

Management and Budget (OMB) control number 0910-0032.

III. Significance of Guidance

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." Because guidance documents are not binding, mandatory words such as "must," "shall," and "will" in the original VICH document have been substituted with "should." Similarly, words such as "require" or "requirement" have been replaced by "recommend" or "recommendation" as appropriate to the context.

The VICH guidance (#159) is consistent with the agency's current thinking on the subject matter. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

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.

V. Electronic Access

Copies of the guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish a Microbiological ADI" (VICH GL-36) may be obtained on the Internet from the CVM home page at <http://www.fda.gov/cvm>.

Dated: February 3, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-2643 Filed 2-10-05; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Cancer Institute, Subcommittee 1—Clinical Sciences and Epidemiology.

Date: March 7-8, 2005.

Open: March 7, 2005, 8:30 a.m. to 10:45 a.m.

Agenda: Joint Session of NCI, Board of Scientific Advisors and BSC Subcommittees.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 10, Bethesda, MD 20892.

Closed: March 7, 2005, 10:45 a.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, National Cancer Institute, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

Closed: March 8, 2005, 8 a.m. to 12:45 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Holiday Inn Bethesda, Versailles IV, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Brian E. Wojcik, PhD, Senior Review Administrator, Institute Review Office, Office of the Director, National Cancer Institute, 6116 Executive Boulevard, Room 2114, Bethesda, MD 20892, (301) 496-7628, wojcikb@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-2645 Filed 2-10-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

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 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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; CA05-018: CISNET.

Date: March 4, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Bethesda North, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Administrator, Special Review and Logistics Branch,

Division Of Extramural Activities, National Cancer Institute, National Institutes Of Health, 6116 Executive Boulevard, Room 8057, MSC 8329, Bethesda, MD 20892-8329, (301) 496-7421, kerwinm@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-2646 Filed 2-10-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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: National Center for Research Resources Special Emphasis Panel.
Date: March 16, 2005.

Time: 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, Rockville; 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Harold L. Watson, PhD, Scientific Review Administrator, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd., Room 1078, Bethesda, MD 20892, (301) 435-0813, watsonh@mail.nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel.
Date: April 4, 2005.

Time: 8 a.m. to Adjournment.

Agenda: To review and evaluate grant applications.

Place: NCRR, OR, 6701 Democracy Blvd., Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Harold L. Watson, PhD, Scientific Review Administrator, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Boulevard, 1 Democracy Plaza, Room 1070, MSC 4874, Bethesda, MD 20892-4874, (301) 435-0813, watsonh@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: February 4, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-2647 Filed 2-10-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Meeting

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 meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Center for Research Resources Initial Review Group, Research Centers in Minority Institutions Review Committee.

Date: March 15, 2005.

Open: 8 a.m. to 9 a.m.

Agenda: To discuss program planning and other matters.

Place: Double Tree Hotel, Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Closed: 9 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Harold L. Watson, PhD, Scientific Review Administrator, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Boulevard, Room 1070, MSC 4874, Bethesda, MD 20892-4874. (301) 435-0813. watsonh@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: February 4, 2005.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-2650 Filed 2-10-05; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; 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: National Center for Research Resources Special Emphasis Panel, Scientific and Technical Review Board.

Date: March 24, 2005.

Time: 9 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Office of Review, Bethesda, MD 20892. (Telephone conference call.)

Contact Person: Sheryl K. Brining, PhD, Director, Office of Review, NCRR, National Institutes of Health, 6701 Democracy Blvd, 1 Democracy Plaza, Room 1074, MSC 4874, Bethesda, MD 20892-4874. (301) 435-0809. sb44k@nih.gov.

Name of Committee: National Center for Research Resources Special Emphasis Panel.
Date: May 24-25, 2005.

Closed: May 24, 2005, 8 a.m. to adjournment.

Agenda: To review and evaluate grant applications.

Place: Double Tree Hotel, Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Carol Lambert, PhD, Scientific Review Administrator, Office of