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.

[FR Doc. 00–16669 Filed 6–30–00; 8:45 am]

BILLING CODE 4150–04–M

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.

[FR Doc. 00–16779 Filed 6–30–00; 8:45 am]

BILLING CODE 3195–01–M

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,

industry, is a clinical investigator, etc.), main points of presentation, how much time requested (no more than 5 minutes), and telephone number and other contact information.

FOR FURTHER INFORMATION CONTACT: Stuart L. Nightingale, FAX 202–205–8835, e-mail: *coi@OSASPE.dhhs.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

In recent years, clinical research has generally become ever more complex—which, in turn, has engendered a new degree of complexity in accompanying ethical and conflict of interest considerations. Financial conflict of interest in clinical trials has been of concern for a number of years, both from the perspective of research objectivity and human subject protection. Both the PHS and FDA have requirements/regulations and guidance in place relating to financial conflict of interest. Recently, financial arrangements between commercial interests and institutions have become more common and some institutions have arrangements with the same commercial organizations as investigators. This has been highlighted in the area of gene transfer research. Additionally, although IRBs are required to deal with conflict of interest issues, these have been understood to be directed more toward members' own conflict of interest rather than those of investigators or institutions. There is little guidance to IRB's and a recent HHS Inspector General's Report found that only 25 percent of IRBs review these issues and consider them for inclusion in the informed consent document.

B. The Secretary's Initiatives To Strengthen Human Subject Protection

Notwithstanding the many successes over the years in protecting human research subjects from undue and undisclosed risks, we recognize that the protection system itself needs to be enhanced. In this regard, we agree with the finding of the HHS Inspector General that Institutional Review Boards (IRBs)—the central element of the system—often have difficulty fulfilling even their fundamental responsibilities because many of them are overworked and few have been accorded adequate resources by their parent institutions. These findings have been reinforced over the last two years by a series of inspections by the HHS Office for Protection from Research Risks (OPRR). Several inspections resulted in complete or partial cessation of human subjects research until the institutions involved took appropriate actions.

In response to these developments, Secretary Shalala recently announced five initiatives designed to enhance protection for human research subjects.

First, HHS will take steps to require that clinical investigators and IRB members and staff undergo continuing education in issues relating to human subjects.

Second, HHS will issue guidance making clear that research institutions and clinical trial sponsors are expected to take stringent continuing review actions, such as audits of research records, to promote compliance with current informed consent requirements.

Third, HHS will expand its requirements for study monitoring—thereby improving the oversight of even small-scale clinical trials. Large-scale phase III clinical trials, already have the requirement to have data and safety monitoring.

Fourth, HHS will undertake an extensive public consultation to identify new or improved means to manage financial conflict of interest that could threaten the safety of research subjects or the objectivity of the research itself. The insights gained from this process will be expressed in new guidance for the research community regarding what information about the financial interests of investigators and research institutions should be disclosed to research subjects and others. The objective of this guidance will be to make current conflict of interest regulations more effective.

Fifth, HHS will seek new legislation to enable FDA to level civil money penalties for violation of informed consent and other important regulatory requirements so that they can be applied to clinical investigators and institutions. This new authority would fill a significant gap in the current spectrum of sanctions against those who fail to obey Federal regulations for protection of human research subjects.

C. HHS/PHS Grant Award Requirements for Dealing With Financial Conflict of Interest

In 1995 the Public Health Service promulgated regulations establishing standards and procedures to be followed by institutions that apply for research funding to ensure that the design, conduct and reporting of research under PHS grants, contracts or cooperative agreements would not be biased by any conflicting financial interest of those investigators responsible for the research. These regulations require that investigators disclose to an institutional official a listing of significant financial interests (and those of his/her spouse and dependent children) that would reasonably appear to be affected by the research. The institutional official must review the disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct or reporting of the research and, if so, the institution must, prior to any expenditure of funds, report the existence of any conflicting interests to the PHS awarding component and assure that the conflict of interest has been managed, reduced or eliminated in accordance with the regulations.

D. FDA Regulations Requiring Financial Disclosure by Clinical Investigators

On February 2, 1998, FDA published a final rule requiring that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to FDA be identified and disclosed to FDA by the applicant. Clinical research data provide the basis for FDA's assessment of whether a product is approvable under statutory requirements. It is essential that these data be reliable and that steps be taken to minimize possible effects on the data resulting from potential bias on the part of any investigator. This regulation, which became effective on February 2, 1999, applies to any applicant who submits a marketing application or reclassification petition for a human drug, biological product, or medical device and who submits any clinical study of a drug or device in humans that the applicant or FDA relies on to establish that the product is effective, or any study in which a single investigator makes a significant contribution to the demonstration of safety. The regulation requires applicants to certify to the absence of certain financial interests of clinical investigators or to disclose those financial interests. If the applicant does not include certification and/or disclosure, or does not certify that it was not possible to obtain the information, the agency may refuse to file the application. On December 31, 1998, FDA published an amended final rule that reduced the need to gather certain financial information for studies completed before February 2, 1999.

E. Purpose of This Conference

As discussed above, the issue of financial conflict of interest in research is one of the 5 main areas 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 HHS will hold public discussions this summer to find new ways to manage conflicts of interest so that research subjects are appropriately informed, and to further ensure that research results are analyzed and presented objectively. In addition, these public discussions also will focus on clarifying and enhancing the informed consent process.

This Conference Will:

Implement one of the Secretary's five initiatives to strengthen human subject protection in clinical research.

Remind participants of current PHS/FDA regulations, guidelines and guidance through documents and presentations.

Present examples of how the issue of financial conflict of interest is dealt with at the level of: Institutions, IRBs, and Clinical Investigators (including Sponsor/Investigators), and Industry/Sponsors.

Receive public comments on questions posed in the **Federal Register** announcing the conference.

Provide information for the Department of Health and Human Services to develop more useful and detailed guidance to implement current regulatory requirements.

Who Should Attend?

Institutional Officials, IRB staff and members, Clinical Investigators, Industry/Sponsors, National Organizations/Health Professionals, Patient and Advocate groups, Patients and Research Participants.

General information about the conference, the conference Program is available on the ASPE Website (*http://aspe.hhs.gov/sp/coi*) and at the Website of MasiMax Resources, Inc. (www.masimax.com/coi/index.html).

F. Questions for Comment

Members of the Public who wish to respond to the following questions, should send their comments by August 1, 2000 or comment at the Conference during the public session (To comment at the conference during the session for Public Comment, a Notice of Participation should be submitted).

1. For each group listed below, what types of financial interests are associated with human subjects research funded or regulated by HHS agencies?

Clinical investigators (including sponsor/investigators)
IRB members and staff
Awardee institutions

2. Is there empirical evidence that informing research participants about financial relationships or financial conflict of interest of the investigator, the institution, or the IRB:

Can cause or prevent real or perceived harm (physical or psychological) to human research subjects?

Can compromise the objectivity of the associated research?

Can adversely or positively affect participation in the trial?

Can enhance the informed consent process by more fully informing potential participants?

Can be understood by and is meaningful to the potential research participant?

3. If information about financial interests is disclosed to potential participants in clinical trials, what information should be disclosed and at what level of detail?

Should potential participants be told of all of the financial interests of investigators, IRB members, or institutions, or only those financial interests which constitute a financial conflict of interest or might constitute a financial conflict of interest? Should potential participants be told what protections are in place and are working to ensure that financial conflicts are managed, reduced, or eliminated to promote objectivity and enhance human subject protection in the trial? Are the financial limits set forth in current PHS regulations covering awardee institutions still appropriate for clinical researchers? What are appropriate levels of reportable financial relationships for IRB members and institutions?

4. If information about financial interests is disclosed to potential participants, when and how should information about financial conflict of interest be provided to them?

If information about financial interests/conflict of interest involving institutions, IRBs, and investigators should be provided, what is the optimal point in the process for disclosure?

Should information be provided by the institution, the research investigator, the IRB, or a third party?

Should disclosure information and institutional policy be provided in the informed consent document or in an entirely separate document?

5. What are appropriate roles for the institution, the IRB, the clinical investigator (including sponsor/investigators), and perhaps other entities in dealing with financial interests or financial conflict of interest?

What are the responsibilities and obligations of each entity?

How should each entity relate to the other entities?

Should disclosed information on which determinations are made (including deliberations) be shared with the other entities? If so, what information should be shared and how and when should the disclosures be conducted?

What confidentiality protections are/should be in place to safeguard the privacy and confidentiality of the investigator, IRB member, and institution?

6. Other than those at the Federal level, what protections exist to ensure that the financial conflicts are managed, reduced, or eliminated to promote objectivity in the trial and to enhance human subjects protection?

References

HHS NEWS, U.S. Department of Health and Human Services, May 23, 2000: ''Secretary Shalala Bolsters Protections for Human Research Subjects''

HHS FACT SHEET, U.S. Department of Health and Human Services, May 23, 2000 ''Protecting Research Subjects''

Code of Federal Regulations, Title 45, Part 46, Subpart A. Federal Policy for the Protection of Human Subjects (Basic DHHS Policy for Protection of Human Research Subjects).

Code of Federal Regulations, Title 42, Part 50, Subpart A. Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Code of Federal Regulations, Title 42, Part 50, Subpart F. Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

Frequently Asked Questions Concerning the Department of Health and Human Services' Objectivity in Research Regulations and the National Science Foundation Investigator Financial Disclosure Policy, **Federal Register:** July 3, 1996 Volume 61, Number 129, p. 34839.

Required Education in the Protection of Human Research Participants. NIH Guidance, June 5, 2000

Financial Conflict of Interest and Research Objectivity: Issues for Investigators and Institutional Review Boards. NIH Guidance, June 5, 2000.

FDA Information Sheets, Guidance for Institutional Review Boards and Clinical Investigators, 1998 Update, Revised February 1999. Also available at www.fda.gov

Code of Federal Regulations, Title 21, Part 50. Protection of Human Subjects (FDA)

Code of Federal Regulations, Title 21, Part 54. Financial Disclosure by Clinical Investigators (FDA)

Code of Federal Regulations, Title 21, Part 56. Institutional Review Boards (FDA)
Code of Federal Regulations, Title 45, Part 76. HHS Debarment Regulations

Dated: June 27, 2000.

William F. Raub,

Deputy Assistant Secretary for Science Policy, Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

[FR Doc. 00–16760 Filed 6–30–00; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00095]

Cooperative Agreement for Birth Defects Surveillance, Research, and Prevention Activities; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 2000 funds for a cooperative agreement program for the University of South Alabama Birth Defects Surveillance, Research, and Prevention Activities.

B. Eligible Applicants

Single Source: Assistance will be provided only to the University of South Alabama. No other applications are solicited.

This authority is granted under the Consolidated Appropriations Act 2000 (Public Law 106–113), which states: ''* * * under section 1509 of the Public Health Service Act * * * $1,000,000 shall be for the University of South Alabama birth defects monitoring and prevention activities.''

C. Availability of Funds

Approximately $800,000 is available in FY 2000 to fund this award. It is expected that the award will begin on or about September 30, 2000, and will be made for a 12-month budget period within a project period of only 1 year. Funding estimates may change.

D. Where To Obtain Additional Information

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from: William A. Paradies, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–4146, Telephone number (770) 488–2721, Email address: WParadies@cdc.gov.

For program technical assistance, contact: Larry D. Edmonds, State Services, Birth Defects and Pediatric Genetics Branch, Division of Birth Defects, Child Development, Disability and Health, National Center for Environmental Health, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE., Mailstop F–45, Atlanta, GA 30341–3724, Telephone number (770) 488–7171, E-mail address: LEdmonds@cdc.gov.

Dated: June 27, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–16719 Filed 6–30–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 00105]

TB Epidemiologic and Operational Research; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year 2000 funds for a new cooperative agreement to enhance the capabilities of recipients of state and local tuberculosis (TB) elimination and laboratory agreements to conduct TB epidemiologic and operational research. This program addresses the ''Healthy People 2010'' focus areas of Immunization and Infectious Diseases. For the conference copy of ''Healthy People 2010'', visit the internet site http://www.health.gov/healthypeople

The purpose of this cooperative agreement is to build capacity at state and local health departments to conduct and implement protocol-driven epidemiologic and operational research. Such actions are consistent with recommendations issued by the Advisory Council for the Elimination of Tuberculosis (ACET) calling for decisive actions to: Better understand the changing epidemiology of TB to rebuild the public health infrastructure; identify challenges and opportunities for TB control in an era of changes in health care organizations and delivery; recognize the interdependence of global TB and TB in the United States; and develop and evaluate new tools for TB diagnosis, treatment and prevention. This new cooperative agreement will be awarded to successful applicants from state and local health agencies to support health department-based investigators with access to patients with tuberculosis, latent tuberculosis infection, or recent exposure to persons with active tuberculosis (''contacts'') in the implementation of protocols for epidemiologic and operational research. Recipients of this award will be expected to conduct site-specific epidemiologic and operational research activities in TB which rely upon the implementation of common, agreed-upon study protocols. Award recipients will be expected to successfully compete for one or more of the specific TB research projects listed below. Eligible applicants may request support for activities under one or more of the following three separate focus areas. See Attachments 1–3 in the application kit for details under each focus area:

1. *Development of Contact Investigation Self-Evaluation Tools:* (See Attachment 1): Assist local TB control programs in building local-level capacity for evaluation of contact investigation processes by providing them with a package of self-evaluation tools. These tools will enable programs to systematically assess contact investigation processes and target programmatic revisions accordingly. The package will include economic evaluation tools to show how program changes will impact resource use and outcomes, thus enabling programs to plan strategically. The package of tools will be pilot tested to ensure usefulness and feasibility. These funds will give state and local health departments the ability to develop practical evaluation tools, based on the CDC's Recommended Framework for Evaluation, that can be used by local TB programs to use local data to evaluate contact investigation processes. They will also provide for the development of educational support materials to enable local level program staff to understand evaluation principles and conduct self-evaluations.

2. *Improving Contact Investigations in Foreign-Born Populations:* (See Attachment 2) Improve contact identification for foreign-born (FB) TB cases. Improve completeness and timeliness of screening for identified contacts to FB TB cases. Improve the interpretation of screening results for contacts to FB TB cases in [a] the context of screening results for US-born contacts to the same cases and [b] using serum immunologic profile (IFN-gamma