

REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER <i>NI-443-99-6</i>	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		DATE RECEIVED <i>8-6-99</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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	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 Clinical Center			
4. NAME OF PERSON WITH WHOM TO CONFER Leslie Watson	5. TELEPHONE 301-496-2833	DATE	ARCHIVIST OF THE UNITED STATES
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>17</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 JUN 21 1999	SIGNATURE OF AGENCY REPRESENTATIVE <i>A. Prentice Barnes, Sr.</i> A. Prentice Barnes, Sr.	TITLE HHS Records Manager	

7. Item No.	8. DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9. GRS OR SUPERSEDED JOB CITATION	10. ACTION TAKEN (NARA USE ONLY)
	<p>Approval is requested to revise/modify/update the NIH Records Control Schedule B-361, covering Clinical Center records. These changes were necessitated by regulatory, procedural and/or operational considerations, (as noted). Some items include a disposition for electronic records.</p> <p>These items will appear in the NIH Records Control Schedule as follows:</p>		<i>Withdrawn</i>

NC1-90-78-9 (7a)

1100-B-2 Clinical Center Central Files related to general policy and procedures, admissions policies and procedures, general administrative documents, or any other documents related to the official duties of the Director, Clinical Center.

Location: CC, Office of the Director.

Disposition: PERMANENT. Offer to National Archives when 7 years old.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

NC1-90-78-12 (7a, 74); NC1-90-77-2 (2, 2b)

1100-C-12 IC Program Analysis and Review Files including progress reports, statistical compilations, program audits and analyses of programs with comments and recommendations, for specific programs which support NIH's biomedical research, education and communications missions.

a. Located in IC Directors' offices.

Disposition: PERMANENT. Transfer to Federal Records Center when 7 years old. Offer to National Archives when 22 years old.

b. Program Records which Document unique activities illustrating the history of the Clinical Center. These may involve significant events, policy matters not documented in the Clinical Center Central File, or special or historic meetings. The records may include copies of printed programs and other varied materials.

Located in: CC, Office of the Director.

Disposition: PERMANENT. Incorporated into Clinical Center Central File when 7 years old. File with other Clinical Center Central File records scheduled for offer to the National Archives.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

c. Program analysis and review files.

Located in all other offices.

Disposition: Destroy when no longer needed for reference or when 5 years old, whichever is sooner.

a. NC1-90-78-9 (7a); b. NC1-90-78-12 (7a); c. NC1-90-77-2 (3)

1100-D-1 Organization and Functions files consisting of functional statements, organizational and staffing charts and reorganization studies of NIH and the IC's. Included are official statements published in the Federal Register with supporting correspondence and other records which document successive changes at branch, section and lower-level organizations and reasons therefore. These documents state the mission of the agency and subordinate organizations; establish, reorganize, centralize or decentralize, and discontinue programs and organizational structures; or show organizational charts and codes; and include records created in the development of and influencing decisions on these matters.

a. Located in CC, Office of the Director

Disposition: PERMANENT. Transfer a complete set of superseded statements to Federal Records Center at 10-year intervals. Offer to the National Archives 10 years after transfer to the Federal Center.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

NC1-90-78-19 (7a) **ADD electronic version**

1100-H-5 Minutes of Meetings maintained in the Clinical Center Central File.

Located in CC, Office of the Director

Disposition: PERMANENT. Offer the recordkeeping copy to the National Archives when 7 years old.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

NC1-GRS-23 (1); NC1-90-78-9 (39) **ADD electronic version**

1100-M-1 Administrative Files accumulated by individual offices that relate to the internal administration or housekeeping activities of the office rather than the functions for which the office exists. In general, these records relate to the office organization, staffing, procedures, and communications; the expenditure of funds, including training and travel; supplies and office services and equipment requests and receipts; and the use of office space and utilities. They may include copies of

internal activity and workload reports (including work progress, statistical, and narrative reports which are prepared in the office and forwarded to higher levels) and other materials that do not serve as official documentation of the programs of the office.

Disposition: Destroy the recordkeeping copy when 2 years old.

Electronic Version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

(Changed retention period; combined a-c in description to just one)

1900-F-6 Patients' Emergency Fund Records, relating to the collection and disbursement of, and accounting for, funds donated to meet emergency needs of patients, summary records of withdrawals and deposits, and "thank you" letters from patients and their families.

Located in CC, Social Work Department.

Disposition: Destroy when 3 years old.

NC1-443-93-1 (changed disposition; added electronic version)

2300-293-4 Medical Staffs' credential files, documenting approval by Clinical Center Administration of physicians, dentists, and other health professionals involved in patient treatment or other contacts. The files contain record of participation in patient care, signed agreements to abide by Medical Staff by-laws, delineation of clinical privileges, and related papers. (NOTE: These records are part of Privacy Act system of records 09-25-0169.)

Located in CC, Medical Records Department.

Disposition: Purge hard copy files immediately after medical staff member leaves patient care. Transfer hard copy files of medical staff members employed in Clinical Center departments to the Federal Records Center in 5-year blocks by retiring all materials through the fiscal year, ending September 30. Retire all materials through FY 1998. Then in 5-year blocks thereafter by fiscal year. (For example, in fiscal year 1999, transfer files closed out in fiscal years 1984-1998; in fiscal year 2004, transfer files closed out in fiscal years 1999-2003.) Destroy when 30 years old.

Electronic version: Computer files, maintained indefinitely; inactive information in the database deleted, when referencing or updating is completed.

2300-410-1 Training Records. EXCLUDING records of formally established schools which train agency employees in specialized program areas, such as law enforcement and national defense.

a. General file of NIH-sponsored training, EXCLUDING record copy of manuals, syllabuses, textbooks, and other training aids developed by NIH.

(1) Correspondence, memoranda, agreements, authorizations, reports, requirements reviews, plans, and objectives relating to the establishment and operation of training courses and conferences.

Disposition: Destroy when 5 years old or 5 years after completion of a specific training program.

(2) Background and working files.

Disposition: Destroy when 3 years old.

b. Employee Training: Correspondence, memoranda, reports and other records relating to the availability of training and employee participation in training programs sponsored by other government agencies or non-government institutions.

Disposition: Destroy when 5 years old or when superseded or obsolete whichever is sooner.

2300-792-4 Employees' radiological records: These records consist of original radiology imaging studies.

a. Film

Located in CC, Diagnostic Radiology Department, Film Library.

Disposition: Retain for 5 years from latest patient activity. Transfer to intermediate storage after 5 years of inactivity. Offer to Occupational Medical Services (OMS) after 10 years of inactivity. If not accepted by OMS, destroy after 10 years of inactivity.

b. All other records

Located in NIH, Occupational Medical Services (OMS).

Disposition: Destroy when 5 years old, except those that, in the judgement of Medical Officers in charge and/or roentgenologists, have further scientific or instructional value.

2600-C-30 Blood Storage Records, showing temperatures maintained in preserving blood in the department.

Located in CC, Transfusion Medicine Department.

Disposition: Destroy the recordkeeping copy when 5 years old or when any blood components associated with these records have expired, whichever is later. (21CFR606)

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

(NOTE: Expanded description of records to include documentation required for all blood components manufactured, stored or distributed by DTM. Record retention requirements are dictated by federal regulation under 21CFR606.)

2600-C-31 Blood distribution and disposition records, showing patients' name, blood types, and other data related to transfusion, name and address of consignees, final disposition of all blood components collected, manufactured, or stored in the department.

(NOTE: These records are part of Privacy Act system of records 09-25-0011.)

Located in CC, Transfusion Medicine Department.

Disposition: Retain the recordkeeping copy on-site for 50 years or upon notification of expiration of the patient or subject, whichever is longer. Transfer to the Federal Records Center following the 50-year on-site retention or upon notification of expiration of the patient or subject. Destroy after 30 years of storage at the FRC. (21CFR606)

Electronic version: Delete after recordkeeping copy has been produced or when no longer needed for reference or updating.

Add electronic version NC1-443-96-1

3000-E-21 Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

NC1-90-78-4 (1)

3000-E-22 Medical Records Case Files of Patients of the NIH Clinical Center, filed by the unit system, using hospital number and patient name. Each medical record includes the complete record of admissions and medical treatment for a patient accepted in a research project. Inactive records for patients who have not received treatment for a period of five consecutive years will be microfilmed periodically.

(NOTE: These records are part of Privacy Act System of records 09-25-0099)

Located in CC, Medical Record Department

Disposition:

- a. Recordkeeping Paper File - Destroy when microfilm has been accepted.
- b. Microfilm File - PERMANENT. Transfer microfilm master copy to the National Underground Storage. These records must be microfilmed in accordance with FPMR 101-11.504.
- c. Diagnostic By-Products copy: Transfer to the Federal Records Center 1 year after inactivity. Destroy when 30 years old.

NC1-90-78-9-(23)

3000-E-24 Patient Report Files: Reports of findings in laboratory analysis for reference and research.

Located in CC, Clinical Pathology Department.

Disposition: Destroy the recordkeeping copy when 2 years old.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

(NOTE: New Laboratory Information System will be installed in March 1999, which will

eliminate the need to retain patient report files any longer than 2 years. Microfilming is no longer needed as patient data is now captured electronically and will be a permanent record on line for physician retrievals.)

nc1-90-78-9 (32a, 33)

3000-E-26 Diagnostic Radiological Records and Radionuclide Scans, comprising X-rays and other roentgenographic images produced by various devices and procedures such as body and head scans created by computerized transaxial tomography and following use of isotopes.. Files include positive photographic images resulting from ultrasound procedures and related studies and interpretations.

Located in CC, Diagnostic Radiology Department.

Disposition: Retain in Diagnostic Radiology Department for 5 years from latest patient activity. Transfer to intermediate storage after 5 years of inactivity. Transfer records to the Federal Records Center after 10 years of inactivity. Destroy when 30 years old.

3000-E-30 Radiopharmaceutical Records, showing the amount, nature, dates and purposes of radionuclides dispensed to patients in testing.

Located in CC, Nuclear Medicine Department.

Disposition: Retain the recordkeeping copy in the Nuclear Medicine Department for 5 years from latest patient activity. Destroy when 5 years old.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

(NOTE: Documentation and record retention requirements dictated by Nuclear Regulatory Commission (NRC) and the NIH Radioactive Materials License administered by the NIH Radiation Safety Officer.)

3000-E-36 Serological Test Records for Clinical Center patients: showing results of blood typings, antibody screening and compatibility testing.

(NOTE: These records are part of Privacy Act system of records 09-25-0011).

Located in CC, Transfusion Medicine Department.

Disposition: Destroy the recordkeeping copy 5 years after patient is discharged.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

3000-E-37 Transfusion Service Records: Interpretations of adverse reactions to transfusion, identification of clinically significant antibodies, and special transfusion requirements for Clinical Center patients. NOTE: These records are part of Privacy Act system of records 09-25-0011).

Located in CC, Transfusion Medicine Department.

Disposition: Retain the recordkeeping copy on site for 50 years or upon notification of expiration of the patient or subject, whichever is longer. Transfer to the FRC following on site retention for 50 years or notification of expiration of the patient or subject. Destroy after 30 years retention at the Federal Records Center.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

Blood Donors

3000-E-50 Blood Donor History and consent records, showing name of donor, medical history and physical data. Inactive records for donors will be microfilmed periodically. (NOTE: These records are part of Privacy Act System of records 09-25-0011)

Located in CC, Transfusion Medicine Department.

Disposition:

- a. Donor Medical History Cards: - File by calendar year. Microfilm inactive records at the end of each calendar year. Destroy after microfilming and verification of film.
- b. Original Microfilm copy - PERMANENT. File original copy of microfilmed records in Transfusion Medicine Department.
- c. Other Microfilm copy: Transfer to the Federal Records Center for 30 years. Destroy when 30 years old.

3000-E-51 Blood Donation Records, including blood collection data and results of testing performed to qualify the donor and the collection product.

Located in CC, Transfusion Medicine Department.

- a. Product Cards: - File by calendar year. Microfilm inactive records at the end of each calendar year. Destroy after microfilming and verification of film.
- b. Original Microfilm copy - PERMANENT. File original copy of microfilmed records in Transfusion Medicine Department.
- c. Other Microfilm copy: Transfer to the Federal Records Center for 30 years. Destroy when 30 years old.

Clinical Research Volunteers

Records about individual clinical research volunteers who serve as controls in clinical studies.

EXCLUDED from this section are:

Records related to sponsoring agencies (see item 1100-J-5).

3000-E-61 Clinical Research Student Volunteer Program Files, containing medical histories and admission information.

(NOTE: These records are part of Privacy Act system of records 09-25-0012)

Located in CC, Clinical Research Volunteer Program.

Disposition: Destroy 3 years after volunteer period ends.

3000-E-62 Copies of Clinical Research Volunteer Visit Reports, showing time spent by the volunteer, and payment made to the volunteer.

(NOTE: These records are part of Privacy Act system of records 09-25-0012)

Located in CC, Clinical Research Volunteer Program.

Disposition: Destroy when 2 years old.

iii. Nursing, Surgical and Other Patient Services

Operational records of Nursing, Surgical, Outpatient and Rehabilitation Departments of the Clinical Center.

EXCLUDED from this section are

Records about individual patients (see subsection 3000-E-ii).

NC1-90-78-9 (60)

3000-E-78 Operating Room Memoranda. Originals are maintained in the department. Copies are forwarded to the Medical Record and Information Systems Departments.

Located in, CC, Surgical Services Department

Disposition: Destroy when 2 years old.

iv. Volunteer Services

Records related to auxiliary services in the Clinical Center provided by volunteers from the general public, the Red Cross and other institutions.

3000-E-90 Volunteer Services Case Files, containing applications, discharges, agreements and related correspondence regarding persons donating their services to the Clinical Center.

Located in: CC, Volunteer Services Office.

Disposition: Destroy the recordkeeping copy 18 months after end of volunteer's service.

Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

F. Laboratory Operations, Materials and Resources

Records concerning laboratory performance, equipment and instrument maintenance and use, test media and preliminary processing of laboratory test results in clinical or research laboratories.

EXCLUDED from this section are:

- (1) Clinical and Research data records (see sections 3000-E and 3000-G through K);
- (2) Records concerning laboratory safety (see section 1300-B);
- (3) Records on production and supply of laboratory animals (see section 3000-C);
- (4) Records created in the development of laboratory instruments and data processing systems (see section 3000-D and 2800-A).

NC1-90-78-9 (25) **Added electronic version only**

3000-F-1 Quality Control Records, consisting of charts, graphs, and other records showing the quality of laboratory performance, and reflecting the adequacy of laboratory procedures and/or equipment.

Located in CC, Clinical Pathology Department.

Disposition: Destroy when 2 years old.

Official Electronic copies: Delete when 2 years old

NC1-90-78-9 (26) **Added electronic version only**

3000-F-2 Instrument Maintenance Records, documenting repairs or other adjustments made to instruments used in the department.

Location: CC, Clinical Pathology Department.

Disposition:

- a. Recordkeeping copy (paper): Destroy when instrument is no longer used.
- b. Electronic copies: Delete after recordkeeping copy has been produced or when referencing or updating is completed.
- c.

NC1-90-78-2 (27)

3000-F-3 Log books, recorder charts, and other working papers used to prepare reports or analyses.

Located in CC, Clinical Pathology Department.

Disposition: Destroy when 2 years old.

HEW-B-370 (4g) **Added electronic version only**

3000-F-10 Media Preparation Case Files and Indexes related to requisitions for laboratory media and cells, including description of the method of preparation and the

research, the methodology involved, projected aims and justifications, notations and records of approval actions, names of principal investigators, project reviews, and related correspondence and memoranda.

Located in CC Medical Record Department.

Disposition: PERMANENT. Transfer files of terminated protocols to the Federal Records Center on an annual basis by fiscal year, ending September 30. (For example, in fiscal year 1999, transfer files closed out in fiscal year 1998). Offer to the National Archives after 20 years.

Electronic version: PERMANENT. Computer files maintained indefinitely.

H. Clinical Research

Records generated or collected in research programs which aim specifically and directly at developing, identifying, improving, testing or evaluating methods, procedures, tests, instruments or drugs used in any aspect of medical practice. This section includes records of preclinical screens, clinical trials and drug testing and development.

EXCLUDED from this section are:

- (1) Records kept for clinical care rather than research (see section 3000-E).
- (2) Records of biomedical research not directly related to specific clinical applications (see section 3000-G, I or J).
- (3) Records of the Veterinary Resources Branch (see section 3000-C).

i. Drug Testing and Development Records of the Clinical Center Pharmaceutical Development Service.

NC1-90-77-9 (114) **Add electronic version**

3000-H-4 Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

NIH Clearances:

ingredients used.

Located in CC, Clinical Pathology Department.

Disposition: Official Electronic copies: Destroy when 10 years old.

G. Biomedical Research Projects: General

Records related to planning, development and oversight of specific projects and programs of biomedical research performed by NIH investigators, contractors and/or collaborative research and development agreements (CRADAs); includes experimental, observational and control data generated in such research and the products of research such as articles, reports and data sets. Use this section only for records not specifically identified in items 3000-H through 3000-K.

EXCLUDED from this section are:

- (1) Broad scope and long-term research planning and review files at IC and higher levels (see section 1100-C);
- (2) Research records containing data relevant to patent and invention rights (see item 1100-L-1).
- (3) Records of clinical trials, drug testing and development and other clinical research identified in section 3000-H.
- (4) Records of epidemiological and biometric research identified in section 3000-I.
- (5) Records of laboratory experiments identified in section 3000-J.
- (6) Critically analyzed data and reference data identified in section 3000-K.
- (7) Records of the Veterinary Resources Branch (see section 3000-C).

a. NC1-90-78-12 (58) ;

3000-G-2 Research Protocols

- a. Concerning standards and procedures to be followed in use of animals in research.

Disposition: Destroy when protocol is no longer in force.

NC1-90-77-9 (116)

- b. Clinical Center Protocol files, documenting proposals made by the Institutes and approved by the Director of the Clinical Center for use of human subjects in research, development, and related activities. Each file normally contains the official copy of the protocol, describing the nature of the proposed

DELETE c. Copies of Research Protocols NC1-90-77-9 (95) No longer maintained.

Disposition: Destroy 1 year after end of research project.

H. Clinical Research

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- (1) Records kept for clinical care rather than research (see section 3000-E).
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See previous page

i. Drug Testing and Development Records of the Clinical Center Pharmaceutical Development Service.

NC1-90-77-9 (114) **Add electronic version**

3000-H-4 Electronic version: Delete after recordkeeping copy has been produced or when referencing or updating is completed.

- 3000-H-5 **DELETE** NC1-90-77-9 (115) No longer maintains records
- 8000-D-4 **DELETE** NC1-90-78-12 (90, 92, 35a, 35b) No longer maintains records
- 8000-G-1 **DELETE** NC1-90-78-9 (6) No longer maintains records

NIH Clearances:

Jerry King: 
CC Records Officer

5/19/99
Date

Leslie Watson: 
MH Records Officer

5/25/99
Date