

not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two copies of any mailed comments, except that individuals may submit one copy. The draft guidance and the comments submitted to the docket may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/cder/guidance/index.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 27, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Solicitation of Information and Recommendations for Developing Compliance Program Guidance for Recipients of NIH Research Grants

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice seeks the input and recommendations of interested parties as the OIG develops compliance program guidance (CPG) for recipients of extramural research grant and cooperative agreement (grant) awards from the National Institutes of Health (NIH). The OIG is soliciting comments, recommendations and other suggestions from interested parties and organizations on the value and fundamental principles of compliance programs for colleges, universities, and other recipients of NIH grants, along with the specific elements that these grant recipients should consider when developing and implementing an effective compliance program.

DATES: To assure consideration, comments must be delivered to the

address provided below by no later than 5 p.m. on November 4, 2003.

ADDRESSES: Please mail or deliver your written comments, recommendations and suggestions to the following address: Department of Health and Human Services, Office of Inspector General, Attention: OIG-13-CPG, Room 5527, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

We do not accept comments by facsimile (FAX) transmission. In commenting, please refer to the file code OIG-13-CPG. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 5527 of the Cohen Building at 330 Independence Avenue, SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Richard Stern, Office of Counsel to the Inspector General, (202) 619-0335; or Joel Schaer, Office of Counsel to the Inspector General, (202) 619-0089.

SUPPLEMENTARY INFORMATION:

1. Past CPGs

The development of compliance program guidances is a major initiative of the OIG in its effort to assist participants in Department programs in preventing and reducing fraud and abuse and in complying with Federal program requirements. Over the past several years, the OIG has developed and issued 11 compliance program guidances. The suggestions contained in the guidances are not mandatory, nor do they represent an exclusive discussion of the advisable elements of a compliance program.

2. Developing Draft CPG for NIH Research Grant Recipients

Through this **Federal Register** notice, the OIG is seeking input from interested parties as the OIG considers the development of a CPG for recipients of extramural research grant awards from NIH. Under its governing statute, the OIG's oversight responsibility extends to all programs and operations of the Department, and the OIG promotes compliance efforts by all recipients of Department funds. One community of paramount importance to the Government's public health efforts is the colleges, universities, and other recipients of public funds committed to furthering biomedical research. These organizations are largely non-profit and educational, with over 50 percent of recipients of NIH research grant awards

in the last several years being medical schools. Many of these organizations have instituted health care compliance programs in their hospitals, and an increasing number have begun developing compliance programs for sponsored research.

As with OIG's earlier CPGs, the purpose of this guidance will be to assist organizations in preventing fraud and abuse and in better complying with Federal requirements. We anticipate that the guidance for recipients of NIH research grants will contain seven elements that we consider necessary for a comprehensive compliance program. These seven elements include:

- Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate Federal agency.

We are also considering an eighth element, "Defining roles and responsibilities and assigning oversight responsibility," that would include a discussion of the importance of effectively delegating oversight authority.

We would appreciate specific comments, recommendations and suggestions on aspects of these elements.

We are also interested in comments on (a) the scope of the guidance, and particularly the types of activities, such as grant administration, that should be subject to the CPG; and (b) the risk areas for recipients of NIH research grants. Based on our fraud investigations at research institutions, we have identified internal control deficiencies that may warrant attention in a CPG. OIG would also appreciate suggestions from the public on risk areas. Risk areas we have tentatively identified include: (i) The proper allocation of charges to grant projects; (ii) "time and effort" reporting, including an accurate reporting of the commitment of effort by researchers; and (iii) use of program income. We would also be interested in comments on each of these areas.

We will consider all comments, recommendations and suggestions received within the time frame