

hazard reduction strategies that minimize risk in the MRI environment.

Through this effort, FDA and stakeholder groups will take steps to promote the safe use of MRI by increasing awareness of safety issues that may occur in the MRI environment and by identifying regulatory, policy and system-oriented solutions to mitigate risk. FDA can advance these goals by collaborating with medical device and health care industries, and the healthcare provider and consumer communities.

## II. Topics for Discussion at the Public Workshop

The public workshop will be organized to discuss the following topic areas:

### A. General MRI Safety

- Multiple professional organizations, patient safety groups and accrediting bodies, i.e. the American College of Radiology (ACR), the International Society for Magnetic Resonance in Medicine (ISMRM), Emergency Care Research Institute (ECRI Institute), and the Joint Commission (TJC), have sponsored MRI safety conferences and published recommendations and strategies for MRI safe practices. FDA would like public comment on the extent these practices have been adopted, and if they have not, what are the reasons for not adopting/ implementing these practices, and given that FDA does not regulate the practice of medicine, what can FDA do to improve adoption.

- FDA would like public comment on the policies and procedures individual sites have in place governing the use of non-implanted medical devices entering the MRI suite.

### B. Ferromagnetic Detectors (FD)

- FDA would like public comment on the user experience with ferromagnetic detectors (FD) and to gather information on whether these devices improve MRI safety. FDA would also like to understand any drawbacks to the use of FD and other risk/benefit/cost considerations by sites that are considering adopting the technology.

- FDA would also like public comment on the reasons for not adopting/implementing use of FD.

### C. Scanning Subjects Known To Have Medical Implants

- FDA would like public comment on the clinical scenario and the challenges (technical and otherwise) involved in the scanning of patients with implanted medical devices. FDA is particularly interested in hearing how individual

sites make the decision of whether or not to scan a patient with an implanted medical device, or any special monitoring of the patient's condition or the implanted medical device's performance.

- Safely scanning patients with implanted medical devices requires coordination between any MRI system and the implanted medical device, as not all implants can be safely scanned in all MRI systems. Current FDA labeling requirements for "MR Conditional" implants include the static magnetic field, maximum spatial gradient, and maximum specific absorption rate (SAR) under which the device can be safely scanned. FDA would like public comment on whether this information is or is not sufficient to make an informed decision about whether it is safe or is not safe to scan a patient.

- FDA would like public comment on the challenges sites face in obtaining the specific conditions of use (i.e. the "MR Conditional" labeling) for medical implants and what is done when information about MRI compatibility is unavailable. For example, when presented with a patient with an implanted medical device, how is the identity of the implant definitively determined and how is MR labeling information obtained to make a decision of whether or not to scan the patient? If "MR Conditional" labeling cannot be found or the device cannot be identified, how is the decision of whether or not to scan a patient determined?

### D. The Impact of Innovation on MRI Safety Concerns

- FDA would like comment from stakeholders on future technical developments and changing clinical practice scenarios that may affect the safety profile of MRI.

## III. Transcripts

As soon as the transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857. A link to the transcripts will also be available on the Internet at <http://www.fda.gov/MedicalDevices/>

*NewsEvents/WorkshopsConferences/default.htm* (select this public workshop from the posted events list), approximately 45 days after the public workshop.

Dated: September 13, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

#### Proposed Project: National Survey of Organ Donation Attitudes and Practices (OMB No. 0915-New)

The Division of Transplantation (DoT), Healthcare Systems Bureau, Health Resources and Services Administration (HRSA), is planning to conduct a telephone survey of public knowledge, perceptions, opinion, and behaviors related to organ donation. Two key missions of the DoT are (1) to provide oversight for the Organ Procurement and Transplantation Network and policy development related to organ donation and transplantation, and (2) to implement efforts to increase public knowledge, attitudes, and behaviors related to organ donation. With a constantly growing deficit between the number of Americans needing donor organs (currently nearly 112,000) and the annual number of donors (14,505 in 2010), increasing the American public's willingness to donate becomes increasingly critical. Effective education and outreach campaigns need to be based on knowledge of the public's

attitudes and perceptions about, and perceived impediments to, organ donation. Two national surveys using nearly identical survey instruments to identify public views and behaviors related to organ donation were conducted in 1993 and 2005.

The proposed study will identify current organ donation views and practices of the American public and various population subgroups using a survey instrument similar to the two earlier studies in order to track changes over time. It will measure issues such as public knowledge about and attitudes toward organ donation, public commitment to or willingness to donate, impediments to public willingness to

donate, and attitudes toward living donation, donation practices, policy issues, allocation policy, presumed consent, and financial incentives for donation. Demographic information also will be collected. The randomly drawn sample will consist of 3,250 adults (age 18 and over), including an oversample of Asians, Hispanics, African Americans, and Native Americans, and will be geographically representative of the United States. The survey instrument will be administered in English and Spanish languages through computer-assisted telephone interviews.

In addition to being useful to the DoT, especially in its donation outreach initiatives, results of this survey also

will be of assistance to the donation and transplant community, DoT grantees and other research efforts, and to the Secretary's Advisory Committee on Organ Transplantation (ACOT) as it fulfills its charge to advise the Secretary of Health and Human Services on the numerous and often controversial issues related to donation and transplantation. In its first meeting, the ACOT suggested such a survey to gather information to inform both public education efforts and policy decisions on the issue of organ donation.

The annual estimate of burden is as follows:

Instrument	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Telephone survey .....	3,250	1	3,250	0.3	975
Total .....	3,250	1	3,250	0.3	975

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov) or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: September 13, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

[FR Doc. 2011-24121 Filed 9-19-11; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**National Advisory Council on Migrant Health; 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:* National Advisory Council on Migrant Health.

*Dates and Times:* November 8, 2011, 8:30 a.m. to 5 p.m. November 9, 2011, 8:30 a.m. to 5 p.m.

*Place:* Hotel Albuquerque at Old Town, 800 Rio Grande Boulevard, Northwest, Albuquerque, New Mexico 87104, Telephone: 505-843-6300, Fax: 505-842-8426.

*Status:* The meeting will be open to the public.

*Purpose:* The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families and to formulate recommendations for the Secretary of Health and Human Services.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworker health at the local and national levels.

In addition, the Council will be holding a public hearing at which migrant farmworkers, community leaders, and providers will have the opportunity to testify before the Council regarding matters that affect the health of migrant farmworkers. The hearing is scheduled for Tuesday, November 8, 2011, from 1 p.m. to 4 p.m., at the Hotel Albuquerque at Old Town.

The Council meeting is being held in conjunction with the Midwest Stream Farmworker Health Forum sponsored by the National Center for Farmworker Health, which is being held in Albuquerque, New Mexico, November 10-12, 2011.

Agenda items are subject to change as priorities indicate.

*For Further Information Contact:* Gladys Cate, Office of Special Population Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Room 15-62, Maryland 20857; telephone (301) 594-0367.

Dated: September 13, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shriver National Institute of Child Health & Human Development Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Child Health and Human Development Special Emphasis Panel; Transition to Fatherhood: Fatherhood Trajectories and Consequences for Men.

*Date:* October 6, 2011.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Carla T. Walls, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health And Human Development, NIH, 6100 Executive