

On January 17, I transmitted a set of comments on behalf of the Association of American Medical Colleges (AAMC) regarding the Draft Interim Guidance. In subsequent deliberations and consultation with colleagues, we have identified an additional provision (4.4) that requires comment, and we have given further thought to the matter of "institutional financial conflicts" that is addressed in provisions 1.6, 1.7, 1.8, 4.1 and 5.3. Accordingly, we request that this communication be combined with our earlier one for the record.

4.4 Although we are very cognizant of the sensitivity involved in permitting a Clinical Investigator with "any financial conflict of interest issues" to function as principal investigator in a trial involving human subjects, we believe that the proposed language is inappropriately conclusory and far too absolute. There are certainly instances in which the faculty inventor of a novel therapeutic modality in which he/she has a potential or real financial interest is inarguably the best qualified individual to conduct the trial and protect the subject participants, especially in early Phase I trials. Accordingly, to adopt the language proposed in 4.4 might very well mean that the trial would not take place, or that because of an arbitrary standard, a less qualified principal investigator would be conscripted perform. Accordingly, it is the AAMC's position that flexibility must be retained which would permit the institution, when appropriate, to establish appropriate oversight or monitoring mechanisms while permitting the conflicted investigator to conduct the trial. Rigid proscription would not be in the best interest of the human subjects or of the science. Provision 4.4 should be redrafted to reflect this concern.

1.6, 1.7, 1.8, 4.1 and 5.3 In our earlier communication, we noted that the issue of "institutional financial conflicts" represented totally unexplored ground, and that both the AAU and the AAMC have formed task forces to try to address both individual and institutional financial conflicts. In approaching these tasks, it has become clear that there is no consensus within the academic community about institutional conflicts; indeed, there is not yet even a commonly accepted definition. It is very important that the academic community be given time to examine this complicated issue and develop a set of principles and guidelines that could be widely accepted and implemented. It is

clear from the early work of the task forces that this task is difficult, if for no other reason than that there is little if any consensus pre-existing among research institutions. Although one can certainly imagine hypothetical cases in which troublesome institutional conflicts would be self-evident, in the usual circumstances of university investment practices, the issues are much more complicated and nuanced. Accordingly, the AAMC believes that it is premature for OHRP to attempt to issue any specific guidance on the matter of institutional financial conflicts, and at this time should simply sound the alert that such conflicts may exist and may require attention. Since even a consensual definition of institutional financial conflicts is lacking, any kind of more detailed guidance or requirement would be entirely premature. We strongly urge NHRPAC to revise the language in the relevant provisions of the Interim Draft Guidance, and to permit the academic community to engage in the deliberation and discussion that will be necessary before effective mechanisms of recognition and management of such institutional financial conflicts can be achieved.

The AAMC appreciates the opportunity to provide these further comments. We would be pleased to discuss them further at your request.

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