NIH INTRAMURAL RECORDS RETENTION SCHEDULE ITEMS

Overview of Intramural Research Records

These records are related to the planning, development, oversight and execution of biomedical research projects and programs performed by NIH research staff, contractors or under collaborative research and development agreements (CRADAs). These records span the project lifecycle 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, 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; and
- Defend against allegations of research misconduct and malpractice.

This records schedule is designed to cover all intramural research records, as such, all intramural research records must be evaluated and assigned to one of the following three schedule items, which are listed in order from longest to shortest retention period.

Item I-0001 - Records of Intramural Research Projects of Historical Significance
Item I-0002 - Research Records that Support Intellectual Property Rights
Item I-0003 - Records of All Other Intramural Research Projects

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. All records originally identified for permanent retention shall be confirmed by the sponsoring IC as supporting a permanent retention value prior to accessioning to NARA.

In addition, the following items also belong to the intramural research class of records and as such, have the opportunity to be deemed historically significant and retained permanently if a criterion for significance is met. These record items are identified separately due to each having specific statutory retention requirements associated with them.

Item I-0004 - FDA Regulated Research Records
Item I-0005 - Institutional Review Board (IRB) Records

Item I-0001: Records of Intramural Research Projects of Historical Significance

(DAA-0443-2012-0007-0001)

These records span the project life cycle and include, but are not limited to:

- 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;
- Showed the development of new and nationally or internationally significant techniques that are critical for future scientific endeavors; or
- Made a significant impact on the development of national or international scientific, political, economic, or social priorities.

Disposition: **PERMANENT.** Cut off annually at termination of project/program or when no longer needed for scientific reference. Transfer to inactive storage 5 years after cutoff. Transfer electronic records to the National Archives for pre-accessioning 5 years after cutoff. Transfer paper records to the National Archives in 5 year blocks when the oldest records in the block are 30 years old.

Item I-0002: Research Records that Support Intellectual Property Rights
(DAA-0443-2016-0001-0001)
These records consist of project documentation that supports patents or inventions rights that do not meet the retention criteria for Item I-0001 - Records of Intramural Research Records Projects of Historical Significance. (Please note: Records pertaining to abandoned patents or patent applications are to be retained in accordance with either item I-0001 or I-0003.)

Disposition: **TEMPORARY.** Cut off annually after the patent is filed. Destroy 30 years after cutoff.

Item I-0003: Records of All Other Intramural Research Projects
(DAA-0443-2012-0007-0003)
These records do not meet the retention criteria for Item I-0001 - Records of Intramural Research Records Projects of Historical Significance, or Item I-0002 - Research Records that Support Intellectual Property Rights.

Disposition: **TEMPORARY.** Cut off annually at termination of project/program or when no longer needed for scientific reference, whichever is longer. Destroy 7 years after cutoff.

Item I-0004: FDA Regulated Research Records
(DAA-0443-2012-0007-0004)
These are records required by 21 CFR that pertain to the receipt, shipment, and 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.

Disposition: **TEMPORARY.** Cut off annually after application is approved/disapproved, or if no new application is filed, after the study is completed/discontinued and FDA is notified of discontinuation or when no longer needed for business and scientific use, whichever is longer. Destroy 3 years after cutoff.

Item I-0005: Institutional Review Board (IRB) Records
(DAA-0443-2012-0007-0005)
These records document 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 research proposals, scientific evaluations, approved sample consent documents, progress reports submitted by research staff, and reports of injuries to research subjects.

Disposition: **TEMPORARY.** Cut off research-specific IRB records annually at the completion of the research project and IRB operational and governance records at the end of each fiscal year or cut off when no longer needed for business and scientific use, whichever is longer. Destroy 3 years after cutoff.

Overview of Clinical Care Services and Departmental Operations Records

These records document 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, preliminary evaluations, quality assessments, routine patient examinations, treatment logs and worksheets, laboratory equipment analyses and testing, patient accommodations, and plans for care.

Item I-0006 - Clinical Care Services Records
Item I-0007 - Radiology and Imaging Records
Item I-0008 - Blood Donor and Receiving Records
Item I-0009 - Blood Product Manufacture, Storage and Distribution Records
Item I-0010 - Patient Medical Records
Item I-0011 - Medical Staff Credentialing Records
Item I-0012 - Pathology Test Records

Item I-0006: Clinical Care Services Records

(DAA-0443-2012-0007-0006)

These records consist of clinical care services and clinical care department operational records that are consolidated under this one common temporary retention item. Exclusions and exceptions are noted and cross referenced to their appropriate item numbers within this schedule. The records associated with this common schedule item 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 I-0012 – Pathology Test Records);
- Medical records services (exception noted in Item I-0010 – Patient Medical Records);
- 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 I-0007 - Radiology and Imaging Records);
- Pharmacy services;
- Rehabilitation medicine (exception noted in Item I-0011 - Medical Staff Credentialing Records);
- Social work;
- Spiritual ministry; and
- Transfusion medicine (exceptions noted in Item I-0008 Blood Donor and Receiving Records and Item I-0009 Blood Product Manufacture, Storage and Distribution Records).

Disposition: **TEMPORARY.** Cut off annually at end of fiscal year. Destroy 7 years after cutoff.

Item I-0007: Radiology and Imaging Records

(DAA-0443-2012-0007-0007)

These records are comprised of 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.

Disposition: **TEMPORARY.** Cut off in 5 year intervals by fiscal year after file becomes inactive or when no longer needed for clinical reference, whichever is longer. Destroy 60 years after cutoff.

Item I-0008: Blood Donor and Receiving Records
(DAA-0443-2012-0007-0008)
These records relate to 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 intervals 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.

Disposition: **TEMPORARY.** Cut off annually after 50 years or annually after expiration of the patient/subject, whichever is longer. Transfer to inactive storage 1 year after cutoff. Destroy 30 years after cutoff.

Item I-0009: Blood Product Manufacture, Storage and Distribution Records
(DAA-0443-2012-0007-0009)
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.

Disposition: **TEMPORARY.** Cut off annually at end of fiscal year. Destroy 10 years after cutoff or 6 months after latest expiration of any components, whichever is longer. If no expiration date, records shall be retained indefinitely. (21 CFR 606.160 - Records. (d))

Item I-0010: Patient Medical Records
(DAA-0443-2012-0007-0010)
These records document 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 or clinical research study.

Disposition: **TEMPORARY.** Cut off patient case file annually after 5 years of inactivity. Destroy when case file is no longer needed for scientific reference.

Item I-0011: Medical Staff Credentialing Records
(DAA-0443-2012-0007-0011)
Medical Staff credentialing records documenting approval of physicians, dentists, and other health professionals for involvement in patient treatments or other patient 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.

Disposition: **TEMPORARY.** Cut off annually after medical staff member leaves patient care. Transfer to inactive storage 1 year after cutoff. Destroy 30 years after cutoff.

Item I-0012: Pathology Test Records

(DAA-0443-2012-0007-0012)
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.

Disposition: **TEMPORARY.** Cut off annually after the date of reporting. Destroy 10 years after cutoff.