

indicated the pursuit of that end should not interfere with necessary changes to the NPRM. As noted above, many of the changes result in greater uniformity between these regulations and the NSF guidelines. The few remaining differences between these regulations and the NSF guidelines are based upon requirements in section 493A of the PHS Act, 42 U.S.C. 289b-1, and differences between the grant programs and experiences under those programs.

The effective date for these regulations, October 1, 1995, is the same as the effective date for the NSF guidelines. Although some commentors felt that a longer lead time would be necessary to enable institutions to prepare for implementation of the regulations, we believe the time period provided is ample, particularly because institutions have had since June 28, 1994, to prepare for implementation of the similar provisions of the NSF guidelines and because many institutions already have conflict of interest procedures.

### Comments Not Resulting in Any Changes

#### 1. Title

Two commentors felt that the title of the regulations should be changed to focus upon investigator financial disclosure or conflict of interest. These are not inappropriate titles, but we have chosen to focus the title upon the desired outcome of the review of investigator financial disclosures, that is, objectivity in the design, conduct and reporting of the research.

#### 2. Section 50.602 Applicability

Several commentors recommended that the regulations be limited to clinical research. As explained in the preamble to the NPRM, experience indicates that financial conflicts of interest can arise in all types of research. It is expected that the risk of a conflict of interest will be higher in clinical research than in other types of research, but we have concluded that the latter risk is sufficiently likely that pertinent financial interests should be disclosed and reviewed.

In response to a specific request for comments on the NSF exemption from its conflict of interest policy for grantees employing fifty persons or less, it was generally agreed by those responding that PHS-funded investigators working for small entities may be just as subject to conflicts of interest as investigators working at large institutions. This view is consistent with the PHS experience referred to in the preamble of the NPRM. The NSF experience has

differed, apparently because of the differences between the research funding that is provided to small entities by HHS and NSF.

#### 3. Section 50.603 Definitions

*Investigator.* There were diverse comments on the definition of the term, "Investigator." Although one commentor supported the approach of the NPRM of leaving it to the institutions to determine who are persons "responsible for the design, conduct, or reporting" of the PHS funded research, others felt that the definition should offer more guidance on who would fall within that category. It was recommended that the term be limited to Principal Investigators, Co-Principal Investigators, and faculty collaborators and that students and technical staff be excluded. It was also recommended that administrators be excluded by limiting the definition to the "scientific design" of the research. The definition of Investigator has not been changed, except for deleting the phrase "at the institution," as explained above. The degree to which individuals are responsible for the design, conduct, or reporting of the PHS-funded research will vary. In some circumstances students, technical personnel and administrators may not be "responsible," but in other circumstances, they may be, in that they are given responsibility for a task that could have a significant effect on the design, conduct or reporting of the research. Based on their knowledge of the specific circumstances, we believe the institutions are in the best position to determine who is responsible for the design, conduct or reporting of the research to such a degree that his/her financial interests should be reviewed.

*Significant Financial Interest.* As noted above, the public comments led to several changes in this definition. There were a number of other detailed comments that were not adopted, primarily because they would have: Complicated the definition and its application (e.g., have different threshold levels for publicly traded equity interests and those not so traded, differentiate between large and small companies, and adopt criteria for determining reasonably anticipated future value); led to a long, cumbersome list of additional exclusions (e.g., exclude copyright that is not licensable, mutual funds, pensions, and reimbursement for expenses); or were based upon a misunderstanding of the definition and its effect (some apparently did not understand that any remuneration an investigator receives from the applicant institution was

excluded). Some commentors questioned the exclusion of ownership interests in SBIR applicants. No change has been made in response to that comment because we believe such ownership interests are apparent to PHS funding agencies based on the application. Furthermore, the exclusion does not prohibit institutions from adopting more rigorous standards, if they wish to do so.

The definition of Significant Financial Interest alone does not delineate what the investigator must disclose or what the institution must manage, reduce or eliminate. The Investigator must consider all Significant Financial Interests, but need disclose only those that would reasonably appear to be affected by the research proposed for funding by the PHS, including the Investigator's financial interest in entities whose interests would be affected. Following this disclosure, the institutional official must determine, on the basis of the regulatory standard, whether there are conflicting interests that need to be managed, reduced, or eliminated. We think it is appropriate to have a relatively broad range of financial interests considered by the Investigator in making his/her determination of those that must be disclosed. In this manner, broad consideration of possibly conflicting interests is assured with minimal burdens, since only a limited number of interests need to be disclosed and an even smaller number will need to be managed, reduced or eliminated.

There were a number of comments recommending different thresholds than those that were adopted, including a threshold adjusted for inflation. The threshold amounts adopted were recommended in many comments and seem to represent a reasonable balance between the need to consider a broad range of financial interests and the burdens imposed upon the investigators and the institutions.

#### 4. Section 50.604

Many commented that the requirement for updating financial disclosures (in § 50.604(c) of these regulations) needed to be clarified. The provision, which has not been changed, except for a minor word change, states that financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained. We believe this language is reasonably clear in conveying that the institutions have the option of adopting either of two methods for investigators to report changes in financial interests during the