Supporting Statement for Annual Report on Possible Research Misconduct and Assurance of Compliance by Sub-Award Recipients form PHS-6315
and Supporting Regulations Contained in 42 CFR Part 93

Background

This is a revision to add the Assurance of Compliance by Sub-Award Recipients form PHS-6315 to the currently approved collection of the Annual Report on Possible Research Misconduct form (PHS 6349). The OMB approval (OMB No. 0937-0198) of this form expires on June 30, 2015.

Attachment 1 - Assurance of Compliance by Sub-Award Recipients form PHS-6315.

The purpose of Assurance of Compliance by Sub-Award Recipients form PHS-6315, 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any investigation or alleged misconduct and 3) will follow the requirements of 42 CFR Part 50, Subpart A which has been superseded by 42 CFR Part 93.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 January 24, 2014 in the Federal Register Volume 79, Pages 4162-4165) to solicit public comment for PHS-6315.

Response to comments on “Agency Information Collection Activities; Proposed Collection; Public Comment. Document Identifier: HHS-OS-21329-60D:

The purpose of this announcement was to note that the Office of Research Integrity (ORI) is modifying an existing Information Collection Request (ICR) by adding form PHS-6315. This form is to be used only for those recipients of sub-awards of Public Health Service (PHS) awards that do not otherwise have an assurance with ORI. The public comments received primarily dealt with two basic concerns: the descriptions of the burden and compliance by small institutions.

The concern that the burden statements in the table were confusing and misleading has been corrected to account for the slightly increased overall burden associated with the additional forms that are expected to result from this new requirement.

There was also apparently some confusion about whether the burden associated with this requirement was relevant to an institution's burden resulting from conducting inquiries and investigations into allegations of research misconduct. The burden related to this notice is related only to the process of filling out and electronically filing Form PHS-6315 one time, and, thereafter, PHS-6349 on an annual basis. This process is expected to take only a few minutes, and does not address the process that the entity employs to ensure that it has policies and procedures in place to qualify for the assurance being sought.

A second concern dealt with whether small entities receiving sub-awards, such as clinics and hospitals with limited research programs, would be qualified to conduct an unbiased review of allegations of research misconduct. ORI recognizes that this could be a concern but notes that there are a number of approaches that could be taken to alleviate this concern. The issue for ORI is that, pursuant to 42 C.F.R. Section 93.300(i) all sub-awards need to be covered by an assurance. This is required of all institutions and institutional members, which include sub-awardees as defined by 42 C.F.R. Sections 93.213 and 214. However, it is also clear that the primary grant holder has a substantial interest in ensuring that the PHS funded research being carried out by its sub-awardees is performed competently and honestly, and that its sub-awardees are observant of applicable statutes and regulations. If allegations of possible research misconduct nevertheless do arise, the assurance provides ORI with jurisdiction, but the review of those allegations remains the responsibility of the assurance holder. However, how those allegations are reviewed is largely up to both the primary grantee and sub-awardee. The process following may involve a consortium, as permitted at 42 C.F.R. Section 93.306, or any degree of joint review by the primary awardee and sub-awardee, and may include experts from outside either institution.

Lastly, there was some concern about contractual language that might be used by the primary awardee to ensure that the sub-awardee obtains an assurance by filing PHS-6315. This is a matter to be resolved by the awardee.

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 and Sub-awardee Institutions	6,296	1	10/60	1,049
PHS-6315	Sub-award Institutions (without an ORI assurance)	200	1	5/60	17
Total					1,066

The burden estimate for the PHS-6349 has been reduced substantially. 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 and Sub-awardee Institutions	1,049	$75.00	$78,675
PHS-6315	Sub-award Institutions (without an ORI assurance)	17	$75.00	$1,275
Total				$79,950

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 and the Assurance of Compliance by Sub-Award Recipients forms 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 to the Annual Report 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.