

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator; American Health Information Community Biosurveillance Workgroup Meeting

ACTION: Announcement of meeting.

SUMMARY: This notice announces the sixth of the American Health Information Community Biosurveillance Workgroup in accordance with the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C., App.)

DATES: June 22, 2006 from 1 p.m. to 3 p.m.

ADDRESSES: Mary C. Switzer Building (330 C Street, SW., Washington, DC 20201), Conference Room 4090.

FOR FURTHER INFORMATION CONTACT: http://www.hhs.gov/healthit/ahic/bio_main.html.

SUPPLEMENTARY INFORMATION: The meeting will be available via Web cast as <http://www.eventcenterlive.com/cfm/ec/login/login1.cfm?BID=67>.

Kathryn Barr,

Director, American Health Information Community, Office of Programs and Coordination, Office of the National Coordinator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Advisory Committee on Genetics, Health, and Society; Request for Public Comment

AGENCY: Office of the Secretary, HHS.

ACTION: A request for public comment on a draft report to the Secretary of Health and Human Services on policy issues raised by the prospect of a U.S. large population cohort project for the study of genetic variation, the environment, and common disease.

SUMMARY: The Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) is requesting public comment on a draft report on policy issues raised by the prospect of the U.S. undertaking a large population cohort project for the study of genes, environment, and disease. A copy of the report, "Policy Issues Associated with Undertaking a Large U.S. Population Cohort Project on Genes, Environment, and Disease," is available electronically at http://www4.od.nih.gov/oba/sacghs/public_comments.htm. A copy may also be obtained from the National Institutes

of Health (NIH) Office of Biotechnology Activities (OBA) by e-mailing Ms. Amita Mehrotra at mehrotraa@od.nih.gov or calling 301-496-9838.

DATES: In order for public comments to be considered by SACGHS in finalizing its report to the Secretary, the public is asked to submit comments by July 31, 2006.

ADDRESSES: Public comments on the draft report should be addressed to Reed V. Tuckson, M.D., Chair, SACGHS, and transmitted to SACGHS via an e-mail to Ms. Mehrotra at mehrotraa@od.nih.gov. Comments may also be submitted by mailing or faxing a copy to NIH OBA at 6705 Rockledge Drive, Suite 750, Bethesda, MD, 20892 NIH OBA's fax number is 301-496-9839.

FOR FURTHER INFORMATION CONTACT: Ms. Amita Mehrotra, NIH OBA, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892, 301-496-9838, mehrotraa@od.nih.gov.

SUPPLEMENTARY INFORMATION: The Department of Health and Human Services (HHS) established SACGHS to serve as a public forum for deliberations on the broad range of human health and societal issues raised by the development and use of genetic and genomic technologies and, as warranted, to provide advice on these issues. For more information about the Committee, please visit its Web site:

<http://www4.od.nih.gov/oba/sacghs.htm>. In a 2004 priority-setting process, SACGHS determined that opportunities and challenges associated with conducting large population cohort studies aimed at understanding the relationships of genes, the environment, and common, complex diseases warranted in-depth study. A large population initiative raises many policy issues for a number of reasons, including: (1) It will involve an unprecedented number of people (500,000 to 1,000,000 or more individuals) and, thereby, will have a significant public profile and a direct impact on many people; (2) it requires a relatively large investment of public resources and, as such, warrants deliberation and a broad consensus about the relative value to science, society, and the Nation; and (3) the nature of the information that will be derived from it raises ethical, legal, social and public policy concerns could be unique and/or significant, particularly in view of the number of potential participants.

NIH Director, Elias A. Zerhouni, M.D., specifically requested SACGHS's advice on the scientific, public, and ethical processes and pathways that might help NIH or HHS make decisions about

undertaking such an effort. Dr. Zerhouni specified that the Committee could be most helpful to the Secretary by conducting an inquiry that includes the following steps:

- Step 1: Delineate the questions that need to be addressed in order for policymakers to determine whether the U.S. Government should undertake, in any form, a large population project to elucidate the influence of genetic variation and environmental factors on common, complex disease.
- Step 2: Explore the ways in which, or processes by which, the questions that are identified in Step 1 can be addressed, including the need for any intermediate research studies, pilot projects, or policy analysis efforts.
- Step 3: Taking into account the possible ways in which the questions could be addressed, determine which approaches are optimal and feasible and recommend a specific course of action for moving forward.

SACGHS has developed a draft report that summarizes its findings and conclusions relevant to the development of a large population research initiative in the United States. The report focuses on preliminary and intermediate questions, steps, and strategies in five areas that should be addressed before an informed decision can be made about whether the United States should undertake such a project. These five areas are: (1) Research policy; (2) research logistics; (3) regulatory and ethical issues; (4) public health implications of research results; and (5) social implications of research results. The report also identifies options for how these issues might be addressed. A central theme of the report is that decisions about such a project must take account of public views and attitudes and that public engagement must be sought in planning for and implementing a large population project.

In view of the wide range of public policy issues and questions raised in the draft report, SACGHS hopes to receive input from the wide range of individuals, communities and groups who may have an interest in whether a large population cohort project is undertaken in the U.S. These include but are certainly not limited to members of the general public and patient community; scientists in many fields but certainly genomics, environmental health, epidemiology, and public health; health professionals; bioethicists; and legal, public policy, and public engagement experts. Comments on any aspect of the draft report are welcome. In particular, the committee would