Supporting Statement for Annual Report on Possible Research Misconduct and Supporting Regulations Contained in 42 CFR Part 93

Background

This is a request for OMB to approve a revision of a currently approved collection for three years, the Annual Report on Possible Research Misconduct form (PHS 6349) developed to implement the regulation. The OMB approval (OMB No. 0937-0198) of this form expires on May 31, 2012.

Attachment I, the current Annual Report on Possible Research Misconduct (Annual Report) (PHS 6349).

The purpose of the Annual Report on Possible Research Misconduct (Annual Report) form, in addition to providing an annual assurance that the institution has established and will follow administrative policies and procedures for responding to allegations of research misconduct that comply with the Public Health Service (PHS) Policies on Research Misconduct (42 CFR Part 93), is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS supported research. Research misconduct is defined as receipt of an allegation of research misconduct and/or the conduct of an inquiry and/or investigation into such allegations. These data enable the ORI to monitor institutional compliance with the PHS regulation.

Lastly, the form will be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

A. Justification

1. Need and Legal Basis

Section 493 of the Public Health Service Act, as amended by Pub. L. 99-158, the Health Research Extension Act of 1985, provides that the Secretary by regulation shall require that each entity that applies for a grant, contract or cooperative agreement which involves the conduct of biomedical or behavioral research shall submit an approved assurance. This assurance developed under the regulation promulgated to implement Pub. L. 99-158 states that the institution 1) has established policies and procedures to review, investigate and report allegations of research misconduct in connection with biomedical and behavioral research conducted at or sponsored by the applicant institution with PHS supported funds, 2) will comply with its own policies and will report to the Secretary any investigation or alleged misconduct and 3) will follow the requirements of 42 CFR Part 50, Subpart A which has been superseded by 42 CFR Part 93. The regulation, (42 CFR Part 50, Subpart A), which was published in 1989 states that "An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

Section 493 of the PHS Act was further amended by the NIH Revitalization Act of 1993 that mandated the creation of the Office of Research Integrity (ORI) to administer the regulation. ORI replaced the Office of Scientific Integrity and the Office of Scientific Integrity Review that had been created in 1989 by the Assistant Secretary for Health. In June 2005, the original regulation was superseded by the Public Health Service Policies on Research Misconduct (42 CFR Part 93) which states that "an institution must file an annual report with ORI which contains information specified by ORI on the institution's compliance with this part."

2. Information Users

The data are used by PHS agencies and ORI to verify the eligibility of institutions and organizations to receive PHS funds for research, research training and research related activities. To be eligible for funding, institutions and organizations must keep their assurance active by filing their Annual Report with ORI. The data are also used by ORI to monitor the implementation of the regulation by institutions and organizations. Data on the reported misconduct activity are also presented to the research community through the ORI Newsletter, ORI Annual Report, ORI website and conferences and workshops.

3. Improved Information Technology

Beginning with the CY 2000 Annual Report, the burden on awardee institutions and ORI was substantially reduced with the introduction of electronic submission as an option for submitting the Annual Report. About 98 percent of awardee institutions can electronically file their Annual Report in less than ten minutes. Automatic data entry substantially reduced the effort needed to update the ORI assurance database. The accuracy of the database is also enhanced because institutions may update their institutional information throughout the year.

Global email messages provide advance and ongoing reminders about submitting the Annual Report. The availability of the Annual Report form on-line and the computerized fax transmission of the form have dramatically reduced the use of mail.

4. Duplication of Similar Information

Similar data are not collected by ORI or any other organization.

5. Small Businesses

Section 493 of the Public Health Service Act provides that the Secretary by regulation shall require each entity to develop an administrative process for investigating and reporting incidents of misconduct. Small businesses must file their Annual Report, but may submit a "Small Organization Statement" in lieu of extensive policies and procedures if they do not have enough employees to conduct investigations with conflicts of interest. Under the Small Organization Statement, a small business is required to inform ORI of any allegation of research misconduct it receives. ORI and the small business develop procedures for responding to the allegation. The burden on a small business or entity is not significant.

6. Less Frequent Collection

The data collected in the Annual Report cannot be collected less frequently because the data are necessary for maintaining an accurate assurance database that determines institutional eligibility for PHS funding. The data also permits ORI to annually monitor compliance with the regulatory requirement to report the opening annually monitor compliance with the regulatory requirement to report the opening of an investigation. Receipt of an allegation of research misconduct and conduct of an inquiry are only reported in the Annual Report unless the inquiry continues into an investigation. Accurate data on institutional officials responsible for implementing the regulation are essential for referring allegations to institutions and for communicating educational and preventive activities. Recordkeeping over a longer time period would be problematic and further reduce the accuracy of the data submitted in the reports.

7. Special Circumstances

Regulations are consistent with 5 CFR 1320.5.

8. Federal Register Notice

A 60 day notice was published December 8, 2011 in the Federal Register Volume 76, Page 236 to solicit public comment for PHS-6349. No comments.

9. Payment/Gift to Respondent

No payments or gift were given to Respondent.

10. Confidentiality

Data are not collected that could identify an individual.

11. Sensitive Questions

The Annual Report on Possible Research Misconduct collects data on the number of research misconduct allegations received by an institution, the number of inquiries and investigations conducted into those allegations, and the types of research misconduct being alleged. No information is collected on the persons involved in the allegations. The information collected in the report is not protected by an statute.

12. Burden Estimate (Total Hours and Wages)

Estimated Annualized Burden Table

Forms (If necessary)	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden hours per Response	Total Burden Hours
PHS-6349	Awardee Institutions	6096	1	10/60	1,016

The burden estimate has been reduced substantially for two reasons. First, the new definition of research misconduct in the PHS Polices on Research Misconduct is limited to fabrication, falsification, and plagiarism. The clause, Aother practices that seriously deviate from those that are commonly accepted with the scientific community@ was deleted from the definition, thereby, reducing the amount of information that needed to be collected and reported. Second, the previous estimate of one hour per institution to complete the report was grossly overestimated because about 97 percent of the institutions have no misconduct activity to report and those that do have misconduct activity to report usually have only one case. The current estimate for on-line submission is six minutes.

12.(B) Estimated Annualized Cost to Respondents

Forms (If necessary)	Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
PHS-6349	Awardee Institutions	1,016	$75.00	$76,200

13. Capital Costs

(Maintenance of Capital Costs)

These data can be collected with systems that the institutions and organizations already have.

14. Cost to Federal Government

The estimate of the annual cost of the information collection requirement in the Annual Report form to the government is approximately 50% of a person year at a GS-12 level. The annual cost is $38,685.00 total.

15. Program or Burden Changes

The burden estimate is a program change due to 850 increase of responses from 5,246 to 6,096. About 97 percent of the institutions have no misconduct activity to report and the 3% that do have misconduct activity to report usually have only one case. The current estimate for on-line submission is ten minutes.

16. Publication and Tabulation Dates

The information collected will be analyzed and used for reporting to authorized administrative officials and for responding to congressional and public inquiries. In addition, there are plans to publish the information in aggregate form in the ORI Newsletter and ORI Annual Report and on the ORI web site. No individuals or institutions will be identified.

17. Expiration Date Approval date may be visible.

18. Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

ORI is not utilizing statistical methods to collect information.