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## COUNCIL ON GOVERNMENTAL RELATIONS

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May 30, 2003

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

SUBJECT: Docket No. 02N-0475

The Council on Governmental Relations (COGR) is an association of 150 research intensive universities in the United States that works with federal agencies to develop a common understanding of the impact that policies, regulations and practices may have on the research conducted by its membership. We share the Department of Health and Human Services' goal of upholding the highest ethical standards for all research activities. Universities are acutely aware of the perception that their financial relationships may undermine the objectivity of research and compromise the protection of human research subjects. We, therefore, appreciate the acknowledgment in the draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" that "financial interests are not prohibited and not all financial interests cause conflicts of interest or harm to subjects."

We are pleased that this current draft of the Department's Guidance for Human Subject Protection focuses explicitly on how financial interests might affect the rights and welfare of human subjects. It directs the Institutional Review Board's attention to determining the best process for protecting human subjects, leaving the review of financial relationships and management of financial interests to the institution. In order to ensure the fundamental integrity of their research, universities have implemented policies and programs to guide their faculty, students and staff in maintaining the very highest research standards including managing financial relationships. These university-initiated activities are consistent with many of the approaches described in the Department's guidance.

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## The Use of Alternative Approaches

We appreciate the Department's clarification that its intent is to provide guidance for human subjects protection without changing existing regulations or imposing new requirements and, as included in the first footnote, that "an alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations." We believe this endorsement of alternatives is significant enough that it should be included in the main body of the text rather than being consigned to a footnote. The guidance will be more effective if it includes a clearer, more prominent reminder to the research and regulatory communities that this guidance encourages universities to seek the very best strategies to protect human subjects – including alternative strategies tailored to the unique characteristics and culture of each institution.

The real strength of this revised Guidance is the manner in which it asks thought-provoking general questions and points for consideration – a device used in the first two parts of Section II - A, General Approaches, and B, Points for Consideration. This approach should be carried through the third and final part II.C, Specific Issues for Consideration. This type of rhetorical device challenges the institutions, IRBs and investigators to describe current practices and consider different solutions or mechanisms rather than prescribing specific actions. We fear that the specific recommendations characteristic of many of the bulleted items in section II.C will become a checklist used by federal regulatory and audit agencies and offices to determine compliance and fail to achieve the Department's goal of guidance to ensure the protection of human subjects.

**Guidance for Institutions, IRBs and Investigators:** Some of the Specific Actions for Consideration in section II.C raise particular concerns and we offer the following recommendations.

### **Institutions:**

Universities have chosen a variety of paths to review financial relationships and financial interests – some rely on individuals, others use committees. How a university elects to review and manage these issues will vary depending on the nature of the university – public or private – and its governance structure. Similarly, the management of university financial resources and organizational reporting structures present as many models as there are universities in the country. In light of this diverse environment, simple, uniform approaches will not work and we recommend eliminating items or bullets one, eleven, and twelve in Section II. C. 1.

We note the addition of recommendations concerning institutional conflicts of interest, including developing criteria to determine what constitutes a conflict, and

mechanisms for disclosing and reviewing these potential conflicts. As the Department knows potential institutional conflicts represent complex relationships and interests that will require careful and thorough consideration by the university.

### **Institutional Review Boards – Operation and Review**

The recommendations for Institutional Review Board (IRB) operations reflect the regulatory requirement for IRB members with conflicting interests to recuse themselves from the discussion and decision on an affected protocol. Without question, IRBs must ensure that conflict of interest issues do not interfere with their review. However, we should not distort the review process by over emphasizing conflict of interest at the expense of the many other areas that require thoughtful consideration. Specifically, proposing repeated polling and recording of polls and verification of non-participation for each protocol under review seems excessive. Current regulations require that the IRB minutes reflect when members recuse themselves or when there is any change in the participation of a member during a meeting, for any reason. Meeting that regulatory requirement should be sufficient for identifying conflicts of interest.

In the considerations offered for IRB review, we would argue that the focus of the recommendations, and any IRB review, should remain on assessing the protections afforded the subjects. In our critique of the previous January 2001 guidance, we argued that individuals with appropriate expertise should address the management of financial conflicts of interest and we objected to the central role prescribed for the IRB in managing conflicts of financial interests. In this current version, the recommendation that IRBs assess the methods used to manage financial conflicts is not the appropriate focus for the IRB. The last two bullets in this section are key IRB tasks – what actions can be taken to minimize risk and how to convey that information to the subjects. This focus on providing sufficient information to the subject to support truly informed decisions is appropriately echoed in the section for investigators.

### **Evaluation**

The Secretary asks in the Notice how to best assess the impacts or outcomes from this guidance and other non-federal efforts to enhance protections. We understand that some associations will be monitoring the development of university policies and procedures designed to enhance participant protections. These efforts should assist the Department in assessing the impact of its Guidance. We would suggest that there are many equally or, in some cases, more overarching questions to study – how decisions to participate in research are made and if the financial interests of the Investigator affect the decision, or how to design a consent process that enhances comprehension and understanding. We hope the Department will consider directing some of its attention to examining how answers to these types of questions focused on comprehension and decision-making might enhance the protection of subjects.

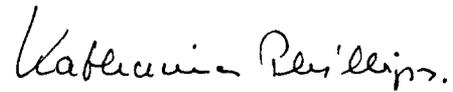
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Thank you for the opportunity to provide these comments on the draft guidance. COGR and its member institutions will continue to address the management of financial conflicts of interest in research. We recently prepared a new guide to help faculty and staff identify potential investigator financial conflicts and are exploring ways to assist our members in developing policies to manage institutional relationships and interests. We believe these efforts will contribute to the Department's goal of ensuring the protection of human research participants.

Sincerely,

A handwritten signature in cursive script that reads "Katharina Phillips".

Katharina Phillips  
President