing? Yes</p> <p data-bbox="358 1193 813 1289">Do any of the records covered by this item exist as structured electronic data? Yes</p> <p data-bbox="358 1321 659 1353">Disposition Instruction</p> <p data-bbox="358 1374 1292 1406">Cutoff Instruction Cutoff at termination of project/program.</p> <p data-bbox="358 1427 1438 1502">Transfer to Inactive Storage Transfer paper records to the National Archives 30 years after cutoff.</p> <p data-bbox="358 1523 1455 1630">Transfer Electronic Records to the National Archives for Pre-Accessioning Transfer electronic records to the National Archives for pre-accessioning 5 year(s) after cutoff, or based on agreements between NIH and NARA.</p> <p data-bbox="358 1651 1390 1757">Transfer to the National Archives for Accessioning Pre-accession or transfer electronic records at an earlier date (e.g., 5 to 10 years) based on agreements between NIH and NARA.</p> <p data-bbox="358 1789 659 1821">Additional Information</p> <p data-bbox="358 1842 886 1938">What will be the date span of the initial transfer of records to the National Archives? Unknown</p>

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		Records have been sent under previous schedules. Records under this schedule, anticipate records in approximately 2017
	How frequently will your agency transfer these records to the National Archives?	Unknown Dependent on research projects.
2	Item 1.1b: Intellectual property records consisting of project documentation supporting patents or inventions rights not included under item 1.1a. Disposition Authority Number DAA-0443-2012-0006-0002 These records include Intellectual property records consisting of project documentation supporting patents or inventions rights not included under item 1.1.a. Final Disposition Temporary Item Status Withdrawn 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? Yes Do any of the records covered by this item exist as structured electronic data? Yes Disposition Instruction Cutoff Instruction Cutoff at expiration or abandonment of patent family or when no longer needed for scientific reference, whichever is longer. Transfer to Inactive Storage Transfer to inactive storage upon expiration or abandonment of patent family or when no longer needed for scientific reference . Retention Period Destroy or delete 10 years after cutoff. Additional Information GAO Approval Not Required	
3	Item 1.1c: Records of all other intramural research projects not included under items 1.1a and 1.1b. Disposition Authority Number DAA-0443-2012-0006-0003 Records of all other intramural research projects not included under 1.1a and 1.1.b.	

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Final Disposition	Temporary
Item Status	Withdrawn
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?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes
Disposition Instruction	
Cutoff Instruction	Cutoff at termination of project/program or when no longer needed for scientific reference, whichever is longer.
Retention Period	Destroy 7 year(s) after termination of project/program or when no longer needed for scientific reference, whichever is longer.
Additional Information	
GAO Approval	Not Required
Item 1.2: Registries and data sharing systems	
Disposition Authority Number	DAA-0443-2012-0006-0004
Registries and data sharing systems, collaborative tools and repositories used to collect and maintain research information to facilitate the secondary use of research data. These systems contain data collected from multiple sources for the purpose of analyzing, integrating, and disseminating information on research and/or patient care.	
Final Disposition	Temporary
Item Status	Withdrawn
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?	Yes
Do any of the records covered by this item exist as structured electronic data?	Yes
Disposition Instruction	

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5	Cutoff Instruction	Cutoff and destroy when no longer needed for scientific research and/or administrative use.
	Retention Period	Destroy when no longer needed
	Additional Information	
	GAO Approval	Not Required
	Item 1.3: FDA regulated research records	
	Disposition Authority Number	DAA-0443-2012-0006-0005
	FDA regulated research records as required by 21 CFR. These records pertain to the receipt, shipment, or other disposition of new or investigational drugs or devices. FDA regulated research records include, but are not limited to, Investigational New Drug (IND) applications, Investigational Device Exemptions (IDE) and New Drug Applications (NDA), amendments, safety reports, annual reports, and drug dispositions.	
	Final Disposition	Temporary
	Item Status	Withdrawn
	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?	Yes
	Do any of the records covered by this item exist as structured electronic data?	Yes
Disposition Instruction		
Cutoff Instruction	Cutoff at application approval or disapproval.	
Retention Period	Destroy 3 year(s) after application is approved or disapproved; if no new application is filed, destroy or delete 3 years after the study is completed or discontinued and FDA is notified of discontinuation..	
Additional Information		
GAO Approval	Not Required	
6	Item 1.4: Institutional Review Board (IRB) records	
	Disposition Authority Number	DAA-0443-2012-0006-0006
	Institutional Review Board (IRB) records documenting ethical and regulatory oversight of research involving human subjects as required by 45 CFR 46 and 21 CFR 56. These records document IRB activities and may include IRB procedures, membership rosters, meeting minutes, decisions/approvals, copies of reviewed	

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research proposals, scientific evaluations, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to research subjects.

Final Disposition Temporary

Item Status Withdrawn

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? Yes

Do any of the records covered by this item exist as structured electronic data? Yes

Disposition Instruction

Cutoff Instruction Cutoff records related to research which is conducted after completion of the research. Cutoff all other records at end of fiscal year.

Retention Period Destroy 3 year(s) after cutoff.

Additional Information

GAO Approval Not Required

Item 1.5: Clinical care services records

Disposition Authority Number DAA-0443-2012-0006-0007

Clinical care services records documenting clinical care and patient case management activities encapsulating the clinical and operational processes for proficient patient throughput. Clinical care services records document patient care operations, and include the output of functions such as: prescriptions, and preliminary evaluations, quality assessments, routine patient examinations, treatment logs and worksheets, laboratory equipment analyses and testing, patient accommodations, and plans for care. Clinical care services and clinical care department operational records are consolidated under one common temporary retention item. Exclusions and exceptions are noted. These records include, but are not limited to, the following clinical care functions: Ambulatory and outpatient care Bioethics Clinical epidemiology and biostatistics services Credentialing services Critical care medicine Hospital epidemiology services Internal medicine Laboratory medicine (exception noted in Item 1.11) Medical records services (exception noted in Item 1.9) Nursing and patient care services Nutrition services Pain and palliative care services Pediatric care Perioperative medicine Positron Emission Tomography (PET) imaging services (exception noted in Item 1.6) Pharmacy services Rehabilitation medicine (exception noted in Item 1.10) Social work Spiritual ministry Transfusion medicine (exception noted in Item 1.7, 1.8)

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8	Final Disposition	Temporary
	Item Status	Withdrawn
	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?	Yes
	Do any of the records covered by this item exist as structured electronic data?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cutoff at end of fiscal year.
	Retention Period	Destroy 7 year(s) after cutoff.
	Additional Information	
	GAO Approval	Not Required
	Item 1.6: Radiology and imaging records	
	Disposition Authority Number	DAA-0443-2012-0006-0008
	Radiology and imaging records comprising X-rays and other roentgenographic images produced by devices and procedures such as bodyhead scans created by computerized transaxial tomography (CT). Files may include physician interpretations of images/scans. Examples include, but are not limited to, positive photographic images resulting from ultrasound, MRI, PET, PET/CT, PET/MRI, and radiologist reports and interpretations.	
	Final Disposition	Temporary
	Item Status	Withdrawn
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?	Yes	
Do any of the records covered by this item exist as structured electronic data?	Yes	
Disposition Instruction		
Cutoff Instruction	Cutoff in 5 year intervals after file becomes inactive or when no longer needed for clinical reference, whichever is longer.	
Retention Period	Destroy 60 year(s) after cutoff.	

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9	Additional Information	
	GAO Approval	Not Required
	Item 1.7: Blood donor and receiving records	
	Disposition Authority Number	DAA-0443-2012-0006-0009
	Blood donor and receiving records for blood and its components that are collected, processed, compatibility tested, stored, and distributed by NIH. These records identify blood donors, document donor deferrals and identify and describe blood products received from other collection facilities. These records shall be retained for such interval beyond the expiration date for the blood or blood component as necessary to facilitate the reporting of any unfavorable clinical reactions as required by 21 CFR 606.	
	Final Disposition	Temporary
	Item Status	Withdrawn
	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?	Yes
	Do any of the records covered by this item exist as structured electronic data?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cutoff after 50 years or after expiration of the patient/subject, whichever is longer.
	Transfer to Inactive Storage	Transfer to the Federal Records Center in 10 year intervals.
Retention Period	Destroy 30 year(s) after cutoff.	
10	Additional Information	
	GAO Approval	Not Required
	Item 1.8: Blood product manufacture, storage and distribution records	
	Disposition Authority Number	DAA-0443-2012-0006-0010
	Blood product manufacture, storage and distribution records that document FDA regulated good manufacturing practices for blood and blood components as required by 21 CFR 606. These include records documenting donor selection and blood product collection, processing, inventory and distribution.	
	Final Disposition	Temporary
Item Status	Withdrawn	

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11	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?	Yes
	Do any of the records covered by this item exist as structured electronic data?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cutoff at end of fiscal year.
	Retention Period	Destroy 10 year(s) after cutoff or 6 months after latest expiration of any components, whichever is longer. If no expiration date, records shall be retained indefinitely.
	Additional Information	
	GAO Approval	Not Required
	Item 1.9: Patient medical records	
	Disposition Authority Number	DAA-0443-2012-0006-0011
	Patient medical records documenting admissions and medical treatment for a patient accepted in a research project. These records are the primary source of evaluation and analysis for either clinical care and/or clinical research study.	
	Final Disposition	Temporary
	Item Status	Withdrawn
	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?	Yes
	Do any of the records covered by this item exist as structured electronic data?	Yes
	Disposition Instruction	
	Cutoff Instruction	Cutoff patient case file after 5 years of inactivity. Convert to long-term format.
Retention Period	Destroy when the Director of the Clinical Center determines it is no longer needed for scientific reference.	
Additional Information		

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GAO Approval Not Required

Item 1.10: Medical Staff credentialing records

Disposition Authority Number DAA-0443-2012-0006-0012

Medical Staff credentialing records documenting approval of physicians, dentists, and other health professionals for involvement in patient treatments or other contacts. These records document participation in patient care and include signed agreements to abide by Medical Staff bylaws, delineations of clinical privileges, and related records. Information is collected from individual members of the Clinical Center Medical Staff and is used to document their credentialing and privileging.

Final Disposition Temporary

Item Status Withdrawn

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? Yes

Do any of the records covered by this item exist as structured electronic data? Yes

Disposition Instruction

Cutoff Instruction Cutoff after medical staff member leaves patient care.

Transfer to Inactive Storage Transfer to Federal Records Center in 10 year intervals.

Retention Period Destroy 30 year(s) after cutoff.

Additional Information

GAO Approval Not Required

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Item 1.11: Pathology test records

Disposition Authority Number DAA-0443-2012-0006-0013

Pathology test records including media preparation case files, indices and formulas as required by 42 CFR 493. The records contain information related to requisitions for laboratory media and cells, including a description of the method of preparation and the ingredients used.

Final Disposition Temporary

Item Status Withdrawn

Is this item media neutral? Yes

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Do any of the records covered by this item exist as structured electronic data?	Yes
Disposition Instruction	
Cutoff Instruction	Cutoff after the date of reporting.
Retention Period	Destroy 10 year(s) after cutoff.
Additional Information	
GAO Approval	Not Required

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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
07/26/2012	Certify	Kimberly Johnson	Records Officer	OMA - DMS
07/30/2012	Return for Revision	Valerie Terray	Archives Specialist	National Archives and Records Administration - Records Management Services
07/31/2012	Submit For Certification	Kimberly Johnson	Records Officer	OMA - DMS
09/23/2016	Certify	Amanda Pomicter	NIH Records Officer	NIH - NIH
10/06/2016	Return Without Action	Carly Docca	Archives Specialist	National Archives and Records Administration - ACRA

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