contained in the agency's annual report to indicate the types of arbitration issues, the average or median arbitration fees and days spent on cases, and the timeliness of the awards rendered.

Agency: Federal Mediation and Conciliation Service.

Title: Notice to Mediation Agencies.

OMB Number: 3076–0004.

Agency Number: Form F–7.

Frequency: Once per collective bargaining contract.

Affected Entities: Private sector employers and labor unions involved in interstate commerce who file notices for mediation services to the FMCS and state, local, and territorial agencies, who receive copies of these notices filed.

Number of Respondents: 70,000.

Estimated Time Per Respondent: 10 minutes.

Total Burden Hours: 4,167

Total Annualized capital/startup costs: $0.

Total annual costs (operating/maintaining systems or purchasing services): $0.

Description: The F–7 form was created to establish conformity throughout interstate commerce and to allow FMCS to gather desired information in a uniform manner. The collection of such information, including the name of employer or employer association, address and phone number, official contact, bargaining unit and establishment size, location of affected establishment and negotiations, industry or type of business, principal product or service, union address, phone number, and official contact, contract expiration date or renewal date, whether the notice is filed on behalf of the union or employer, and whether this is health car industry notice for initial contracts or existing contracts, is critical for reporting and mediation purposes.

Dated: June 27, 1996.

Wilma B. Liebman,

Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Science Foundation

Frequently Asked Questions Concerning the Department of Health and Human Services Objectivity in Research Regulations and the National Science Foundation Investigator Financial Disclosure Policy

AGENCIES: Public Health Service, and Office of the Secretary, HHS; National Science Foundation.

ACTION: Responses to questions.

SUMMARY: This document responds to frequently asked questions regarding PHS' and NSF's recently-issued rules on investigator conflicts of interest. This guidance document is intended to help institutions implement conflict of interest policies that comply with both PHS and NSF requirements.

FOR FURTHER INFORMATION CONTACT: *For PHS:* Geoffrey Grant, Acting Director, Office of Policy for Extramural Research Administration, National Institutes of Health, Room 2192, 6701 Rockledge Drive, MSC 7730, Bethesda MD 20817, (301) 435–0949. *For NSF:* Christopher L. Ashley, Assistant General Counsel, National Science Foundation, 4201 Wilson Boulevard, Room 1265, Arlington, VA 22230, (703) 306–1060.

SUPPLEMENTARY INFORMATION: On July 11, 1995, the Public Health Service (PHS) and the Office of the Secretary of the Department of Health and Human Services (HHS) and the National Science Foundation (NSF) issued rules regarding investigator conflict of interest. As explained in the preambles to those rules, PHS and NSF have been working together to ensure that the rules impose consistent obligations on institutions receiving PHS and NSF funding. To that end, PHS and NSF announced that the agencies would be developing a set of questions and answers (Q&As) to help institutions implement conflict of interest policies that comply with both PHS and NSF requirements. This set of Q&As provides answers to frequently asked questions received by both agencies. Where there are minor differences between the PHS and NSF rules, they are clearly noted.

Q1: Does NSF or PHS have a suggested format for investigator disclosures?

A1: No. The rules are designed to defer to the expertise of grantee institutions in developing policies and supporting documentation.

Q2: May an institution have different conflict of interest policies that vary among departments or professional schools?

A2: Yes, as long as all policies meet the minimum requirements of the NSF and PHS rules.

Q3: Which offices within an institution should be involved in administering the conflict of interest rules?

A3: An institution is free to administer its policy through whatever office or structure it wishes, as long as the policy reaches all investigators on NSF- and PHS-funded projects and the requirements of the PHS and NSF rules are met.

Q4: Must institutions routinely require financial disclosures from graduate students working on NSF- or PHS-sponsored research?

A4: The term ''investigator'' is defined to encompass individuals ''responsible for the design, conduct or reporting'' of NSF- or PHS-funded research. It is up to the institution to decide whether graduate student co-authors are ''responsible for reporting'' the research.

Q5: Will a proposal be processed if it does not contain the new certification required by the NSF and PHS rules?

A5: NSF will not process a proposal in the absence of the new certification, but in most cases the institution will not be required to re-submit the entire proposal. An addendum page to the *Cover Sheet to the National Science Foundation* (NSF Form 1207) has been developed that contains the required certification. The NSF administrative officer typically will forward a new certification page to the institution, and will process the proposal upon receipt of a completed and executed new page. The PHS would process the application without the proper certification but no award would be made until the awarding component received the certification in the form of a signed, revised application face page.

Q6: Do the PHS and NSF conflict of interest rules apply to all researchers and faculty members at institutions that receive NSF or PHS support?

A6. No. The NSF policy applies only to grantee institutions that employ more than fifty persons and the PHS rule exempts Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Phase I applications. In those institutions subject to the NSF policy and/or the PHS rule, only persons involved in PHS- or NSF-funded research are subject to the rules. However, institutions may choose to cover other researchers or faculty members under their policies for institution-specific reasons.

Q7: Do the PHS or NSF rules apply to subgrantees of PHS or NSF grantees?

A7: Consistent with current regulations and policies, the PHS rule applies to subgrants; the NSF Policy does not. Accordingly, institutions conducting PHS-funded research through subgrantees, contractors, or collaborators must take reasonable steps to ensure that investigators working for such entities comply with the regulations (42 C.F.R. § 50.604(a)) either by requiring the investigators to comply with the grantee institution's policy or by requiring the entities to provide appropriate assurances to the grantee institution. An institution conducting NSF-funded research through subgrantees must certify that the institution itself has in place a written, enforced policy on investigator conflicts of interest, but is not required to ensure that subgrantees comply with the NSF Policy. However, the Policy may apply to a subgrantee employing investigators who collaborate on NSF-sponsored research (see Q&A 14).

Q8: Do the NSF or PHS rules apply to post-doctoral fellowships?

A8: Not in most cases. The NSF policy applies only to grantee institutions that employ more than 50 persons and therefore would not apply to post-doctoral fellowships awarded to individuals. The PHS rule applies to PHS-funded research and to any person who is responsible for the design, conduct or reporting of research funded by the PHS. Thus, if a post-doctoral fellow served in such a capacity in PHS-funded research he or she would be subject to the rule. The PHS rule would apply to a postdoctoral fellowship application to the PHS only if the funding would be used for research and the fellow served in one of the research capacities described above.

Q9: Are investigators required to disclose interests in mutual funds?

A9: An interest in a pooled fund such as a diversified mutual fund may be sufficiently remote that it would not reasonably be expected to create a conflict of interest for a NSF- or PHS-funded investigator. For example, an investigator may own an interest in a diversified mutual fund which has assets placed in many securities. It is possible that certain of the securities held by the mutual fund were issued by an entity whose interests would reasonably appear to be affected by activities proposed for funding by NSF or PHS. However, because it is likely that an investigator's interest in a mutual fund is only a small portion of the fund's total assets and because only a limited portion of the fund's assets are placed in the securities of a single issuer, it is unlikely that an investigator's activities on an NSF or PHS award would affect his or her interest in the mutual fund. Institutions therefore may determine that certain interests in a diversified mutual fund could never directly and significantly affect the design, conduct or reporting of PHS- or NSF-funded research and exempt such interests from disclosure by the investigator on that basis.

The federal government's Office of Government Ethics has detailed regulations regarding the treatment of diversified mutual funds under the government's conflict of interest rules. 5 C.F.R. § 2634.310(c); *see also* 60 Fed. Reg. 47,208 (Sept. 11, 1995) (proposed rule). Institutions may consult these regulations for guidance on how they might wish to treat interests in mutual funds under their policies.

Q10: Are investigators required to disclose interests in ''blind trusts''?

A10: Institutions may determine that the research will not be affected by qualified blind trust assets not known to the investigator that are managed by an independent fiduciary. Because such assets would not be known to an investigator, they could not directly and significantly affect the design, conduct or reporting of the research. Of course, an investigator is aware of the assets originally placed in the trust at the time of its formation and would be required to disclose any such assets that would reasonably appear to be affected by NSF- or PHS-funded research. Only new assets purchased with the proceeds from the original assets would be unknown to the investigator.

As with diversified mutual funds, the Office of Government Ethics has detailed regulations describing the type of trusts that qualify for the ''blind trust'' exception to the government's conflict of interest rules. 5 C.F.R. Part 2634 Subpart D. Institutions may consult these guidelines in determining how they wish to treat certain trusts under their policies.

Q11: Are foreign investments (e.g., shares in a foreign corporation) covered by the financial disclosure requirement.

A11: Yes, if they would reasonably appear to be affected by NSF- or PHS-funded research and do not fall within one of the exceptions to the definition of ''significant financial interest.''

Q12: Which conflicts of interest must be reported to the federal government?

A12: Neither the PHS nor NSF rules require any institution to report to the federal government the details of any conflict of interest that has been resolved pursuant to the institution's Policy. Consistent with the statute authorizing its conflict of interest rule, the PHS requires institutions, prior to the institution's expenditure of any funds under an award, to report to the PHS Awarding Component the existence of any conflicting interests and assure that the interest has been managed, reduced or eliminated in accordance with PHS regulations. NSF requires that only conflicts that have not been managed, reduced or eliminated prior to the expenditure of funds under an award be reported to NSF.

Q13: Will investigator financial records be subject to public disclosure?

A13: No. Normally, neither PHS nor NSF would possess records of the financial interests of investigators, because institutions are not required to submit those records. However, in the event NSF or PHS had such information either as a result of an audit or compliance review or in connection with a conflict of interest that cannot be managed satisfactorily under the institution's policy, it would not be disclosed to the public. Where a member of the public submits a request under the federal Freedom of Information Act (FOIA) for financial information in the possession of NSF or PHS, the agencies would assert all applicable FOIA exemptions in response to such a request.

Q14: Is the applicant institution required to obtain financial disclosures from investigators who are not employed by the applicant institution?

A14: The PHS rule provides that if the institution carries out the PHS-funded research through a collaborator, the institution must take reasonable steps to ensure that investigators working for the collaborator comply with the rule, either by requiring those investigators to comply with the applicant institution's policy or by requiring an assurance from the collaborating institution which will enable the applicant institution to comply with the rule. NSF would expect that where an investigator does not work for the applicant institution, the applicant institution would obtain an assurance from the institution employing the investigator indicating that the investigator has complied with the requirements of the policy at that institution.

Q15: Are all ''senior personnel'' listed in NSF proposals and ''key personnel'' listed in PHS proposals subject to the financial disclosure requirements of the conflict of interest rules?

A15: As explained in Q&A 4, the term ''investigator'' is defined functionally rather than categorically. Although the agencies believe that senior and key personnel will be ''responsible for the design, conduct or reporting of research'' under the rules in almost all

cases, it is possible to conceive situations in which senior or key personnel might not meet the definition of ''investigator.'' Institutions are also responsible for obtaining financial disclosures from persons other than senior or key personnel who meet the definition of ''investigator.''

Q16: How should institutions with fewer than 50 employees complete the certification page for NSF proposals?

A16: Such institutions should annotate NSF Form 1207 or the addendum page (See Q&A1 above) to indicate that they have fewer than 50 employees and are therefore exempt from the Investigator Financial Disclosure Policy. These institutions are not exempt from the PHS regulations.

Q17: Salary, royalties and other payments that ''are not expected to exceed $10,000 over the next twelve month period'' are excluded from the definition of ''significant financial interest.'' How should an investigator estimate expected income over the next twelve months?

A17: The agencies have no preferred estimation method. Investigators must make their best reasonable estimates of expected income in determining whether salary, royalties or other payments constitute ''significant financial interests.'' This issue is separate from an investigator's ongoing duty to update financial disclosures either annually or as new significant financial interests are obtained throughout the period of the award.

Q18: How can an institution determine that all required disclosures have been made before submitting a proposal to NSF or PHS?

A18: As part of the institution's routine proposal preparation procedures institutions should require investigators to ensure that they have made all required financial disclosures in accord with the regulations prior to the time the organizational representative makes the certification in an NSF or PHS proposal. NSF and PHS staff, auditors and others concerned with the proper implementation of these regulations would expect such an arrangement at any institution that certifies to the maintenance of an appropriate written, enforced policy on conflict of interest.

Q19: Must an investigator report to the institution a single share of stock?

A19: A single share of stock would have to be reported only if (i) it is valued at more than $10,000 *or* represents more than a five percent ownership interest in the corporation; *and* (ii) it would reasonably appear that the value of the stock could be affected by the research for which funding is sought or that the financial interest of the corporation would be so affected.

The rules define a significant financial interest as anything of monetary value including equity interests (*e.g.*, stocks, stock options, or other ownership interests) but the definition excludes an equity interest that does not exceed $10,000 in value *and* represents no more than a 5% ownership interest in any single entity. This means that, under the rules, an investigator would never have to report an equity interest of $10,000 or less which represents 5% or less ownership interest in any single entity because that combination of value and ownership is excluded by definition from the term ''significant financial interest.'' On the other hand, under the rules, an investigator would always have to report an equity interest exceeding $10,000 or an ownership interest exceeding 5% in any single entity, regardless of value, if that equity interest or ownership interest was held in an entity whose financial interests would reasonably appear to be affected by the specified activities for which funding is sought.

Q20: When and how will the NSF and PHS rules be reviewed and revised?

A20: The agencies anticipate that after two or three years of experience with the rules, they will solicit public comments regarding whether changes are necessary or appropriate.

Dated: June 13, 1996.

Dr. Harold Varmus, M.D.,

Director, National Institutes of Health.

Lawrence Rudolph,

General Counsel, National Science Foundation.

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Centers for Disease Control and Prevention

[INFO–96–18]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer at (404) 639–7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Survey of State-Based Diabetes Control Cooperative Agreement Programs—New—Diabetes mellitus and related complications are the seventh leading cause of death in the United States, and accounts for $105 billion in direct medical costs and lost productivity each year. Approximately 14 million Americans have been diagnosed with diabetes, a leading cause of new blindness and end-stage renal failure in the United States and a major co-morbid factor in lower extremity amputation, cardiovascular disease and related death, and neonatal morbidity and mortality.

Through the support of the Centers for Disease Control and Prevention's (CDC) ''State-Based Program to Reduce the Burden of Diabetes: A Health Systems Approach,'' public health departments in 42 states and four U.S. territorial affiliated jurisdictions have been charged with providing leadership in reducing the gap between what should be and what is the current standard of diabetes care.

CDC will collect information from diabetes State Program Coordinators regarding the four key areas of program implementation. They are (1) capacity building and infrastructure development, (2) surveillance and data collection, (3) health systems change, and (4) working with local programs.

The survey has three main objectives:

1. Document the progress made by Diabetes Control Programs in the four main areas of program implementation.

2. Assess the relationship between the level of infrastructure development, and a program's efforts to carry out surveillance activities, health systems change activities, and work with local programs. Information will help improve technical assistance (TA) and guidance offered to states by CDC.