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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rockville, Maryland 20852

RE: Docket No. 2006D-0331 Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research

Conveyed electronically to: http://www.fda.gov/dockets/ecomments

The National Association of EMS Physicians (NAEMSP) is an organization of physicians and other professionals partnering to provide leadership and foster excellence in out of hospital emergency medical services. NAEMSP has over 1275 members, and counts medical directors and administrators from nearly every major metropolitan area's Emergency Medical Service in the United States among its membership.

Prehospital care is given when and where it is needed: in urban settings with vertical challenges and gridlock; in rural settings with limited access; in confined spaces; within entrapments; or simply in the street, exposed to the elements. Despite more than 30 years of dedicated service by thousands of EMS professionals, academic researchers, and public policy makers, the nation's EMS system is treating victims of illness and injury with little or no evidence that the care they provide is optimal. A national investment in the EMS research infrastructure is necessary to overcome obstacles currently impeding the accumulation of essential evidence of the effectiveness of EMS practice. Research is integral to the professional lives of NAEMSP members, and we applaud the efforts of the FDA in developing guidance for investigators conducting research under the emergency exception to informed consent guidelines.

The aim of prehospital EMS research is to guide the field with respect to clinical interventions and system designs. Research provides an evidence base to support the application of particular medical treatments. Systems-related research seeks to address operational and structural questions such as the optimum configuration of EMS personnel and the impact of medical direction in EMS systems. The guidelines for emergency exception to informed consent are needed to support the development of effective prehospital treatments for the diseases that drive the design of the EMS system, including injury and sudden cardiac arrest.

NAEMSP would like to emphasize the importance of strengthening the proposed guidelines in the following areas:

- Defining the purpose and criteria for assessment of community consultation;
- Defining the purpose and criteria for assessment of public notification.
- Definition of “unsatisfactory or unproven” and the need for incremental risk assessment;
- Guidance for multi-center trials and the use of central IRBs;
- Guidance for out of hospital research;
- Patient populations that are not considered in the Final Rule, such as children;

Innovative strategies to make EMS research easier to accomplish in emergency situations are vital. Researchers must have access to patient outcome information in order to evaluate and improve prehospital care. New biomedical and technical advances must be evaluated using scientific methodology. Research is the key to maintaining focus on improving the overall health of the community in a competitive and cost conscious health care market. Most importantly, research is essential to ensure that the best possible patient care is provided in the prehospital setting. Only through the refinement of these guidelines for emergency exception to informed consent can high quality research be conducted in the prehospital seting.

Sincerely,

Robert E. O'Connor, M.D., MPH
President