U. S. Department of Health and Human Services (HHS)
Office of Research Integrity (ORI)
Data Management Standard Operating Procedures Survey

Supporting Statement A

Background

ORI in the Office of the Assistant Secretary for Health of HHS is requesting approval from the Office of Management and Budget for a Data Management Standard Operating Procedures (DMSOP) Survey. Information from respondents to the survey will be used to develop a DMSOP toolkit that will be disseminated to researchers, research administrators and research institutions to implement. In addition, other products will be developed to disseminate survey results and findings to include, social media posts, YouTube video, webinar, and summary report for the research community. This is a new information collection request (ICR).

A. Justification

1. Need and Legal Basis

The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of HHS with the exception of the regulatory research integrity activities of the Food and Drug Administration.

The PHS Policies on Research Misconduct at 42 C.F.R. Part 93 were first enacted on June 16, 2005 (70 FR 28370). 42 C.F.R. 93.300(c) requires research institutions that receive funding from the ORI (or any of the ten PHS Funding Components) to, "Foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct."

Development and implementation of education and outreach activities that aid PHS-funded research institutions in their efforts "to teach the responsible conduct of research, promote research integrity, prevent research misconduct, and …to respond effectively to allegations of research misconduct" is core to ORI's mission" [65 FR 30600, 30601, May12, 2000]. ORI's contributes to this mission by supporting projects that advance the evolving field of research integrity and build the knowledge base in research misconduct, research integrity, and prevention. Responsible management of data throughout the research lifecycle is key to ensuring the integrity, reliability, and availability of data acquired in connection with PHS-funded research.

Under the authority of Sec. 301 of the Public Health Service Act, 42 U.S.C. § 241, as delegated to the Director of ORI, and in response to growing interest in developing effective approaches for data management and resources, ORI, during FY 2021, awarded a two-year cooperative agreement to the University of Maryland (hereafter referred to as "Awardee Institution" in this document). The broad goals of the awarded cooperative agreement are to:

- Support development of effective approaches and resources for data management that help enhance the integrity and reliability of data generated with PHS funds;
- Ensure data acquired using PHS funds are available for subsequent use by the research community; and,
- Ensure data are available for examination should there be an issue related to the integrity, authenticity, reproducibility, and/or reliability of the research.

The awardee institution's project to address the goals of the awarded cooperative agreement, include doing the following:

(1) Conduct a thorough review of data management practices by researchers, research institutions, and research administrators, and develop a data management standard operating procedure (DMSOP) practice survey;
(2) Conduct research on responsible data management and stewardship approaches and practices among American Statistical Association (ASA) and American Society for Cell Biology (ASCB) stakeholders; and,
(3) Based on the results of that research, develop a DMSOP toolkit and other products that will be disseminated to researchers, research institutions, and research administrators for implementation.

2. Purpose and Use of Information Collection

ORI can use the information to identify data management practices by PHS-funded researchers, research institutions, and research administrators in each of the following essential areas: data provenance, record keeping, organization of data,

storage of data, reporting of research data and results, sharing and access, institutional policies, and data management standard operating procedures. In addition, the information will assist in the development of a comprehensive and effective data management toolkit. The collected information and the resulting data management product (i.e., DMSOP toolkit) will allow researchers to assess their data management practices and follow data management standards. Use of the toolkit is expected to help ensure on-going improvement of data management practices and address potential data quality problems, such as, data loss, inconsistent data, and faulty findings.

3. Improved Information Technology and Burden Reduction

Survey respondents will enter responses into a cloud-based data collection and reporting system called Qualtrics (http://www.qualtrics.com/), a widely adopted data collection tool. All responses will be electronic which will reduce the burden of handwriting responses and mailing of survey form. Qualtrics can reduce user entry errors by allowing respondents to go directly to the questions they are supposed to answer based on their conditions, without having to go through the system in a linear progression. Qualtrics can also automatically perform necessary calculations, validate responses and avoid duplicated entries. This cloud-based system allows all responses to be checked for consistency before the information is stored in a database. It is flexible and easy for text fields, dropdowns, checkboxes, radio buttons, skip patterns, or other features, which will enhance data quality. Qualtrics is designed in such a manner that if the respondents cannot complete the survey for any reason in a single session, they may return later and resume where they left off by clicking into the survey link. The reentered survey link will always prompt the respondent directly to the unfilled questions.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplication of efforts or use of similar information.

5. Impact on Small Businesses or Other Small Entities

The DMSOP survey will be completed by individuals and not by any organizations, and therefore will not affect small businesses.

6. Consequences of Collecting the Information Less Frequently

Respondents are asked to complete the survey only once. Less frequent completion will impede upon ORI's ability to provide a DMSOP toolkit and other products to researchers, research institutions, and research administrator in order to advance the integrity and reliability of data associated with PHS-research that ORI funds.

7. Special Circumstances Relating to the Guidelines of 5 C.F.R. 1320.5

There are no special circumstances for this information collection.

8. Comments in Response to the Federal Register Notice/Outside Consultation

Public comments were solicited for a 60-day period in the Federal Register published on September 16, 2022 (87 FR 179, p.56963). No comments were submitted. Regarding outside consultation, several individuals from the University of Maryland in College Park, Maryland and the Stanford Health Center in Menlo Park, CA, respectively, contributed to, reviewed, and/or approved the survey design, instrumentation, and sampling. In addition, the survey was reviewed and approved by the University of Maryland's Institutional Review Board.

9. Explanation of any Payment/Gift to Respondents

A $50 Amazon gift card will be offered to respondents for their time, upon completion of the survey. It may enhance response rate and in turn generalizability of the survey findings.

10. Assurance of Confidentiality Provided to Respondents

The survey is anonymous and will collect no identifying information. Once the collected information is saved in the database, it cannot be linked to any particular respondent.

11. Justification for Sensitive Questions

No sensitive information is being collected.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on a pilot test of the information collection instrument/survey by 7 non-federal individuals. In the pilot test, the average time to complete the survey, including time for reviewing instructions, was approximately 45 minutes. We estimate that up to 1200 respondents will complete the survey once. The total annual burden hours are estimated to be 900.

Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) Bureau of Labor Statistics for Life, Physical and Social Sciences Occupations (https://www.bls.gov/oes/current/oes190000.htm) mean hourly wage. We estimate an average respondent's hourly wage rate of $38.81 (biostatisticians and bioscience researchers). The total annual costs for reading and understanding instructions and completing the survey instrument are estimated to be 900 burden hours times $38.81/hour equals $34,929.00.

12a. Estimated Annualized Burden Hours

Form name	**Type of Respondent**	**Number of Respondents**	**Number of Responses per** Respondent	**Average Burden per Response (in hours)**	**Total Burden Hours**
Data Management Standard Operating Procedures Survey	Biostatisticians and Bioscience Researchers	1200	1	45/60	900
Total					**900**

12b. Estimated Annualized Respondent Costs

Form name	**Type of Respondent**	**Total Burden hours**	**Hourly Wage Rate**	**Total Respondent Costs**

Data Management Standard Operating Procedures Survey	Biostatisticians and Bioscience Researchers	900	$38.811	$34,929.00
Total				**$34,929.00**

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Annualized Cost to Federal Government

The total estimated cost to the Federal government is $87,000 for the primary and supplemental award costs related to the survey and ORI oversight costs.

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Products will be developed to disseminate survey results and findings to include, social media posts, YouTube video, webinar, and summary report for the research community, that may be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No certification exception is requested.

LIST OF ATTACHMENTS

Attachment 1 – Legal Authorities

a Sec. 301 of the Public Health Service Act, 42 U.S.C. § 241 - https://www.govinfo.gov/content/pkg/USCODE-2020-title42/pdf/USCODE-2020-title42-chap6A-subchapII-partA-sec241.pdf

b. 42 C.F.R. Part 93 Regulations, PHS Policies on Research Misconduct - 05-9643.pdf (govinfo.gov)

c. Statement of Organization, Functions and Delegation of Authority [65 FR 30600, 30601] - 00-11958.pdf (govinfo.gov)

Attachment 2 – Survey Instrument

Attachment 3 – Informed Consent Form