

- Managed care plans could adopt the project and encourage their enrollees to have themselves assessed for risk and alter their lifestyles if the risk warrants;

- Colleges and universities could conduct detection events for their student populations;

- Area agencies on aging could form a component of a statewide program.

Where a statewide program is not in place, partnering organizations such as these could proceed on their own.

Availability of Funds

There are no Federal funds available for these partnerships.

Content of Request for Partnership

Each request for partnership should contain a description of: (1) The entity or organization; (2) its proposed involvement in the Department's diabetes detection initiative; and (3) resources or services the partnering organization would like to offer.

Evaluation Criteria

Partners will be selected by the Office of Disease Prevention and Health Promotion using the following criteria:

(1) Requester's qualifications and capability to contribute to the partnership;

(2) Requester's creativity for contributing to the diabetes detection initiative.

Dated: March 25, 2003.

Elizabeth Majestic,

Acting Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion), Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 02N-0475]

Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection"

AGENCY: Office of the Secretary, Office of Public Health and Science, HHS.

ACTION: Notice.

SUMMARY: The Office of Public Health and Science, Department of Health and Human Services (HHS) is soliciting public comment on a draft guidance document for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." This draft

guidance document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This guidance applies to human subjects research conducted or supported by HHS or regulated by the Food and Drug Administration.

DATES: Submit written or electronic comments on the draft guidance on or before 4:30 p.m. on May 30, 2003. Comments on HHS guidance documents are welcome at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Docket Number 02N-0475, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. All comments submitted should be identified with the docket number found in brackets in the heading of this notice. Comments received may be viewed on the Food and Drug Administration (FDA) Web site at <http://www.fda.gov/ohrms/dockets/default.htm> or may be seen in the FDA Docket Management Branch at 5630 Fishers Lane, Room 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday.

Submit requests for single copies of the draft guidance document to the address identified below for further information. Requests may be made by mail or e-mail. Persons with access to the Internet also may obtain the document at <http://www.fda.gov/ohrms/dockets/GUIDANCES/DGUIDES.HTM>.

FOR FURTHER INFORMATION CONTACT: Glen Drew, Office for Human Research Protections, Office of Public Health and Science, The Tower Building, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852, (301) 402-4994, facsimile (301) 402-2071; e-mail gdrew@osophs.dhhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

OPHS is seeking comments on the HHS draft guidance for IRBs, investigators, and research institutions, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." In May 2000, HHS announced five initiatives to strengthen human subject protection in clinical research. One of these was to develop guidance on financial conflict of interest that would serve to further protect research participants. As part of this initiative, HHS held a conference on the topic of human subject protection and

financial conflicts of interest on August 15-16, 2000. A draft interim guidance document, "Financial Relationships in Clinical Research: Issues for Institutions, Clinical Investigators, and IRBs to Consider when Dealing with Issues of Financial Interests and Human Subject Protection," based on information obtained at and subsequent to that conference was made available to the public for comment on January 10, 2001. This document will replace that draft interim guidance.

The draft guidance recommends consideration of approaches and methods for dealing with issues of financial interests under the HHS human research subject protections regulations, 45 CFR part 46 and 21 CFR parts 50 and 56. The draft guidance expressly does not address regulatory requirements designed to enhance data integrity and objectivity in research found in 42 CFR part 50, subpart F, 45 CFR part 94, and 21 CFR part 54.

The draft guidance recommends that, in particular, IRBs, institutions engaged in research, and investigators consider whether specific financial relationships create financial interests in research studies that may adversely affect the rights and welfare of subjects. The guidance poses general considerations in evaluating financial relationships and their possible effects on human subjects. More detailed points for consideration are also offered for institutions, IRBs, and investigators.

II. Request for Comments

OPHS is distributing this draft guidance document for public comment. The Secretary is interested not only in reactions to the Guidance in general, and specifically the Points for Consideration, but also wishes to solicit views and ideas as to how to best assess any impacts of this guidance, as well as related non-Federal recommendations on enhancing the protection of human subjects. HHS guidance on consideration of financial interests in human subjects research will be issued after the public comments have been considered.