

March 2, 2001

Greg Koski, MD  
Director  
Office of Human Research Protections  
Department of health and Human Services  
6100 Executive Boulevard, Suite 3B01  
MSC-7507  
Rockville, MD 20852

Dear Dr. Koski:

On behalf of the Society of Research Administrators International (SRA), I am writing to provide written comments on the Office of Human Research Protection's (OHRP) draft interim guidance entitled "Financial Relationships in Clinical Research: Issues of Financial Interests and Human Subjects Protection" (Guidance). SRA firmly believes that the rights of human subjects who volunteer to participate in research studies should be protected, and that any perceived or apparent conflict of interest related to human subjects research is disclosed and managed or eliminated. However, before a Guidance of this importance and magnitude is developed and disseminated to the research community, there should be careful, thoughtful and deliberate discernment of the moral, legal and ethical aspects of the Guidance and their impact on human subjects research.

SRA is a professional society that: 1) provides education and professional development to individuals involved in the management of research programs and activities; and 2) enhances public understanding of the importance of research and its administration. The Society has more than 3400 members representing institutions of higher education, academic health centers, independent research centers, research hospitals, veterans administration hospitals, military hospitals and businesses involved in the research enterprise. Accordingly, many of our members have extensive training and experience in the protection of human subjects research as well as vital knowledge and experience that only comes from the day-to-day experiences of managing both large and small human subjects protection programs.

The Guidance as written appears to greatly expand the role and responsibilities of Institutional Review Boards (IRB). IRBs would be prescribed to review real or apparent conflicts of interest and make determinations about them. IRBs are neither prepared to handle these issues, nor do they want this added administrative burden, which is the responsibility of other aspects of research administration or other offices. As proposed, the Guidance appears to divert the focus and function of IRBs away from protection of the rights and welfare of subjects from research risks.

The Guidance appears to be reactionary in mode without having solicited appropriate and sufficient input from the various constituencies involved in human subjects research. OHRP should slow the process in order to listen to the various constituencies and to conduct a series of open forums to discuss the moral, legal, and ethical aspects of the issue of conflict of interest related to human subjects research. The forums also should include an assessment of procedural issues to be followed, such as:

- ◆ What protections are already in place,
- ◆ To whom disclosures should be made when human subjects are involved,
- ◆ What is the best way to manage any conflicts that are identified, and
- ◆ What dialogue must occur within the research administration offices of an institution when a conflict occurs.

To obtain a complete assessment of the issues, any dialogue needs the broadest possible participation. In the federal government alone, the issue has implications beyond the Department of Health and Human Services. It should entail discussions among all federal agencies that have signed on as part of the Common Rule.

The dialogue also must include the spectrum of entities that conduct human subjects research, the sponsors of human subjects research as well as the public. The groups that conduct human subjects research include: universities, academic medical centers, research hospitals, non-profit research institutes, and a growing number of for-profit clinical research sites.

In addition, the pharmaceutical, biotechnology, and medical device companies whose research may be effected by the regulations also should be involved in the discussions. As the Guidance will impact on the subjects of the research, ethicists and others who represent the public should be included in the discussions.

The level of interest among all groups was evident from the unanticipated high attendance at the August 15 – 16, 2000 meeting that DHHS convened. However, this should have been the beginning of the deliberations to establish a Guidance that addresses the issue of financial interests and human subjects protection, and not the only forum for such discussion.

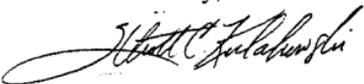
Other organizations are openly discussing the issue and are developing guiding principles. The SRA is convening a nationally televised videoconference on September 13, 2001 to discuss the issue that would allow viewers from all over the country to participate in the discussion and to ask questions. The AAMC and AAU are developing principles for their member institutions. OHRP participation in these venues is vital and any Guidance should follow on the outcome of these and other forums and principles that are being developed over the next year.

SRA considers this to be an issue of utmost importance and concern, and we appreciate the opportunity to provide these written comments. As an organization with a diverse membership, SRA is willing to assist OHRP as it pursues development of an appropriate Guidance.

Please feel free to contact me by telephone at 215-456-7215 or by email at [kulakowe@aeht2.ein角度.edu](mailto:kulakowe@aeht2.ein角度.edu) if you have any questions or need any additional information.

With best regards, I am

Sincerely,

A handwritten signature in black ink, appearing to read "Elliott C. Kulakowski". The signature is fluid and cursive, with a long horizontal flourish extending to the left.

Elliott C. Kulakowski, Ph.D.  
President