



PREHOSPITAL CARE RESEARCH FORUM

924 Westwood Blvd., Suite 720, Los Angeles, CA 90095-1369

Tel (310) 794-8798 Fax (310) 794-8796 E-mail pcrf@mednet.ucla.edu

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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:

Emergency medical services (EMS) can be one of the most daunting environments in which to conduct meaningful research. In an effort to improve the quality and quantity of EMS research, a group of medical directors and field EMS providers formed the Prehospital Care Research Forum (PCRF) in 1992. The PCRF was founded with the mission "to assist, recognize and disseminate prehospital care research at all provider levels." In fulfilling that mission, we have always advocated for the ethical and responsible conduct of research. We strongly believe that all research must adhere to the principles of respect for persons, beneficence and justice. Therefore, the Prehospital Care Research Forum supports the position 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The draft guidance (Docket #: 00D-0805) for institutional review boards, clinical investigators and sponsors is a well-written and thoughtful document.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 about what may not be practicable within the main document. It might be particularly helpful to include examples of practicability in each section — therapeutic window; community consultation; public disclosure; and contact of legally authorized representatives or family members.

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Even in the absence of additional discussions about practicability, the Prehospital Care Research Forum 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.

The Prehospital Care Research Forum is committed to supporting all efforts aimed at ensuring that research is conducted in an ethical manner. If we can be of any further assistance to you in this or any other matter, please feel free to contact us.

On behalf of the Board of Advisor and our Associates, Sincerely,

A handwritten signature in black ink, appearing to read 'Edith Pryor', with a long, sweeping line extending from the end of the signature towards the right.

Edith Pryor
Managing Director