



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

Board of Advisors

Marv Birnbaum, MD, PhD
Lawrence H. Brown, EMT-P
Elizabeth Criss, RN, MEA
William J. Koenig, MD, FACEP
Todd F. LeGassick, MPH
Gregg Margolis, MS, NREMT-P

Director

Baxter Larmon, PhD, MICP

Managing Director

Edith Pryor

Associates

Terry Abrams, MS, EMT-P
Scott S. Bourn, RN, MSN, EMT-P
Elaine Christiansen, PhD, EMT-P
Dwayne E. Clayden, MEM, EMT-P
Harold C. Cohen, PhD, EMT-P
Joseph Corley, BSHS, EMT-P
Megan Corry, MA, EMT-P
Chuck Crawford, MS, EMT-P
Andrew Dahl, BA
Alice Dalton, RN, BSN
Robert De Lorenzo, MD, FACEP
Robert Delagi, MA, NREMT-P
Jim Dernocoeur, PA-C, EMT-P
Phillip Dickison, NREMT-P
William Dunne, MS, NREMT-P
Scott Eamer
Michael R. Gunderson, EMT-P, CQM
David Harrawood, RM, REMT-P
Nancy Hays, MPH
Todd LeDuc, NREMT-P
Thomas LeMaster, RN, REMT-P
Wolfgang H. Maleck, Arzt, EMT-P
Mark Marchetta, BS, RN, NREMT-P
Mary Kay Margolis, MHA, MPH
Richard Narad, DPA
Madeleine O'Donnell, RN, MEA
Thomas Raithby, BS, EMT2
Louise Reynolds, PhD
Steven J. Rottman, MD, FACEP
Chris Thos. Ryther, BS, NREMT-P
David L. Schriger, MD, MPH
Helen Snooks, PhD
Andrew W. Stern, MPA, MA, NREMT-P
Ronald D. Stewart, MD, FACEP
Walt Alan Stoy, PhD, EMT-P
Mike Taigman
William F. Toon, BA, NREMT-P
Atilla Üner, MD, FAAEM
Donald Walsh, PhD, EMT-P
Jeremy Wilkinson, BS, NREMT-P
Matthew Zavarella, NREMT-P

Founding Partner

JEMS Communications

Benefactors

Laerdal Medical Corp.
Medtronic Physio-Control Corp.

Partners

SSCOR, Inc.
Zoll Medical Corp.

April 23, 2002

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

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 the practice of "IRB shopping" threatens the integrity of the research process. Therefore, the Prehospital Care Research Forum supports the position that an IRB considering a research protocol should be informed of the results of any other IRB review.

Importantly, EMS systems are usually not affiliated with an academic institution, and often have no official relationship with any specific health care institution while necessarily interacting with all of their community's hospitals. Thus, prehospital care studies frequently involve multiple IRBs, and some effort is required to determine which IRB should serve as the primary IRB for a study. Because of this unique nature of the EMS research environment, we do believe it is important to differentiate between activities intended to identify the appropriate IRB(s) and those activities intended to circumvent a negative action by an IRB. The former is a de facto part of many prehospital care studies; the latter is absolutely unacceptable.

While recognizing the need for regulation, the Prehospital Care Research Forum encourages a principle-based approach to the issue of IRB shopping. We would argue that these principles are already well established, albeit indirectly, in existing documents, declarations, guidelines and regulations. Nonetheless, the FDA (and OHRP) should clearly establish that:

(1) IRB shopping is unethical. Ethical sponsors and investigators may legitimately disagree with the actions of an IRB, but they

OIN-0322

C6

must be willing to discuss those actions and the basis for their disagreement in all subsequent IRB submissions.

(2) Everyone involved in the research process is responsible for ensuring the ethical conduct of research. Ethical investigators, sponsors, and other individuals involved in the research process must make sure that the IRB(s) reviewing a study has all of the information relevant to that study, including information about the actions of other IRBs, and any new information that develops after an IRB has acted.

These two principles can be used to address all of the questions raised in the advance notice of proposed rulemaking: the FDA and OHRP should deal with violations of these ethical principles in the same manner with which they would deal with any other breach of ethics.

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 flourish extending upwards and to the right.

Edith Pryor
Managing Director
Prehospital Care Research Forum

Cc: Prehospital Care Research Forum Board of Advisors



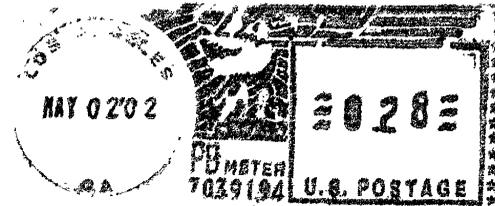
PREHOSPITAL CARE
RESEARCH
FORUM

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

HD 88



PARSONS
FIRST CLASS
D/S #35



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

CAOYN#B 20857

