

Office of the Vice Provost for Research

May 30, 2003

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

Re: Docket Number 02N-0475

Dear Madam/Sir:

Cornell University – Ithaca campus, is grateful for the opportunity to comment on the draft guidance document for IRB's, investigators, and research institutions, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." As a national research institution, Cornell's Ithaca campus conducts a significant amount of human subject research annually, principally in the social and behavioral sciences. Cornell recognizes that the use of human subjects for research in these particular academic disciplines is significantly and substantively different than in clinical trials and that social/behavioral research carries a proportionally lower level of risk associated with potential financial conflicts of interest. The majority of studies in the social and behavioral sciences conducted at Cornell do not have commercial, medical or clinical implications. The principal exceptions to this statement are: 1) a handful of studies conducted by experimental psychologists, where the eventual goal may be the development of a measure or inventory of symptoms that is copyrighted and marketed as a research or evaluation tool; 2) marketing studies and surveys, many of which qualify for exemption under 45 CFR 46. Furthermore, the majority of psychological experiments and marketing studies reviewed by the Cornell IRB are conducted by graduate students for their dissertations rather than by established faculty who are required by university policy to disclose potential financial conflicts of interest; in the social and behavioral sciences graduate students often conduct research which is independent of that of their mentors.


Earlier guidance from OHRP appeared to focus financial conflict of interest policies on clinical research and by implication clinical trials. Cornell finds the new guidance document unclear with respect to the applicability of the guidelines to non-clinical research. Noting the important

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distinction between clinical research and social/behavioral research, Cornell recommends the new guidelines make explicit their applicability to clinical research and associated clinical trials.

Sincerely,

A handwritten signature in black ink that reads "Charles R. Fay". The signature is written in a cursive style with a large initial "C" and a stylized "F".

Charles R. Fay  
Vice Provost for Research Administration

Cc R. Richardson  
E. Wethington