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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 C.F.R. 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:

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SUPPLEMENTARY INFORMATION:

Background: 42 C.F.R. 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 C.F.R. 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.

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