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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: Draft "Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subject Protection"

Dear Sirs:

As a leading academic and research-intensive institution committed to protecting the safety of our research participants and the integrity of our research programs, Purdue University endorses and shares fully the Department of Health and Human Services' goal of promoting and upholding the highest ethical standards for all research activities. Purdue University also recognizes the value-added to our programs through investigator engagement with the public and private sector entities in relationships that may create potential or perceived financial conflicts of interest. While recognizing the value that may accrue from these financial relationships, we remain acutely aware of our institutional responsibility as stewards of public funds and of the public trust to ensure the objectivity of our research and the protection of human participants in these research endeavors. To this end, we have established and implemented policies and procedures to guide our faculty, staff and students in maintaining the very highest research standards and in satisfying all federal requirements.

Purdue University shares the view expressed by the Council on Governmental Relations (COGR) in their comment letter that this current version of the Department's draft guidance on Financial Relationships and Interests in Research Involving Human Subjects has been improved by focusing explicitly on how financial interests might affect the rights and welfare of human participants. The revised draft guidance appropriately directs the Institutional Review Board's attention to determining the best process for protecting human participants, leaving the review of financial relationships and management of potential financial conflicts of interest to the institution.

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

Overall, this guidance represents an important revision that poses thought-provoking general questions and points for consideration in Section IIA and B. We encourage the Department to extend use of this format through Section IIC, titled "Specific Issues for Consideration," to direct the institutions, IRBs and investigators to focus on their roles and responsibilities in decision-making rather than prescribing specific actions. We fear that the specific recommendations provided in the current draft will become a checklist to be used by federal regulatory and audit agencies to determine compliance, and fail to achieve the Department's goal of guidance to ensure the protection of human participants. For example, there are potentially many ways to approach the review of investigator financial

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disclosures – some institutions rely on individuals, others use committees. How a university elects to manage these issues will vary depending on the nature and governance structure of the institution. Similarly, a review of the management of university financial resources or organizational reporting structures will present as many models as there are institutions. What is important is the outcome, not the process. In particular, we join COGR in recommending elimination of bullets one, eleven, and twelve in Section II.C.1.

In general, the recommendations for IRB operations reflect the regulatory requirement for IRB members with conflicting interests to recuse themselves from the discussion of and decisions concerning an affected protocol. However, we believe the explicit recommendations for repeated formal polling and recording of polls and verification of non-participation of conflicted members for each protocol under review are excessive in terms of necessary record keeping.

A further concern relates to the considerations offered for IRB review presented in the draft guidance. We join COGR in noting that the focus of the recommendations and IRB review should remain on assessing the protections afforded the research participants through conveying critical information needed to make informed decisions. In this revised guidance, the recommendation that IRBs assess the methods used to manage financial conflicts is not the appropriate focus of 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 participants. This focus on providing sufficient information to the participant to support truly informed decisions is appropriately echoed in the section for investigators.

We thank you for the opportunity to provide these comments on the draft guidance.

Sincerely,

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