Evaluation of the Impact of the New Conflicts of Interest Regulations on the National Institutes of Health's Ability To Recruit and Retain Staff

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Section A

A.1. Circumstances Requiring the Collection of Data

As stated in Title 42, Chapter 6A of the Unites States Code, the Secretary of Health and Human Services "shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man" (42 USC 241). Further, 42 USC 282 says that the Director of the National Institutes of Health "shall be responsible for the overall direction of the National Institutes of Health and for the establishment and implementation of general policies respecting the management and operation of programs and activities within the National Institutes of Health" and "shall coordinate and oversee the operation of the national research institutes and administrative entities within the National Institutes of Health." (See Attachment 1 for a copy of the relevant U.S. Code.) Under this authority, NIH's Office of Human Resources (OHR), under the Office of the Director, requests clearance to collect information for an evaluation of the impact of NIH's new conflict-of-interest regulations on its ability to recruit and retain staff. Gauging the impact of these regulations is critical to NIH's ability to develop and maintain the skilled, experienced staff necessary to fulfill its mission of protecting and improving the public health.

In December 2003 the House Energy and Commerce Committee raised concerns about potential conflicts of interest at NIH. In response to these concerns, NIH Director Dr. Elias Zerhouni, ordered an internal investigation and in June 2004 proposed changes to the agency's conflict-of-interest policies. The interim final Conflicts of Interest regulations were published in the Federal Register, Volume 70 Number 22, page 5543 to 5565 on February 3, 2005, and final amendments were published on August 31, 2005 in Volume 70 Number 168, page 51559 to 51574 (See Attachment 1 for a copy of the regulations.). The regulations apply to all NIH employees and place limits on certain financial holdings of employees, their spouses, and dependent children and on certain outside activities in which NIH staff may engage. With respect to financial holdings, the regulations prohibit senior-level employees from holding more than $15,000 worth of stock in

an individual pharmaceutical, biotechnology, or related company that is considered a substantially affected organization ($50,000 total for all holdings), except as part of a diversified mutual fund. Other employees' stock holdings may also be restricted on a case-by-case basis. A cap of $200 is placed on awards that employees can receive, with the exception of significant scientific awards such as the Nobel Prize, and limitations are also placed on outside activities such as consulting agreements.

The regulations were intended to fulfill the commitment Dr. Zerhouni made to Congress to find a solution to the issue of conflicts of interest while maintaining NIH's ability to fulfill its mission. However, some key NIH senior directors and scientists have chosen to leave NIH rather than comply with the new regulations. Furthermore, other senior directors and scientists who planned to join NIH have now reconsidered and have withdrawn or delayed their employment with NIH, because of concerns about the effect the new regulations would have on their lives. The extent of the impact of the regulations needs to be established in order to avoid damage to NIH and to the public. Delaying or not performing this evaluation could cause public harm, both to NIH because of the loss of people and knowledge, and to any individual employees or their family members who may suffer as a result of having to make serious financial decisions because of the regulations.

On page 5543 of the February 3, 2005 Federal Register Notice of the regulations, it states that "HHS intends to evaluate certain provisions in the rule, particularly on outside activities and financial holdings," and that HHS will specifically "evaluate possible effects on hiring and retention that may result from the imposition of outside activity and financial holdings prohibitions." The goal of this collection is to produce data that will help NIH and HHS leaders determine the impact of the new regulations on NIH's ability to attract and keep qualified staff, and to determine how NIH can best handle these impacts. To obtain this data, NIH will first assess the attitude of current NIH staff through a series of focus groups, stakeholder interviews, and through a survey of all current staff. OMB clearance is being requested for the second phase of the evaluation— telephone interviews of prospective applicants for jobs at NIH and a mail survey of senior scientists and administrators who have voluntarily left NIH since the implementation of the regulations. This is a request for OMB approval of the Evaluation of the Impact of the New Conflicts of Interest Regulations on the National Institutes of Health's Ability To Recruit and Retain Staff.

A.2. Purposes and Uses of the Data

As was mentioned in A1, HHS and NIH must evaluate the impact of the new regulations in order to establish how to best address and deal with any impact from the regulations on recruiting and retaining staff. The purpose of this information collection is to meet that requirement by assessing the extent to which the new ethics rules would affect the decision of an individual to become and remain an employee at NIH, and whether the rules were a factor in the decision to leave NIH. The primary use of the data will be to provide NIH and HHS leadership with information needed to make informed decisions about how to address the effects of the regulations and to ensure that NIH does not lose key personnel and endanger the continuity of its work, both of which would result in public harm.

Information will be collected from two groups of respondents. The first group, potential applicants for employment at NIH, will be asked about their awareness of the regulations, their opinions on the need for and effectiveness of the regulations, and whether the regulations have affected or would affect the likelihood of their accepting a job at NIH. The second group of respondents, which has come into existence since the implementation of the regulations, are those

senior scientists and administrators who have voluntarily left NIH since February 3, 2005 (when the interim final regulations were implemented). Information collected from these respondents will include factors that led to their decision to leave NIH and the extent to which the conflicts of interest regulations played a role in their decision.

A.3. Use of Information Technology To Reduce Burden

Surveys of potential employees will be conducted using computer-assisted telephone interviewing (CATI). The use of CATI technology minimizes the time burden on respondents. A copy of the survey instruments is included in Attachment 2.

A.4. Efforts To Identify Duplication

Information collected by these surveys is unduplicated by any other source, and no other information or data can be used or modified for this purpose. The new Conflicts of Interest regulations were implemented on February 3, 2005 and this collection will be the first effort to evaluate their impact. The data gathered from NIH staff through focus groups and an all-staff survey will complement the data gathered in this collection, but will not replicate the information provided by these outside individuals.

A.5. Small Business

While some respondents may be physicians in private practice, most will be researchers affiliated with universities or other research institutions. We anticipate that very few small businesses will be affected by the survey, but care will be taken to minimize any burden that does fall on small entities.

A.6. Consequences of Not Collecting the Information

This is a one-time collection of information.

A.7. Special Circumstances Justifying Inconsistencies with Guidelines in 5 CFR 1320.6

This project has no special circumstances relating to the guidelines of 5 CFR 1320.5.

A.8. Consultation Outside the Agency

A Federal Register notice requesting comments on the collection was published on January 30, 2006(Volume 71, Number 19). A copy of the text of that notice is included in Attachment 3. The new regulations themselves have been widely publicized; they have been the subject of both press coverage and congressional hearings since 2004. The regulations were published in the Federal Register on February 3, 2005, with the statement that comments submitted by April 4, 2005 would be considered prior to the issuance of the final regulations. More than 1400 comments were received and reviewed by the Department of Health and

Human Services and were described in more detail in the August 31, 2005 amendments published in the Federal Register.

A.9. Payments or Gifts to Respondents

No payments or gifts will be made to respondents.

A.10. Assurance of Confidentiality

During the interviews, respondents will be informed of the use and protection from disclosure of their individual responses. Respondents will be informed that the information they provide will be kept confidential and will not be disclosed to anyone but the researchers conducting the study, except as otherwise required by law. Individual identifiers will be removed and replaced by codes by the data collection contractor; at no time will the data be searched by name or other individual identifier. The contractors will not provide the complete dataset to the NIH, and will release only aggregate data. The contractor will only hold telephone numbers or e-mail addresses for the duration of this project. Within 30 days of the end of data collection, the contractor will eliminate all identifying information from all survey databases. The NIH Privacy Act Officer has determined that the Privacy Act does not apply to this data collection (See Attachment 5 for a letter from the NIH Privacy Act Officer stating that this survey is exempt). In addition, the names of potential applicants will be drawn from the NIH Information for Management, Planning, Analysis, and Coordination (IMPAC) II database, which falls under System 09-25-0036, Extramural Awards and Chartered Advisory Committees (IMPAC 2), Contract Information (DCIS), and Cooperative Agreement Information, HHS/NIH. This is a legitimate use of the data from those systems of records and confidentiality will be maintained.

A.11. Questions of a Sensitive Nature

No questions of a sensitive nature are included in the data collection.

A.12 Estimates of Response Burden

For telephone interviews and a mail survey, the total estimated respondent burden is 116.7 hours. This estimate is based on the completion of 400 telephone interviews at an average length of 15 minutes each and 100 mail surveys at 10 minutes each. The estimate of average length is based on operational pretests of the instruments. The cost to individual respondents is very small because record-keeping and written information are not required, and the survey instruments are brief.

Table A12-1. Estimates of Hour Burden

Type of Respondent	Number of Respondents	Frequency of Response	Average Time Per Response	Annual Hour Burden
Potential Applicants	400	1	15 minutes	100 hours
Former NIH Employees	100	1	10 minutes	16.67 hours
TOTAL	**500**			**116.67 hours**

Table A12-2. Annualized Cost to Respondents

Type of Respondent	Number of Respondents	Frequency of Response	Average Time Per Response	Hourly Wage Rate	Respondent Cost
Potential Applicants	400	1	15 minutes	$33.00	$3,300

Former NIH Employees	100	1	10 minutes	$33.00	$550
TOTAL	500				**$3,850**

Hourly rates for respondents were determined using the Bureau of Labor Statistics' National Occupational Employment and Wage Estimates data on the average salary for medical scientists.

A.13. Estimate of Total Capital and Startup Costs/Operation and Maintenance Costs to Respondents or Record Keepers

There is no other annual cost burden to respondents or record-keepers.

A.14. Estimates of Costs to the Federal Government

A contract to conduct the data collection and analysis was awarded to ORC Macro under contract number GS23F-9777H by NIH. The total cost of the contract was budgeted at $282,661. The cost for this portion of the data collection and analysis, including designing the survey, conducting the survey, and performing analysis is $93,259.

A.15. Changes in Burden

This is a new collection, so there are no program changes or adjustments**.**

A.16. Plans for Publication, Analysis, and Schedule

Data collected from the respondents will be prepared for analysis by the data collection contractor immediately after collection. This preparation includes cleaning the data, applying the predetermined protocol for incomplete surveys, and creating the final analysis datasets. The types of analyses that will be done include descriptive analysis; segmentation; driver analysis, which uses correlation analysis or regression analysis to identify the statistical impact of the new ethics regulations on recruitment and retention relative to other decision factors; and other analyses as needed. After analysis is completed, the results will be incorporated into Top-Line and Final Reports to be delivered to OHR. Only aggregate data, and not the complete dataset, will be delivered to NIH. The following is the expected schedule for data collection, analysis, and reporting:

Table A16-1. Project Time Schedule

Activity	Time Schedule
Conduct telephone and mail surveys	3-11 weeks from OMB approval
Initial analysis of data	11-12 weeks from OMB approval

Complete Top-Line report	12 weeks from OMB approval
Continued data analysis	11-15 weeks from OMB approval
Complete Final Report	15 weeks from OMB approval

A.17. Approval to Not Display Expiration Date

The OMB number, expiration date, and full burden statement will be placed on the first page of the information collection instruments.

A.18 Exceptions to Item 19 of OMB Form 83-I

There are no exceptions to the certification statement.