

REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER <i>NI-443-99-4</i>	
To: NATIONAL ARCHIVES and RECORDS ADMINISTRATION (NIR) WASHINGTON, DC 20408		DATE RECEIVED <i>4-15-99</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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10.	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 301-496-2832	DATE <i>7-29-99</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>3</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	SIGNATURE OF AGENCY REPRESENTATIVE <i>[Signature]</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 GRS OR SUPERSEDED JOB CITATION	10.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 modify the NIH Records Control Schedule, B-361, covering several record series, under Section 3000, E Clinical Care. These changes were necessitated by regulatory, procedural and/or operational considerations, (as noted). Approval is requested to replace two old items with two new items in the 3000-E series and to add two new items to the 3000-F series.</p> <p>To replace item 3000-E-28 <u>Radionucleide scan files</u>, (which were combined under 3000-E-26) with <u>Positron Emission Tomography (PET) Files</u>, consisting of various electronic images of body and organ PET scans on patients. Also, to replace 3000-E-35 <u>Copies of all other records on patients made as a result of surgical procedures</u> (which are no longer maintained by the Surgical Services Department) with, <u>Receiving Records</u>, including identification and description of blood products for transfusion received from other collection facilities, in the NIH Records Control Schedule (B-361).</p> <p><i>see attached Clinical Care Records</i></p>		

*copy to: agency NWCT
NWME NR, NWMD SEP 10 1999 MNR
NWMM*

Approval is requested to modify the NIH Records Control Schedule B-361, covering several record series, under Section 3000, E Clinical Care. These changes were necessitated by regulatory, procedural and/or operational considerations, (as noted).

NEW

3000-E-28 Positron Emission Tomography (PET) Files, consisting of various electronic images of body and organ PET scans on patients. Files include interpretations.

Located in: CC, Positron Emission Tomography Department.

Disposition: Official electronic copy: Retain on-site for 50 years or expiration of the patient or subject, whichever is longer. Destroy when 50 years old.

NEW

3000-E-35 Receiving Records, including identification and description of blood products for transfusion received from other collection facilities.

Located in: CC, Transfusion Medicine Department.

Disposition: Retain on-site for 50 years or expiration of the patient or subject, whichever is longer. Transfer to the Federal Records Center for 30 years. Destroy when 30 years old. (21CFR606)

NEW

3000-F-4 Laboratory Testing Records. Includes documentation of pre- and post-analytical phases of testing process and all laboratory data generated in the analytical phase, including quality control, observed values and Interpretations associated with patient testing. Used for reference and research.

Located in: CC, Transfusion Medicine Department.

Disposition: Destroy when 2 years old, or when no longer useful for research. (42CFR493)

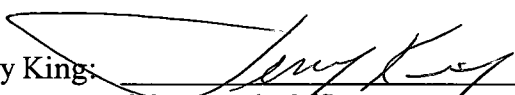
NEW

3000-F-5 Process Control Records. Laboratory and manufacturing control records associated with patient testing, donor testing, or blood product manufacturing. Includes documentation related to validation, maintenance and quality assurance of equipment, supplies, reagents and processes. Used for reference and research.

Located in: CC, Transfusion Medicine Department.

Disposition: Destroy after 5 years, or 6 months after any blood product associated with these records has expired, or when the data is no longer useful for research, whichever is the latest date. (21CFR606)

NIH Clearances:

Jerry King:  3/22/99
CC Records Officer Date

Leslie Watson:  3/23/99
NIH Records Officer Date