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

SUBJECT: Docket No. 02N-0475

As a research administrator with over thirty years experience, and presently Director of Sponsored Programs Administration at Virginia Commonwealth University, I offer my comments on the draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection".

The Department of Health and Human Services' goal of upholding the highest ethical standards for all research activities is of greatest importance. Universities, including my own, are thoroughly aware that perceptions of inappropriate financial relationships may undermine the objectivity of research and also compromise the protection of human research subjects. Hence I clearly appreciate the language in the draft "Financial Relationships..." that "financial interests are not prohibited and not all financial interests cause conflicts of interest or harm to subjects." This statement is of utmost importance in the draft.

It is admirable that this current draft of the Department's Guidance for Human Subject Protection focuses explicitly on how financial interests might affect the rights and welfare of human subjects, and that it directs the IRB attention toward determining the best process for protecting human subjects. In this institution and many others the review of financial relationships and management of financial interests is of paramount importance in ensuring the fundamental integrity of research. Here and elsewhere universities have implemented policies and programs to guide faculty, students and staff in maintaining the very highest research standards including management of financial relationships that appear to suggest conflicts of interest. These university-initiated activities are consistent with many of the approaches described in the Department's guidance.

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I believe that the language in the first footnote, that "an alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations," is of such great importance that that it should be included in the main body of the text rather than being consigned to a footnote. The Department's intent of providing guidance for human subjects protection without changing existing regulations or imposing new requirements is very significant. This guidance will be much more effective and better received by the research university community if it includes a very clear and prominent reminder to the research and regulatory communities that it encourages universities to seek the very best strategies to protect human subjects – including alternative strategies tailored to the unique characteristics and culture of each institution.

A great strength of this revised Guidance is the device of asking thought-provoking general questions and points for consideration, as it does in the first two parts of Section II, A, General Approaches, and B, Points for Consideration. I very strongly urge that approach be carried through the third and final part II.C, Specific Issues for Consideration. This rhetorical device challenges the institutions, IRBs and investigators to describe current practices and consider different solutions or mechanisms, rather than prescribing specific actions. On the other hand, section II.C is extremely directive, rather than thought provoking. Too easily it can be seen as a checklist that can be used by federal regulatory and audit agencies and offices to determine compliance, and therefore will fail be seen as guidance, which will better ensure the protection of human subjects.

In addition to this recommendation to alter the tone of section part II.C, I have several specific comments on the specific Actions for Consideration.

Section II C 1 has references to institutional COI that are inappropriate because there is no consensus as to what institutional COI is, and moreover stray into the arena of institutional governance rather than leading to thoughtful consideration of the protection of human subjects. Specifically, these include:

- Bullet 1, "Separate...." To the extent that this refers to institutional financial decisions as being separate from research practice decisions, it is wholly inappropriate for this guidance. This separation necessarily exists in many institutions, based on their internal organization and in some cases, on even legislated responsibilities for institutional financial decisions.
- Bullet 3, "Extend ...." This is not the province of an IRB or of a COI committee focusing on protection of the objectivity of research, but of an institutional governance instrument.
- Bullet 4, "Establish...." Again a matter of institutional governance.
- Bullet 11, "Use...." This is not only a matter of institutional governance, but one which in many instances may not fit within the legal requirements of some institutions' governance.

- Bullet 12, "Include...." A further matter of institutional governance not the appropriate subject of this guidance. In regards to institutional financial interests, this is in place through the board of governance of the institution, which is almost always made up of individuals from outside the institution. In regards to individual financial interests, it is, in my opinion, the province of researchers' peers, not outsiders, to establish institutional norms to protect the objectivity of research and the interests of human subjects.

Section II C 2 makes detailed specific recommendations for IRB operations that stray into the area of pointless administrative detail. Certainly IRBs must ensure that conflict of interest issues do not interfere with their mission. However, there already exist regulatory requirement for IRB members with conflicting interests to recuse themselves from the discussion and decision on an affected protocol. Current regulations require that the IRB minutes reflect when members recuse themselves or when there is any change in the participation of a member during a meeting, for any reason. Meeting that regulatory requirement should be sufficient for identifying conflicts of interest within the IRB. This section would be greatly strengthened by recasting it in the form of questions for the IRB to consider, focusing on the thrust of the first and last bullets.

Section II C 3 does focus on information an IRB needs to protect the welfate of human subjects. However, this section, too, would be better cast as questions for consideration. It also should specifically avoid implying that an IRB is responsible for reviewing conflicts of interest, but only responsible that any COI management minimizes risks to human research subjects. In many institutions there is a relationship between COI Committees guiding COI management and the IRB that ensures that the primary charge of the IRB, minimizing risks to human research subjects, is integrated into any COI management; a question regarding the existence of such a relationship would be very important to this section of the guidance.

Section II C 4, again, focuses on very important matters; it merely needs to be recast as questions to stimulate IRB focus on them.

Thank you for the opportunity to provide these comments on the draft guidance.

Sincerely,

Herbert B. Chermside, CRA
Director