



2781 '03 MAY 30 A9:23

May 28, 2003

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

132 Boylston Street, 4th Floor
Boston, MA 02116
617.423.4112 | Fax 617.423.1185
info@arena.org | www.arena.org

RE: Comments on Docket Number 02N-0475

To whom it may concern:

On behalf of the Applied Research Ethics National Association (ARENA), we appreciate the opportunity to comment on the Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection" published in the Federal Register on March 31, 2003. ARENA is a membership organization for professionals whose responsibilities include the protection of human and animal research subjects. ARENA is a division of Public Responsibility in Medicine and Research (PRIM&R), and shares with that organization a commitment to advance the highest ethical standards governing research and to foster their consistent application. ARENA's members include administrators, chairs and members of Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs), representing organizations across the nation with varying volumes and complexities of research.

ARENA wishes to congratulate DHHS for taking the initiative in generating this guidance to institutions regarding identification and management of financial conflict of interest in research involving human subjects. Overall, ARENA concurs with the substance of the guidance and believes that it represents an excellent and necessary first step toward a comprehensive and effective policy.

We recognize that institutions, owing to their differing structures, research mix and goals, are best served by guidance that aids them in examining the issues. Therefore, ARENA offers the following comments that we hope will be useful to you in preparing the final guidance document.

02N-0475

C13

COMMENTS ON COMPONENTS OF THE DRAFT GUIDANCE:

Item II. Guidance for Institutions, IRBs and Investigators

II.A. General Approaches to Address Financial Relationships and Interests in Research Involving Human Subjects

ARENA agrees with the deliberative questions offered in this section of the draft Guidance. They represent a good first step for an organization evaluating and assessing its management program.

II.B. Points for Consideration

ARENA agrees with the suggested approaches. They provide flexibility to varying organizational infrastructures in developing effective plans for managing and/or mitigating the potential negative impact of financial interests.

II.C. 1. Specific Issues For Consideration Regarding Institutions

1. ARENA would strongly encourage a requirement that institutions develop a "COI Management Plan." This defined plan would provide some means for accountability and reflection on oversight performance. The DHHS guidance could clearly serve as the basis for the contents of the plan.
2. ARENA notes that the role of COICs in the guidance is not entirely clear. The guidance states that COICs are established to "deal with individuals' financial interest in research or verify their absence." The phrase "deal with" seems somewhat vague. ARENA presumes that this means that COICs are responsible for creation of a management plan for COIs, should that become necessary. It is also unclear who (COICs, IRBs or other bodies) will be responsible for evaluating the effectiveness of the management plan.
3. ARENA concurs with the recommendation to support establishment of clear communication channels between IRBs and COICs. One possible method to achieve this goal would be to require IRB representation on COICs. IRBs and COICs may be able to devise other procedures, including exchange of minutes or tagging of files.
4. ARENA concurs with the recommendation for training of "appropriate individuals regarding financial interest requirements." ARENA would encourage HHS to expand this recommendation to include training for all key personnel (defined by NIH as "individuals who contribute in a substantive way to the scientific development or execution of the project".)

II.C. 3. Specific Issues For Consideration Regarding IRB Review

ARENA notes that the decision regarding disclosure to subjects in the consent form is the IRB's responsibility. ARENA presumes that COICs can make this recommendation in their management plan. Nonetheless, ARENA believes IRBs should retain authority to require disclosure even if the COIC does not recommend this action, or to override the COICs recommendation for modification of the consent form.

II.C. 4. Specific Issues For Consideration Regarding Investigators

ARENA notes that the guidelines to investigators appear vague and inconsistent. ARENA certainly agrees that investigators should consider "whether to take any of the following actions" with respect to inclusion of COI information in the consent form. However, ARENA recommends that the guidance be clear that the ultimate decision whether or not to disclose information to the potential subject is the responsibility of the IRB and COIC as discussed above.

More importantly, ARENA recommends that the guidance be revised to add that, based on the potential effect of a financial relationship, and irrespective of the recommendations of the COIC, the actions investigators may consider should also include divesting financial interests, or absentsing themselves from the consent process or from the conduct of the research itself.

SUGGESTIONS FOR INCLUSION IN THE DRAFT DOCUMENT

ARENA suggests that comments directed to the sponsors of research be included in the guidance. At a very minimum, there should be a discussion of the responsibilities commercial sponsors have to participate in an entity's conflict of interest process, particularly in the area of the disclosure of information about real or potential conflicts.

RECOMMENDATIONS FOR ASSESSING IMPACT OF THIS GUIDANCE

In keeping with the considerable latitude afforded to institutions and IRBs in structuring COI policies based on their individual needs and organizational structure, ARENA believes that there would be benefit in assessing what specific policies institutions have put in place. Therefore ARENA encourages organization of a one-day forum on best practices to take place one year after implementation of these guidances. ARENA respectfully suggests that this forum could be organized by DHHS or under the auspices of PRIM&R/ARENA, concurrent with our annual meeting.

Thank you for the opportunity to share our comments and recommendations. Members of our Public Policy Committee are available to provide more specific, detailed information and clarifications to assist you in finalizing the guidance document.

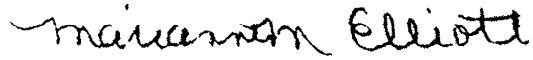
Sincerely,



Bruce Gordon, MD
Member
ARENA Public Policy
Committee



Karen Hansen
Co-Chair
ARENA Public Policy
Committee



Marianne Elliott
ARENA President

Cc: ARENA Public Policy Committee Contributors:

Mark Waxman, Melody Sacatos, Mary Adams, Ada Sue Selwitz, Susan Kornetsky, Helen McGough, Erica Heath, Molly Greene, Gwenn Oki, Liz Bankert