

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Sally Hojvat, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496.

#### **SUPPLEMENTARY INFORMATION:**

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

Under FDA's current regulations governing the conduct of *in vitro* diagnostic (IVD) studies, the definition of human subject includes human specimens (see 21 CFR 812.3(p)). Because these regulations require informed consent for all FDA-regulated human subject research, except in limited circumstances specified in FDA regulations, informed consent is required before specimens can be used in FDA-regulated research (see 21 CFR part 50). This aspect of FDA's human subject protection regulations has created confusion and difficulty for persons developing IVDs. Many clinicians, research hospitals, and companies have viewed the requirement for informed consent for IVD studies using leftover specimens to be unnecessary to protect human subjects and to be overly burdensome and costly.

FDA has recently focused on unnecessary obstacles to medical product development. The agency has received comments from trade associations and research institutions that identify the challenge of obtaining informed consent for the use of leftover specimens as an unnecessary obstacle and expense to investigational efforts.

When leftover specimens are available, it is often difficult, if not impossible, to locate the donor and obtain consent.

The confusion regarding the application of informed consent requirements to IVD studies and concerns about unnecessary obstacles to product development have prompted FDA to issue this guidance document. The agency believes that the policy expressed in this guidance will facilitate product development in a manner consistent with values of human subject protection.

FDA intends that the exercise of enforcement discretion expressed in this guidance document begin immediately. In accordance with FDA's GGP regulation (21 CFR 10.115), you may comment on this guidance at any time. The agency will consider your comments and determine whether to revise the guidance at a later date.

##### **II. Significance of Guidance**

This guidance is being issued consistent with FDA's GGP regulation. The guidance represents the agency's current thinking on this topic. 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 statute and regulations.

##### **III. Electronic Access**

To receive "Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1588 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search

capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

##### **IV. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collection of information in this guidance was approved under the emergency processing provisions of the PRA and was assigned OMB control number 0910-0582.

##### **V. 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.

Dated: April 11, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6-6145 Filed 4-24-06; 8:45 am]

**BILLING CODE 4160-01-S**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Resources and Services Administration**

##### **National Advisory Council on Migrant Health; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* National Advisory Council on Migrant Health.

*Dates and Times:* May 21, 2006, 9 a.m. to 1 p.m. May 21, 2006, 2:30 p.m. to 7:30 p.m. (site visit and public hearing). May 22, 2006, 10 a.m. to 6 p.m.

*Place:* Westin Riverwalk Hotel, 420 West Market Street, San Antonio, Texas 73205. Telephone: (210) 224-6500. Fax: (210) 444-6000.

*Status:* The meeting will be open to the public.

*Purpose:* The purpose of the meeting is to discuss services and issues related to the health of migrant and seasonal farmworkers and their families to be able to formulate recommendations to the Secretary of Health and Human Services. There will also be a site visit and public hearing regarding matters that affect the health of migrant farmworkers.

*Agenda:* The agenda includes an overview of the Council's general business activities. The Council will also hear presentations from experts on farmworker issues, including the status of farmworkers health at the local and national level.

In addition, the Council will be going on a site visit and holding a public hearing at which migrant farmworkers, community leaders, and providers will have the opportunity to testify before the Council regarding matters that affect the health of migrant farmworkers. The site visit and hearing are scheduled for Sunday, May 21, from 2:30 p.m. to 7:30 p.m., at the Community Health Development, Inc., 200 South Evans Street, Uvalde, Texas 78801; telephone (830) 278-5604, extension 200, fax (830) 278-1836.

The Council meeting is being held in conjunction with the National Farmworker Health Conference sponsored by the National Association of Community Health Centers, in San Antonio, Texas, during the same period of time.

Agenda items are subject to change as priorities indicate.

*For Further Information Contact:* Anyone requiring information regarding the Council should contact Gladys Cate, Office of Minority and Special Populations, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Maryland 20857; telephone (301) 594-0367.

Dated: April 19, 2006.

**Tina M. Cheatham,**

*Director, Division of Policy Review and Coordination.*

[FR Doc. E6-6144 Filed 4-24-06; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Alternative Medicine; 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 National Advisory

Council for Complementary and Alternative Medicine (NACCAM) meeting.

The meetings 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.

A portion of the meeting will be closed to the public in accordance with 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 Advisory Council for Complementary and Alternative Medicine.

*Date:* June 8, 2006.

*Closed:* 9 a.m. to 12 p.m.

*Agenda:* Deliberation on grant applications.

*Open:* 1 p.m. to 3:30 p.m.

*Agenda:* Presentations on current and proposed research.

*Place:* National Institutes of Health, 9000 Rockville Pike, Building 31C, 6th Fl., Conference Room 10, Bethesda, MD 20892.

*Contact Person:* Martin H. Goldrosen, PhD., Executive Secretary, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892. (301) 594-2014.

This public comments session is scheduled from 3-3:30 p.m. but could change depending on the actual time spent on each agenda item. Each speaker will be permitted 5 minutes for their presentation. Interested individuals and representatives or organizations are requested to notify Dr. Martin H. Goldrosen, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland, 20892, 301-594-2014, Fax: 301-480-9970. Letters of intent to present comments, along with a brief description of the organization represented, should be received no later than 5 p.m. on May 29, 2006. Anyone representative of an organization may present oral comments. Any person attending the meeting who does not request an opportunity to speak in advance of the meeting may be considered for oral presentation, if time permits, and at the discretion of the Chairperson. In addition, written comments may be submitted to Dr. Martin H. Goldrosen at the address listed above up to ten calendar days (June 18, 2006) following the meeting.

Copies of the meeting agenda and the roster of members will be furnished upon request by contacting Dr. Martin H. Goldrosen, Executive Secretary, NACCAM, National Center for Complementary and Alternative Medicine, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, Maryland 20892, 301-594-2014, Fax 301-480-9970, or via e-mail at [naccames@mail.nih.gov](mailto:naccames@mail.nih.gov).

In the interest of security, NIH has instituted stringent procedures for entrance into the building by nongovernment 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.

Dated: April 17, 2006.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 06-3872 Filed 4-24-06; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Alternative Medicine; 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 Complementary and Alternative Medicine Special Emphasis Panel; Basic Science.

*Date:* June 1-2, 2006.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Dale L. Birkle, PhD, Scientific Review Administrator, Office of Scientific Review, National Center for Complementary and Alternative Medicine, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892. (301) 451-6570. [birkled@mail.nih.gov](mailto:birkled@mail.nih.gov).

*Name of Committee:* National Center for Complementary and Alternative Medicine Special Emphasis Panel; Clinical Research Review.