

in the Program Performance Report will be used (1) in the preparation of the biennial Report to the President, the Congress, and the National Council on

Disabilities and (2) to provide a national perspective on program accomplishments and continuing challenges. This information will also

be used to comply with requirements in the Government Performance and Results Act of 1993.

*Respondents:* State Governments.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Council on Developmental Disabilities Program Performance Report ..	55	1	138	7,590
Estimated Total Annual Burden Hours: .....	.....	.....	.....	7,590

#### *Additional Information:*

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: November 24, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E8-28249 Filed 11-28-08; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0576]

#### **Guidance for Sponsors, Clinical Investigators, and IRBs; Data Retention When Subjects Withdraw From FDA-Regulated Clinical Trials; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the

availability of a guidance entitled "Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials." This guidance clarifies FDA's position that it is critical that data be retained from trial participants who decide to discontinue participation in a clinical study of an investigational product, who are withdrawn by their legally authorized representative, as applicable, or who were discontinued from participation by the clinical investigator. The guidance will be of interest especially to sponsors, clinical investigators, and members of investigational review boards (IRBs). **DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sara F. Goldkind, Office of Science and Health Coordination/Good Clinical Practice Program (HF-34), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301-827-3340.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a guidance for sponsors, clinical investigators, and IRBs entitled "Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials." This guidance clarifies FDA's long-standing position that it is critical that data be retained from individuals who decide to discontinue participation in a clinical study of an investigational product, or who were discontinued from participation by the clinical investigator.

FDA developed this guidance in response to questions from sponsors, clinical investigators, and members of IRBs about previously collected data from subjects who withdraw or are withdrawn from clinical investigations. This guidance describes the regulatory and statutory basis for FDA's position, as well as the supporting ethical and quality standards, and outlines key points regarding the withdrawal of subjects from a clinical investigation. Because data resulting from these clinical investigations is used to support research applications and new product approvals, it is critical that FDA have a complete and accurate data set. If data were to be removed from the study database, the scientific validity of the data and thus FDA's analysis of it could be jeopardized potentially compromising the agency's ability to safeguard the public health.

This Level 1 guidance is being issued for immediate implementation to prevent the potential loss of important clinical trial data. This approach is consistent with FDA's good guidance practices regulation (21 CFR 10.115). If comments are received on this Level 1 guidance, FDA will review the comments and revise the guidance if appropriate. This guidance represents the agency's long-standing policy and current thinking on the retention of data when subjects withdraw from FDA-regulated clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. Interested persons may submit written comments on the guidance to the Division of Dockets Management (see **ADDRESSES**).

Elsewhere in this issue of the **Federal Register**, the Office of Human Research Protections (OHRP) is announcing the availability of a draft guidance document entitled "Guidance on Important Considerations for When

Participation of Human Subjects in Research Is Discontinued.” FDA believes the interpretation provided in its guidance is consistent with that provided in OHRP’s draft guidance document.

## II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information under the investigational new drug regulation have been approved under OMB Control No. 0910–0014. The collections of information under the investigational device exemptions regulation have been approved under OMB Control No. 0910–0078.

## III. 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 Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

## IV. Electronic Access

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

Dated: November 5, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E8–28387 Filed 11–28–08; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

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 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:* Center for Scientific Review Special Emphasis Panel Neural Degeneration, Biophysics and Differentiation.

*Date:* December 8, 2008.

*Time:* 11 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mary Custer, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892–7850, (301) 435–1164, [custerm@csr.nih.gov](mailto:custerm@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Cartilage/Musculoskeletal Soft Tissue Biology and Mechanics.

*Date:* December 8, 2008.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* John P. Holden, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301–496–8551, [holdenjo@csr.nih.gov](mailto:holdenjo@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Chemoprevention.

*Date:* December 8, 2008.

*Time:* 1 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Zhiqiang Zou, MD, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6190, MSC 7804, Bethesda, MD 20892, 301–451–0132, [zouzhiq@csr.nih.gov](mailto:zouzhiq@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Member Conflict: Oncology.

*Date:* December 9, 2008.

*Time:* 3 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mary Bell, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7804, Bethesda, MD 20892, 301–451–8754, [bellmar@csr.nih.gov](mailto:bellmar@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel LIRR and RIBT Member Conflicts.

*Date:* December 16–17, 2008.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* George M. Barnas, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2180, MSC 7818, Bethesda, MD 20892, 301–435–0696, [barnasg@csr.nih.gov](mailto:barnasg@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel Neurogenetics, Neurodevelopment and Neurological Disorders.

*Date:* December 17, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Vilen A. Movsesyan, PhD., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4040M, MSC 7806, Bethesda, MD 20892, 301–402–7278, [movsesyanv@csr.nih.gov](mailto:movsesyanv@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)