Partnership for
Human Research Protection, Inc.

May 30, 2003

The Honorable Tom[illegible]y G. Thompson
Secretary of Health [illegible]d Human Services
Attn: Dockets Mana[illegible]ement Branch (HFA-305)
Docket Number 02N-0475
Food and Drug Admi[illegible]nistration
5630 Fishers Lane, R[illegible]oom 1061
Rockville, MD 2085[illegible]

Re: Draft "Finan[illegible]ial Relationships and Interests in Research Involving Human Subjects: Guidance f[illegible]r Human Subject Protection"; Request for Comments

Dear Secretary Thom[illegible]pson:

The Partnership for H[illegible]uman Research Protection, Inc. (PHRP), appreciates the opportunity to comm[illegible]nt on the draft "Financial Relationships and Interests in Research Involving Human Su[illegible]jects: Guidance for Human Subject Protection" as provided by the Office of Public Heal[illegible]h and Science, Department of Health and Human Services (HHS) in the March 31, 200[illegible] issue of the Federal Register [68 FR 15456-15460]. The PHRP applauds the Depart[illegible]ent's commitment to fostering greater awareness of and protection against financial con[illegible]licts of interest in research involving human subjects. The draft Guidance provide a [illegible]ood first step towards highlighting the need for greater accountability in the [illegible]se of human subjects where potential or actual conflicts of interests among research insti[illegible]utions, investigators, and Institutional Review Boards (IRBs) may exist.

PHRP and its Accr[illegible]ditation Program.
The PHRP is a priva[illegible]e, nonprofit organization created by the National Committee for Quality Assurance (N[illegible]CQA) and the Joint Commission on Accreditation of Healthcare Organizations (JCA[illegible]O), the nation's two largest health care accrediting organizations, and is dedicated to im[illegible]proving the protection of human research subjects. Its primary activities in pursuit o[illegible]f this goal are accrediting human research protection programs and independent review [illegible]oards and providing related publications and education services. PHRP was formed to[illegible] offer a new accreditation program that will seek to protect the safety and rights of p[illegible]articipants in clinical trials and research programs in public and private hospitals, aca[illegible]demic medical centers, and other research facilities in the United

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States and abroad. The standards that form the PHRP accreditation program largely derive from the Common Rule, FDA regulations and related regulatory guidance. PHRP standards were drawn primarily from these sources to outline basic required protections for human research subjects.

The new PHRP Accreditation Program, to be launched in mid-2003, specifically addresses the principal issues involving human research protection, including:

- Organization responsibilities
- Institutional Review Board structure and operations
- Consideration of risks and benefits
- Informed consent

The accreditation survey will be conducted in two parts: (1) an off-site survey of a Web-based survey tool and supporting documentation and (2) an on-site survey, during which a team of PHRP surveyors—research clinicians and others experienced in biomedical research—will validate performance against the standards. The on-site component of the review is expected to be 2-3 days long, and will include interviews with organization leaders.

PHRP applauds the Department's draft Guidance.

PHRP strongly agrees with HHS that managing conflicts of interest in research involving human subjects is critically important for institutional research. However, given the non-obligatory nature of the HHS Guidance on institutions, researchers, and IRBs, there is no effective form of enforcement to assure that research organizations will consider the implications of financial conflicts for the protection of human subjects. The PHRP suggests that HHS consider ways of creating incentives for research organizations to adopt practices consistent with these guidelines. The Department could take a strong step in that direction by adding language in the draft Guidance encouraging research organizations to voluntarily undergo accreditation under the PHRP program.

PHRP accreditation will play a valuable role in holding research organizations accountable for effectively managing conflicts of interest. The PHRP Accreditation program requires research organizations to comply with several important conflict of interest provisions that the draft Guidance recommends:

- Processes for identifying and reporting conflicts of interests;
- Inclusion of unaffiliated individuals in making conflicts determinations;
- Policies for disclosure of conflicts to research subjects, IRBs, and the general public;
- Active management of conflicts, including the elimination or mitigation of their effects; and
- Provisions for removing conflicted IRB members from participation.

The standards and scoring guidelines set by the PHRP Accreditation Program encompass the purpose of the draft Guidance and incorporate conflict of interest provisions into a broader set of comprehensive and systematic standards designed to protect human subjects. Recognition of this entire accreditation program by the Department will create

a voluntary means of demonstrating compliance with HHS regulations and guidance on research involving humans.

In sum, PHRP endorses the Department's endeavor to promote consideration and independent review of potential and actual conflicts among IRB members, individual researchers, and research institutions. In light of the non-binding nature of the draft Guidance, PHRP suggests that the Department amend the draft Guidance to encourage research organizations and IRBs to undergo voluntary accreditation as a recommended way of meeting the guidance issued by the Department.

Sincerely,

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President

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