

on this proposed clinical investigation. In particular, comments are solicited on the following questions: (1) What are the potential benefits, if any, to the subjects and to children in general; (2) what are the types and degrees of risk that this research presents to the subjects; (3) are the risks to the subjects reasonable in relation to the anticipated benefits, and is the research likely to result in knowledge that can be generalized about the subjects' disorder or condition; and (4) does the research present a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

To facilitate the public review and comment process, FDA has established a public docket and placed in that docket information relating to the proposed clinical investigation, including the following items: Correspondence from the University of Chicago referring the proposed research protocol to HHS for consideration under 45 CFR 46.407, correspondence from FDA and OHRP to the University of Chicago regarding the proposed protocol, the research protocol, NIH's grant funding the protocol, IRB's deliberations on the proposed research, and the parental permission documents. Electronic copies of these documents can be viewed at PAC's Docket Web site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to Pediatric Ethics Subcommittee of PAC meetings.) These materials are also available on OHRP's Web site at <http://www.hhs.gov/ohrp/children/>. (FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

All written comments concerning this proposed research should be submitted to FDA's Division of Dockets Management under 21 CFR 10.20, no later than 4:30 p.m. on Tuesday, November 1, 2005. The background materials and received comments may be viewed on FDA's Web site at <http://www.fda.gov/ohrms/dockets/05n0404/05n0404.htm> or may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. The background materials may also be viewed on OHRP's Web site at <http://www.hhs.gov/ohrp/children/>. (FDA has verified the Web site address but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Dated: October 3, 2005.

Jason D. Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. 05-20301 Filed 10-5-05; 11:25 am]

BILLING CODE 4160-01-S

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 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 Cancer Institute Initial Review Group. Subcommittee F—Manpower & Training, NCI-F Initial Review of Manpower and Training Grants.

Date: October 25–26, 2005.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Crystal Gateway, 1700 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Lynn M. Amende, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8105, Bethesda, MD 20892, 301-451-4759, amendel@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: September 27, 2005.

Anthony M. Coelho, Jr.,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 05-20234 Filed 10-6-05; 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 a meeting of the Board of Scientific Counselors, National Cancer Institute.

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 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 Clinical Sciences and Epidemiology.

Date: November 7, 2005.

Time: 9 a.m. to 3 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 10, Bethesda, MD 20892.

Time: 7 p.m. to 11 p.m.

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

Place: Holiday Inn Select Bethesda, Versailles I, 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.

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)