

five-county Pennsylvania portion of the Philadelphia Area does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Nitrogen dioxide, Ozone, Incorporation by reference, Reporting and recordkeeping requirements, Volatile organic compounds.

**Authority:** 42 U.S.C. 7401 *et seq.*

Dated: April 28, 2009.

**William C. Early,**

*Acting Regional Administrator, Region III.*  
[FR Doc. E9-10675 Filed 5-7-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 50

### 45 CFR Part 94

[Docket No. NIH-2008-0002]

RIN 0925-AA53

### Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought and Responsible Prospective Contractors; Request for Comments

**AGENCY:** Department of Health and Human Services.

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** On behalf of the Department of Health and Human Services (HHS) and the Public Health Service (PHS), a component of the HHS, the National Institutes of Health (NIH) seeks comments from the public on whether the HHS should amend its regulations on the responsibility of applicants for promoting objectivity in research for which PHS funding is sought and on responsible prospective. We are interested particularly in receiving comments on the issues presented below from the general public, individual Investigators, scientific societies and associations, Members of Congress, other Federal agencies that support or conduct research, and institutions that receive PHS funds to conduct or support biomedical or behavioral research.

**DATES:** To assure consideration, comments must be received by July 7, 2009.

**ADDRESSES:** Individuals and organizations interested in submitting comments, identified by RIN 0925-AA53 and Docket Number NIH-2008-0002, may do so by any of the following methods:

#### Electronic Submissions

You may submit electronic comments in the following way:

- *The Regulations.gov portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

To ensure timelier processing of comments, NIH is no longer accepting comments submitted to the agency by e-mail. The NIH encourages you to continue to submit electronic comments by using the Regulations.gov portal: <http://www.regulations.gov>.

#### Written Submissions

You may send written submissions in the following ways:

- *Fax:* 301-402-0169.
- *Mail: Attention:* Jerry Moore, NIH Regulations Officer, NIH, Office of Management Assessment, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669.
- *Hand Delivery/Courier (for paper, disk, or CD-ROM submissions):* Attention: Jerry Moore, 6011 Executive Boulevard, Suite 601, Rockville, MD 20852-7669.

#### Docket

For access to the docket to read background documents or comments received, go to the Regulations.gov portal and insert the docket number provided in brackets in the heading on page one of this document into the "Search" box and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Jerry Moore at the address above, or telephone 301-496-4607 (not a toll-free number) concerning questions about the rulemaking process; and Sally J. Rocky, PhD, Deputy Director, Office of Extramural Research, One Center Drive, Building 1, Room 142, Bethesda, MD 20892, e-mail [FCOI-ANPRM@NIH.GOV](mailto:FCOI-ANPRM@NIH.GOV) concerning programmatic questions.

**SUPPLEMENTARY INFORMATION:** Proper stewardship of Federal funds includes ensuring objectivity of results by protecting federally funded research from compromise by financial conflicts of interest (FCOI).

In 1995, the PHS and the Office of the Secretary of Health and Human Services published the regulations at 42 CFR Part 50 Subpart F and 45 CFR Part 94, designed to promote objectivity in PHS-

funded research.<sup>1</sup> The regulations are applicable to Institutions<sup>2</sup> that apply for PHS funding for research (except for Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications/proposals) and, through implementation of the regulations by these Institutions, to each Investigator<sup>3</sup> participating in the research. Generally, under the regulations:

- The Institution is responsible for complying with the regulations, including developing and maintaining a written and enforced policy; managing, reducing, or eliminating identified conflicts; and reporting identified conflicts to the PHS funding component. The reports denote the existence of a conflict and assure that it has been managed, reduced, or eliminated.

- The participating Investigators are responsible for complying with their Institution's written Financial Conflict of Interest (FCOI) policy and for disclosing their Significant Financial Interests<sup>4</sup> (SFI) to their Institution.

<sup>1</sup> 48 CFR Subpart 9.1, "Responsible Prospective Contractors," and 48 CFR Subpart 9.5,

"Organizational and Consultant Conflicts of Interest," also address conflicts of interest in Federally-funded projects. These provisions apply only to acquisitions, not to grants or cooperative agreements.

<sup>2</sup> An "Institution" is defined under 42 CFR Part 50, Subpart F, as any domestic or foreign, public or private, entity or organization (excluding a Federal agency), and under 45 CFR Part 94 as any public or private entity or organization (excluding a Federal agency) that (1) submits a proposal for a research contract whether in response to a solicitation from the PHS or otherwise, or (2) that assumes the legal obligation to carry out the research required under the contract. See 42 CFR 50.603; 45 CFR 94.3.

<sup>3</sup> An "Investigator" is defined under the regulations as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded by PHS, or proposed for such funding. For purposes of the regulatory requirements relating to financial interests, the term "Investigator" includes the Investigator's spouse and dependent children. See 42 CFR 50.603; 45 CFR 94.3.

<sup>4</sup> A "Significant Financial Interest" is defined under the regulation as anything of monetary value, including but not limited to (1) Salary or other payments for services (e.g., consulting fees or honoraria); (2) equity interests (e.g., stocks, stock options or other ownership interests); and (3) intellectual property rights (e.g., patents, copyrights and royalties from such rights). The term does not include (1) Salary, royalties, or other remuneration from the institution; (2) any ownership interests in the institution, if the institution is an applicant under the SBIR program; (3) income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities; (4) income from service on advisory committees or review panels for public or nonprofit entities; (5) an equity interest that, when aggregated for the investigator and the investigator's spouse and dependent children, does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership

• The PHS funding components are responsible for overseeing Institutional compliance with the regulations.

Ensuring objectivity in research requires a commitment from Institutions and their Investigators to complete disclosure, appropriate review, and robust management of identified conflicts consistent with the level of risk presented. The existing regulations were designed to provide standards to ensure that the design, conduct, or and reporting of PHS-funded research is not biased by any FCOI.

In the intervening years since the publication of these regulations, the pace of translation of new discoveries from the research bench into effective treatment of patients has significantly accelerated. As a result, the biomedical research enterprise in the United States is extensive and growing in size and complexity. Researchers frequently work in multidisciplinary teams to develop new strategies and approaches for translating basic research into clinical application. In addition, these newer translational strategies often involve complex collaborations between investigators and the private sector. Together, these factors may generate an increased potential of investigators to hold financial interests in multiple sources which, if not reported and appropriately managed, reduced, or eliminated, could introduce bias into the conduct of their research.

Recognition of the growing complexity of biomedical research, the increased interaction between Government and the private sector in meeting common public health goals, and recent public scrutiny have raised the question of whether a more rigorous approach to Investigator disclosure, management of conflicts, and Federal oversight is required.

Ensuring the objectivity of research results requires a commitment to uphold the following principles:

1. Research must be conducted with transparency and the highest scientific and ethical standards in a manner that promotes and respects the rights, safety, and welfare of all human research participants.

2. Appropriate interactions and relationships between government, academia, and industry, which do not compromise objectivity in research, frequently have beneficial outcomes and should be encouraged.

interest in any single entity; and (6) salary, royalties, or other payments that when aggregated for the investigator and the investigator's spouse and dependent children over the next twelve months are not expected to exceed \$10,000. 42 CFR 50.603; 45 CFR 94.3.

3. The integrity of the scientific record is critical to the conduct of science.

4. Risk management is essential in evaluating and managing conflict of interest; risk management should be commensurate with the level of risk of the research.

5. Complete and timely disclosure of financial interests and effective management of conflicts of interest are essential to ensuring objectivity in research.

For the reasons cited above, we are considering whether to revise the current regulations to provide Institutions with a more comprehensive set of guidelines based on these five principles. The complex and controversial issues surrounding FCOI warrant a carefully considered, open dialogue with all affected parties. Consequently, we invite public comments on all aspects of potential regulation in this area, and particularly on the following issues:

### **I. Expanding the Scope of the Regulation & Disclosure of Interests**

The regulations are applicable to Institutions that apply for PHS funding for research and, through implementation of the regulations by each Institution, to each Investigator participating in such research. However, the regulations do not apply to Phase I SBIR/STTR applications (42 CFR 50.602, 45 CFR 94.2).

The regulations require that Investigators disclose to the Institution only those Significant Financial Interests (SFI) (1) that would reasonably appear to be affected by the research for which funding is sought from the PHS; and (2) in entities whose financial interests would reasonably appear to be affected by the research (42CFR 50.604(c)(1); 45 CFR 94.4(c)(1)).

a. Should the regulations be expanded so that they also apply to Phase I SBIR/STTR research applications/proposals for PHS funding?

b. In May 2004, HHS issued a guidance document entitled, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" that raises points to consider in determining whether specific financial interests, including Institutional financial interests, in research affect the rights and welfare of human subjects and if so, what actions could be considered to protect those subjects. In February 2008, the Association of American Medical Colleges (AAMC) and the Association of American Universities (AAU) Advisory Committee on Financial Conflicts of Interest in Human Subjects Research issued a report, "Protecting Patients,

Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research," which offered a number of recommendations designed to enhance Institutional conflict of interest policies. One recommendation was that investigators conducting human subjects research should be required to report all of their outside financial interests directly or indirectly related to their professional responsibilities to their Institution, regardless of dollar amount and regardless of whether or not the investigator believes that the reported financial interests might reasonably appear to be affected by his or her current or anticipated research. In light of the above, should Investigators be required to disclose to their Institutions all Significant Financial Interests that are related to their Institutional responsibilities? Would this expanded disclosure allow the Institution to better determine which of these Significant Financial Interests constitute a FCOI?

### **II. Definition of "Significant Financial Interest"**

A "Significant Financial Interest" is defined by the current regulations as anything of monetary value, including but not limited to:

- Salary or other payments for services (e.g., consulting fees or honoraria);
- Equity interests (e.g., stocks, stock options or other ownership interests);
- Intellectual property rights (e.g., patents, copyrights and royalties from such rights).

The term does not include the following types of financial interests:

- Salary, royalties, or other remuneration from the Institution;
- Any ownership interests in the Institution, if the Institution is an applicant under the SBIR/STTR program;
- Income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- Income from service on advisory committees or review panels for public or nonprofit entities;
- An equity interest that, when aggregated for the Investigator and the Investigator's spouse and dependent children, does not exceed \$10,000 in value as determined through reference to public prices or other reasonable measures of fair market value, and does not represent more than a five percent ownership interest in any single entity;
- Salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve

months, are not expected to exceed \$10,000. (42 CFR 50.603; 45 CFR 94.3).

a. Should the current exemptions be maintained?

- If so, are the current de minimis thresholds (\$10,000 and 5 percent ownership interest in any single entity) reasonable? If not, how should the de minimis thresholds be changed? Should these thresholds be the same for all types of research?

- If not, which exemptions should be reconsidered, and why?

b. Should certain Significant Financial Interests (i.e., Significant Financial Interests received from specific sources or related to certain types of research) automatically be considered a FCOI under the regulations? If so, what types of Significant Financial Interests?

### III. Identification and Management of Conflicts by Institutions

The regulations require that an official(s) designated by the Institution review all financial disclosures; determine whether a financial conflict of interest exists; and, if so, determine what actions the Institution should take to manage, reduce, or eliminate the conflict of interest (42 CFR 50.605; 45 CFR 94.5). The regulations provide that a conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the research funded by the PHS (42 CFR 50.605; 45 CFR 94.5). The regulations currently do not define the term “designated Institutional official(s)”, or mandate specific actions that Institutions must take to manage, reduce or eliminate particular types of FCOIs.

a. Should large Institutions (defined as greater than 50 employees) be required to establish an independent committee to review financial disclosures, and require that committee to report to an organizational level within the Institution that is not conflicted by the short-term financial interests of the Investigator or Institution? Would a 50 employee threshold reasonably balance the risk of a more relaxed requirement for smaller Institutions against the burden imposed by requiring an independent panel for these evaluations?

b. For certain types of research, should the Institution be required to develop a conflict management plan when the Institution decides to manage or reduce, rather than eliminate, the conflict? If so, for which types of research? Should there be prescribed standards for the conflict management

plans? Should the Institution be required to submit this plan to the PHS funding component when it reports the existence of a conflict to the component?

c. Should Investigators who are involved in participant selection, the informed consent process, and clinical management of a trial, be prohibited from having a Significant Financial Interest in any company whose interests could be affected by their research or clinical trial? If so, what special circumstances would justify waiving this condition, if any?

d. Should the regulations prescribe specific approaches for the management, reduction, or elimination of particular types of FCOI? If so, for which types of FCOI? Which approaches?

e. Should specific requirements related to the identification, management, and reporting of FCOI be established for subrecipients (i.e., subgrantees, contractors, subcontractors, collaborators)?

f. Should amounts received by Investigators from certain kinds of organizations be limited to certain maximum thresholds if an Investigator is supported with PHS research funds? If so, which kinds of organizations? At what thresholds?

### IV. Assuring Institutional Compliance

Under the current regulations, the PHS funding component may at any time inquire into the Institutional procedures and actions regarding conflicting financial interests in PHS-funded research, including a requirement for submission, or review on site, of all records pertinent to compliance with the regulation (42 CFR 50.606; 45 CFR 94.6). On the basis of its review of records and/or other information that may be available, the PHS funding component may decide that a particular conflict of interest will bias the objectivity of the research it funds to such an extent that further corrective action is needed or that the Institution has not managed, reduced, or eliminated the conflict of interest in accordance with the regulation(s) (42 CFR 50.606; 45 CFR 94.6). The PHS funding component may determine that suspension of funding/the issuance of a Stop Work order is necessary until the matter is resolved (42 CFR 50.606; 45 CFR 94.6).

a. Should the regulations enhance existing enforcement options in the event of noncompliance?

b. Should Investigators be required under the regulations to complete routine FCOI training?

c. Should independent confirmation of an Institution's compliance with the regulation be required? If so, what should this confirmation look like (e.g., accreditation by an outside body, an independent audit)?

### V. Requiring Institutions to Provide Additional Information to the PHS

Under the current regulations, prior to spending any funds under an award, the Institution must report to the PHS funding component the existence of any conflicting financial interest found by the Institution and assure that the interest has been managed, reduced, or eliminated in accordance with the regulation(s) (42 CFR 50.604(g)(2), 45 CFR 94.4(g)(2)). The regulations do not require the Institution to report to PHS officials the nature of the interest or other details (42 CFR 50.604(g)(2), 45 CFR 94.4(g)(2)).

a. Should Institutions be required to submit to the PHS funding component additional information on any identified conflict? If they should not be required to submit additional information for all identified conflicts, should they be required to submit additional information for identified conflicts involving certain types of research? If so, for which types of research? What kind of information would provide valuable data to the PHS funding component in evaluating these reports and the potential risk of bias in conduct of research?

### VI. Institutional Conflict of Interest

Institutional conflict of interest is currently not addressed by the regulations, although there has been movement in the research community toward incorporating Institutional standards in conflict of interest policies (see, for example, the February 2008 AAMC/AAU report, “*Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research*”), and some Institutions have adopted such standards. This is an area of increasing concern. If the regulation were to be amended to address Institutional conflict of interest, how should it address the following issues?

a. How would Institutional conflict of interest be defined?

b. What would an Institutional conflict of Interest policy address in order to assure the PHS of objectivity in research?

Dated: February 2, 2009.

**Raynard S. Kington,**

*Acting Director, National Institutes of Health.*

Approved: April 9, 2009.

**Charles E. Johnson,**

*Acting Secretary.*

[FR Doc. E9-10666 Filed 5-7-09; 8:45 am]

BILLING CODE 4140-01-P

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 1

[DA 09-904; WT Docket No. 08-61, WT Docket No. 03-187]

#### Petition for Expedited Rulemaking and Other Relief on Behalf of American Bird Conservancy, Defenders of Wildlife and National Audubon Society

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** In this document, comment is sought on a petition for Expedited Rulemaking and Other Relief on Behalf of American Bird Conservancy, Defenders of Wildlife and National Audubon Society (Petitioners). Petitioners request that the Commission adopt new rules on an expedited basis to comply with the National Environmental Policy Act (NEPA), the Endangered Species Act (ESA), and the Migratory Bird Treaty Act (MBTA), and their implementing regulations, and to carry out the mandate of the U.S. Court of Appeals for the District of Columbia Circuit in *American Bird Conservancy, Inc. v. FCC*, 516 F.3d 1027 (DC Cir. 2008).

**DATES:** Interested parties may file comments on or before May 29, 2009, and reply comments on or before June 15, 2009.

**ADDRESSES:** You may submit comments, identified by WT Docket No. 08-61 and WT Docket 03-187, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site:* <http://www.fcc.gov/cgb/ecfs/>. Follow the instructions for submitting comments.
- *Mail:* Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of

the Secretary, Federal Communications Commission.

• *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by *e-mail:* [FCC504@fcc.gov](mailto:FCC504@fcc.gov) or *phone:* 202-418-0530 or TTY: 202-418-0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

**FOR FURTHER INFORMATION CONTACT:**

Aaron Goldschmidt, Spectrum and Competition Policy Division, Wireless Telecommunications Bureau at (202) 418-7146 or [Aaron.Goldschmidt@fcc.gov](mailto:Aaron.Goldschmidt@fcc.gov).

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's public notice released on April 29, 2009. The full text of the public notice is available for public inspection and copying during business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. It also may be purchased from the Commission's duplicating contractor at Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554; the contractor's Web site, <http://www.bcpweb.com>; or by calling (800) 378-3160, facsimile (202) 488-5563, or e-mail [FCC@BCPIWEB.com](mailto:FCC@BCPIWEB.com). Copies of the public notice also may be obtained via the Commission's Electronic Comment Filing System (ECFS) by entering the docket number, WT Docket No. 08-61 or WT Docket No. 03-187. Additionally, the complete item is available on the Federal Communications Commission's Web site at <http://www.fcc.gov>.

On April 14, 2009, American Bird Conservancy, Defenders of Wildlife and National Audubon Society (Petitioners) filed a petition requesting that the Federal Communications Commission (Commission) adopt new rules on an expedited basis to comply with the National Environmental Policy Act (NEPA), the Endangered Species Act (ESA), and the Migratory Bird Treaty Act (MBTA), and their implementing regulations, and to carry out the mandate of the U.S. Court of Appeals for the District of Columbia Circuit in *American Bird Conservancy, Inc. v. FCC*, 516 F.3d 1027 (DC Cir. 2008).<sup>1</sup>

Specifically, Petitioners request that the FCC undertake the following

actions: Amend the Commission's regulations that implement NEPA, "consistent with Council on Environmental Quality regulations and guidance," to "cure deficiencies" and to ensure that only Commission actions that have no significant environmental effects individually or cumulatively are categorically excluded; Prepare a programmatic environmental impact statement addressing the environmental consequences of its Antenna Structure Registration (ASR) program on migratory birds, their habitats, and the environment; Promulgate rules to clarify the roles, responsibilities and obligations of the Commission, applicants, and non-federal representatives in complying with the ESA; Consult with the U.S. Fish and Wildlife Service on the ASR program regarding all effects of towers and antenna structures on endangered and threatened species; and complete the proposed rulemaking in WT Docket No. 03-187 to adopt measures to reduce migratory bird deaths in compliance with the MBTA.<sup>2</sup>

*Procedural Matters:* This proceeding has been designated as a "permit-but-disclose" proceeding in accordance with the Commission's ex parte rules.<sup>3</sup> Parties making oral ex parte presentations in this proceeding are reminded that memoranda summarizing the presentation must contain the presentation's substance and not merely list the subjects discussed.<sup>4</sup> More than a one- or two-sentence description of the views and arguments presented is generally required.<sup>5</sup>

Pursuant to §§ 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before May 29, 2009 and reply comments on or before June 15, 2009. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. See Electronic Filing of Documents in Rulemaking Proceedings, 63 FR 24121 (May 1, 1998).

*Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: <http://www.fcc.gov/cgb/ecfs/> or the Federal eRulemaking Portal: <http://www.regulations.gov>. Filers should follow the instructions

<sup>2</sup> Petition at iv-v.

<sup>3</sup> See 47 CFR 1.1200(a), 1.1206.

<sup>4</sup> See Commission Emphasizes the Public's Responsibilities in Permit-But-Disclose Proceedings, Public Notice, 15 FCC Rcd 19945 (2000).

<sup>5</sup> See 47 CFR 1.1206(b)(2). Other rules pertaining to oral and written presentations are also set forth in 1.1206(b). See 47 CFR 1.1206(b).

<sup>1</sup> In the Matter of Amendment of Part 1 of the Commission's Rules Regarding Environmental Compliance Procedures for Processing Antenna Structure Registration Applications, WT Docket No. 08-61, filed April 14, 2009 (Petition).