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Dockets Management Branch (HFA-305)
Docket Number 02N-0475
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville MD 29852

SUBJECT: Docket No. 02N-0475

The Rockefeller University is a center for research and graduate education in the biomedical sciences, chemistry, bioinformatics and physics. The University's seventy five laboratories conduct both basic and clinical research. In addition to the 75 heads of laboratories, Rockefeller has 200 senior research and clinical scientists and 300 postdoctoral investigators on campus, supported by scientists who staff core facilities for spectroscopy, mass spectrometry, bio-imaging, biological computing and animal care, among others. The Rockefeller University Hospital has a medical staff consisting of approximately one hundred medical professionals and is the locus of implementation for approximately sixty protocols involving human subjects each year.

The University appreciates the delicacy and complexity of designing guidance that addresses the financial relationships and interests in research involving human subjects. This task is made the more complex by the varieties of settings in which human subject research takes place. It is with appreciation for the effort reflected in this docket that the University offers the following comment.

The following sentence appearing in Section I. Introduction, Part A. Purpose is the subject of this comment:

“A financial interest related to a research study may be a conflicting financial interest if it will, or may be reasonably expected to, create a bias stemming from that financial interest.”

Two problems emerge out of this text:

1. The standard set out is quite narrow inasmuch as a conflict arises only where the financial interest “will” or “may be reasonably expected to” create a problem. The

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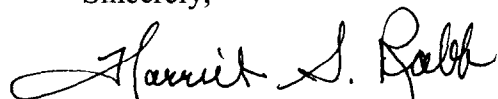
Public Health Service regulation on conflict of interest speaks in terms of a financial interest that “could” yield a conflict. 42 C.F.R. Part 50, Subpart F and Part 94. With the greater latitude inhering in that standard, an institution such as this University can ask for broader disclosure from its investigators and from itself than would be called for under the “will” or “reasonably expected” standard.

2. In your Guidance text, a conflict arises if a “bias” stemming from a financial interest will or may reasonably be expected to be created. The Public Health Service regulation provides that a conflict of interest exists when a significant financial interest could directly and significantly affect the design, conduct or reporting of research. It does not speak in terms of “bias” but rather in terms of “effect.” The difference in vocabulary is important. The Webster’s Ninth New Collegiate Dictionary defines “bias” as “a highly personal and unreasoned distortion of judgment.”

If the only financial interests that are significant are those that will or may reasonably be expected to give rise to a highly personal and unreasoned distortion of judgment, the scope of disclosure, again, is too narrow. Grounding conflict in a PHS-like standard of effect on the design, conduct or reporting of research would be less objectionable to investigators, who may find inferences of “bias” insulting and unwarranted, and would give university conflict managers broader latitude for inquiry and disclosure.

The University appreciates the opportunity to comment on the Guidance in Docket No. 02N-0475. The comment made here seems to us to warrant special note though we associate our University, as well, with the comments filed on this date of the Council on Government Relations.

Sincerely,

A handwritten signature in cursive script that reads "Harriet S. Rabb". The signature is written in black ink and is positioned above the printed name.

Harriet S. Rabb