THE ALLIANCE FOR HUMAN RESEARCH PROTECTION (AHRP)

142 West End Ave. suite 28P
New York, NY 10023

April 4, 2003
Tommy Thompson, Secretary
Department of Health and Human Services
Dockets Management Branch
(HFA–305), Docket Number 02N–0475,
Food and Drug Administration, 5630
Fishers Lane, Room 1061
Rockville, MD 20852.

Re: Docket No. 02N–0475: Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection"

Dear Secretary Thompson:

We appreciate the sustained effort initiated by your office to formulate guidelines for the purpose of curbing, hopefully eliminating, financial and other conflicts of interest that adversely impact on the protection of human subjects in clinical research conducted or supported by the Department of Health and Human Services (DHHS) and its agencies, which are overseen by the Office for Human Research Protections (OHRP) or the Food and Drug Administration (FDA). We gratefully accept the opportunity offered by your solicitation of public comments.

The Alliance for Human Research Protection (AHRP) is a national network of professionals and lay people dedicated to advancing responsible and ethical medical research practices, to ensure that the human rights, dignity and welfare of human subjects are adequately protected. Members of our organization are on record having pointed out as early as 1997 that underlying conflicts of interest have threatened to undermine both the safety of human subjects and the integrity of research findings reported in scientific literature

Within the last two years numerous independent surveys and investigative news reports have documented systemic breach of research ethics. In October 2002, a Duke University survey of 108 U.S. medical schools revealed that medical institutions fail utterly to meet national and international standards aimed at ensuring the integrity of clinical research and the safety of human subjects. [See, Schulman KA, et al, Provisions in clinical trial agreements, *New England Journal of Medicine*, v. 347, no 17, Oct 24, 2002, pp 1335-1341.]

Corporate sponsors maintain control over the entire process including, research design, subject selection, data collection analysis, and corporate sponsors selectively skew the findings that are published, thereby corrupting the integrity of the scientific literature that informs the public and clinicians who may be misled to prescribe harmful medications.

Ethical scientists as well as concerned citizens are appalled that corporate influences in academia have given rise to conflicts of interest that have derailed ethical conduct in clinical research. Dr.

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Drummond Rennie, an editor at *The Journal of the American Medical Association,* acknowledged that the Duke University report "shows what an appalling state everyone was in." [See, Science & Technology Desk. Research contracts violate guidelines, *United Press International,* October 23, 2002. Accessed on April 4, 2003 at: http://www.upi.com/view.cfm?StoryID=20021023-035801-7188r]

Accordingly, the Alliance for Human Research Protection (AHRP) takes the opportunity to provide DHHS with a model affidavit whose purpose is to assist in operationalizing the proposed Guidance for Human Subject Protections (March 31, 2003). The AHRP Affidavit Stating No Significant Conflicts of Interest is in full accord with existing federal regulations [42 CFR 50.603, 45 CFR 94.3] and does not change any existing regulations or requirements.

Enforceable truth telling in our view is the antidote to many of the problems that the proposed new DHHS guidelines address. We believe, the affidavit is a self-executing, valid method for ensuring the absence of significant conflicts of interest—as defined in the HHS Draft Guidance—while also revealing possible non-significant, but demonstrable, conflicts of interest. If adopted by DHHS, research investigators, institutions, members of Institutional Review Boards (IRB), and any other parties involved in the conduct, monitoring, or reporting of clinical research, would personally execute the affidavit.

The AHRP affidavit incorporates the language of: (a) the DHHS proposed new federal guidelines, (b) the New York State Disclosure Statement for Certain Academic Employees pursuant to the State Ethics Commission Advisory Opinion No. 90-15 relative to the filing requirements of Section 73-a of the Public Officers Law, and (c) the U.S. Income Tax Return for Estates and Trusts. Furthermore, by utilizing the AHRP Affidavit, the proposed DHHS Guidance can be operationalized without any added cost to the taxpayer—as no additional agents are needed to monitor or oversee those executing the Affidavit.

Sincerely,

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Vera Sharav, President, AHRP
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Affidavit Stating No Significant Conflicts of Interest

I _____ swear, subject to the penalties of perjury in federal and state
Name
laws, that I assume the duties and responsibilities of the role of (check one) study investigator ☐, member of research team ☐, Institutional Review Board (IRB) member ☐, journal peer reviewer ☐, other ☐ (specify: _____) with no **significant**[1] conflicts of interest in relation to the named project or manuscript:

_____.
Project or Manuscript Name

These possible significant conflicts of interest are listed in the U.S. Department of Health and Human Services guidance for Institutional Review Boards (IRBs), investigators, research institutions, and other interested parties, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection."

These significant conflicts of interest may arise from any financial or other relationship that could adversely affect the rights and welfare of human subjects or the complete and accurate review of proposed research, reporting of research findings, or review of manuscripts for publication that involve such subjects, including:

- How the research is supported or financed
- Where and by whom the study is designed
- Where and by whom the resulting data is analyzed
- Receipt of compensation that may be affected by the study outcome, e.g.
  - Proprietary interests in the project, including patents, trademarks, copyrights, and licensing agreements
  - Equity interest in the research sponsor as either a publicly held company or non-publicly held company
  - Significant payments of other sorts, e.g., grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria
  - Receipt of payment per participant or incentive payments that exceed the norm of individual or institutional hourly compensation

I attest to having possible **non-significant** conflicts of interest in relation to one or more of the aforementioned sources as herein specified:

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_____

[1]As defined in the Draft Guidance, pursuant to **42 CFR 50.603, 45 CFR 94.3.**

1. List below the source and description of any outside employment and sources of honoraria, consultant or lecture fees, whether public or private for the most recent past chronological year and those anticipated for the present year. Use additional sheets as necessary.

Source	Description

2. List any office, trusteeship, directorship, partnership, or position of any type, whether or not compensated, held by you or your spouse or marital partner within the past 10 chronological years, with any firm, corporation, association, partnership or other organization other than the named current employer _____ _____.
Employer's Name

DO NOT LIST COMPENSATION AMOUNTS. Use additional sheets as necessary.

Self / Spouse	Organization and Address	Position	Description

3. List name and describe the nature and source of any current employment or occupation of spouse or marital partner

Source	Nature

4. List the name of warrants or stocks, and investment interests in limited or general partnerships owned by you or your spouse or both at time of this filing. DO NOT LIST AMOUNTS. Use additional sheets as necessary.

Self/Spouse	Issuing Entity

Self/Spouse	Issuing Entity

Pursuant to federal and state law and regulations governing disclosure of public information, the stated information on this form is available for public inspection. Statements are not available for photocopying; handwritten notes may be taken.

Under penalties of perjury in federal and state laws, I declare that to the best of my knowledge and belief the above information is true, correct, and complete.

Signature

Date