

On behalf of the Association of American Medical Colleges (AAMC), I am pleased to send you these brief comments on the draft Interim Guidelines published on the OHRP web site on January 12, 2001. In general, the Association regards the Guidelines as thoughtful, reasonable, and appropriate. Our specific concerns follow:

1.1 Conflict of Interest Committee: Although the arguments for establishing such a committee are straightforward, it has been my experience at Stanford University that many faculty feel much more comfortable disclosing personal financial information to a designated institutional official (dean or provost) than to a committee of peers. This is a privacy issue as much as anything else, and in publications and guidances on the matter, this issue has not, in my judgment, received appropriate attention. The matter becomes especially acute in light of consideration 1.2.

1.2 The recommendation that investigators submit to the designated institutional official the same information that they submit to the sponsor of an FDA regulated study again raises the issue of investigator privacy. The heart of FDA reporting requirements, whether of financial relationships or of adverse events, for that matter, is the tight confidentiality with which all such information is protected by the agency. Again from my experience, faculty researchers would be loath to reveal such information within the university setting unless assured that the information would be kept confidential and not shared unedited or lightly with institutional committees. Privacy considerations are powerful and real within the campus communities. The goal of the guidelines is full disclosure, and one must be careful not to let the processes of disclosure undermine the intent of the policy.

1.6, 1.7, 1.8, 4.1 The matter of institutional financial conflicts of interest in clinical research is relatively unexplored ground and presently the topic of concern for 2 Task Forces, one formed by the AAMC, the other by the Association of American Universities (AAU). In the absence of consensus within the university community about how these matters should be managed, the guidance in the OHRP document is generally sensible. The establishment of an institutional conflicts of interest committee (1.7) would seem to be reasonable advice, but it raises difficult questions of implementation, scope of authority, and credibility that touch on university self governance and are anything but straightforward. This will certainly be a topic of attention for the Task Forces. Also unclear is the nature of the institutional investment that should trigger conflict of interest concerns. We assume that what is intended here are specifically designated investments in start-up companies, often, but not necessarily, founded on the intellectual property of a faculty researcher, in which the linkage between the clinical research and financial benefit to the institution is apparent and direct. We further assume that the portfolio of investments in biotechnology, device, or pharmaceutical companies which are contained in the institution's merged endowment accounts are not of concern to OHRP, or to IRBs or prospective research participants. This is an important point conceptually and operationally and must be clarified in the final guidance.

5.2 Finally, we are unclear about how OHRP intends an IRB to determine when an investigator's financial arrangements (sources of funding for the study, payment arrangements, etc.) are or are not

to be considered "material to the potential subjects' decision making process." The AAMC believes that disclosure should be required to the IRB and to prospective subjects during the consent process of all financial relationships of the investigator(s) with the study's sponsor or with a provider of materials that are to be evaluated in the study. Put differently, we believe that any and all such arrangements are material and should be disclosed to potential participants.

The AAMC appreciates the opportunity to provide these comments and hopes that they are helpful. We would be pleased to discuss them further at your request.

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