

provide (such as name, address, telephone number, e-mail address, whether you wish to make a presentation or participate in the vendor display and how to provide FDA with a summary of your presentation or product).

You may register to attend the meeting at www.fda.gov/cdrh/ocd/udi/index.html. Seating is limited to 300 persons, and if capacity is reached, registration will close. If you register as a presenter or to participate in the vendor display, you do not need to also register as an attendee.

Because of time constraints, vendors may register either to present at the meeting or participate in the vendor display. You may not register for both. If you choose to participate in the vendor display, you will have the opportunity to share information about your products with the FDA and other attendees when they visit your display.

Because of the format of the meeting, we will only have a short time for additional presentations. We encourage attendees to raise their issues and concerns during the discussion portion of the four main topic areas. We also encourage persons and groups having similar interests to consolidate their information and present it through a single representative. By October 16, 2006, we will schedule each presentation and, by e-mail or telephone, notify each participant who will present of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. The time allotted for presentations may be between 5 to 15 minutes, depending on the number of people who wish to present. Confirmed presenters need to send final electronic presentations in Microsoft PowerPoint, Microsoft Word, or PDF by October 20, 2006 to CDRHUDI@fda.hhs.gov.

VI. Transcripts

The meeting will be transcribed and will be available on the Internet at www.fda.gov/cdrh/ocd/udi/index.html.

You may also request a copy of the transcript by writing to our Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857. We anticipate that transcripts will be available approximately 10 days after the public meeting at a cost of 10 cents per page. The transcripts will also be available for public examination at the Division of Dockets Management (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 15, 2006.
Jeffrey Shuren,
Assistant Commissioner for Policy.
 [FR Doc. 06-7969 Filed 9-21-06; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer at (301) 443-1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Stem Cell Therapeutic Outcomes Database—(New)

The Stem Cell Therapeutic and Research Act of 2005 provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Health Resources and Services Administration's (HRSA), Healthcare Systems Bureau (HSB), is establishing the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain record keeping and reporting requirements in order to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. The Act requires the Secretary to contract for the collection and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data will be collected from transplant centers in a manner similar to the data collection activities conducted by The Center for International Blood and Marrow Transplant Research (CIBMTR) and will be used for ongoing analysis of transplant outcomes. HRSA will use the information in order to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation, and to provide the Secretary with an annual report of transplant center-specific survival data.

The estimate of burden is as follows:

Record keeping	Number of responses	Responses per respondent	Total responses	Hours per response	Total burden hours
Baseline Patient/Day of Transplant Data	250	40	8,000	2.25	18,000
Product Receipt/Analysis/Preparation Data	250	40	8,000	1	8,000
100-Day Post-Transplant Data	250	40	8,000	2.25	18,000
6-Month Post Transplant Data	250	28	5,538	2.25	12,460.5
12-Month Post-Transplant Data	250	22	4,308	2.25	9,693
Annual Post-Transplant Data (year two and beyond)	250	40	8,000	2.25	18,000
Death Information	250	25	4,923	0.5	2,461.5
Total	250	46,769	86,615

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: September 15, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. 06–8020 Filed 9–21–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (ACHDGDNC).

Dates and Times: November 2, 2006, 9 a.m. to 5 p.m. November 3, 2006, 8:30 a.m. to 3 p.m.

Place: Hilton Washington Hotel, Georgetown Room, 1919 Connecticut Avenue, NW., Washington, DC 20009.

Status: The meeting will be open to the public with attendance limited to space availability.

Purpose: The Committee was established specifically to advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders. The Committee also provides advice and recommendations concerning the grants and projects authorized under the Heritable Disorders Program and technical information to develop policies and priorities for this program. The Heritable Disorders Program was established to enhance the ability of State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders.

Agenda: The meeting will include a report on the nomination process for newborn screening candidate conditions, as well as the continued work and reports by the Committee's subcommittees on laboratory standards and procedures, follow-up and treatment, and education and training.

Proposed agenda items are subject to change.

Time will be provided each day for public comment. Individuals who wish to provide public comment or who plan to attend the

meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACHDGDNC Executive Secretary, Michele A. Lloyd-Puryear, M.D., Ph.D. (contact information provided below).

For Further Information Contact: Anyone interested in obtaining a roster of members or other relevant information should write or contact Michele A. Lloyd-Puryear, M.D., Ph.D., Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–1080. Information on the Advisory Committee is available at <http://mchb.hrsa.gov/programs/genetics/committee>.

Dated: September 15, 2006.

Cheryl R. Dammons,

Director, Division of Policy Review and Coordination.

[FR Doc. 06–8018 Filed 9–21–06; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting of the Advisory Committee on Organ Transplantation

AGENCY: Health Resources and Services Administration, HHS.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the eleventh meeting of the Advisory Committee on Organ Transplantation (ACOT), Department of Health and Human Services (HHS). The meeting will be held from approximately 9 a.m. to 5:30 p.m. on November 2, 2006, and from 9 a.m. to 3 p.m. on November 3, 2006, at the Bethesda DoubleTree Hotel, 8120 Wisconsin Avenue, Bethesda, MD 20814. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are

serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

ACOT will hear presentations on the revised Uniform Anatomical Gift Act; the United Network for Organ Sharing Department of Evaluation and Quality; the Hollywood Health and Society Project; new developments in immunosuppression; and payment for organs.

The draft meeting agenda will be available on October 16 on the Department's donation Web site at <http://www.organdonor.gov/acot.html>.

A registration form will be available on October 2 on the Department's donation Web site at <http://www.organdonor.gov/acot.html>. The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234–1701. Individuals without access to the Internet who wish to register may call Sowjanya Kotakonda with PSA at (703) 234–1737. Registration can also be completed electronically at <http://www.psava.com/dot/acot2006/>. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the ACOT Executive Secretary, Remy Aronoff, in advance of the meeting. Mr. Aronoff may be reached by telephone at 301–443–3264, e-mail: Remy.Aronoff@hrsa.hhs.gov or in writing at the address provided below. Management and support services for ACOT functions are provided by the Division of Transplantation, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Building, Room 12C–06, Rockville, Maryland 20857; telephone number 301–443–7577.

After the presentations and ACOT discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public