

INDIANA UNIVERSITY



May 30, 2003

RESEARCH AND
THE UNIVERSITY
GRADUATE SCHOOL

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

Dear Sirs:

Indiana University wishes to express its general support of the new draft document "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," issued by the Department of Health and Human Services.

We concur with the letter submitted by the Council on Governmental Relations that the current draft strikes the right balance between providing critical guidance as to the interests to be protected and allowing institutions the needed flexibility to implement policies and programs best suited for their individual institutions at the same time. We also share the Council's concerns, outlined in their letter; in particular the concern that the proposal for "repeated polling and recording of polls and verification of non-participation for each protocol" at each IRB meeting is excessive and may end up distorting the review process.

We appreciate the opportunity to provide comments on the draft guidance. Thank you.

Very truly yours,

A handwritten signature in cursive script that reads "Ann J. Gellis".

Ann J. Gellis
Associate Dean
for Research Compliance

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