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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0937-0198]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Submit your comments to Sherrette.Funn@hhs.gov or by calling (202) 795-7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0937-0198-60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, Sherrette.funn@hhs.gov, or call 202-795-7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3)

ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection:

Type of Collection: Public Health Service Policies on Research Misconduct (42 CFR Part 93)-
OMB No 0937-0198-Extension- Office of Research Integrity

Abstract: The Office of Research Integrity is requesting an extension on a currently approved collection. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form PHS-6349 is to provide data on the amount of research misconduct activity occurring in institutions conducting PHS-supported research. The purpose of the Assurance of Compliance by Sub-Award Recipients form PHS-6315 is to establish an assurance of compliance for a sub-awardee institution. Forms PHS 6349 and PHS-6315 are also used to provide 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). 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.

Need and Proposed Use: The information is needed to fulfill section 493 of the Public Health Service Act (42 USC 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavioral research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR Part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

Estimated Annualized Burden Hour Table

Forms (If necessary)	Respondents (If necessary)	Number of Respondents	Number of Responses per Respondents	Average Burden per Response	Total Burden Hours
PHS-6349	Awardee Institutions	5,748	1	11/60	1054
PHS-6315	Sub-award Institution's	110	1	5/60	9
Total			2		1063

Dated: February 19, 2020.

Terry Clark,

Asst Paperwork Reduction Act Reports Clearance Officer,

Office of the Secretary.

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