

Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received on or before August 2, 2000.

Dated: June 15, 2000.

Dennis P. Williams,

Deputy Assistant Secretary, Budget.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of National AIDS Policy; Notice of Meeting of the Presidential Advisory Council and HIV/AIDS and Its Subcommittees

June 27, 2000.

Pursuant to P.L. 92-463, notice is hereby given of the meeting of the Presidential Advisory Council on HIV/AIDS scheduled for September 21-22, 2000 at the Madison Hotel, Washington, DC. The meeting of the Presidential Advisory Council on HIV/AIDS will take place of Thursday, September 21, and Friday, September 22 (8:30 a.m. to 6 p.m. on Thursday and Friday) at the Madison Hotel, 1177 15th Street, NW, Washington, D.C. 20005. The meetings will be open to the public.

The purpose of the subcommittee meetings will be to finalize any recommendations and assess the status of previous recommendations made to the Administration. The agenda of the Presidential Advisory Council of HIV/AIDS may include presentations from either of the Council's subcommittees, Services or Prevention.

Daniel C. Montoya, Executive Director, Presidential Advisory Council on HIV and AIDS, Office of National AIDS Policy, 736 Jackson Place, NW, Washington, DC 20503, Phone (202) 456-2437, Fax (202) 456-2438, will furnish the meeting agenda and roster of committee members upon request. Any individual who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Vanessa Vaughn at (301) 986-4870 no later than August 25, 2000.

Daniel C. Montoya,

Executive Director, Presidential Advisory Council of HIV and AIDS.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Human Subject Protection and Financial Conflict of Interest: Conference

AGENCIES: OASPE, OPHS, NIH, FDA, and CDC, HHS.

ACTION: Notice of conference; request for comments.

SUMMARY: A Conference on Human Subject Protection and Financial Conflict of Interest will be held at Natcher Auditorium, NIH Campus on August 15-16, 2000. The issue of financial conflict of interest is one of the 5 main issues identified by the Secretary of Health and Human Services in her announcement of steps being taken to strengthen human subject protection during clinical trials. In that announcement, the Secretary stated that there would be a public process to review this issue. She said that HHS would undertake an extensive public consultation to identify new or improved means to manage financial conflicts of interest that could threaten the safety of research subjects or the objectivity of the research itself. Emphasis will be placed on the informed consent process and how it might be clarified and enhanced in dealing with issues related to financial conflict of interest.

The Conference will review the current regulatory requirements and guidance, serve as a forum for presentations of current approaches being taken for dealing with real and potential financial conflict of interest at the institution, IRB, and clinical investigator levels. This conference will help the government refine its current guidance and may lead to other changes. NIH has developed a set of issues to consider related to its regulations which is now available as background for the conference. Further guidance will be issued based on the responses to questions posed in this Notice and the conference deliberations.

To facilitate review of current policies, regulations, and guidance documents, these documents are cited as references at the end of this Notice. The references cited are also available electronically at the OASPE Website (<http://aspe.hhs.gov/sp/coi/index.htm>).

To maximize the efficiency of this process, six questions (see below) have been developed. Please address these in writing by August 1, 2000. This will help in organizing the plenary and concurrent work group sessions. There

will be a public session where brief comments on these topics can be addressed during the conference.

DATES: *Conference on Human Subject Protection and Financial Conflict of Interest:* The Conference will be held on Tuesday August 15, 2000 from 8:30 AM to 5:30 PM and Wednesday August 16, 2000 from 8:30 AM to 1:00 PM. Although the entire conference is open to the public and there will be no registration fee, it is requested that all those who wish to participate in the conference register by August 1, 2000. This will allow us to prepare an adequate number of conference background materials and to make appropriate assignments for the breakout sessions.

Request for Comments: Written responses to the six questions are requested by all parties, whether or not they will be attending the conference, by August 1, 2000 as described below.

Opportunity for Public Comment during the Conference on August 15, 2000, 2:15-3:30 PM. There will be an opportunity to make brief presentations during this session set aside for public comments. The comments should be responses to any or all of the six questions listed below. Anyone wishing to make comments should file a written Notice of Participation as described below by August 1, 2000. You will be contacted after all the requests are reviewed and given information about the time of your presentation and other details.

ADDRESSES: The Conference will be held at Natcher Auditorium, Building 45, NIH Campus, 9000 Rockville Pike, Bethesda, MD 20892.

Registration Information: To register for the conference please contact Mr. Mark Brown, CMP, MasiMax Resources, Inc., phone 240-632-5618, FAX 240-632-0519, e-mail: Mbrown@masimax.com. Please register by August 1, 2000.

Comments and Notices of Participation in Public Session: Written or electronic responses to the six questions as well as submissions of written or electronic Notices of Participation to speak during the Public Session of the Conference should both be addressed to: Stuart L. Nightingale, M.D., Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, 200 Independence Avenue, SW, Washington, DC 20101, Fax: 202-205-8835 email: COI@aspe.dhhs.gov

Notices of Participation to present during the Public Session should include name, affiliation, (whether person is from an IRB, an institution,