

## II. Agenda

The purpose of the public workshop is to discuss the development and implementation of a rational, standardized approach for conducting feasibility trials (i.e., ablate and resect trials) examining thermal ablation of breast cancer as part of the treatment care path for patients with breast cancer. Representatives from various areas involved with the development, testing, and use of thermal ablation devices for breast cancer have been invited. There will be focused sessions, addressing the key issues of breast cancer thermal ablation treatment related to imaging, pathology, operative resection and axillary staging, chemotherapy and radiation therapy.

Participation in the workshop is open to both invited participants and audience members. The invited participants include medical experts from various specialties involved in the care of patients with breast cancer and use of thermal ablation devices. Invited participants will have completed a work assignment in advance of the public workshop in order to optimize the time spent during the public workshop. Audience participation is open to all who are interested in clinical trials for local treatment of breast cancer by thermal ablation and will be scheduled throughout the sessions.

The agenda for this public workshop is available on the Internet at <http://www.blsmmeetings.net/2008ThermalAblationWorkshop>.

## III. Registration

Those interested in attending may register online at <http://www.blsmmeetings.net/2008ThermalAblationWorkshop>. There is no registration fee to attend the public workshop, however all participants must submit a registration form. Space is limited, so please submit your registration early to reserve a space. Registrations will be accepted through August 30, 2008; however, onsite registration will be permitted on a space-available basis.

Persons without Internet access may call Paula Gumb at 301-577-0244, ext. 25 by September 12, 2008, to register for onsite workshop attendance.

## IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at either <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm> or <http://www.blsmmeetings.net/2008ThermalAblationWorkshop>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug

Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: July 11, 2008.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood 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 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Ancillary Studies in Clinical Trials.

*Date:* August 14, 2008.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Rd., Bethesda, MD 20814.

*Contact Person:* Chang Sook Kim, PhD, Scientific Review Officer, Review Branch, DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190 Bethesda, MD 20892, 301-435-0287, [carolko@mail.nih.gov](mailto:carolko@mail.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel; Research Projects in Lung Diseases.

*Date:* August 14, 2008.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Keith A. Mintzer, PhD, Scientific Review Officer, Review Branch/

DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, 301-435-0280, [mintzerk@nhlbi.nih.gov](mailto:mintzerk@nhlbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 11, 2008.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Child Health and Human Development; 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 Institute of Child Health and Human Development Special Emphasis Panel; "Aging In Adults With Down Syndrome".

*Date:* August 14, 2008

*Time:* 3:30 p.m. to 4:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6100 Executive Boulevard, Room 5B01, Rockville, MD 20852, (Telephone Conference Call).

*Contact Person:* Norman Chang, PhD., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5b01, Bethesda, MD 20892, (301) 496-1485, [changn@mail.nih.gov](mailto:changn@mail.nih.gov).

*Name of Committee:* National Institute of Child Health and Human Development Special Emphasis Panel; "Changes In Functioning Among Mentally Retarded Adults".

*Date:* August 14, 2008.

*Time:* 12 p.m. to 3 p.m.