

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting of the Osteoarthritis Initiative—A Public-private Research Collaboration

Notice is hereby given of the Meeting The Osteoarthritis Initiative—A Public-Private Research Collaboration, February 28–29, 2000, to be held at the Lister Hill Auditorium, NIH Campus, Bethesda, Maryland 20892. This meeting will be open to the public from 8 a.m. to 5 p.m. on both days.

This meeting is being organized by several NIH Institutes and Centers, the FDA, and numerous pharmaceutical and biotechnology companies who have formed a consortium to develop and support a project that will enhance and facilitate the development of clinical interventions for osteoarthritis. The development and testing of treatments for osteoarthritis through clinical trials are now limited because good biological markers to serve as surrogates for disease endpoints are not available. This consortium was formed in response to a 1998, NIH-wide initiative from Dr. Harold Varmus to foster investigations that utilize fundamental knowledge and laboratory technologies to develop surrogate biomarkers of disease. In all areas of medicine there has been an enormous growth in the identification of potential targets for disease modification. Without the tools for rapid and inexpensive testing of potential targets, the development of new drugs will continue to be limited. Osteoarthritis presents great scientific opportunity and public need.

The consortium that has resulted from meetings of an Osteoarthritis Initiative Steering Group is exploring the options for government and industry to cosponsor, as a public-private consortium, the establishment of a research infrastructure to develop and evaluate biomarkers for osteoarthritis. Summaries of the meetings held can be found at <http://www.nih.gov/niams/news/oisg/index.htm>.

The overall scientific goal of the OA Initiative is to examine the progressive development of OA through the support of an epidemiological, human cohort prospective study with the following aims:

- Identifying specific quantitative surrogate markers of OA disease which can be used to monitor disease progression and response to therapy and become acceptable as registrable end

points in clinical studies evaluating disease modifying agents;

- Enabling more efficient and effective clinical trials and a better understanding of the causative pathological mechanisms responsible in the development and progression of the OA disease;

- Initiating a new paradigm in which registrable clinical endpoints are established in non-interventional studies; and

- Establishing the managerial framework for similar Public/Private Partnerships in other disease areas.

The broad questions stated below represent starting points for the discussion of the scientific plan at and following the OA Initiative Meeting February 28–29, 2000:

- Are structural (anatomic) features of the joint (hip, knee, and hand) and associated tissue, such as joint space narrowing and osteophyte development, reliable markers of disease and disease progression?

- Are there biochemical or biophysical markers that would allow assessment of response to disease-modifying therapies?

- What research tools, resources, and knowledge are needed to develop reliable biomarkers of OA that may serve as surrogate endpoints in clinical trials?

The February 28–29, 2000 meeting will focus on the development of a strategic plan for the Osteoarthritis Initiative. Input from the scientific community to this strategic plan based on the questions stated above is invited and welcomed.

Ms. Maureen Knowles (NIAMS; Extramural Program; Natcher building; Room 5As-43; Bethesda, MD 20892-6500; Phone: 301-594-5055, Fax: 301-480-4543, e-mail: mk92w@nih.gov) will provide further information or it can be accessed at the following Web site <http://www.nih.gov/niams/news/currmeetregmat.htm>.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Knowles at 301-594-5055, in advance of the meeting.

Dated: December 20, 1999.

Ruth L. Kirschstein,

Deputy Director, National Institutes of Health.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel.

Date: January 6, 2000.

Time: 12:00 p.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: 6000 Executive Blvd., Suite 409, Rockville, MD 20852.

Contact Person: M. Virginia Wills, Lead Grants Technical Assistant, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Blvd., Bethesda, MD 20892-7003, 301-443-6106, vw21k@nih.gov.

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

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, ZAA1 CC (02) Special Emphasis Panel.

Date: January 6, 2000.

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: 6000 Executive Blvd., Suite 409, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: M. Virginia Wills, Lead Grants Technical Assistant, Extramural Project Review Branch, National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Suite 409, 6000 Executive Blvd., Bethesda, MD 20892-7003, 301-443-6106, vw21k@nih.gov.

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

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National