

For example, HRSA is interested in the public's assessment of the likely impact if OPTN policies concerning issues such as membership designation to receive organs, the retrieval of organs, allocation of organs, data collection and reporting, and OPTN policy compliance oversight were extended to vascularized composite allograft transplants. HRSA seeks feedback concerning whether regulation under the OPTN final rule would be effective in addressing special safety and allocation issues presented by vascularized composite allograft transplants as the field grows. Further, HRSA is interested in the public's assessment as to whether the clinical aspects of transplants of such vascularized composite allografts are more analogous to transplants of organs, as defined currently by the final rule, than to conventional tissue transplantation without surgical revascularization.

Presently, it is HRSA's understanding that these transplants of vascularized composite allografts are done by individual arrangements with local organ procurement organizations (OPOs) to allow retrieval of the needed structure during routine deceased donor organ retrievals. However, some of these vascularized composite allografts, e.g., testes, ovaries, or other endocrine glands, may come from living donors. HRSA is interested in perceived vulnerabilities concerning the current regulatory status of such transplants and the potential benefits of subjecting such transplants to the oversight of the OPTN and HRSA under the final rule.

The Definition of Human Organs Under Section 301 of NOTA

HRSA is also seeking feedback as to whether it should explore rulemaking to add vascularized composite allografts to the definition of human organs covered by section 301 of NOTA, as well as the potential consequences of such an action. Section 301 prohibits the purchase, sale, or other exchange for valuable consideration of human organs for transplantation. Although the statute lists covered human organs, the Secretary is authorized to add to this list through rulemaking. "Human organ," as defined by NOTA and modified by the Secretary, means "the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract." Adding to the definition of human organs covered by section 301 would make transfers of organs meeting the statute's requirements subject to its criminal

sanctions. If, after receiving public comments, HRSA is persuaded that a change to this definition may be appropriate, HRSA may initiate rulemaking setting forth a more specific set of proposals.

Defining Vascularized Composite Allografts

To assist the Secretary in the event that he proposes, through rulemaking, to add vascularized composite allografts to the definition of organs covered by the final rule and/or to the definition of human organs governed by section 301 of NOTA, HRSA seeks feedback from stakeholders and from the public as to how such allografts should be defined. HRSA has identified two potential approaches.

Under the first approach, a regulatory definition could be broad, describing the features of the allografts without listing particular body parts. Under such an approach, the definition might extend to transplants of body parts that are not known to have been performed clinically to date, or even to body parts whose transplantation has not yet been envisioned. HRSA is interested in what elements would need to be included in such a definition in order to be broad enough to cover the universe of intended body parts, but narrow enough to put the public on notice as to which parts meet the regulatory definitions of organs. Shared characteristics that might be included in a regulatory definition could include some or all of the following: (1) A vascularized allograft containing multiple tissue types; (2) recovered from a human donor as an anatomical/structural unit; (3) transplanted into a human recipient as an anatomical/structural unit; (4) minimally manipulated, as defined by FDA in Title 21 CFR 1271.3(f); (5) for homologous use as defined by FDA in Title 21 CFR 1271.3(c); (6) not combined with another article such as a device; (7) used fresh and not cryopreserved; (8) susceptible to ischemia and, therefore, only stored temporarily (e.g., cold storage in preservation medium and intended for implantation into a recipient within hours of the recovery); and (9) susceptible to allograft rejection which requires immunosuppression that may increase infectious disease risk to the recipient. HRSA seeks feedback from the public as to whether some or all of these characteristics describe vascularized composite allografts, which would be included in the definition of organ. HRSA invites feedback on such an approach as well as the particular characteristics listed here and invites suggestions concerning

the advisability of including any additional characteristics.

Under a second alternative, HRSA could propose a definition that lists specific body parts to be added to the definition of organs (e.g., face, hand, etc.). HRSA seeks feedback as to the feasibility of creating such a definition, which body parts should be included in such a definition, and whether such a definition would necessarily exclude certain body parts for which transplantation might be possible, but has not been performed to date (either in the United States or internationally).

Following this comment period and meeting, if HRSA decides to proceed with rulemaking to include vascularized composite allografts in the definition of organ, this decision will be written and published as a Notice of Proposed Rulemaking.

Dated: February 20, 2008.

Elizabeth M. Duke,
Administrator.

[FR Doc. E8-3994 Filed 2-29-08; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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/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, Innovations in Cancer Sample Preparation.

Date: March 20, 2008.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Sherwood Githens, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116

Executive Blvd., Room 8053, Bethesda, MD 20892, 301/435-1822, githenss@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Antibody Array for Cancer Detection.

Date: March 26-27, 2008.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: Sherwood Githens, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8053, Bethesda, MD 20892, 301/435-1822, githenss@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Stem Cells.

Date: March 27, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Irina Gordienko, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Room 7073, Bethesda, MD 20892, 301-594-1566, gordienkoiv@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Portable Energy Balance Review Panel (PEBRP).

Date: April 2, 2008.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 8057, Bethesda, MD 20892-8329, 301-496-7421, kerwinm@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, A web-based tailored health behavior intervention for African American colon cancer.

Date: April 2, 2008.

Open: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: C. Michael Kerwin, PhD, MPH, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 8057, Bethesda, MD 20892-8329, 301-496-7421, kerwinm@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Development of Clinical Mass Spectrometric Immunoassays.

Date: April 3, 2008.

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

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6116 Executive Boulevard, CR 6008, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Sherwood Githens, PhD, Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8053, Bethesda, MD 20892, 301/435-1822, githenss@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Network for Translational Research: Optical Imaging (NTRIOI).

Date: June 2-3, 2008.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC North—Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Kenneth L. Bielat, PhD, Scientific Review Officer, Special Review Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892-8329, 301-496-7576, bielatk@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Prevention Research.

Date: June 17-18, 2008.

Time: 7 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Irina Gordienko, PhD, Scientific Review Officer, Scientific Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6166 Executive Blvd., Rm. 7073, Bethesda, MD 20892, 301-594-1566, gordienkoiv@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 21, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08-906 Filed 2-29-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, April 7, 2008, 8 a.m. to April 7, 5 p.m.,

Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD, 20877 which was published in the **Federal Register** on February 15, 2008, 73FR8886-8887.

This notice is amended to change the name from "Biosensors for Early Cancer Detection & Risk Assessment/Novel & Improved Methods to Measure Cancer Epigenetic Biomarkers" to "Biosensors/Cancer Epigenetic Biomarkers". The meeting is closed to the public.

Dated: February 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 08-908 Filed 2-29-08; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Closing 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 section 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 Eye Institute Special Emphasis Panel, NEI Cooperative Agreement Review.

Date: March 6, 2008.

Time: 9 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Houmam H. Araj, PhD, Scientific Review Administrator, Division of Extramural Research, National Eye Institute, NIH, 5635 Fishers Lane, Suite 1300, Bethesda, MD 20892-9602, 301-451-2020, Haraj@mail.nih.gov.

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

Name of Committee: National Eye Institute Special Emphasis Panel, NEI Cooperative Agreement Review.

Date: March 20, 2008.

Time: 12 p.m. to 1 p.m.

Agenda: To review and evaluate grant applications.