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May 29, 2000

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

2
RE: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research Docket 95S-0158

To Whom It May Concern:

This Guidance document is thorough and clear, and will be of great help to investigators, sponsors, and IRBs as they implement and interpret the regulations. The authors of this document should be congratulated.

There are two questions that have arisen in discussion with investigators and IRB members concerning the regulations and this guidance that have not been answered.

VII. A. Procedures: each study must develop and each IRB must approve an informed consent form and process, in the event that one might be used. For studies with a therapeutic window that is a few hours in duration, this seems reasonable and appropriate. However, for studies in which the therapeutic window is very short (e.g.; cardiac arrest research where therapeutic window is usually less than 5 minutes), one could never conceive of using a consent process and form. In such a case, it seems unnecessary for the investigator to prepare and for the IRB to review and approve such a form. The regulations and the guidance document do not seem to provide any exceptions to the requirement for preparing and approving a consent form. It would help if this point could be clarified.

VIII. May an IRB Serve as a DMC?: While I agree that most IRBs are not constituted in such a manner as to have its members also meet the qualifications for a DMC, there may be a subset of an IRB who in fact could qualify as members of a DMC. For example, and IRB on which I previously served had an ethicist, a clinical expert in emergency medicine, a biostatistician, a lay person, and others who might have appropriate qualifications for a DMC. The question is one of "independence" –if the IRB members have "no financial interest in the

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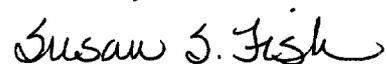
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outcome of the study” and “have not been involved in the design or conduct of the study”, are they independent enough to serve as a DMC?

In addition to the above questions, I have one additional small question. In the second paragraph of the Introduction, the term “emerging, life-threatening medical condition” is used. Did the authors mean “emerging” or “emergent”? They seem to have different meanings in this context.

In summary, this document is long awaited by both the investigator community and the IRB community. Thank you for consideration of these comments.

Sincerely,



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