

AAMC Association of American Medical Colleges
AAU Association of American Universities
COGR Council on Governmental Relations
NASULGC National Association of State Universities and Land-Grant Colleges

June 15, 2004

Chris B. Pascal, J.D. Director
Office of Research Integrity
1011 Wooten Parkway, Suite 750
Rockville MD 20852

SUBJECT: RIN #0940-AA04
Public Health Service Policies on Research Misconduct

Dear Mr. Pascal:

This letter presents comments of the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the Council on Governmental Relations (COGR), and the National Association of State Universities and Land-Grant Colleges (NASULGC). The AAMC represents the nation's 126 accredited medical schools, over 400 major teaching hospitals and health systems, and 94 academic medical societies representing nearly 105,000 faculty members. The AAU is an organization of public and private research universities devoted to maintaining a strong system of academic research and education, and consists of 60 U.S. and 2 Canadian universities. COGR is an association of 150 research intensive universities, affiliated hospitals and research institutes in the United States organized to work with federal agencies to develop a common understanding of the impact that policies and regulations may have on the research conducted by its membership. NASULGC is a voluntary association of public universities, land-grant institutions and many of the nation's public university systems, and member campuses are located in all 50 states, the U.S. territories and the District of Columbia.

Our memberships are pleased to comment on the Department of Health and Human Services (HHS) Public Health Service (PHS) proposed revisions to its Policies on Research Misconduct (currently at 42 CFR part 50, Subpart A). We strongly endorse the changes in the definition of research misconduct and the incorporation of the three elements necessary for a finding of research misconduct proposed by the PHS Office of Research Integrity (ORI). These key components provide the critical foundation for a common and systematic approach to addressing allegations of research misconduct, and bring the proposed regulations into conformity with the Federal Policy on Research Misconduct issued by the Office of Science and Technology Policy (OSTP).

This uniform approach allows institutions to apply a single standard in addressing allegations of misconduct in federally sponsored research. Our institutions welcome the setting of time limits on the filing of allegations of research misconduct and the clarification in the Supplemental Information of the roles and responsibilities of the institutions, complainants, and witnesses. We also support the inclusion of administrative law judges (ALJ) in the hearing process for greater consistency and clarity; provided, however, that science advisors or experts

are required to participate in those cases which involve complex scientific, medical, or technical issues. These and other additions and clarifications have greatly expanded the level of detail and direction in complying with the regulations – detail that was formerly a part of guidance provided by ORI to the institutions. We are disappointed that ORI has used the occasion of adopting the OSTP policy to place its current guidance into regulation. The incorporation of detailed processes and procedures is contrary to OSTP’s goal of a more uniform federal-wide approach to the management of research misconduct and contrary to the government-wide efforts to simplify and streamline processes called for in P.L. 106-107. ORI should simplify the proposed regulations with a focus on the key OSTP recommendations and add only critical sections missing from the current regulations like the appeals process.

There are two principal problems with the regulations as proposed: a question of scope or applicability and the evidentiary standards related to the burden of proof. These questions of applicability and burden of proof set the stage for problems that ripple throughout the entire document. It is difficult at times to determine whether, for example, a particular section is applicable to all research conducted at the university or just PHS-supported research. We will discuss first our concerns in these two key areas and follow with additional items of concern with recommendations for modification.

General Policy and Applicability § 93.100 and 93.102

PHS should limit the applicability of its regulations to PHS-supported research and research training activities. This limitation appears in some but not all sections defining the scope of the regulations. As we understand § 93.100(b), PHS requires that an institution that applies for or receives PHS support must comply with these regulations in responding to any and all allegations of research misconduct that occur at the institution irrespective of whether or not the misconduct occurs in relation to a PHS-supported activity. Clearly, if that is the intention of 93.100(b), PHS has exceeded its authority. PHS can appropriately set standards only for those research and research training activities it supports. The limitation to PHS-supported research and research training is incorporated in 93.100 (a) and (c) and should be included in (b).

In § 93.102 (a) and in the definition of PHS- supported research at §93.223, PHS asserts the applicability of its regulations beyond PHS-supported research and research training to “activities related to” that research and training. This creation of an element of relatedness is not described or explained in the policy and, if interpreted in the broadest sense, could cover research and training activities throughout a college or university. This perspective is re-enforced by §93.302 (c). This section asserts ORI’s right to request information about university misconduct proceedings outside the jurisdiction of PHS/ORI. Again, we strongly object to reporting on proceedings outside those with a direct funding link to PHS. §93.302(c) should be deleted in its entirety.

This problem of scope is exacerbated further by the extension of PHS jurisdiction over the plagiarism of any PHS-supported research result regardless of whether the user or reviewer receives PHS support. The plagiarism of parts of research applications or research results, e.g., from journal articles, books, presentations, etc., is an act of misconduct that has not altered the scientific record prepared with PHS support. The publication of an article or book or submission of an application that includes the plagiarized material is the act of misconduct. This misconduct may occur in relationship to another sponsor or unfunded activity. As such, PHS is not the affected party and its assertion of jurisdiction over the management of such an allegation is inappropriate.

Evidentiary Standards § 93.106

This section puts the burden of proof for making a finding of misconduct appropriately on the institution, but it then inappropriately converts honest mistake into an affirmative defense rather than its converse being explicitly a part of the institution's burden of proof. The institution should have the full burden of proving each and every element of research misconduct, including intent, recklessness, or knowing disregard of applicable standards. Thus the proposed rules' placing the burden of proving "honest error" onto the respondent seems to allow the institution simply to offer evidence of, for example, plagiarism, without going the next step to demonstrate that it was intentionally, knowingly, or recklessly committed.

Of course the respondent may try to prove honest mistake, whether it is an affirmative defense or not. But the proposed rules can be read to eliminate from the institution's burden the necessity of showing that conduct was entered into "intentionally, knowingly, or recklessly" as the OSTP Federal Policy and the PHS proposed policy at §93.104 requires.

We believe that the institution must make a determination on the question of honest error or difference of opinion as a critical step in determining whether or not misconduct has occurred. §93.307 (d)(2) that describes the criteria for an investigation should be modified to conclude with the phrase "after considering the possibility of honest error or differences of opinion." Another safeguard would be to include a requirement in §93.307(f) for the institution to review any assertion of honest error or differences of opinion that are raised by the respondent in his/her comment on the inquiry report before making a final determination to proceed with an investigation.

All of these steps will ensure that the respondent in an allegation of research misconduct is treated fairly, and the institution addresses the allegation with a rigorous level of review to protect the reputation of a respondent who did not knowingly or intentionally engage in misconduct, or whose work represents an honest difference in opinion or approach.

Other Areas of Concern:

In addition to the concerns raised above, the changes proposed in the following sections most likely will result in substantial institutional management problems and/or vary significantly from the OSTP Federal Policy, and warrant revision by PHS.

Confidentiality §93.108

While this section provides some safeguards for the identities of respondents, complainants and human subjects who may be involved in research misconduct proceedings, the protections are not sufficient to ensure the integrity of the process or defend volunteer research misconduct committee members or witnesses, who are critical to institutional misconduct inquiries and investigations. Although Section 93.300 mandates that institutions take all reasonable steps to provide the confidentiality accorded under this section, institutions, and especially public universities that are subject to state open-records laws, cannot practicably provide such protections and assurances - unless the research record, the record of the research misconduct proceedings, and the institutional investigation report are also protected under the proposed rule. Though the status of such records may vary under state public records laws to which public institutions are subject, the status accorded the

records by federal regulations is critically important to the ability of public universities as well as private institutions to achieve the requisite confidentiality for all concerned. Additional safeguards are especially needed to protect the identities of committee members and witnesses, which are often available, or readily ascertainable, from the record of the research misconduct proceedings or the institutional investigation report. As noted, such records and final reports are afforded variable degrees of protections under state and local law and, in some locales, must be disclosed upon request to respondents, aggressive legal counsel for and supporters of respondents, and even to the popular press, which finds research misconduct investigations increasingly newsworthy. Respondents who have been found not to have engaged in research misconduct following an inquiry or investigation may therefore, nonetheless, also face ridicule, ostracism, or loss of professional reputation from public release and misuse of allegations of research misconduct detailed in the proceeding records or the institutional investigation report.

In order to assure the integrity of the misconduct inquiry and investigation processes and to protect complainants, respondents, committee members, witnesses and human subjects who may be involved, the proposed policy should provide the same protections accorded by the OSTP Federal Policy, which protects misconduct records during the inquiry, investigation, and decision-making processes and specifies that the records maintained by the agency are exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation. Section 93.108 should, at a minimum, be rewritten as:

- (a) Disclosure of the identity of respondents, complainants, witnesses and committee members involved in research misconduct proceedings should be limited, as allowed by law, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding; provided, however under section 93.517(g) that PHS administrative hearings must be open to the public.
- (b) As allowed by law, confidentiality must be maintained for the research record, the record of the research misconduct proceedings and the final institutional investigation report, including any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

Finally, to promote and protect the integrity of the research misconduct review process, ORI and the Secretary should take steps necessary to provide immunity from personal liability for institutional committee members and witnesses who serve and participate in research misconduct review committees. Such protections could be similar to those provided by the Health Care Quality Improvement Act of 1986 to physicians who serve on clinical peer review committees.

Coordination with other Agencies §93.109

Sections 93.109 (a), “the agencies may coordinate responses to the allegation,” and (b), “HHS will seek to resolve allegations jointly with the other agency or agencies,” directly contradict the OSTP Federal Policy recommendation regarding the designation of a **lead agency** to oversee any research misconduct investigation.

Having a designated lead agency makes the most sense and contributes to a quicker and more efficient process and resolution of the allegation. We fear that ORI’s insistence on “coordination” rather than the designation of a lead agency may be prompted by a desire to expand and protect ORI jurisdiction and maintain the greatest flexibility for ORI to widen the scope of an investigation.

Allegation (Definition) §93.201:

Allegation is defined as “a disclosure . . . through any means of communication . . .” and explicitly provides for either oral or written disclosures. We object to the acceptance of oral allegations. Though anonymous allegations can be accepted, we believe that the allegations must be reduced to writing by the person making them. Unless there is some impairment, a requirement that allegations be reduced to writing is necessary to achieve the requisite degree of reliability at the institutional and federal level. If the concern is to protect anonymity, as we expect, then it should be explicitly authorized although we would argue that anonymous allegations prevent a determination of whether or not the allegation is made in good faith. Nonetheless, oral allegations that are not reduced to writing by the complainant, whether or not anonymous, should not be accepted, with or without identifiers or attribution.

Research Record § 93.226

The definition of a research record exceeds the definition used by OSTP in the Federal Policy. However, we would agree with the expansion of the definition to include in the research record any material provided by a respondent. The inclusion of respondent-generated materials is particularly necessary because of the provisions in § 93.106 (a) that shift the burden of proof to the respondent. Under this provision the respondent may bring forward credible evidence corroborating the research or explaining the absence of records to rebut the presumption of misconduct.

What is more troubling is the long description included in the Supplemental Information II. B. 1 that provides ORI’s interpretation of the phrase “data or results.” This broad interpretation’s goal seems excessive in its inclusion of all forms of information without regard to format. It goes well beyond any reasonable definition of the data or results to include computers and scientific equipment. The actual OSTP and PHS definition includes physical and electronic records, thus listing the range of possible media – hard drives, floppy disks, slides, tissue samples, etc. – seems unnecessary.

Furthermore, broadening this definition in the context of the requirements at §93.305, Responsibilities for the Maintenance and Custody of Research Records and Evidence, and §93.317, Retention and Custody of the Research Misconduct Proceeding Record, creates a significant burden to the institution and will inevitably lead to halting research during the inquiry and investigation at the institution and PHS. Under the provisions at §93.305, institutions are required to obtain custody, inventory, and sequester all research records and evidence with copies or reasonably supervised access to the respondent. §93.317 requires the institution to maintain the records of the research misconduct proceedings for seven years. These requirements seem reasonable if the context is a laboratory notebook, progress reports, etc. If the evidentiary record includes scientific instruments – instruments that may be shared by a number of investigators – ORI’s interpretation will do unnecessary damage to the research enterprise. §93.305 should be rewritten to include the following:

- (c) Undertake all reasonable and practical efforts to take custody of additional research records or evidence that are discovered during the course of a research misconduct proceeding. Where the inquiry or investigation involves instruments shared by a number of users, however, such custody may be limited to obtaining secure copies, if practicable, of data or evidence residing on such shared instruments.

It is important for ORI to acknowledge the difficulty with the six-year time limitation and the availability of records. ORI's expectation of the availability of records for misconduct investigations any time within six years of the allegation conflicts with the OMB Circular A-110 requirements that limit grant record retention to three years following the closing of an award. The Federal Acquisition Regulations (FAR) Subpart 4.7 sets different records retention requirements, generally not more than four years, for contracts. We would note that the Circular A-110 expressly prohibits Federal agencies from imposing any other retention or access requirements. ORI must understand that the university may have limited records related to allegations brought four or more years after the closing of an award by PHS.

General Responsibilities for Compliance §93.300

93.300(a). The requirement for written policies and procedures for conducting and reporting inquiries and investigations of allegations is not consistent with the current regulations. Universities currently report allegations of misconduct to PHS/ORI only when an inquiry determines that an investigation is warranted. This section should be re-written as:

- (a) Have written policies and procedures for conducting inquiries and investigations of allegations of research misconduct and reporting the findings of investigations of allegations in compliance with this part;

93.300 (c). Though we strongly support the concept and practice of inculcating ethical habits of research that will foster responsible research practices and, among other things, prevent research misconduct, the requirement to foster a research environment that promotes the responsible conduct of research is beyond the scope of a policy on research misconduct and should not be included as one of a set of general responsibilities in the area of misconduct. Though responsible conduct of research is clearly an imperative that our institutions embrace, the nature of the general research environment and the promotion of the responsible conduct of research are not tied only to research misconduct as ORI staff have asserted in many venues, and, as a consequence, should not be linked in this particular policy. The research community has engaged in discussions on instruction in the responsible conduct of research with ORI and is willing to continue those discussions but not as a part of the long-delayed implementation of the PHS research misconduct policy revisions. This section should be rewritten as:

- (c) Fosters a research environment that discourages misconduct in research and deals promptly with allegations or evidence of possible research misconduct for which PHS funds have been provided.

Institutional Investigations 93.310 (g); 93.310 (h)

These sections together require the institution to, respectively, “interview each respondent, complainant, and any other available person . . .” and “pursue diligently all significant issues and leads...” The two underlined adjectives, “any” and “all”, should be deleted, as they establish an impossible performance standard for institutions. Instead, what should be required is a full, thorough, and fair investigation with evidence responsibly identified and appropriately pursued. Institutions must be in a position to make reasonable judgments about what interviews should and should not reasonably be conducted and what leads should and should not reasonably be pursued, without having to meet the absolute standard imbedded in “any” and “all”, and without facing the uncertainty about the adequacy of the investigation being conducted that the current

language makes inevitable. As written, for example, interviews could be continued and cases kept open indefinitely. This “open-endedness” must be eliminated from the final regulations.

Completing the Research Misconduct Process §93.316(a) and (b)

ORI has a legitimate right to request notification of a settlement based on an admission of misconduct whenever it occurs – in the midst of an inquiry or an investigation. This provision, however, requires the institution to report if it plans to end an inquiry before completion for any reason. Beyond an admission of guilt, the ending of an inquiry is likely to be the result of a finding that no misconduct has occurred. As such, universities are not required to report to ORI.

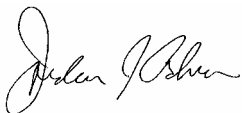
If ORI wishes to address the question of the university reaching a settlement that the institution determines is in the best interest of the university – an option available to the PHS itself – ORI should take that thorny question on directly. For clarity, the policy would be better served to address the question of settlements based on admissions of misconduct as a reportable action. If ORI wants to take on the question of settlements made in the best interests of the university, then ORI should substitute a modified version of the provisions in §93.409 (b) and require notification of ORI in cases of research involving PHS-support as a substitute for 93.316 (a). Provision should also be made to allow for settlements that call for sealing the records associated with the particular matter – a provision not infrequently encountered when there is a finding that no misconduct has occurred.

ORI Allegation Assessment §93.402

93.402 (d). When ORI receives an allegation directly, it will conduct an assessment. If it determines an inquiry is warranted, it will forward the allegation to the institution. Under the provisions of section (d), ORI can close a case when it determines an inquiry is not necessary. However, institutions may have separate standards of conduct as acknowledged in §93.319. ORI should notify an institution of any allegation it receives.

We appreciate the opportunity to comment on these proposed regulations. Our institutions share a commitment with the Office of Research Integrity to maintain the very highest standards in the conduct of research and to investigate any allegation of research misconduct in a manner that is timely, ensures the reliability of the science, and is fair to all parties.

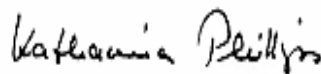
Sincerely,



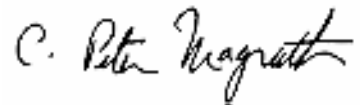
Jordan J. Cohen, M.D.
President, AAMC



Nils Hasselmo
President, AAU



Katharina Phillips
President, COGR



C. Peter Magrath
President, NASULGC