Arsenal, 5650 Havana Street, Building 129, Commerce City, Colorado 80022–1748. Hours: 12 p.m. to 4 p.m., Monday through Friday, excluding legal holidays, or by appointment (call 303–289–0983).

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Chergo, Community Involvement Coordinator (8OC), U.S. Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129; *telephone number:* 1–800–227–8917 or 303–312–6601; *fax number:* 303–312–7110; *e-mail address: chergo.jennifer@epa.gov.*

Dated: July 13, 2010.

Stephen S. Tuber,

Acting Regional Administrator, Region 8.

[FR Doc. 2010–17714 Filed 7–20–10; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 50

45 CFR Part 94

[Docket Number NIH–2010–0001]

RIN 0925–AA53

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

AGENCY: Department of Health and Human Services.

ACTION: Proposed rule; extension of comment period; request for comments.

SUMMARY: The Department of Health and Human Services (HHS or the Department), including the HHS Public Health Service (PHS), is extending the comment period for a proposed rule that would amend the regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought and Responsible Prospective Contractors, and is clarifying certain elements of the proposed rule for which we are seeking additional comment. The proposed rule was published in the **Federal Register** on May 21, 2010 (75 FR 28688). The comment period is extended by 30 days and thus will end on August 19, 2010.

DATES: Comments must be received on or before August 19, 2010 in order to ensure we will be able to consider the comments when preparing the final rule.

ADDRESSES: Individuals, organizations and institutions interested in submitting comments identified by RIN 0925–AA53 and Docket Number [NIH–2010–0001] may do so by any of the following methods:

Electronic Submissions

You may submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- To ensure timely processing of comments, NIH is no longer accepting comments submitted to the agency by e-mail.

Written Submissions

You may submit written comments in the following ways:

- *Fax:* 301–402–0169.
- *Mail:* Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 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.

Instructions: All submissions received must include the agency name and Regulatory Information Number (RIN) [0925–AA53] and docket number [NIH–2010–0001] for this rulemaking action. All comments may be posted without change, including any personal information provided.

Docket: For access to the docket to read background documents or comments received concerning this rulemaking action, go to the eRulemaking.gov Portal: *http://www.regulations.gov* and follow the instructions provided for conducting a search, using the docket number [NIH–2010–0001].

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852–7669, telephone 301–496–4607, fax 301–402–0169, e-mail *jm40z@nih.gov,* concerning questions about the rulemaking process and Dr. Sally Rockey, NIH Deputy Director for Extramural Research, concerning substantive questions about the proposed rule, e-mail *FCOI-NPRM@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: HHS published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on May 21, 2010 (75 FR 28688), with a deadline for written comments of July 20, 2010. The NPRM proposed changes to 42 CFR Part 50, Subpart F, and 45 CFR Part 94 (the regulations) to expand and add transparency to Investigator disclosure of significant financial interests (SFIs) to Institutions, as well as enhance regulatory compliance and effective oversight of financial conflicts of interest (FCOIs). The current regulations at 42 CFR Part 50, Subpart F, are applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through implementation of the regulations by each Institution, to each Investigator participating in such research.[1] The current PHS contracting regulations at 45 Part 94 similarly apply to each Institution that seeks PHS funding for research and, through implementation of the regulations, to each Investigator who participates in such research.[2]

Since the NPRM was published, the Department has received questions concerning the authorities that exist under the current regulations and the proposed revisions to enable the PHS to enforce compliance by Institutions and Investigators with the regulations. In addition, the Department has considered whether, as part of the proposed revisions, it should clarify how the regulations apply in circumstances in which an Investigator or a PHS-funded research project transfers from one Institution to another, or in which a new Institution, and Investigators at the new Institution, become involved in an ongoing PHS-funded research project (*e.g.,* where the new Institution becomes a subgrantee on the project). The Department recognizes that scientific discovery is a fluid process, and sometimes necessitates the movement of people and projects between Institutions. Under most ordinary circumstances, this type of movement presents no concerns. However, the Department is fully committed to protecting the objectivity of PHS-funded research and wants to be sure that the transfer of an Investigator or research project from one Institution to another does not compromise the integrity of PHS-funded research. As a result, we are seeking comment whether the recently-published proposed rule should be

[1] In those few cases where an individual, rather than an institution, is an applicant for PHS grants or cooperative agreements for research, PHS Awarding Components will make case-by-case determinations on the steps to be taken to ensure that the design, conduct, and reporting of the research will not be biased by any conflicting financial interest of the individual.

[2] In neither case do the regulations currently apply to Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) Phase I applications.

further enhanced for clarity in protecting research integrity.

With regard to enforcement authorities, the current regulations include in 42 CFR 50.606 and 45 CFR 94.6 a description of remedies available to HHS and a PHS Awarding Component when identifying concerns regarding FCOI or compliance with the regulations. In addition, 42 CFR 50.607 identifies other HHS regulations that apply, including uniform administrative requirements, as well as debarment and suspension procedures. The NPRM includes proposed revisions to all three of these sections. Among the proposed changes, with regard to matters determined to require corrective action under the regulations, we proposed revising paragraph 50.606(b) to incorporate by reference 45 CFR 74.14 (special award conditions), and proposed revising paragraph 94.6(b) to reference "other enforcement action" in addition to, or in lieu of, a Stop Work Order by the Contracting Officer. In section 50.607, we proposed minor revisions to update the CFR location or title of the existing references, but also specifically requested comment with regard to the necessity of this section.

In conjunction with the comment period extension, we seek public comment on whether the proposed changes to the regulations' references to the enforcement authorities available to the PHS, including those discussed above, should be further revised and clarified in the regulations. This includes comment on whether the regulations should include one or more descriptions of specific measures that the Department, including a PHS Awarding Component, may initiate as a result of particular types of identified FCOI or non-compliance under the regulations. As one example, the regulations potentially could describe situations in which an Investigator's identified FCOI or an Investigator's failure to comply with an Institution's FCOI policy or FCOI management plan necessitates notification to other Institutions (*e.g.,* when the Investigator, or the PHS-funded research project on which he or she is working, transfers from one Institution to another).

In addition to possible clarification of enforcement authorities, the Department also seeks comment as to whether it should clarify how the regulations apply in circumstances in which an Investigator or a PHS-funded research project transfers from one Institution to another, or in which a new Institution, and Investigators at the new Institution, become involved in an ongoing PHS-funded research project (e.g., where the new Institution becomes a subgrantee on the project). As one example, we proposed in the NPRM to revise substantially 42 CFR 50.604(f) and 45 CFR 94.4(f) such that these paragraphs would require an Institution, through its designated officials, to determine whether an Investigator's SFI is related to PHS-funded research and, if so related, whether the SFI is a FCOI. We request comment as to whether the regulations should further clarify that, as part of the Institution's FCOI determination process, institutional officials must consider whether an Investigator's SFI was previously determined to be a FCOI and subject to a management plan with regard to other PHS-funded research project(s). Such consideration could be based on information in the Institution's own records or from publicly accessible sources (*e.g.,* the Web site of an Institution that previously employed the Investigator). We welcome additional public comment on alternative approaches or additional clarifications that may be incorporated into the regulations to protect further the objectivity of PHS-funded research in situations involving a transfer of an Investigator or PHS-funded project between Institutions, or the introduction of a new Institution and Investigators to an existing PHS-funded project.

Dated: June 22, 2010.

Francis S. Collins,

Director, National Institutes of Health.

Approved: July 6, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–17739 Filed 7–20–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

RIN 0920–AA34

Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a) (the Bioterrorism Act) requires the biennial review and republication of the HHS list of select agents and toxins. Accordingly, we are soliciting public comment on the current HHS list of select agents and toxins, including whether any biological agent or toxin should be added to or removed from the list. We are also seeking comments as to whether we should "tier" the HHS select agent list based on the relative bioterrorism risk of each agent or toxin and possibly further "stratify" the security requirements for agents in the highest tier based on type of use or other factors.

DATES: We will consider all comments received on or before August 20, 2010.

ADDRESSES: Comments in response to this notice should be marked "Comments on the changes to the list of select agents and toxins" and mailed to: Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Road, MS A–46, Atlanta, GA 30333. Comments may be e-mailed to: *SAPcomments@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Rd., MS A–46, Atlanta, GA 30333. *Telephone:* (404) 718–2000.

SUPPLEMENTARY INFORMATION: The Bioterrorism Act requires the HHS Secretary to establish by regulation a list of each biological agent and toxin that has the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers the effect on human health upon exposure to the agent or toxin; the degree of contagiousness of the agent; the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from the agent or toxin; the potential for the agent or toxin to be used as a biological weapon; and the needs of children and other vulnerable populations. The current list of HHS biological select agents and toxins can be found at *http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html.* The Bioterrorism Act requires that the HHS Secretary review and republish the HHS list of select agents and toxins on at least a biennial basis.

Background

The HHS Secretary last republished the HHS select agent and toxin list in the **Federal Register** on October 16, 2008 (73 FR 61363). The HHS select agent and toxin list, found in part 73 of Title 42 of the Code of Federal Regulations (42 CFR part 73), is divided