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Primary Changes from Old Rule

Q: **What are the primary differences between the new regulation, 42 CFR Part 93 and the old regulation, 42 CFR Part 50, Subpart A, regarding the policies on research misconduct?**

A:

• **Applicability.** The new rule includes PHS intramural research programs and contracts that support research, research training or activities that are related to research or research training. The new rule applies to an allegation that PHS-supported research involving journal peer review has been plagiarized. Section 93.102.

• **Limitations period.** Because of the problems that may occur in investigating older allegations and the potential unfairness to the respondent in defending against them, the new rule is limited to research misconduct occurring within six years of the date on which HHS or the institution receives the allegation of misconduct, unless: (1) the respondent continues or renews any incident of alleged research misconduct that occurred outside the six-year limit through the citation, republication or other use for the potential benefit of the respondent of the research record that is the subject of the allegation; (2) ORI, or the institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public; or (3) if HHS or the institution received the allegation before the effective date of the new rule. Section 93.105

• **Definition of Research Misconduct.** Consistent with the Office of Science and Technology Policy (OSTP) government wide definition and guidelines on research misconduct, the new rule uses the term "research misconduct" rather than "misconduct" or "misconduct in science"and, among other changes, defines this term to include a new element: misconduct occurring in connection with the "reviewing" of research. The "other practices" part of the existing definition has been dropped. Section 93.103. Falsification, fabrication, and plagiarism have also been separately defined.

• **Burden of Proof.** Consistent with the OSTP guidance that the exclusion of honest error or difference of opinion from the definition of research misconduct does not require HHS and the institutions to disprove possible honest error or difference of opinion, the new rule provides that these elements are an affirmative defense that the respondent has the burden of proving by a preponderance of the evidence. However, the institutions and HHS retain the burden of proving research misconduct by a preponderance of the evidence and any admissible, credible evidence the respondent submits to prove honest error or difference of opinion must

be weighed in determining whether the institution and HHS have carried this burden. Sections 93.106(b)(1) and (2) and 93.516(b).

• **Institutional Responsibilities.** The new rule describes in greater detail the responsibilities of the institutions in responding to allegations of research misconduct. Institutions must take certain steps to ensure a fair and thorough investigation, such as securing the evidence and giving the respondent opportunities to access the evidence and comment on the investigational report. In addition, the new rule provides greater detail on ORI's oversight of the institution's investigation or other misconduct proceeding and the actions that ORI may take if an institution fails to comply with the rule. Specific institutional responsibilities are addressed in the Qs & As that follow. Subpart C, Sections 93.300 - 93.319.

• **Hearing Process**. The new rule sets forth a detailed hearing process that is modeled on the HHS Office of Inspector General (OIG) regulation, 42 CFR part 1005, that governs the hearing process for the exclusion of health care providers from Medicare and State health care programs. Among the changes from the current ad hoc hearing process is that the trier of fact will be an Administrative Law Judge, rather than a three-person panel of the Departmental Appeals Board (DAB). Subpart E, Sections 93.500 - 93.523.

• **Responsibilities of ORI and the ASH.** The new rule changes the respective responsibilities of ORI and the Assistant Secretary for Health (ASH). The ALJ's findings of fact and conclusions of law constitute a recommended decision to the Assistant Secretary for Health (ASH). Under the final rule, the ASH may let the ALJ's recommended decision stand, or take final agency action, exercising authority to affirm, reverse, or modify the ALJ's recommended decision, if it is found to be arbitrary and capricious, or clearly erroneous. If debarment or suspension from eligibility for Federal financial assistance and/or contracts is proposed, the decision of the ALJ or of the ASH, as the case may be, constitutes proposed findings of fact to the HHS Debarring Official. If the ASH takes final action on the ALJ's recommended decision and the Debarring Official concurs, the ASH decision constitutes final agency action. Section 93.523. In order to ensure a separation of this ASH responsibility from the responsibility of making a finding of research misconduct, ORI will propose initial findings of research misconduct, subject to the DAB hearing process, and recommend settlements to HHS. This change will maintain the separation between investigation and adjudication, because ORI will not conduct any inquiry or investigation on behalf of HHS. There will rarely be a need for HHS, rather than an institution, to conduct an inquiry or investigation, but if it is necessary, the OIG would carry out that responsibility. Sections 93.400, 93.404, 93.500, and 93.523.