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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

RE: Comments on Docket Number 02N-0475

To whom it may concern:

The University of North Carolina at Chapel Hill views conflict of interest management as a serious concomitant of its mission to perform ethical research and translate it into benefits for the state and national communities we serve, and we appreciate the opportunity to comment on the Department of Health and Human Service's recent draft guidance entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection."

We sincerely applaud the Department's intent to assist all those involved in the research enterprise by identifying issues and questions key to evaluating whether specific financial interests in research may affect the rights and welfare of human subjects, while at the same time recognizing that the optimal institutional processes for evaluating and managing conflicts of interest are as diverse as the organizational contexts of the research entities.

We suggest that the Guidance should be addressed to research institutions, Institutional Review Boards and also research sponsors as the entities with specific administrative roles in structuring research to protect the welfare and rights of human research subjects with respect to financial conflicts of interest. Individual researchers are not the most appropriate audience for this guidance document because while individual investigators have ethical responsibilities relative to conflicts of interest, generally they do not have administrative responsibility for reviewing and resolving conflicts of interest.

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We strongly endorse the comments of the Council on Governmental Relations, and would like to add commentary regarding the following points in particular:

1. The strength of the guidance is in its identification of key issues and questions in Sections II. A and II.B. Section II.C is less effective in communicating principles that can be applied to varied contexts and unfortunately is too likely to be perceived by some external reviewers as a required checklist. We would add that the clarity and utility of the issues and questions identified in sections II.A and II.B would be enhanced by segregating them into those points that address analysis of specific instances of potential conflict of interest as distinguished from the questions relevant to assessing how to structure an institutional program for identifying, analyzing, minimizing and resolving potential individual and institutional conflict of interest.

2. We share COGR's appreciation that this draft guidance recognizes the need for flexibility in the manner in which conflict of interest review is integrated into IRB review. Our experience is that the breadth and depth of factors that the IRB must consider in evaluating welfare and rights of human research subjects in a given protocol require that the IRB be able to use expert consultants to provide assistance and additional information for the IRB review. The institution's conflict of interest review process findings and recommendation may serve as subordinate review and expert assistance to the IRBs with respect to conflict of interest issues. Control of ultimate approval or denial of the institution's human subjects research remains with the IRB even when the conflict of interest review process is handled by other panels. The IRB may accept or reject, in whole or in part, the findings and recommendations of the conflict of interest review process relative to the performance of human subjects research. The IRB's responsibility and authority are firmly and clearly established in existing federal regulation and are not at issue.

3. We also agree with COGR that conflict of interest is only one of the many significant issues in protecting the rights and welfare of human research subjects. Our needs are even greater for harmonization and consolidation of existing federal regulation of human subjects research and for tools to enhance informed consent for all of our diverse populations of human subjects.

Thank you for the opportunity to share our view.

Sincerely,

Tony G. Waldrop
Vice Chancellor for Research and Economic Development