



COLUMBIA-PRESBYTERIAN MEDICAL CENTER

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April 10, 2000

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

Gentlemen:

Below are my comments and questions with regard to the draft guidance document released for comment on March 30, 2000, Docket No. 00D-0805.

There are several aspects of the guideline document that I believe could be more helpful with specific clarifications. These issues are as follows:

1. It is unclear as to intent of the statement of required "prospect of direct benefit" to those included in the research study. Is this statement compatible with the acknowledgment that placebo control studies are appropriate? How can there be a prospect of direct benefit to an individual randomized to placebo? Is it that individuals included in research are generally treated better than those who are not? Or do we acknowledge that to gain information we must do placebo control studies in which there are no prospects of direct benefit to whatever percentage of individuals are randomized to placebo. Clearly, there is a chance of benefit if randomized to the intervention arm.
2. The document refers Page 3, the last paragraph of the Introduction, to a "unique IND or IDE." What does the word "unique" mean? Does it refer to some different type of IND or IDE related to this type of research? Or, does it just refer to an IDE or IND that covers only the research study which is to be performed with a waiver of informed consent?

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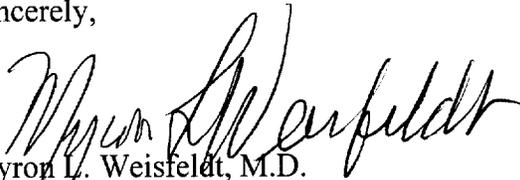
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3. It would be very helpful to understand what types of emergency research are not covered by this document or, if covered by the document, what the IDE or IND implications are. Examples would include:
 - (1) research into the dose or method of administration of an already approved drug;
 - (2) research into the user of a medical device such as a defibrillator;
 - (3) research into the energy for defibrillation with an approved device;
 - (4) research intervention that does not use a drug or device such as mechanics of manual compression;
 - (5) research in which standard treatment is withheld where there is no established benefit.

4. Do the overall provisions of these regulations supercede or eliminate the granting of consent to do human investigations which is viewed as having minimal or no risk to the subject? That is, can a waiver of informed consent be approved by an IRB with an opinion that the protocol provides minimal risk only?

Sincerely,

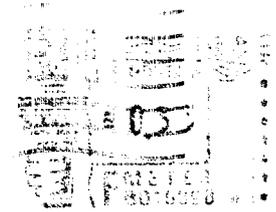


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