

November 28, 2006

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

Re: FDA Presentation Abstract; Docket Number 2006D-0331;
Conduct of Emergency Clinical Research; Public Hearing

Dear Dr. Shuren:

The American College of Emergency Physicians (ACEP) appreciates the opportunity to provide the Food and Drug Administration (FDA) with a formal version of the oral comments provided by Charles B. Cairns, MD, FACEP, on the Exception from Informed Consent for Emergency Research hearing on October 11, 2006 in Rockville, MD.

ACEP is a national medical specialty society representing emergency medicine with more than 25,000 members. ACEP is committed to advancing emergency care through continuing education, research and public education.

Emergency research advances the field of Emergency Medicine and improves clinical acute care. Emergency research should be supported in whatever means are possible, including the use of the consent exception and guidelines that govern its use. The recently released Institute of Medicine report on the *Future of Emergency Care* (June 2006) describes the scarcity of clinical effectiveness trials for the treatment of critically ill or injured patients, especially in the pre-hospital setting, underscoring the critical need for continued research in this setting.

In response questions posed by the FDA, ACEP believes that the draft guidance for (1), (2) and (4), has been responsive to researchers' concerns and has helped to clarify the requirements in CFR 50:24.

Regarding the work of the FDA, NIH, and IRBs to date, ACEP makes the following general comments:

1. The agencies that have been responsible for this research guidance and support have done an excellent job in crafting the regulations and working with investigators to implement them in support of quality emergency research.
2. ACEP looks forward to working with all concerned federal agencies, local IRBs and advocacy groups, all emergency health care societies and providers, as well as individual citizens as we strive to improve patient outcomes through the conduct of ethical and effective emergency research that utilizes the exception to informed consent.

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Any revisions to current regulations should serve to expand the ability to perform the highest quality emergency research and to enhance patient protections through fairness, openness, and use of all media that provide explicit detail regarding the research. Burdens should not be placed upon researchers in a way that is disproportionate to the inherent risks and need to advance emergency care through the conduct of quality emergency research utilizing the exception to informed consent.

Question 7: The use of community consultation is relatively new in research and merits further study. While the overall process has been well received, many unresolved issues remain, such as which community to consult, who counts as a community representative or member to be consulted with, and what purpose this consultation serves. One important step is to conduct research on community consultation in order to identify best practices before further guidance can be given. Further, ACEP suggests that if the goals of community consultation and public disclosure could be more clearly delineated, these goals would also guide investigators and sponsors in enhancing the process of conducting clinical trials while providing quality emergency care.

Question 8: ACEP suggests that current opt-out mechanisms may be necessary, but not sufficient to identify patients deferring participation in the research inclusion. Although patients in extremis cannot be assumed to be competent to provide informed consent, they should be assumed to be competent to refuse participation in research that utilized the exception. As such, ACEP contends that patients should be briefly asked if they wish to participate in the research, and if they decline to participate, their wishes should be honored.

Questions 9 and 10: ACEP believes that community consultation could not only provide information on the study, but could also help the IRB identify risks and protections from risk. ACEP suggests that the use of the exception must be explicitly stated to all who might be at risk or benefit from the research, including the hospital, its staff and IRB, the population of potential patients who might become involved in the research, and the governmental agencies that might oversee the research. This includes full notification of the results of all IRB deliberations, including those who decline to participate, the results of the community consultations and public disclosure, and the results of the clinical trial itself.

Question 11: ACEP suggests that there should be a record of all suggestions generated by community consultation and how the IRB and investigator handled them. This documentation should be the responsibility of the sponsor and available on the FDA Web site or Clinicaltrials.gov.

Questions 13 and 14: ACEP believes that while full study protocols do not necessarily need to be formally presented to communities or the general public, these study details should be available upon request.

Questions 16 and 17: ACEP believes that the results of clinical investigation should be disclosed when the study has been peer reviewed and ready for publication. The results of all studies that utilize the exception of informed consent should be published in the medical literature, even if the results of the clinical trials do not demonstrate benefit with the tested therapy or procedure. Journal editors should be encouraged to support publication of negative trials that utilize the exception in order to assist with the process of utilizing the exception.

In summary, ACEP supports fully the processes necessary to conduct high quality emergency research, including this review of the exception to informed consent process. It is through continued dialogue on important matters such as this that clinical science will improve emergency care and optimize outcomes for the patients who we serve on a daily basis in the out-of-hospital and Emergency Department settings. If you need additional information, please contact Barbara Marone, Federal Affairs Director, at (202) 728-0610 or bmarone@acep.org.

Best wishes,

A handwritten signature in black ink that reads "Brian F. Keaton" followed by a small flourish.

Brian F. Keaton, MD, FACEP

President