

applicant under the SBIR or STTR program. We have not expanded the exclusion for ownership interests to encompass all institutions, because we believe there may be situations in which an ownership interest in a for-profit applicant could be in conflict with the investigator's responsibility for the conduct of the PHS-funded research and that ownership interest should be subject to appropriate institutional review. Experience under the regulations may prove this reasoning to be incorrect. If so, we will consider appropriate amendments to the regulations.

### Regulatory Impact

The Department has concluded that this rule is not economically significant under Executive Order 12866 and that it thus does not require the development of a comprehensive benefit-cost analysis. While we agree with comments received that the initial estimate of implementation costs was low, none of these comments indicated that the costs would exceed \$100 million annually; in addition, changes made in the final regulations will reduce implementation costs. Commentors did not provide any evidence that the rule will hamper desirable research or otherwise have an adverse effect on the conduct of research under PHS-funded grants or on the consequent technological progress that is so important to the Nation's economy.

Executive Order 12866 requires that the Office of Management and Budget (OMB) review all regulations that may create a serious inconsistency with or otherwise interfere with an action taken or planned by another Federal agency. This rule was thus reviewed by OMB and coordinated with the policy of the NSF on this subject (see the notice of technical changes in NSF policy published elsewhere in this separate part of this **Federal Register**).

The Department prepares a regulatory flexibility analysis, in accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. chapter 6), if a rule is expected to have a significant impact on a substantial number of small entities. Although we have not followed the NSF approach of exempting entities with 50 or fewer employees, we have concluded that the regulation will not have a significant impact on small entities. Any such effect is mitigated by the provisions of the regulations and the fact that the regulations impose obligations primarily on those receiving grants that can be used, in part (amounts for indirect costs), to offset the costs of compliance with the regulatory

requirements. The regulations do not apply to SBIR and STTR Phase I applications. These programs are for small businesses and the Phase I grants are for limited amounts. Phase II grants are for larger amounts and thus more funds would be available for meeting the costs of compliance. Furthermore, we have changed the regulations to reduce burdens and costs of compliance for all entities subject to the regulations by eliminating more financial interests from consideration and by reducing burdens upon institutions through changes in the certification requirements. Institutions do not have to take action to identify, report and manage conflicting interests until after being notified by the PHS Awarding Agency of its decision to award funds.

For the same reasons, this rule will not create an unfunded mandate on State-owned institutions and thus would not trigger the requirements of Executive Order 12875 on "Enhancing the Intergovernmental Partnership." The proposed rule has been changed to significantly reduce burdens on institutions and, as noted above, institutions will be able to use amounts awarded for indirect costs to meet the costs of implementing the regulations.

### Paperwork Reduction Act

The final rules contain information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1980. The title, description, and respondent description applicable to the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. These estimates have been revised in light of the comments on the proposed rules and the changes in the regulations. Consistent with the comments and a thorough consideration of the potential burdens imposed by the reporting, recordkeeping and disclosure requirements of the regulations, the statement of the burden has been reduced from that stated in the NPRM, based upon changes in the regulations that will significantly reduce the burdens on institutions and upon more accurate estimates of the burdens imposed by specific requirements.

The mean hours per response for initial reports of conflicts of interest have been significantly increased to account for the review by the institution of all the financial disclosures relating to an award. Although not more than 200 reports of conflicts of interest are expected, the institutions will need to review all financial disclosures associated with PHS funding awards to determine whether or not any conflicts of interest exist. Thus, the total burden

of 16,000 hours is based on estimates that it will take, on the average, four-fifths of an hour to review each of the 20,000 financial disclosures associated with PHS funding awards. If the number of disclosures is reduced because of the increase in the amount of the threshold for significance, the burden may be an overestimate.

The burden for subsequent reports of conflicts (made during the twelve month period after the initial report) is significantly less, because we do not expect many additional reportable conflicts and there will be only a limited number of disclosures to review.

We have significantly reduced the respondent number for reporting that failure of an investigator to comply with the institution's conflict of interest policy has biased the design, conduct or reporting of the research (§ 50.606(a)). We have estimated there will be no more than five such instances and we think that is a generous estimate.

For recordkeeping, we have listed the number of files expected to be necessary, rather than the number of institutions, because it will result in a more accurate estimation. The 20,000 figure is based upon 35,000 awards annually, reduced to account for those investigators who will not have any disclosures (no files are required to be established) and those investigators with more than one award. We have estimated it will take four hours, on the average, for the establishment and maintenance of each file. Although we believe this to be a very generous estimate, we note that it will include the time of both administrative and clerical personnel.

The burden figures for informing each investigator of the institution's policy are based upon 2,000 recipient institutions and 20 hours for the performance of this function. This time burden could be reduced even further if institutions choose to inform investigators through a notice in the grant application procedures. This method of notification would be acceptable because the regulations do not specify the method of notification.

The financial disclosures burden estimate (§ 50.604(c)) is based upon an investigator figure of 35,000 with an average response time of one hour. We believe experience may show that the number of disclosures will be significantly less because of the increases in the reporting threshold. Note that we have not attempted to calculate the overall hours spent by the institution to establish the necessary administrative mechanisms to comply with the regulations. The estimates are for burdens imposed by disclosure,