requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm or http://www.regulations.gov*.

Dated: February 6, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2012–3096 Filed 2–9–12; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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 meetings.

The meetings 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel Multi-Center Study of Tamsulosin for Ureteral Stones in the Emergency Department.

*Date:* March 26, 2012.

*Time:* 11 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8895, *rushingp@extra.niddk.nih.gov*.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Collaborative Interdisciplinary Team Science in NIDDK Research Areas (R24)—Barrett's Oesophagus and IBD.

*Date:* March 30, 2012.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov*.

*Name of Committee:* National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; LRP Reviews.

*Date:* March 30, 2012.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* D.G. Patel, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 756, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7682, *pateldg@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 6, 2012.

**Jennifer S. Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2012–3153 Filed 2–9–12; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Global Rare Diseases Patient Registry and Data Repository (GRDR) Notice and Request for Information (RFI)

**SUMMARY:** The Office of Rare Diseases Research (ORDR), an organizational component of the National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH), is inviting patient organizations without a patient registry and those with established patient registries to be considered for participation in a two-year pilot project to establish the Global Rare Diseases Patient Registry and Data Repository (GRDR), and to submit background information about their organization for consideration by the project's selection committee. More information may be found at *http://rarediseases.info.nih.gov/GRDR.*

The goal of the GRDR is to enable data analysis within and across many rare diseases and to facilitate clinical trials and other studies. An interface will be developed to accept de-identified patient data from existing patient registries to promote data sharing.

The GRDR will serve rare disease patients and their advocacy groups seeking help and information. It will also serve investigators conducting research, clinicians treating patients, epidemiologists analyzing disease data, and investigators seeking patients for new clinical trials and initiating natural history studies.

A researcher portal will allow authorized researchers to gain access to de-identified patient data to identify potential study candidates and to learn about the natural history of disease. Because the GRDR will contain only de-identified data, investigators will recruit prospective participants through the patient organizations. Direct contact with the prospective participants would occur only after the patient has granted permission.

In order to aggregate data from different registries to facilitate pan-disease analysis, data must be captured and collected in a standardized manner. Use of Common Data Elements (CDEs) facilitates the standardization of data collection and allows for harmonization, sharing, and exchange of information across registries. ORDR has developed a set of minimal CDEs that have been accepted and adopted by numerous national and international patient advocacy groups and professional organizations globally. To develop organ systems and disease specific CDEs, ORDR is coordinating and collaborating with the various NIH components, patient advocacy groups, and professional organizations that already have developed similar CDEs or are in the process of developing them.

The purpose of this pilot program is to test the different functionalities of the GRDR. A total of 24 organizations will be selected. Twelve organizations with established registries and 12 organizations that have no registry will be chosen to participate.