DHHS & PHS Policies on Research Misconduct Summary

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The Department of Health and Human Services (HHS) Public Health Service (PHS) finalized its Policies on Research Misconduct on May 17, 2005. Published in the Federal Register (70 FR 28370), the policy creates the processes and procedures for institutions that apply for or receive PHS support and the PHS, itself, to respond to allegations of research misconduct.

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The Department of Health and Human Services (HHS) Public Health Service (PHS) finalized its Policies on Research Misconduct on May 17, 2005. Published in the *Federal Register* (70 FR 28370), the policy creates the processes and procedures for institutions that apply for or receive PHS support and the PHS, itself, to respond to allegations of research misconduct. The new rule delineates the responsibilities of the institution and the PHS Office of Research Integrity (ORI) in conducting inquiries and investigations, and adjudicating a finding of misconduct. It removes the current subpart A of 42 CFR part 50 and replaces it with a new, separate, part 93 (42 CFR part 93). The rule became effective on June 16, 2005. When the proposed rule was published for comment in April 2004 and COGR prepared a joint comment letter with the Association of American Universities (AAU), the Association of American Medical Colleges (AAMC), and the National Association of State Universities and Land-Grant Colleges (NASULGC). A copy of the letter is available on the COGR web site at: www.cogr.edu.

The new rule brings the PHS policy into conformity with the Federal Policy for Research Misconduct issued in December 2000 by the Office of Science and Technology Policy (OSTP). The policy incorporates the Federal Policy definitions of fabrication, falsification or plagiarism and the key elements required for a finding of misconduct. As required by the Federal Policy, PHS retains the inquiry and investigation stages for responding to an allegation that are a part of its current policy. The bulk of the remainder of rule codifies existing PHS guidance and practice, with notable additions. This summary review will focus on those areas of the new rule that are notably different or had been challenged by COGR and the other associations in their letter of comment. Institutions will want to review the new rule and consider the ways in which the institution's policies and procedures may need to be changed in response to this new rule.

Scope or Applicability

The PHS Research Misconduct rule covers allegations and misconduct occurring at any institutions that applies for or receives PHS-support for research, research training, or activities related to that research or training. As clarified in the new rule, related activities include, for example, the operation of data or tissue banks or dissemination of research information. The rule covers research proposed, performed, reviewed, or reported or any research record generated from that research, regardless of whether an application or proposal resulted in an award from PHS. An even broader assertion of coverage over any research misconduct allegation arising at a PHS-supported institution was challenged by

COGR. In response, PHS narrowed the applicability somewhat but the proposed assertion of jurisdiction over allegations of plagiarism of a PHS-supported research record, e.g., a journal article, regardless of the status of the alleged plagiarist has been eliminated in the final rule.

Burden of Proof Including Honest Error

PHS clarified that to reach a finding of misconduct the institution, and HHS, has the burden of proving the act of misconduct as intentional, and a significant departure from accepted practices by a preponderance of the evidence but the respondent carries the burden of proving any and all affirmative defenses including honest error or difference of opinion. The rule notes that the institution must give due consideration to any evidence of honest error or difference of opinion presented by the respondent. In their comment, COGR and the other associations had argued that the proposed rule needed to direct the institution to consider these affirmative defenses before reaching a finding of misconduct. The question of the respondent's affirmative defense concerning honest error became embroiled in the meaning or assumptions related to the absence of documents. In the final rule, the absence of or destruction of documents by the respondent no longer constitutes or confirms research misconduct itself. Rather, the failure of the respondent to produce documents is evidence of misconduct only where the institution proves, by a preponderance of the evidence, that the destruction was intentional and a significant departure from standards.

Institutional Responsibilities

In the final rule, the institution is directed to guard against any conflicts of interest in conducting its inquiries and investigations and to retain the records of a research misconduct proceeding for seven years after the conclusion of the investigation. The meaning of the "research record" and the burden of the seven-year record retention requirement was challenged by COGR in part because the "record" included scientific instruments and equipment. PHS clarifies that equipment is included in the definition of "record" to the extent that it is or contains physical or electronic records of data or results. The institution can take custody of copies of that data or results that are equivalent "in evidentiary value" rather than the equipment or instrument itself. PHS has established a six year limitation on allegations and requires the institution to consult with ORI if it plans to close an inquiry or investigation or appeal on the basis of an admission of misconduct by the respondent or a settlement with the respondent.

HHS Responsibilities

PHS will coordinate its investigations with other agencies when more than one Federal agency may have jurisdiction by cooperating in the designation of a lead agency; a provision required by the Federal Policy and noticeable absent in the proposed rule.

The process for a respondent contesting a PHS/ORI finding of misconduct is described in significant detail in subpart E of the new rule. The respondent may request a hearing which will be conducted by an Administrative Law Judge (ALJ) rather than the Departmental Adjudication Panel currently used. This shift from the adjudication panel to an ALJ has caused serious concern in the scientific community because the ALJ is not required to seek scientific or technical advice and counsel. PHS elected not to make the change requiring scientific or technical consultation requested by many commenters including the COGR and the associations.

Considerations for Research Institutions

The scope of the applicability of the PHS policy may require institutions to conduct a broad review of any allegations to determine whether or not PHS-supported research or research proposed to or reviewed for PHS is involved in the allegation. If PHS-related research, as defined in the policy, is involved and an investigation is recommended, the institution will need to report to ORI (93.102).

Subpart B includes the definitions applicable to the policy. Institutions will want to confirm that their policy definitions conform to those in the PHS policy, as appropriate. The new definition of "good faith" offers institution's some direction in making a determination in its inquiry and, if necessary, investigation (93.210).

Section 93.304 describes the essential parts required in institutional policies and procedures, e.g., who receives notification, records management provisions, etc., and is followed by the requirements for maintaining the research records and evidence (93.305). Section 93.316, Completing the Research Misconduct Process, includes the new requirements to consult with ORI before closing a case because of an admission or settlement.

The new time limitations will need to be considered because the six year limitation is tempered by any subsequent use of the research record by the respondent which is a continuation or renewal of the misconduct (93.105).

Institutions may need to revise policies to reflect the influence of destroyed or absent records or the respondent's failure to produce documents on a determination to move to an investigation or make a finding of misconduct (93.106).

Subpart D describes the responsibilities of HHS/ORI. Institutions will want to be familiar with HHS process and procedures in order to understand how ORI will interact with the institution and, in the case of a finding, the respondent.