

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS-0990-new]

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 April 9, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264-0041 and *PRA@HHS.GOV*.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990-New-60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov*, *PRA@HHS.GOV* or call (202) 264-0041 the Reports Clearance Officer.

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: Research Misconduct and Noncompliance in Clinical Trials and Translational Research.

Type of Collection: New.

OMB No.: 0990-XXXX.

Abstract: The Department of Health and Human Services (HHS) Office of Research Integrity (ORI) has partnered with the Office for Human Research Protections (OHRP) to launch this data collection effort to better understand how to serve those who might benefit from additional education and resources to improve research integrity. ORI and OHRP have found that researchers, Institutional Review Board (IRB) Chairs, Research Integrity Officers (RIOs), Human Protections and Compliance Officers, and Human Protections Administrators, who oversee the conduct of research involving human research subjects, may struggle with identifying reportable noncompliance or unanticipated problems, protocol violations, protocol deficiencies, and falsifications and fabrications of data and methods in that research. Failure to recognize these concerns may result in noncompliance, protocol violations and research misconduct not being adequately addressed; falsified and/or

fabricated methods, data, and results that may be published or used to obtain federal funding; human research subjects being harmed; and/or Public Health Service (PHS) funds not being protected.

This data collection is a new request and includes an online survey instrument used with stakeholders holding positions at institutions holding a Federalwide Assurance (FWA) and/or operating an IRB, and is designed to identify barriers in the identification, evaluation, and reporting of potential research misconduct, protocol violations, reportable noncompliance, and unanticipated problems in research that involves human subjects. This data collection is intended to assist ORI and OHRP in developing approaches to improve how to identify and distinguish incidents that are reportable to ORI and OHRP from those that do not require reporting to these offices. This information is also intended to give RIOs, IRBs, human protections administrators, compliance officers, and other institutional officials involved with human subjects' research insight into how they can strengthen their policies and procedures for identifying, evaluating, and/or communicating potential research misconduct and reportable noncompliance and unanticipated problems by identifying gaps, barriers, and areas in which communication and education may need to be enhanced within their institution.

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
ORI/OHRP Survey	1165	1	20/60	388

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
 [FR Doc. 2024-02649 Filed 2-8-24; 8:45 am]
BILLING CODE 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) hereby gives notice that the National Vaccine Advisory Committee (NVAC) will hold an in-person meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held February 22-23, 2024. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted

online at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting in person or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Tower Building, Room, 1101 Wootton Parkway, Rockville, MD 20852. Email: *nvac@hhs.gov*. Phone: 202-795-7697.

SUPPLEMENTARY INFORMATION: Pursuant to section 2101 of the Public Health