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.

The 12 patient organizations without patient registries will be selected to assist in testing the GRDR and in the implementation of the ORDR Common Data Elements (CDEs) when establishing new patient registries. These organizations will participate in the development and promotion of a new patient registry for their rare disease. The GRDR program will fund the development and hosting of the registry during the pilot program. Thereafter, the patient registry is expected to be self-sustainable.

The 12 established patient registries will be selected to integrate their de-identified data into the GRDR to evaluate the data mapping and data export/import processes. The GRDR team will assist these patient organizations in mapping their existing registry data to the CDEs. Participating organizations (with patient registries) must have a means to export their de-identified registry data into a specified data format that will facilitate loading the data into the GRDR on a regular basis. A HIPAA compliant server infrastructure and secure file transmission protocols will be implemented to protect patient privacy. The Global Unique Identifiers (GUID) program developed by the National Database for Autism Research (NDAR) will be used to assign unique patient identifiers. This will help eliminate duplication and enable integration with tissue repositories in a de-identified manner. Participating registries will gain access to all collected patient and biospecimen information to stimulate collaboration to accelerate the development of therapeutics, drugs and hopefully cures for the rare diseases.

During the two-year pilot project, a web-based template will be developed to assist other patient groups that wish to establish their own patient registry. A HIPAA compliant hosting facility will provide a secure environment to protect properly consented de-identified patient information.

Background: The GRDR project is a follow-up to the January 2010 ORDR workshop, ''Advancing Rare Disease Research: the Intersection of Patient Registries, Biospecimen Repositories, and Clinical Data.'' Information on this workshop can be found at http://rarediseases.info.nih.gov/PATIENT_REGISTRIES_WORKSHOP/.

The ORDR, in collaboration with PatientCrossroads, Children's Hospital of Philadelphia, and Medscape, launched a pilot project to establish the GRDR to collect patient clinical information without personal identifiers (de-identified information compiled by the federal common rule and HIPPA regulations) for research.

The PatientCrossroads registry platform, utilized by many rare disease organizations to collect patient self-report medical history and diagnostic testing information, will be deployed for the 12 new registries. PatientCrossroads will provide all technology, hosting, and management of the GRDR program. Medical oversight and recommendations of CDEs for each participating registry will be provided by Children's Hospital of Philadelphia. Medscape will provide input and recommendations on marketing, promotion, Continuing Medical Education (CME) and physician training programs.

Although any given condition is rare and there might be few patients with each disease, the cumulative public health burden of rare diseases is significant, with great unmet medical needs collectively. Because rare diseases are so uncommon, no single institution, and in many cases no single country, has sufficient numbers of patients to conduct clinical trials and translational research studies. Geographic dispersion of patients has been a major impediment to patient recruitment into clinical trials.

Best estimates are that fewer than 20% of rare diseases have patient registries. Most of these are operated by patients' organizations or academic researchers. Most registries are country-specific, but there are some international efforts. For registry developers and those responsible for providing oversight and maintenance, there is a need for an established forum to share experiences. Each time a new registry is developed, it is started from scratch using a different platform with no ability to ''talk'' to other registries, share data, and exchange information. There is a consensus in the community that there is a need for an infrastructure for rare disease patient registries.

In recognition of both barriers and public health imperatives to advance knowledge regarding optimal methods of improving health and well-being of rare disease patients, the ORDR has embarked on an initiative to establish an infrastructure for an Internet-based, federated global patient registry with the capability to link to patient clinical information to biospecimens. This global registry will develop or utilize existing common data elements, standards, and vocabularies that would provide a forum for exchange of data, experiences, and knowledge. The future goal is to create a partnership with different sectors of the community including advocacy, research, and industry organizations. This joint effort will reduce the costs of developing and maintaining an international registry for many of the rare disease patient advocacy groups.

A federated model requires that individual registries are developed, and those already in existence are enhanced to ensure that they are interoperable—i.e., data are defined in the same way, use the same standards, and use the same vocabulary. Similar to the open-source software community, ORDR believes that an open-science community for rare diseases is needed. Such a community would ensure that the conditions necessary for data exchange are addressed by defining common data-sets, data standards, and vocabulary, and provide a forum for exchange of experience and knowledge. The goal is to increase data compatibility, broaden accessibility, and collect patient data and biospecimen information to accelerate the development of therapeutics, drugs, and cures for the rare diseases.

This global rare disease registry infrastructure will draw new interest in rare diseases from academic researchers and the pharmaceutical industry because it will assist in the recruitment of patient participants much faster and at much lower cost and enable the design of more effective clinical trials. Going forward, ORDR expects the GRDR to sustain itself as a public-private partnership.

Because of the importance of biospecimens as research tool to accelerate research and better facilitate the understanding of the underlying pathogenesis of rare diseases, GRDR will have the capability of linking patient data and medical information to donated biospecimens using a double coded voluntary unique patient identifiers such as the GUID system, which has been developed by National Database for Autism Research (NDAR), a project which recently was chosen as finalist in the HHSinnovates program. For more information, go to http://jamia.bmjjournals.com/content/17/6/689.full.pdf. The link to biospecimens will be interfaced with the patient registry-associated biorepositories and with the Rare Disease Human Biospecimens/Repositories (RD–HUB), and found at http://biospecimens.ordr.info.nih.gov/.

Information Requested: Patient advocacy organizations without a patient registry and those with established patient registries that wish to be considered by the selection committee for the GRDR pilot project are encouraged to submit contact and background information about their

organization and the rare disease(s) or condition(s) that they represent. The information provided should address the eligibility and selection criteria below.

Organizations must meet the following eligibility criteria to submit a response.

Eligibility Criteria

a. Represent a rare disease/condition as defined by law (affects fewer than 200,000 individuals in the United States).

b. Maintain a hard copy or an electronic email list of patients affected by the specific disease/condition.

c. Be willing to seek agreement by their members to share their de-identified data with the GRDR, other databases, and the research community as part of an Institutional Review Board (IRB) approved informed consent.

d. Agree to adopt the ORDR Common Data Elements and elements of the ORDR common consent form template.

e. Have a scientific or medical advisory board to assist on ethical issues of privacy human subject protection, data coding and transmission, as well as issues related to data standards, curation, coding and transmission, scientific issues related to research proposals, and other issues as needed.

Organizations that meet the eligibility criteria are asked to provide a short description of how they will address the selection criteria which are listed below. Please note that the response for each criterion has a word limit and each criterion will be weighed accordingly as indicated.

1. Have a well-defined, credible vision and purpose for establishing a registry. (300 words, weigh 30 points)

2. Have a good plan to sustain the newly established or already existing registry beyond the 2 years of the pilot project. (150 words, weigh 20 points)

3. Have, or plan to develop, a feasible system to capture patient updates of their medical information as well as updates of patients' medical information from healthcare providers. (150 words, weigh 10 points)

4. Agree to assist in the translation of their registry into multiple languages as needed to facilitate the inclusion of non-English speaking participants and appear to be capable of providing such assistance. The GRDR will use English only. (150 words, weigh 10 points)

5. Have a good plan for data verification by an individual with a medical background. (150 words, weigh 10 points)

6. Are engaged or willing to collaborate with other organizations serving the same or related diseases. (150 words, weigh 10 points)

7. Have a developed means of communication with the public, e.g. electronic mailing lists, newsletter, Web site and other social networking media. (150 words, weigh 5 points)

8. Have, or plan for, support to navigate both future registry activities and community outreach. (150 words, weigh 5 points)

The selection committee, comprised of individuals with medical background, patient advocacy leaders, and others, will rank the submissions from the patient groups based on the selection criteria. ORDR will make the final selections of the patient groups based on rare disease categories to achieve maximum distribution of the different rare diseases. In addition, an effort will be made to ensure that large and small patient organizations will be included, *i.e.,* half from organizations that represent a rare disease with more than 2,500 patient participants and half from organizations with less than 2,500 patient participants (based on hard copy or the electronic contact list).

This invitation and related background information will be available on the ORDR Web site http://rarediseases.info.nih.gov/GRDR and distributed through various communication tools. Selected organizations will be notified and their names will be posted on the ORDR Web site.

How To Submit a Response: Reponses will be accepted for 30 days following publication of this notice. All responses must be submitted via the Web site at: http://rarediseases.info.nih.gov/GRDR. An online form will be available to submit the requested information. Submitters are requested not to exceed the number of characters indicated on the online form. Submitted information will not be considered confidential although each submission will be stored using a login and a password.

This Request for Information (RFI) notice provides information and selection criteria only. It should not be construed as a solicitation or as an obligation on the part of the Federal Government, the NIH, or the ORDR. The ORDR does not intend to make any awards to pay for the preparation of any information submitted or for the Government's use of such information.

ORDR will use the information submitted in response to this RFI at its discretion and will not provide comments to any responder's submission. However, names of patient organizations that are selected in response to this RFI will be posted on the Web site at: http://rarediseases.info.nih.gov/GRDR. The ORDR may contact any responder for the sole purpose of enhancing the ORDR's understanding of the RFI submission. Respondents will receive an automated email confirmation acknowledging receipt of their response, but will not receive individualized feedback. No proprietary, classified, confidential, or sensitive information should be included in your response.

DATES: Responses to this notice must be received on or before 30 days following publication of this notice.

FOR FURTHER INFORMATION CONTACT: Yaffa Rubinstein, Ph.D., Director of Patient Resources for Clinical and Translational Research, Office of Rare Diseases Research, National Institutes of Health, 6100 Executive Boulevard, Room 3A07, Rockville, MD 20892–7518, telephone 301–402–4338, Fax 301–480–9655, Web site *http://rarediseases.info.nih.gov.*

Dated: February 1, 2012.

Thomas Insel,

Acting Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health.

[FR Doc. 2012–3155 Filed 2–9–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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