REQUEST FOR RECORDS DISPOSITION AUTHORITY		JOB NUMBER N1-443-09-7	
To NATIONAL ARCHIVES & RECORDS ADMINISTRATION 8601 ADELPHI ROAD COLLEGE PARK, MD 20740-6001		Date received 9/24/09	
1 FROM (Agency or establishment) Department of Health and Human Services		NOTIFICATION TO AGENCY	
2 MAJOR SUBDIVISION National Institutes of Health (NIH)		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request, including amendments, is approved except for items that may be marked "disposition not approved" or "withdrawn" in column 10	
3 MINOR SUBDIVISION OD/OM/OMA/DMS			
4 NAME OF PERSON WITH WHOM TO CONFER Nyja DeFrank	5 TELEPHONE NUMBER 301-496-2463	DATE 1/10/11	ARCHIVIST OF THE UNITED STATES WITHDRAWN

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 11 page(s) are not needed now for the business for 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,

☒ is not required ☐ is attached, or ☒ has been requested

DATE	SIGNATURE OF AGENCY REPRESENTATIVE	TITLE
09/23/2009	Yvonne K Wilson Yvonne K. Wilson	HHS Records Officer

7 ITEM NO	8 DESCRIPTION OF ITEM AND PROPOSED DISPOSITION	9 GRS OR SUPERSEDED JOB CITATION	10 ACTION TAKEN (NARA USE ONLY)
	Approval is needed for the following listed electronic systems under NIH Manual Chapter 1743 – Keeping and Destroying Records (NIH Records Control Schedule), Section 3000 Biomedical Research Activities, 3000-L Biomedical Research Activities Electronic Systems See attached schedule	None (New Schedule)	

3000 L Biomedical Research Activities Electronic Systems

3000-L-1 NIH CC Biomedical Translational Research Information System (BTRIS)

BTRIS will contain longitudinal data, text and images from NIH intramural clinical care and research systems to facilitate data analysis, hypothesis generation and patient recruitment in support of the NIH intramural research mission Principal investigators and designees (e g associate investigators) will be allowed to access identified data only as permitted by their active protocols) Other users with appropriate IRB or OHSR clearances will be able to access and query only data in a de-identified manner.

a. Inputs — N/A

None.

b Master File

BTRIS will allow users to query against the repository based on role For active protocols, the principle investigator or other members of the research team will be able to access identified data on demographics, vital signs, labs, medications, results and clinical documentation Other researchers wishing to develop hypothesis or determine availability of potential subjects will be able to query de-identified data for this same information All data is stored in a relational database

Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference

~~c. Outputs~~ — GRS 20 Items 4, 5, 6, 7, 12, and 16

~~Users can create lists for future use - patient lists, protocol lists, lists of specific medications, or specific lab tests This drives specific query terms for future use. Users can also create a variety of reports in both tabular and graphical format using either identified or de-identified data The system also creates some standard reports~~

~~Disposition TEMPORARY Delete inactive information in the database when no longer needed~~

3000-L-2	NIH CC Clinical Research Information System (CRIS) CRIS consists of the core system and component applications to document clinical care and research for registered patients at the Clinical Research Center· NIH This activity is authorized by Section 301 of the Public Health and Safety Act	
	a Inputs None	N/A
	b. Master File The CRIS Core System includes multiple databases that support Clinical Center patient care and research The CRIS Core master active database is the central point for receipt and distribution of active patient information and clinical data Every item relating to the clinical care of every patient is entered into CRIS Core	
	Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference	
	~~c Outputs~~ ~~Patient information is transferred from CRIS Core to ancillary systems Other outputs are in the form of printed patient information and reports that are a part of the official medical record or are used for clinical care with the patient or care givers~~	NC1-90-78-4 Item 1b (NIH 3000-E-22)
	~~Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference~~	
3000-L-3	NIH CC Executive Information System (EIS) The Executive Information System (EIS) is an application designed to provide real time reporting of key hospital performance indicators The EIS provides query and reporting capabilities for executive decision makers, and allows staff to view daily, monthly, annual patient census information and key hospital performance metrics Census data can be reported by hospital unit and protocol, IC, branch, and Principal Investigator	

a Inputs — N/A
None

b Master File
EIS reports admissions, inpatient days, outpatient visits, average length of stay, discharge, and patient counts Census data can be reported by hospital unit and protocol, Institute/Center, branch and Principal Investigator

Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference.

~~c Outputs~~ — GRS 20 Items 4, 5, 6, 7, 12, and 16
~~Monthly, quarterly and annual census information and key performance metrics shared with CC executive decision makers Data is not transferred to other systems~~

~~Disposition TEMPORARY Delete when the agency determines that they are no longer needed for administrative, legal, audit or other operational purposes~~

3000-L-4 NIH CC Medicolegal Request Tracking System
The Medicolegal Request Tracking System is used to receive requests for and track copies of medical record documentation sent out by the Medical Record Department to Clinical Center patients and the third parties they authorize to receive such information

~~a. Inputs~~ — GRS 20 Item 2a4
~~Information is abstracted and entered by authorized medical record technicians from requests for release of confidential medical information from the official Clinical Center medical record Requests may be received from patients, healthcare organizations, insurance companies, government agencies, etc Manual forms utilized are: Release of Medical Information (NIH-527) and fax cover sheet No other systems or agencies receive data~~

b Master File
Data is abstracted and entered into the system

including patient names, dates of birth, mailing addresses, phone numbers, medical record numbers, and details of the specific request for release

Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference

~~c. Outputs~~
~~Outputs consist of a textual notification letter as well as the specific clinical data requested in the submitted release form. A permanent record is maintained of each release as required by the Privacy Act.~~

~~Disposition. PERMANENT. Incorporate into Clinical Center Central File when 7 years old. File with other Clinical Center Central File records scheduled for transfer to the National Archives. (NC1-90-78-9 Item 31a)~~

~~NC1-90-78-9 Item 31a (NIH 1100-C-12b)~~

3000-L-5 NIH CC Softmed Automated Medical Record Processing and Tracking Applications

Softmed applications contain demographic and tracking information is maintained on registered Clinical Center patients in order to route documents for creation, recording, retention, signature and location

~~a. Inputs~~
~~Data is input from clinical transcription contractors and authorized medical record technicians, including patient and health care provider demographics. Data is used in the analysis, creation and completion of various types of clinical documentation and coding, including that related to dictated medical reports. Forms used are official medical record forms that are far too numerous to list but are available from the CC Medical Record Department. Data is not input from other systems or shared with other agencies.~~

~~GRS 20 Item 2a4~~

b. Master File
Data is input from clinical transcription contractors and authorized medical record technicians, including patient and provider names, dates of birth, mailing addresses, phone numbers, medical record numbers, and specific information related to the routing and

completion of required medical documentation for the official Clinical Center medical record

Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference

~~c Outputs~~
~~Notifications to providers related to required clinical documentation regarding the specific items, their status and their completion Data is not transferred to other systems Various report types are transcribed within the system utilizing NIH approved forms including NIH 513-1 (Consultation Report), M-513-1 (Rehabilitation Medicine Results), M-513-2 (Physical Therapy Results), M-513-3 (Occupational Therapy Results), M-513-4 (Speech Pathology Results), NIH-532-8 (Outpatient Record), NIH-999-2 (Inpatient Record), M-2078 (EEG Results), M-2079 (EMG Results), NIH-2435-1 (Radiation Therapy Summary), and NIH-2435-2 (Radiation Oncology History & Physical Examination)~~

~~Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference~~

~~NC1-90-78-4~~
Item 1b
(NIH 3000-E-22)

3000-L-6 NIH CC Theradoc Infection Control System
The system provides the Hospital Epidemiology Service with continuous infection surveillance, alerts, and analysis to help promote better and timelier infection control practices

~~a~~ Inputs
None

N/A

b Master File
Patient demographic data from the Clinical Research Information System (CRIS) includes, medical record number, name, date of birth, sex, height/weight, and medical information like allergies Pharmacy order information from CRIS includes name of the medication and date of the medication order Test results from the Laboratory Information System (LIS) and Research Information System (RIS) include the test name, date that test was performed and test

results

Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference

~~c. Outputs~~ GRS 20
~~The system provides the Hospital Epidemiology Service (HES) with tools for gathering, analysis and reporting of epidemiologic data. The system will provide real-time notification and alerts to HES staff. Summary reports about infection rates are reviewed by HES staff and shared with the Hospital Infection Control (HIC) Committee. Data is not transferred to other systems.~~ Items 4, 5, 6, 7, 12, and 16

~~Disposition TEMPORARY Delete when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes.~~

3000-L-7 NIH NIDDK Teleresults

The Teleresults/Lab Grabber system manages the clinical and research data for patients of the Transplant Branch and the Autoimmunity and Islet Branch. The driving factors for the installation of the system were i) provide a means to handle the specialized requirements of transplant processes, ii) provide a location to save the large volume of outside clinical data, iii) allow retrieval of data for research purposes

a. Inputs N/A
None

b. Master File
Accumulated data of all types including patient demographics and history, test results, consults, chemistries and hematologies from CRIS, and occasional custom imports of special data sets

Disposition TEMPORARY Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference

~~c. Outputs~~ GRS 20

	~~Reports of patient information and system management information, and research results for tests run on patients within the Transplant Branch and the Autoimmunity and Islet Branch~~ ~~Disposition TEMPORARY Delete when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes~~	Items 4, 5, 6, 7, 12, and 16
3000-L-8	NIH CC Admissions and Travel Voucher Application (ATV) ATV is an ancillary application, part of the CRIS system It serves as a front end for CRIS and facilitates (i) record creation - enter new patients and related information, (ii) submission of requests for admission, and (iii) submission of travel and reimbursement requests for NIH Clinical Center patients	
	a Inputs None.	N/A
	b Master File The information collected is name, gender, date of birth, social security number, mailing address, and phone number The medical record number (MRN) is fed in by CRIS Core (SCM) once an MRN is assigned This information is used to register individuals as participants in clinical trials and to assist in providing travel arrangements for those individuals Information is disclosed to travel agents to assist in making the necessary travel arrangements Social Security Numbers are included for authorized financial reporting requirements Disposition TEMPORARY Cutoff when inactive or superseded Destroy 3 years after cutoff	
	~~c Outputs~~ ~~Only authorized personnel may have access to the system and its output SF Form 54 - Admissions and Vouchers Additionally, a summary can be viewed on the application search screen but it does not constitute a report Patients have no access to the application Applicable information is conveyed to Clinical Center~~	NC1-90-78-9 Item 87 (NIH 3000-E-41)

~~patients by authorized personnel over the phone.~~

~~Disposition: TEMPORARY. Destroy when 3 years old.~~

3000-L-9 NIH CC Blood Bank Collection System (BBCS)

The system contains data regarding donors at the Department of Transfusion Medicine used to conduct clinical care and research at the Clinical Center as authorized by Section 301 of the Public Health Service Act.

~~a. Inputs~~ GRS 20 Item 2b

~~Data is entered about blood donors by Transfusion Medicine staff and contractors at their first registration and is updated before each donation. The results of lab tests on donated blood and blood components are captured through an interface from the Laboratory Information System (LIS).~~

b. Master File

Donor demographic information includes name, date of birth, donor ID#, mailing address, phone numbers, email address, and medical record number if donor is a CC patient, medical information about the donor and the signed Department of Transfusion Medicine Consent for Donation. The Laboratory Information System information includes donor's blood type, lab results, serologic reactions and related medical information.

Disposition: TEMPORARY. Review with NIH Records Management Officer for disposition when 15 years old.

~~c. Outputs~~ GRS 20 Items 4, 5, 6, 7, 12, and 16

~~Routine and ad hoc queries are performed by DTM staff which support scheduling donor appointments, tracking donor history and reporting of aggregated data to the American Association of Blood Banks and FDA. Data is not transferred to other systems.~~

~~Disposition: TEMPORARY. Delete when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes.~~

3000-L-10 NIH CC Clinical Research Volunteer Program (CRVP)

The Clinical Research Volunteer Program (CRVP), in existence since 1954, recruits, registers and compensates individuals who volunteer to participate as healthy control subjects in clinical research protocols. Healthy volunteers provide researchers with important information for comparison with people who have specific illnesses. Every year, nearly 3,500 healthy volunteers participate in studies at NIH. The information captured is used for (i) collecting healthy volunteer registration information (Patient Recruitment Research Center - PRRC database); and (ii) process requests for compensation and authorization of payments to research volunteers (Volunteer database). Checks are issued by the Treasury Department.

a. Inputs — N/A

None.

b. Master File

Information collected includes name, gender, race, date of birth, mailing address, phone number, e-mail addressee, existing medical conditions, medications and other data that might affect participation. Information is shared with intramural research teams recruiting subjects upon request. Medical Record Number (MRN) and Social Security Number (SSN) are captured only for volunteers who actually participate in clinical research protocols. Social Security Numbers are included for financial reporting requirements to allow payments to those individuals who participate in protocols which provide compensation.

Disposition: TEMPORARY. Cut off after volunteer period ends. Destroy 3 years after cutoff.

~~c. Outputs~~ — GRS 20 Items 4, 5, 6, 7, 12, and 16

~~Authorized CRVP staff can run queries against the potential candidate pool (PRRC database). Queries depend on the clinical protocols/trails conducted at the time. Demographic information is shared with intramural NIH research teams actively recruiting~~

~~subjects upon request.~~

~~Disposition: TEMPORARY. Delete when the agency determines that they are no longer needed for administrative, legal, audit, or other operational purposes.~~

3000-L-11 NIH CC Clinical Center Survey Data

Information resulting from various surveys and questionnaires conducted by the Clinical Center from patients and staff regarding quality of care and hospital operations.

~~a. Inputs~~ GRS 20 Item 2a4

~~Data is abstracted from various surveys and questionnaires, including demographics and is primarily related to the quality and performance of various selected hospital services. Data is captured by employees of the Clinical Center Office of the Director and may also be captured and input by contract personnel. Specific questionnaires are developed on a unique, case-by-case basis depending upon the specific survey topic. Data is not input from other systems.~~

b. Master File

Participation is entirely voluntary. Participant names, dates of birth, mailing addresses, phone numbers, medical record numbers, and the specific responses solicited by each individual survey or questionnaire are collected. Information from specific surveys are developed into aggregated results which are reported in a deidentified form. Specific individuals may be followed to survey completion, after which only aggregated data is maintained.

Disposition: TEMPORARY. Cut off annually. Destroy 5 years after cutoff.

~~c. Outputs~~ GRS 20 Items 4, 5, 6, 7, 12, and 16

~~Outputs are in the form of aggregated data presentations including text, tables, graphs etc., as well as textual clarification and summarization.~~

~~Disposition: TEMPORARY. Delete when the agency determines that they are no longer needed for~~

~~administrative, legal, audit, or other operational purposes.~~

3000-L-12 NIH CC ProVation

CC ProVation is a system whose mission is to digitally report findings from gastroenterological endoscopic exams of the upper and lower gastrointestinal tract, including the ability to record digital pictures. Procedures are recorded as they are completed and the information for each procedure is collected from the patient. The application is locally available from workstations attached to the endoscopy cart and in the clinical procedure unit of the hospital.

a. Inputs — N/A

None.

b. Master File

Patient demographic information includes name, date of birth, mailing address, phone number, and medical record number. Procedure information includes name of participating staff, procedure name, devices used and medical notes entered.

Disposition: TEMPORARY. Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference.

~~c. Outputs~~ — NC1-90-78-4 Item 1b (NIH 3000-E-22)

~~Reports include clinical documentation about a patient procedure which is provided to Medical Records Dept for inclusion in the patient's medical record. Data is not transferred to other systems.~~

~~Disposition: TEMPORARY. Destroy when the Director of the Clinical Center determines that it is no longer needed for scientific reference.~~