



November 20, 2008

Dear Dr. Korn,

We appreciate the interest and comments from the Association of American Medical Colleges (AAMC) on the design and execution of the DHHS Office of Research Integrity's (ORI) project entitled Evaluating Institutions' Research Misconduct Education Efforts. We have thoughtfully considered the comments and hereby offer our responses.

We applaud the commitment of the AAMC and its members "to the conduct of responsible, ethical scientific research" and the strength of their "efforts to prevent incidents of misconduct and respond vigorously when such incidents arise." However, we wish to correct the AAMC's impression that this project is an effort to determine from researchers "how their institutions are complying with PHS research misconduct regulations." Our effort is much more modest and focused. Our goal is to assess the effectiveness of institutional efforts to assure that their researchers know what the Federal definition of research misconduct is and know how to report it when they suspect it. We ask no questions of the researchers about how the institution handles the allegations of research misconduct that it receives.

We do not understand the AAMC's expression of concern "about the validity of conclusions that are based on the assessment of individual perceptions of institutional performance". As indicated above, our assessment of the institution's performance of its researcher education responsibility will be based upon the ability of its researchers to identify behavior that falls within the Federal definition of research misconduct, and to recognize this misconduct in realistic but fictitious scenarios. Survey items tapping respondent attitudes (perceptions a la AAMC) will be used in analyses to account for differences in researcher performance across institutions, but not to assess their institutions.

The AAMC states it is puzzled by our "decision to limit the data collection activity to the faculty of medical schools". The reasons we limited this survey to researchers in one institutional domain is a matter of statistical precision – having enough cases within individual institutions to be able to represent them adequately – and the unavailability of time and budget to survey other institutional domains. We have given priority to the medical school domain because, based on NIH data, the largest proportion of PHS research funding is awarded to them, and based on ORI records, most of the misconduct allegations are generated within this domain.

According to its comments, "of greatest importance to the AAMC is that ORI must indicate explicitly ... that the Federal definition of scientific misconduct is purposefully narrowly drawn and limited to fabrication, falsification and plagiarism (FFP)." We do not agree that we must present the Federal definition. A purpose of the

survey is to measure whether researchers know what is included in the Federal definition of research misconduct and are able to distinguish it from many other activities that can be problematic and unacceptable in the context of research conducted in the institution. Providing the Federal definition in the invitation and introduction to the survey would be reactive with our measure and make it useless for its intended purpose. We understand that an institution's policy may cover more than the Federal definition of research misconduct and that education about all of these may be presented together. However, we have been especially careful to always specify when we want the researchers to refer specifically to the Federal definition when responding to questions as opposed to some more expansive institutional definition.

With respect to survey question 4 in Section II, the AAMC notes that the answer options "extend beyond the federal definition of FFP and may prompt inaccurate responses to the questions that follow". The answer options do include more than FFP because ORI wants to measure whether researchers can distinguish between activities that the Federal definition includes and those others that it does not include. We disagree that this may result in inaccurate responses in questions that follow because it is clearly stated that the questions refer to the institution's policy and procedures.

Further, the AAMC comments that "We believe 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 disagree with the characterization of the level of knowledge represented by the items in these survey sections. The items in Section II deal with whether the researchers have read the institution's policy and how familiar they say they are with aspects of it that are critically associated with being able to make allegations of research misconduct, e.g., to whom and how to make their allegations. The items in Section III deal with when and how researchers are exposed to the institution's policy and procedures regarding the making of allegations. Typically, the response options include "Don't Know".

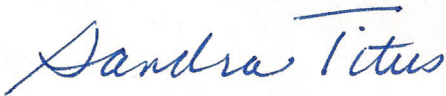
The AAMC also states its objection to the use of terms "such as feel, believe, and think" in Section IV, finding them "subjective and emotive". They would prefer the use of words like "aware, familiar, know", however these terms do not fit the attitudes we want to measure. Attitudes represent an predisposition to act or think in a certain way based on a combination of elements which may include their perspective of facts but also incorporates feelings and beliefs. The items in Section IV request the researcher's perspective of the institution's educational efforts with respect to research misconduct and can be either positive or negative.

In its final comment, the AAMC states that many of the cases presented in Section VII "describe scenarios that, although 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". To the contrary, these items represent scenarios that ask researchers to demonstrate their ability to distinguish between the behaviors that may meet the Federal definition of research misconduct and other undesirable behaviors that are not included in the Federal definition. A recently

published study from ORI suggests that researchers are often not able to distinguish between them.<sup>1</sup>

The US Federal system for safeguarding the integrity of PHS-sponsored research is one that depends upon the good faith reporting of alleged misconduct on the part of researchers by other researchers. This project is an effort to assess *from the perspective of active researchers* the effectiveness of efforts being made by their institutions to impart the relevant elements of the Federal rules regarding research misconduct on projects funded by the U.S. Public Health Service (PHS). This should include a recognition and understanding of what constitutes research misconduct according to the Federal definition. It should also include the elements necessary to report alleged research misconduct according to the institution's policy, e.g. how and to whom to report, etc. To carry out its monitoring and educational mission, ORI needs information on whether researchers know what is necessary to be able to comply with the Federal rules. This project was designed to collect this kind of information for ORI.

Sincerely,



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Director, Intramural Research

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<sup>1</sup> Titus, S. L., Wells J. A., and Rhoades, L. J. Commentary: Repairing research integrity. **NATURE** June 2008; Vol 453: 980-982.