

requirements of the applicable statutes and regulations.

## II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

## III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 6, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E8-5083 Filed 3-12-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Privacy Act of 1974; Revision to Existing System of Records; Revised

**AGENCY:** Health Resources and Services Administration (HRSA), HHS.

**ACTION:** Notification of an Altered System of Records; revised.

**SUMMARY:** In accordance with the requirements of the Privacy Act, the Health Resources and Services Administration (HRSA) is publishing notice of a proposal to alter the system of records for the C.W. Bill Young Cell Transplantation Program. This system of records is required to comply with the implementation directives of Public Law 109-129. Records are used for the C.W. Bill Young Cell Transplantation Program's planning, implementation, evaluation, monitoring, and document storage purposes.

HRSA published in the **Federal Register** of August 17, 2007, a document

concerning notice of a new system of records, 09-15-0068, C.W. Bill Young Cell Transplantation Program (FR. Doc. 07-4019). This document more fully explains the routine uses of records maintained in the system and amends the record retention and disposal policy. Accordingly, the notice is published below in its entirety, as amended.

**DATES:** Persons wishing to comment on this revised system of records notice may do so until April 14, 2008. Unless there is a further notice in the **Federal Register**, this revised system of records will become effective on April 14, 2008.

**ADDRESSES:** Please address comments to Health Resources and Services Administration Privacy Act Coordinator, Donn Taylor, 5600 Fishers Lane, Room 14A-20, Rockville, Maryland 20857; telephone (301) 443-0204. This is not a toll-free number.

Comments received will be available for inspection at this same address from 9 a.m. to 3 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

James F. Burdick, M.D., Director, Division of Transplantation, HSB, HRSA, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-7577; fax (301) 594-6095; or e-mail: [jburdick@hrsa.gov](mailto:jburdick@hrsa.gov). This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** The Health Resources and Services Administration published in the **Federal Register** of August 17, 2007, notice of a new system of records, 09-15-0068, C.W. Bill Young Cell Transplantation Program. The Stem Cell Therapeutic and Research Act of 2005 (the Act) establishes the C.W. Bill Young Cell Transplantation Program (the Program) which maintains information related to patients in need of a blood stem cell transplant and potential adult volunteer blood stem cell donors who have agreed to be listed on the registry maintained by the Program. Additionally, the Program maintains information related to the outcomes of patients who have undergone blood stem cell transplantation.

The Stem Cell Therapeutic and Research Act of 2005 authorizes the C.W. Bill Young Cell Transplantation Program and provides for the collection, maintenance, and distribution of human blood stem cells for the treatment of patients and for research. The Program consists of four interrelated components each operated under a separate contract. The four components are: the Bone Marrow Coordinating Center; the Cord Blood Coordinating Center; the Office of Patient Advocacy/Single Point of Access; and the Stem Cell Therapeutic

Outcomes Database. The contracts for operation of the Bone Marrow Coordinating Center, Cord Blood Coordinating Center, and Office of Patient Advocacy/Single Point of Access were awarded to the National Marrow Donor Program in September 2006. A single contract for the Stem Cell Therapeutic Outcomes Database was awarded to the Center for International Blood and Marrow Transplant Research (CIBMTR) at the Medical College of Wisconsin in September 2006 as well.

As identified by the Act, the Program is charged with: Operating a system for identifying, matching, and facilitating the distribution of bone marrow that is suitably matched to candidate patients; operating a system for identifying, matching, and facilitating the distribution of donated umbilical cord blood units that are suitably matched to candidate patients; providing a means by which transplant physicians, other healthcare professionals, and patients can electronically search for and access all available adult marrow donors available through the Program; recruiting potential adult volunteer marrow donors; coordinating with other Federal programs to maintain and expand medical contingency response capabilities; carrying out informational and educational activities; providing patient advocacy services; providing case management services for potential donors; and collecting, analyzing, and publishing blood stem cell transplantation related data, including patient outcomes data, in a standardized electronic format. This system of records is required to comply with the implementation directives of the Act, Public Law 109-129. The records will be used for the C.W. Bill Young Cell Transplantation Program's planning, implementation, evaluation, monitoring, and document storage purposes.

Dated: February 19, 2008.

**Elizabeth M. Duke,**  
*Administrator.*

**09-15-0068**

**SYSTEM NAME:**

C.W. Bill Young Cell Transplantation Program.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Data collected by the C.W. Bill Young Cell Transplantation Program (the Program) are maintained by the National Marrow Donor Program (NMDP) and the Medical College of Wisconsin, contractors for the Program. The Division of Transplantation within the

Health Resources and Services Administration oversees the Program and the contracts with the NMDP and Medical College of Wisconsin.

Records associated with the C.W. Bill Young Cell Transplantation Program are located at the National Marrow Donor Program, 3001 Broadway Street, NE., Suite 500, Minneapolis, MN 55413.

Additional records associated with the Stem Cell Therapeutic Outcomes Database component of the Program are located at the Medical College of Wisconsin's Center for International Blood and Marrow Transplant Research (CIBMTR), 8701 Watertown Plank Road, Milwaukee, WI 53226.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

1. Volunteers whose bone marrow, peripheral blood or cord blood donations are to be used for hematopoietic reconstitution or other therapeutic applications on behalf of patients in need.
2. Patients searching for an unrelated donor or who are receiving transplant or ancillary services through the C.W. Bill Young Cell Transplantation Program.
3. Recipients of allogeneic blood stem cell transplantation.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Records consist of documents (printed and electronic) containing all information necessary to manage and facilitate patient searches and to track detailed post-transplant clinical status, including documentation and correspondence concerning patients in need of (or recipients of) blood stem cell transplants and volunteers listed on the Program's registry as potential blood stem cell donors. These documents include all information necessary to manage and facilitate patient searches, and to track detailed post-transplant and post-donation clinical status. The following information is maintained in the system: individual identifiers about the recipients and donors (e.g., social security number (voluntary), names, date of birth, etc.); recipient and donor demographics and socio-demographics; recipients' disease, disease history and treatment, transplant procedure details, post-transplantation medical history, events, and complications; donor medical history; donation procedure and blood stem cell product details; long-term follow-up of medical outcomes and assessment of functioning for donors and recipients; provider identifiers; transplant and collection facility identifiers; and, donor management center identifiers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Law 109-129 establishes the C.W. Bill Young Cell Transplantation Program, authorizing the Department to establish by contract a system for identifying, matching, and facilitating bone marrow and cord blood transplants, including recruitment, patient advocacy and maintenance of a stem cell therapeutic outcomes database.

**PURPOSE(S):**

The C.W. Bill Young Cell Transplantation Program is comprised of the Office of Patient Advocacy/Single Point of Access, the Bone Marrow Coordinating Center, the Cord Blood Coordinating Center, and the Stem Cell Therapeutic Outcomes Database. The purpose of the system is to support the Program's mission to facilitate and increase access to blood stem cell transplantation. Additionally, information in the system will be used to advise the Secretary of the Department of Health and Human Services and the Advisory Council on Blood Stem Cell Transplantation on matters related to the Program and for ongoing monitoring of the Program by the Health Resources and Services Administration to determine the effectiveness of the Program and to guide implementation of the policies and procedures that govern the Program's structure. Records from this system will be used to carry out the statutory charge of the C.W. Bill Young Cell Transplantation Program. Specifically, records vital and attendant to the full scope of activities involved at every stage of the process of facilitation of blood stem cell transplantation or other therapies for recipients suitably matched to biologically unrelated donors; analyzing factors affecting transplant outcomes; monitoring and reporting of adverse events; monitoring and reporting of quality, compliance, and performance indicators; monitoring and reporting on the size and composition of the registry of adult bone marrow donors and size and composition of the umbilical cord blood inventory; and to provide pertinent information to transplant programs, physicians, patients, other entities awarded a contract under Section 379 of the Public Health Service Act, donor registries, and cord blood banks as stated in Public Law 109-129.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure of records from this system of records may be made as provided in the Privacy Act, 5 U.S.C. 552a(b), and to

the following recipients for the purposes stated:

1. Departmental contractors who have been engaged by the Department to assist in accomplishment of a departmental function related to the purposes of this system of records and who have a need to access the records in order to carry out that function.

2. Transplant centers, physicians and staff, and NMDP participating organizations, for the purpose of searching for donors or products and/or facilitating transplants, matching donor blood stem cells with recipients, monitoring participant outcomes, and monitoring compliance of member organizations with contractor requirements.

3. Personnel involved in the care of volunteer blood stem cell donors and management of their participation in the Program. Disclosures of clinically relevant de-identified information contained in certain donor records may be made to transplant physicians, patients or their designated representatives for purposes of facilitating searches for blood stem cell donors or products and/or facilitation of unrelated donor transplants.

4. Disclosures may be made by the contractors for the Office of Patient Advocacy/Single Point of Access, the Bone Marrow Coordinating Center, the Cord Blood Coordinating Center, the Stem Cell Therapeutic Outcomes Database, NMDP and CIBMTR participating centers to one another as well as participating umbilical cord blood banks to carry out the purposes of the C.W. Bill Young Cell Transplantation Program.

5. Disclosure may be made to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; (c) any employee of the agency in his or her individual capacity where agency or the Department of Justice has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

6. Disclosure may be made to a court or adjudicative body in a proceeding when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; (c) any employee of the agency in his or her individual capacity where agency or the

Department of Justice has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records is therefore deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

7. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

8. Disclosure may be made for research purposes. Rarely, with the appropriate safeguards and consistent with the applicable provisions of the Privacy Act and the Common Rule (45 CFR Part 46), disclosure for research purposes may be made when the Department, independently or through its contractor(s): (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that a bona fide research/analysis purpose exists; (c) has required the recipient to: (1) Establish strict limitations concerning the receipt and use of patient-identified data; (2) establish reasonable administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent the unauthorized use or disclosure of the record; (3) remove, destroy, or return the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information; and (4) make no further use or disclosure of the record except as authorized by HHS or its contractor(s) or when required by law; (d) has determined that other applicable safeguards or protocols will be followed; and (e) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in file folders and in computer data files.

**RETRIEVABILITY:**

Patient and donor records may be retrieved by a unique ID assigned by the system or through the use of other identifying information (e.g., names, date of birth, social security number, or address).

**SAFEGUARDS:**

1. *Authorized Users:* Access is limited to authorized personnel responsible for administering the program, including program managers and program specialists who have responsibilities for implementing the program and the HRSA Information Systems Security Officer. The contractor(s) shall maintain current lists of authorized users. Retrieval of donor or patient records will be limited to authorized users for search, outcomes data collection and data auditing, or transplant management purposes.

2. *Assign Responsibility for Security:* Responsibility is assigned to a management official knowledgeable of the nature of the information and processes supported by the C.W. Bill Young Cell Transplantation Program and in the management, personnel, operational, and technical controls used to protect it.

3. *Perform Risk Assessment:* A risk assessment was conducted in conjunction with the development of the system. The system design ensures vulnerabilities, risks, and other security concerns are identified and addressed in the system design and throughout the life cycle of the project. This is consistent with the HHS Automated Information Systems Security Program Handbook.

4. *Certification and Accreditation:* The Program's electronic data systems are certified under the auspices of HRSA's Office of Information Technology Certification and Accreditation system.

5. *Physical Safeguards:* All computer equipment and files and hard copy files are stored in areas where fire and life safety codes (e.g., OSHA standards) are strictly enforced. All automated and non-automated documents are protected on a 24-hour basis. Perimeter security includes intrusion alarms, key/passcard/combination controls, and receptionist controlled area. Most hard copy files are maintained in a file room used solely for purposes of the Program with access limited by combination lock to authorized users identified above. Computer files are password protected and are accessible only by use of computers which are password protected. Servers are password protected and protected in locked rooms, with access restricted to specific

authorized staff using controls specified in the certification and accreditation process.

6. *Procedural Safeguards:* A password is required to access computer files. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised area. All authorized users sign a nondisclosure statement. All passwords, keys and/or combinations are changed when a person leaves or no longer has authorized duties. Access to records is limited to those authorized personnel trained in accordance with the Privacy Act and automated data processing (ADP) security procedures. The transmission of records is protected using secure protocols. Individuals with access to the system have User IDs and passwords and must be granted access to the system. External access to the data requires two-factor authentication. The safeguards described above were established in accordance with NIST 800-53 and OMB Circular A-130 Appendix III.

**RETENTION AND DISPOSAL:**

HRSA is working with the National Archives and Records Administration (NARA) to obtain the appropriate retention value of these records.

**SYSTEM MANAGER AND ADDRESS:**

Director, Blood Stem Cell Transplantation Program, HRSA, Parklawn Building, Room 12C-06, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Requests must be made to the System Manager.

*Requests by Mail:* Requests for information and/or access to records received by mail must contain information providing the identity of the writer, and a reasonable description of the record desired, and whom it concerns. Written requests must contain the name and address of the requester, his/her date of birth and his/her signature. Requests must be notarized to verify the identity of the requester, or the requester must certify that (s)he is the individual who (s)he claims to be and that (s)he understands that to knowingly and willfully request or acquire a record pertaining to another individual under false pretenses is a criminal offense under the Privacy Act subject to a \$5,000 fine (45 CFR 5b.5(b)(2)(ii)).

Requests in person or by telephone, electronic mail or facsimile cannot be honored.

**REQUESTS IN PERSON:**

No requests in person at the system location will be honored.

**REQUESTS BY TELEPHONE:**

Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURES:**

Record access procedures are the same as notification procedures. Requesters should also provide a reasonable description of the contents of the record being sought. A parent or guardian who requests notification of, or access to, a minor's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the minor/incompetent person as well as his/her own identity. Records will be mailed only to the requester's address that is on file, unless a different address is demonstrated by official documentation.

**CONTESTING RECORD PROCEDURES:**

To contest a record in the system, contact the official at the address specified above and reasonably identify the record, specify the information being contested, and state the corrective action sought and the reason(s) for requesting the correction, along with supporting documentation to show how the record is inaccurate, incomplete, untimely, or irrelevant.

**RECORD SOURCE CATEGORIES:**

Sources of records include, but are not limited to, patients, donors, and/or their representatives under the C.W. Bill Young Cell Transplantation Program and any other sources of information or documentation submitted by any other person or entity for inclusion in a request for the purpose of facilitating and monitoring blood stem cell transplantation (e.g., transplant center healthcare professionals).

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. E8-5056 Filed 3-12-08; 8:45 am]

BILLING CODE 4165-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of General Medical Sciences; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as

amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of General Medical Sciences Special Emphasis Panel, Pathophysiology of Lung Injury by Smoke Inhalation.

*Date:* March 27, 2008.

*Time:* 1 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Room 3AN 18, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Brian R. Pike, Scientific Review Administrator, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892; 301-594-3907; [pikbr@mail.nih.gov](mailto:pikbr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: March 5, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-4807 Filed 3-12-08; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Mental Health; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Mental Health Special Emphasis Panel, RAPID Autism Intervention.

*Date:* April 1, 2008.

*Time:* 11 a.m. to 1 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Enid Light, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH Neuroscience Center, 6001 Executive Boulevard, Room 6132, MSC 9608, Bethesda, MD 20852-9608; 301-443-0322; [elight@mail.nih.gov](mailto:elight@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: March 5, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E8-4808 Filed 3-12-08; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****National Institute of Environmental Health Sciences; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Environmental Health Sciences Special