Attachment #7

AAMC

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November 11, 2008

BY FACSIMILE: OS OMB Desk Officer 202.395.6974

Sandra Titus, Ph.D.
Director, Intramural Research Program
Division of Education and Integrity
Office of Research Integrity
U.S. Department of Health and Human Services
1101 Wootton Parkway, Suite 750
Rockville, Maryland 20852

RE: Evaluating Institutions Research Misconduct Education Efforts; Proposed Project (OS–0990–New) (73 Fed. Reg. Doc. E8–24297) (October 14, 2008)

Dear Dr. Titus:

The Association of American Medical Colleges (AAMC) welcomes this opportunity to comment on the above-referenced proposed data collection project.

The AAMC is a not-for-profit association representing all 130 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 125,000 faculty members, 70,000 medical students, and 104,000 resident physicians.

Our member medical schools and teaching hospitals have invested substantial time and funds implementing comprehensive institutional research misconduct policies, developing an infrastructure for training in the Responsible Conduct of Research (RCR), and disseminating information to their faculty, staff, students and external collaborators in accordance with the U.S. Public Health Service (PHS) Policies on research misconduct (42 CFR Part 93). They regularly submit research misconduct investigational reports to the Office of Research Integrity (ORI) in accordance with 42 CFR § 93.309.

The Association and our member institutions are committed to the conduct of responsible, ethical scientific research and strongly support efforts to prevent incidents of misconduct and respond vigorously when such incidents arise. We commend ORI for its desire to assess researchers' knowledge of how their institutions are complying with PHS research misconduct regulations.

However, we are concerned about the validity of conclusions that are based on the assessment of individual perceptions of institutional performance. Also puzzling is the ORI's decision to limit

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this data collection activity to the faculty of medical schools, whereas an earlier sample of a similar survey instrument [1] was drawn from a pool of all principal investigators who received research grant support from the NIH Extramural Research Program regardless of whether they were affiliated with medical schools.

Perhaps of greatest importance to the AAMC is that ORI must indicate explicitly in the beginning of the survey and in the invitation letter to the prospective responders that the Federal definition of scientific misconduct is purposefully narrowly drawn and limited to fabrication, falsification, and plagiarism (FFP). The definition does not, and is not intended to, encompass the full scope of problematic professional behaviors that may occur in research, nor does it in any way constrain institutions from creating and enforcing their own policies of research integrity that reach way well beyond the Federal definition. We are deeply concerned that unless respondents clearly understand this critically important point, the responses to Sections II, III, and the instructive case studies in Section VII could easily lead to over-estimations of the prevalence of research misconduct and to misinterpretations and unfounded conclusions by ORI regarding institutional efforts to promote a culture of research integrity.

For example: in the Federal Policy on Research Misconduct, research misconduct is defined as "fabrication, falsification, or plagiarism (FFP) in proposing, performing, or reviewing research, or in reporting research results [2]." All other answer options in Section II, Question 4, while usually addressed by institutions, extend beyond the federal definition of FFP and may prompt inaccurate responses to the questions that follow.

We believe that the extensive emphasis in Sections II and III on procedure and process require far more detailed understanding than should be expected from all faculty members.
We urge ORI to avoid terms that are inherently subjective and emotive, such as "feel", "believe", "think" in Section IV, and instead use words like "aware", "familiar", "know" that will provide more reliable information about respondents' actual knowledge of their institutions' policies and procedures, and support more robust conclusions regarding institutions' educational efforts and misconduct reporting environments.

Many of the short cases presented in Section VII of the proposed survey instrument describe scenarios that, although instances of troubling ethical behaviors, clearly fall outside the scope of FFP. We are concerned by the fact that ORI once again seems to be trying to expand its intentionally circumscribed mandate, viz., to focus on transgressions that fall within the federal definition of "scientific misconduct."

[1] Survey of Research Integrity Measures Utilized in Biomedical Research Laboratories, Final Report, October 31, http://ori.dhhs.gov/documents/research/intergity_measures_final_report_11_07_03.pdf
[2] 42 CFR § 93.103 Research misconduct. http://ori.dhhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf

AAMC appreciates the opportunity to comment on this proposed survey instrument. We share a commitment with the Office of Research Integrity to promote and maintain the highest standards in the conduct of responsible research, and to educate researchers to identify and report behaviors that deviate from those standards, including, but not limited to, those that involve FFP. We would be happy to discuss with ORI any of the issues addressed above or other topics that involve the conduct of responsible research and the identification and reporting of research misconduct.

If you have questions regarding our comments, please feel free to contact Irena Tartakovsky at itartakovsky@aamc.org or at 202-862-6134.

Sincerely,
David Korn, M.D.
Chief Scientific Officer
cc: Chris B. Pascal, J.D.

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