

maintain an appropriate written, enforced conflict of interest policy (this parallels NSF language) and that the Institution must make reasonable efforts to ensure compliance with the regulations by Investigators working for subgrantees and contractors, either by including those Investigators in the Institution's policy or by receiving appropriate assurances from their employers. This latter change was recommended in several comments and is consistent with current regulations and policies on the applicability of grant terms and conditions to subgrantees and contractors.

7. In response to many comments, paragraph (a)(3) (redesignated as paragraph (c)) of § 50.604 has been changed from requiring the institution to "ensure" that investigators have disclosed all Significant Financial Interest to simply "require" disclosures by each investigator. In addition, in response to several comments and for uniformity with the NSF guidelines, this paragraph has been revised to require disclosure, by the time an application is submitted to PHS, of those Significant Financial Interests attributable to the Investigator that would reasonably appear to be affected by the research, including interests in entities whose financial interests would reasonably appear to be affected by the research. This change eliminates the need to cross-reference the description of a conflict interest in § 50.605(a). Also, the changes in this section and in §§ 50.604(c) and 50.605(a) will result in a slightly broader disclosure by the Investigator than under the NPRM. The institutional official(s) will review the disclosures and determine which disclosed interests could directly and significantly affect the design, conduct or reporting of the research, necessitating the management, reduction or elimination of the conflict of interest. In addition, in response to a significant number of comments, the reference to "pendency" of the award has been changed to "period" of the award.

Paragraph (a)(5) of § 50.604 (redesignated as paragraph (e)) has been changed to delete the requirement that records be identifiable to each award, and to refer to the applicable retention requirements in the HHS grants administration regulations. The former change has been made for conformity with the NSF policy, and the latter change clarifies that the recordkeeping requirements of these regulations are intended to be consistent with the HHS grants administration regulations. The change in paragraph (f) of § 50.604 (formerly paragraph (a)(6)) has also been

made for conformity with the NSF policy.

8. In response to many comments, § 50.604(a)(7)(ii), now redesignated as (g)(2), has been revised to reduce the burden on institutions and ensure that the application does not have to state whether a conflict of interest has been found. Rather, the provision now requires the applicant to certify that action will be taken, prior to the institution's expenditure of any funds under the award, to report to the PHS awarding component the existence of a conflicting interest and assure that the interest has been managed, reduced or eliminated in accordance with the regulations. The commentors felt that review of an application would be biased if the application indicated there was a conflict of interest and that, in any case, it would not be feasible for an institution to review the disclosed financial interests and determine whether a conflict of interest was present in the limited time available prior to submission of the application.

In addition, the previous § 50.604(a)(8)(i) has been incorporated into § 50.604(g)(2) with minor changes. Many commentors felt that the 60 day period for management of a conflict of interest found after the award should be doubled. However, the 60 day period does not seem unreasonable, since we have clarified that it is measured from the time the institution identifies the conflict of interest and that only interim action is required by the end of the 60 day period. As stated in the NPRM, section 493A of the PHS Act imposes a continuing obligation on awardees to identify conflicts of interest in clinical research projects and report their management, reduction or elimination. This and other statutory requirements for clinical research have been applied to all PHS-funded research in order to avoid confusion and provide for uniform PHS reporting requirements. We would not expect this reporting requirement to be burdensome, as only a few conflicts of interest are likely to be identified after the award.

Section 50.604(a)(8)(ii) has been incorporated into § 50.606(b), because the review of records referenced in the former section is directly related to the inquiry into actions regarding conflicts of interest addressed in the latter section. Section 50.604(a)(8)(iii) has been deleted as duplicative of the statement in the definition of "Significant Financial Interest" (§ 50.603), that salary, royalties or other remuneration from the institution is not considered a Significant Financial Interest. Under current regulations and policies governing applications for PHS

research grants, if the applicant receives non-PHS grant support for the same project to be supported by the PHS award, the grant must be listed in the "Other Support" section of the application for PHS support.

9. Section 50.605(a) has been revised to clarify that the institutional official(s) must identify and manage, reduce or eliminate any conflicts of interest. Consistent with the language in the NSF guidelines, this provision states 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 PHS-funded research. As noted above in the discussion of the changes to § 50.604(c), Investigators must disclose those Significant Financial Interests that would reasonably appear to be affected by the research and the institutional official must decide which of those interests are conflicting under the standard prescribed in § 50.605(a). This change is intended to more clearly define and limit the types of financial interests that must be managed, reduced or eliminated because they are considered to be conflicting interests.

In response to a few comments, the clause introducing the examples of methods for managing, reducing or eliminating conflicts has been clarified by adding after "include," the phrase "but are not limited to."

10. In § 50.606, the first sentence has been deleted because it essentially duplicated the provision in proposed § 50.604(a)(6). In the next sentence, the term "employee" has been changed to the defined term "Investigator" and, in response to a comment, the phrase "or to be taken" has been added at the end of the sentence. In addition, paragraph (b) has been rewritten to incorporate § 50.604(b), because the two provisions were somewhat duplicative.

11. Many commentors were concerned about what they considered to be a significant underestimation of the annual reporting and recordkeeping burden. In response, burdens have been further reduced by raising the dollar threshold for financial interests that are considered Significant Financial Interests subject to the regulations, and by amending § 50.604(g)(2) to require the reporting of a conflict of interest and its management, reduction or elimination only after an award has been made (but before any expenditure of funds). In addition, the estimated annual reporting and record keeping burden has been recalculated in light of these changes and the public comments.

12. Many commentors urged uniformity with the NSF guidelines, but