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State University of New York

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September 9, 2002

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

Re: Docket #: 00D-0805

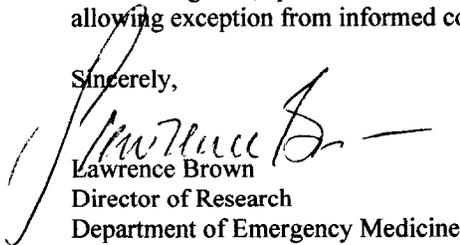
To Whom It May Concern:

I have been involved in emergency medical services (EMS) research for nearly 15 years. Recently, I have had the opportunity to serve as a site-investigator for the Public Access Defibrillation Trial and as a co-principal investigator for the National EMS Research Agenda. In both activities, the issue of exception from informed consent for emergency research required a significant amount of attention. Although I recognize that it sometimes make the process more difficult, I strongly believe that all research must adhere to the principles of respect for persons, beneficence and justice. Therefore, I also strongly believe that exception from informed consent for emergency research must be coupled with efforts to ensure that the interests of this vulnerable population ("persons with life-threatening conditions who can neither give informed consent nor actively refuse enrollment") are protected to the maximum extent possible.

The draft guidance (Docket #: 00D-0805) for institutional review boards, clinical investigators and sponsors is a well-written and thoughtful document. One item that is particularly helpful is the identification, as in Appendix A, of what is not practicable with regards to this issue. One of the recurring concerns among EMS researchers has been that IRBs will take a very narrow view of what is practicable, essentially creating an environment in which exception from informed consent for emergency research, while theoretically allowable, is not possible. Indeed, as discussed at the recent National EMS Research Agenda Implementation Symposium, at least one IRB has taken the stance that identifying potential subjects and obtaining informed consent in advance would *never* be impracticable. Thus, if the guidance lacks anything, it is a more direct admonition — within the main document — about what may not be practicable. It might be particularly helpful to include examples of practicability in each of the sections: therapeutic window; community consultation; public disclosure; and contact of legally authorized representatives or family members.

Even in the absence of additional discussions about practicability, I would encourage any investigator contemplating research under the exception from informed consent requirements to review this guidance document, and to make it available to his or her institutional review board. It helps to clarify the intent of the regulations and to identify the respective responsibilities of those involved in such projects. It will also allay many of the preconceptions and fears that investigators, sponsors, and institutional review boards have about studies conducted under the regulations allowing exception from informed consent for emergency research.

Sincerely,


Lawrence Brown
Director of Research
Department of Emergency Medicine

00D-0805

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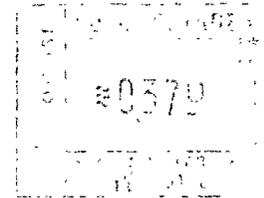
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