

AAEM alert for Academicians: The FDA will examine the emergency exception for informed consent as outlined in the below notice. Concerned parties are advised to consult with the Society of Academic Emergency Medicine regarding this issue as they have been the lead organization on this matter in our specialty.

FDA News

FOR IMMEDIATE RELEASE

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FDA Takes Close Look at Experience Gained from Regulations Allowing Emergency Research With An Exception from Informed Consent Requirements

Agency Issues Draft Guidance and Announces Public Hearing to Discuss Emergency Research

The Food and Drug Administration (FDA) is taking a close look at the implementation of its 1996 regulation, 21 CFR 50.24, which allows clinical emergency research when informed consent cannot be obtained. This federal regulation allows the conduct of research studies to test emergency treatments on patients with specific life-threatening medical conditions (head trauma, cardiac arrest, stroke) when patients cannot give informed consent because of their conditions, and family is not available to give provide consent either. Such emergency research has been allowed under very restricted circumstances since 1996 when FDA regulations went into effect providing for a narrow exception to the informed consent research requirements.

This is part of FDA's ongoing effort to ensure the highest level of scientific and ethical rigor in clinical research and is one of many projects under its Human Subject Protection and Bioresearch Monitoring Program (HSP-BIMO Program).

The Human Subject Protection and Bioresearch Monitoring (HSP /BIMO) Initiative series of new policy and regulatory developments is aimed at strengthening the Agency's oversight and protection of patients in clinical trials and the integrity of resulting data. HSP /BIMO will facilitate the modernization of the regulation of clinical trials and bioresearch monitoring, specifically the protection of human subjects and the integrity of data in clinical trials, and encompasses devices, foods, human drugs, biological drug products and veterinary medicine.

On rare occasions and under carefully regulated circumstances, a person in a life-threatening situation will be enrolled in an emergency research study before arriving at a hospital (and may be treated in an ambulance) or in the emergency room of a hospital without being able to give his or her informed consent because of his or her medical condition. Since 1996, FDA has received

a sizable number of requests to conduct a clinical investigation under § 50.24.

"On the 10-year anniversary of this regulation, it is appropriate that we review the regulation and get the perspectives of those who participated in such studies to make sure that emergency research is being carried out in a scientifically sound and ethical manner," said Dr. Janet Woodcock, FDA's Deputy Commissioner for Operations.

"Unless the medical community can conduct studies in these life-threatening emergency situations we may not truly have scientifically validated solutions to benefit patients in these extremely difficult circumstances. It is critical that this type of research be conducted to help advance the practice of emergency medicine." said Dr. Woodcock.

FDA's review of emergency research with an exception from informed consent has two key components:

- * A public hearing on emergency research that will be held October 11, 2006, at the University of Maryland Shady Grove Center, 9630 Gudelsky Drive, Rockville, MD.
- * A draft guidance (Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research) is being made available to assist IRBs, clinical investigators, and sponsors in the development and conduct of emergency research.

FDA is seeking public input on emergency research at the October 11 public hearing and is also seeking written comment on the guidance www.fda.gov/dockets/ecomments/.

The public hearing will give FDA an opportunity to hear about the challenges of conducting scientifically rigorous emergency research while maintaining human subject protections and consider proposed suggestions for improving the process. FDA is asking that participants address the challenges they have faced in their respective roles related to the conduct of emergency research with an exception from informed consent.

In the Federal Register announcement, FDA is posing a number of questions participants may wish to address as well as related challenges posed by emergency research studies including community consultation, public disclosure prior to initiation and public disclosure of research results following completion of studies. Since adoption of the regulation FDA has not received systematic comment, but has reviewed concerns expressed by investigators, ethicists, and other interested parties, in addition to issues raised in the literature, as well as its own experiences. FDA plans to use the information obtained at the public hearing to help in developing strategies to address identified challenges.

The draft guidance is intended to assist IRBs, clinical investigators, and sponsors in the development and conduct of emergency research involving the exception from informed consent requirements. FDA has expanded on its previous guidance document addressing emergency research with an exception to informed consent in order to:

- * Further delineate the oversight roles and responsibilities of IRBs, clinical investigators, and sponsors,

- * Broaden the discussion of community consultation and public disclosure, and
- * Clarify terminology used in regulations that have been difficult to interpret.

FDA will consider comments received on the draft guidance as well as comments and suggestions received at the public hearing to determine whether the regulation's current framework is adequate for the ethical conduct of emergency research, or whether modifications would be appropriate.

For more on the specific criteria that must be met before a planned clinical emergency research program can be initiated, see the draft Guidance for IRBs, Clinical Investigators, and Sponsors; Exception from Informed consent Requirements for Emergency Research:

- * Federal Register Notice for the Guidance:
www.fda.gov/OHRMS/DOCKETS/98fr/E6-14262.htm
- * Guidance: www.fda.gov/OHRMS/DOCKETS/98fr/06d-0331-gdl0001.pdf

The Federal Register notice for the hearing is available at www.fda.gov/OHRMS/DOCKETS/98fr/E6-14264.htm. It provides information on registration procedures. Those who wish to participate must register by September 20, 2006.