DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH State-of-the-Science Conference on the Role of Active Surveillance in the Management of Men With Localized Prostate Cancer

ACTION: Notice.

Notice is hereby given of the National Institutes of Health (NIH), ''State-of-the-Science Conference on the Role of Active Surveillance in the Management of Men With Localized Prostate Cancer,'' to be held December 5–7, 2011, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The Conference will begin at 8:30 a.m. on December 5 and 6, and at 9 a.m. on December 7, and will be open to the public.

Prostate cancer is the second leading cause of cancer-related deaths among men in the United States. It is estimated that in 2010, approximately 32,000 American men died of prostate cancer and 218,000 were newly diagnosed with the disease. Most prostate cancers are detected by a blood test that measures prostate-specific antigen (PSA), a tumor marker. More than half of cancers detected with PSA screening are localized (confined to the prostate), not aggressive at diagnosis, and unlikely to become life-threatening. However, 90 percent of patients receive immediate treatment for prostate cancer, such as surgery or radiation therapy. In many patients, these treatments have substantial short- and long-term side effects without any clinical benefit. Appropriate management of screen-detected, early-stage, low-risk prostate cancer is an important public health issue given the number of men affected and the risk for adverse outcomes, such as diminished sexual function and loss of urinary control.

Tools that can reliably predict which tumors are likely to progress and which are unlikely to cause problems are not available at present. Currently clinicians rely on two observational strategies as alternatives to immediate treatment of early-stage prostate cancer: Watchful waiting and active surveillance. Watchful waiting involves relatively passive patient follow-up, with palliative interventions if and when any symptoms develop. Active surveillance typically involves proactive patient follow-up in which PSA levels are closely monitored, prostate biopsies may be repeated, and eventual treatment is anticipated. Yet, it is unclear which men will most benefit from each approach and whether observational strategies will yield outcomes similar to immediate treatment when managing low-risk prostate cancer.

To better understand the benefits and risks of active surveillance and other observational management strategies for PSA screening-detected, low-grade, localized prostate cancer, the NIH has engaged in a rigorous assessment of the available scientific evidence. This process, sponsored by the National Cancer Institute, the Centers for Disease Control and Prevention, and the NIH Office of Medical Applications of Research will culminate in a State-of-the-Science Conference December 5–7, 2011, that focuses on these key questions:

1. How have the patient population and the natural history of prostate cancer diagnosed in the United States changed in the last 30 years?

2. How are active surveillance and other observational strategies defined?

3. What factors affect the offer of, acceptance of, and adherence to active surveillance?

4. What are the patient-experienced comparative short- and long-term health outcomes of active surveillance versus immediate treatment with curative intent for localized prostate cancer?

5. What are the research needs regarding active surveillance (or watchful waiting) in localized prostate cancer?

These questions, developed by a multidisciplinary planning committee, will be addressed in an evidence report prepared through the Agency for Healthcare Research and Quality's Evidence-based Practice Centers program. During the Conference, invited experts, including the authors of the report, will present scientific evidence. Attendees will have opportunities to ask questions and provide comments during open discussion periods. After weighing the evidence, an unbiased, independent panel will prepare and present a statement addressing the key questions. The statement will be widely disseminated to practitioners, policymakers, patients, researchers, the general public, and the media.

FOR FURTHER INFORMATION CONTACT: Advance information about the Conference and Conference registration materials may be obtained from the NIH Consensus Development Program Information Center by calling 888–644–2667, or by sending e-mail to *consensus@mail.nih.gov*. The Information Center's mailing address is P.O. Box 2577, Kensington, Maryland 20891. Registration and Conference information are also available on the NIH Consensus Development Program Web site at *http://consensus.nih.gov*.

Please Note: As part of measures to ensure the safety of NIH employees and property, all visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or purses inspected or x-rayed as they enter NIH buildings. For more information about the new security measures at NIH, please visit the Web site at *http://www.nih.gov/about/visitorsecurity.htm*.

Dated: July 1, 2011.

Francis S. Collins,

Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Center For Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel, Member Conflict: Cardiovascular Sciences.

Date: July 29, 2011.

Time: 2 to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lawrence E. Boerboom, PhD, Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435–8367, *boerboom@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)