



DUKE UNIVERSITY MEDICAL CENTER

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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: "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection"

Dear Members of the Office of Public Health and Science, HHS,

We have reviewed the draft guidance document, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subjects Protection", and are very impressed by its thoughtful approach. Within the issue of conflict of interest and clinical research, the highest priority must be given to managing conflict so that the volunteers in clinical trials are treated fairly and that the data from human investigations are meaningful and uncontaminated by bias. Financial conflict cannot be allowed to skew study design or the interpretation of results. The series of questions and points for consideration that make up Section II, the heart of the guidance document, are right on target. They are comprehensive, thought provoking, and instructive, without being proscriptive. Most conflict of interest situations are complex and filled with shades of gray. This draft guidance document takes that range of possibility into consideration, and provides a series of very useful suggestions and ideas for IRBs, institutions, and individual researchers to evaluate.

We congratulate the staff who wrote this draft guidance on a job well done.

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