



Association of American Universities

May 30, 2003

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 The Pennsylvania State University
 Princeton University
 Purdue University
 Rice University
 Rutgers, The State University
 of New Jersey
 Stanford University
 Stony Brook University -
 State University of New York
 Syracuse University
 Texas A&M University
 Tulane University
 University at Buffalo -
 State University of New York
 The University of Arizona
 University of California, Berkeley
 University of California, Davis
 University of California, Irvine
 University of California, Los Angeles
 University of California, San Diego
 University of California, Santa Barbara
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 University of Florida
 University of Illinois, Urbana-Champaign
 University of Iowa
 University of Kansas
 University of Maryland, College Park
 University of Michigan
 University of Minnesota, Twin Cities
 University of Missouri, Columbia
 University of Nebraska - Lincoln
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 University of Oregon
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 University of Southern California
 The University of Texas at Austin
 University of Toronto
 University of Virginia
 University of Washington
 University of Wisconsin - Madison
 Vanderbilt University
 Washington University in St. Louis
 Yale University

Dockets Management Branch (HFA-305)
 Docket Number 02N-0475
 Food and Drug Administration
 5630 Fishers Lane
 Room 1061
 Rockville, MD 20852

The Association of American Universities welcomes the opportunity to comment as requested on the draft *"Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection."* AAU represents 60 leading public and private research universities in the United States and two in Canada. AAU works to ensure that research conducted on our campuses meets the highest ethical standards and promotes public health, and in recent years has issued reports on human research protections and on financial conflict of interest.¹

To begin with, I would like to thank HHS for addressing many of the concerns about which AAU and dozens of our member institutions had written to the Office for Human Research Protections (OHRP) regarding the draft interim guidance which OHRP published in January, 2001. This draft is a substantial improvement over the previous version, which we very much appreciate.

In general, we find that the current draft is consistent with the suggestions contained in our two recent reports on protection of human research participants and on financial conflict of interest. Several organizations have written to you with specific comments, and we endorse those submitted by our colleagues at the Council on Governmental Relations and the Association of American Medical Colleges. In addition to endorsing those letters, I would like to make two observations:

1) The current draft indicates that it contains guidance, not directives, and that multiple approaches may be used if they satisfy the requirements of the applicable statutes and regulations. We welcome such statements, since they recognize the variety of ways that human research participants can be protected from the potential negative effects of financial conflicts of interest, and urge that they be emphasized even further in the final version of this

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guidance. The stronger such statements are in this guidance, the more likely that in the years to come federal staff and auditors will continue to use these suggestions as they are intended -- and that they will *not* eventually get treated as a checklist of requirements.

2) One of the bullet points in Section C1 is vaguely worded, and depending on how it is interpreted, could be of significant concern. In a list of actions which institutions should consider taking, the draft suggests that institutions "use independent organizations to hold or administer the institution's financial interest." It is not clear what 'independent' means in this context. Could it mean entirely independent of the university? AAU's report on financial conflict of interest concluded that:

"In terms of the portion of institutional conflict of interest involving institutional financial holdings, a key goal is to segregate the decision making about the financial activities and the research activities, so that they are separately and independently managed. Much of the challenge involves achieving a high degree of such segregation." (p. 12)

The draft goes beyond upholding this *principle* of separation of decision-making into determining specific ways in which that principle should be administered. We urge you not to recommend *any* specific details for accomplishing this principle, such as the wording in the current draft, since the state of the art in administering institutional conflict of interest policies is still rapidly developing.

Thank you again for the opportunity to comment. If you have any questions about our comments, please direct them to Richard Turman, our Director of Federal Relations. We can both be reached at 202-408-7500.

Cordially,



Nils Hasselmo
President

cc: Dr. Arthur Lawrence, Deputy Assistant Secretary for Health Operations
Dr. Jordan Cohen, President, Association of American Medical Colleges
Katharina Phillips, President, Council on Governmental Relations

¹ *Report on University Protections of Human Beings Who Are the Subjects of Research*, June, 2000; and *Report on Individual and Institutional Financial Conflict of Interest*, October, 2001.