data sets'' to updating digital data streams for analyses?

c. As we move into increased sharing and integrated data sets, how might FDA manage data in a way that avoids unnecessary duplication?

2. Data security, privacy, and management including:

a. How can FDA modernize its data strategy to continue ensuring privacy and security of data?

b. What should FDA do to promote the management and organization of data assets across the Agency, as the amount and complexity of data (*e.g.,* in regulatory submissions to FDA) is rapidly increasing?

3. Data strategies and data sharing, including:

a. How can FDA's data strategy facilitate broader goals of integration and interoperability of health care data and scientific data/virtual patient data generated using scientific models?

b. How can FDA design its data strategy to reflect a global marketplace and promote clarity to data providers like regulated industry and other stakeholders?

c. How can FDA design its data strategy and policy development to facilitate appropriate data access, data sharing within the Agency and via data sharing agreements, as well as the appropriate reuse and repurposing of data to advance Agency regulatory science priorities?

d. For stakeholders, including regulated industry that submit data to FDA, how can FDA enhance the efficiency of the preparation and submission of data to FDA?

III. Attending and Participating in the Public Meeting

Registration: If you wish to attend this public meeting in person, please register via *https://modernizing datastrategy.eventbrite.com* by 5 p.m. Eastern Time on June 26, 2020. Those without email access can register to attend in person by contacting Jessica Berrellez at 301–796–0511 by June 26, 2020 (see **FOR FURTHER INFORMATION CONTACT**). Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. If you registered for the March 27, 2020, public meeting, your registration will NOT carry over and you must register for this as a new meeting. Space will be limited.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by 5 p.m. Eastern Time on June 26, 2020. Early registration is recommended because seating is limited; therefore, FDA may limit the number of in-person attendees from each organization.

Given the current uncertainty related to FDA's ability to hold in-person meetings of more than 10 people on a given future date, it is possible that this may be converted to a virtual meeting or may be postponed. Please check the meeting website for the latest information: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/modernizing-fdas-data-strategy-03272020-03272020.*

If you need special accommodations due to a disability, please contact *Jessica.Berrellez@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) no later than 11:59 p.m. Eastern Time on June 23, 2020.

Participants: FDA is interested in gathering scientific and technical information from individuals with a broad range of perspectives on the topics to be discussed at the public meeting. Participants will include those who submitted nominations through the **Federal Register** notice published January 8, 2020, with docket number FDA–2019–N–5799. They will discuss their scientific and/or technical knowledge on the questions and presentations in each session. Participants will be responsible for their own travel arrangements. New nominations are not being solicited and will not be accepted.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the streaming webcast of the workshop via *https://modernizing datastrategy.eventbrite.com* by 5 p.m. Eastern Time on June 26, 2020. Pre-registration for the webcast is recommended, but not required. This is a new registration. If you registered for the March 27, 2020, public meeting, your registration will NOT carry over. The webcast will be available and active during the public meeting at *https://collaboration.fda.gov/data063020/.* In the event that this meeting is converted to a virtual meeting, options for remote participation may change. Please check the meeting website for the latest information: *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/modernizing-fdas-data-strategy-03272020-03272020.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

An agenda for the public meeting and any other background materials will be made available 5 days before the public meeting at *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/modernizing-fdas-data-strategy-03272020-03272020.*

Persons attending FDA's meetings are advised that the Agency is not responsible for providing access to electrical outlets.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/modernizing-fdas-data-strategy-03272020-03272020.*

Dated: April 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–09045 Filed 4–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Request for information (RFI).

SUMMARY: The Department of Health and Human Services (HHS), Office of Research Integrity (ORI) is seeking information and comments from entities and individuals regarding best practices for sequestering evidence during research misconduct proceedings under 42 CFR part 93. In particular, ORI is interested in learning about challenges and solutions in sequestering digital evidence, such as data stored in cloud environments and on personal electronic equipment or storage devices. ORI will use this information to prepare guidelines to support institutions carrying out research misconduct proceedings.

Responses to the RFI must be received electronically at the email address provided below no later than 5:00 p.m. ET 45 days after the publication of this RFI.

Interested parties are to submit comments electronically to *OASH-ORI-Public-Comments@hhs.gov.* Include ''Sequestration RFI'' in the subject line of the email. Mailed paper submissions

and submissions received after the deadline will not be reviewed.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION:

Background: 42 CFR part 93 establishes several requirements regarding the reporting and investigation of research misconduct to which institutions must adhere to receive Public Health Service (PHS) funding. Per § 93.305(a), an institution must:

> Either before or when the institution notifies the respondent of the allegation, inquiry or investigation, *promptly take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner,* except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. . . . [Emphasis added].

Failing to properly sequester data can have a significant detrimental impact on the outcome of a research misconduct proceeding. Common issues that can negatively affect the examination of evidence include:

- Notifying a respondent about a misconduct proceeding before sequestration
- failing to sequester all relevant evidence, such as digital data stored on personal computers and storage devices
- failing to sequester forensic images of hard drives
- failing to fully document the sequestration process and maintain a detailed chain of custody for each item sequestered

To better support institutions in carrying out their responsibility for maintenance and custody of research records and evidence, ORI intends to publish guidelines that will inform interested parties of best practices for sequestering evidence during a research misconduct proceeding.

Request for information and comments: In preparation for producing guidelines on sequestration, ORI is interested in learning what major challenges exist in the sequestration process and approaches to overcome them. ORI is particularly interested in best practices in the sequestering of digital evidence. Specific topics of interest include but are not limited to the following:

- Digital data can be an important source of evidence for research misconduct proceedings. What unique challenges exist when collecting digital data and what approaches successfully address them? ORI is especially interested in learning the following:
  - ➢ How do institutions identify sources of digital data that need to be sequestered?
  - ➢ Digital data may be located on devices not necessarily owned by the institution, such as personal computers and storage devices, cloud-based and online services, and personal email. What approaches are successful in securing data in these situations? What data policies address this issue?
- ORI has observed that sequestration tends to be more successful when institutions assemble a team of individuals with different expertise to assist in in the gathering and securing of evidence. Thus, ORI is interested in learning the following:
  - ➢ What is the technical makeup of successful teams, especially regarding digital evidence?
  - ➢ How are members selected and trained?
- Institutions may have their own specific policies, procedures, guidelines, instructions, or other tools to enable them to meet their broad obligation under § 93.305(a) to properly sequester evidence for research misconduct proceedings. Thus, ORI is interested in learning the following:
  - ➢ What institutional policies, procedures, and guidelines have been effective in ensuring successful sequestration?
  - ➢ To assist institutions in formulating their own policies, the ORI website provides example Policies and Procedures for Research Misconduct at *https://ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations.* Although institutions are not required to adopt the exact text as presented, ORI considers institutions that do so to be compliant with their obligation under § 93.302(a)(1) to establish policies and procedures in compliance with 42 CFR part 93. What additions or changes are appropriate for these sample Policies and Procedures to reflect the growing digital landscape, especially regarding sequestering digital evidence?

Collection of Information Requirements: Please note: This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposals (RFPs), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or to make a grant award. Further, ORI is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in responding to this RFI; all costs associated with responding to this RFI will be solely at the expense of the interested parties. ORI notes that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request.

ORI will actively consider all input as our office develops future regulatory proposals or future sub-regulatory policy guidance. ORI may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or to issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned.

Dated: April 22, 2022.

Elisabeth A. Handley,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2020–09086 Filed 4–28–20; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990-new]

Agency Information Collection Request. 30-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