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Certifier	<u>M. Bell</u>

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 00D-0805]

**Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors:  
Exception From Informed Consent Requirements for Emergency Research;**

**Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled “Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research.” The draft guidance document provides guidance for developing and implementing research in emergency settings when an exception from the informed consent requirements is requested under the Food and Drug Administration’s (FDA’s) emergency research rule.

**DATES:** Written comments on the draft guidance document are to be submitted by [*insert 60 days after date of publication in the Federal Register*]. General comments on the agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance entitled “Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research” to the Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs (ORA), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Bonnie M. Lee, Division of Compliance Policy (HFC-230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0415

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance document entitled “Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research.” In the **Federal Register** of October 2, 1996 (61 FR 51498), FDA published regulations that provide a narrow exception to the requirement for obtaining and documenting informed consent from each human subject, or his or her legally authorized representative, prior to initiation of an experimental intervention (§ 50.24 (21 CFR 50.24) in part 50 (21 CFR part 50)). The exception would apply to a limited class of research activities involving human subjects who are in need of emergency medical intervention but who cannot give informed consent because of their life-threatening medical condition, and who do not have a legally authorized person to represent them. The preamble to part 50 stated that the agency intends to monitor and evaluate the implementation of these regulations on an ongoing basis. Since the effective date of these emergency research regulations (November 1, 1996), FDA has reviewed the efforts of sponsors, Institutional Review Boards, and clinical investigators to interpret and comply with these regulations and has determined that guidance is needed.

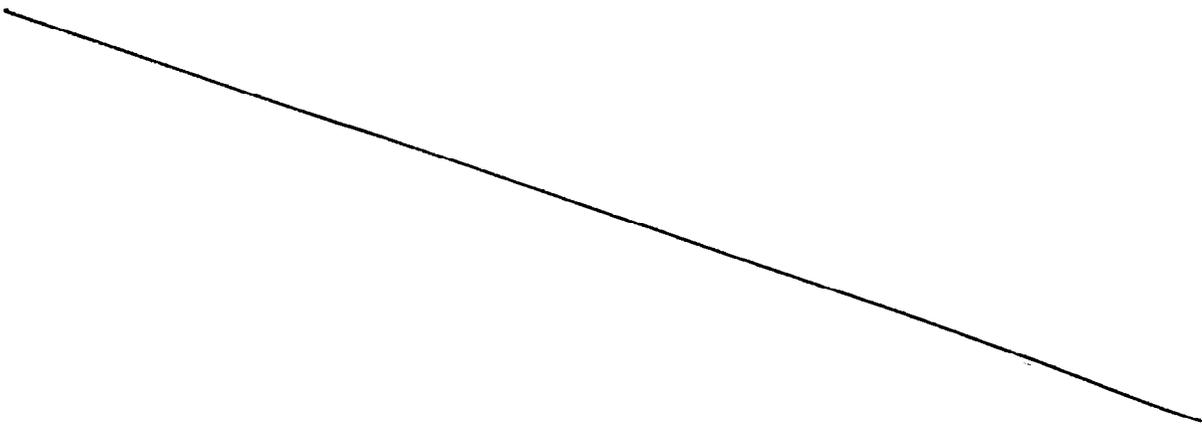
The draft guidance document, available for public comment, addresses issues pertinent to the implementation of FDA’s emergency research regulations. The draft guidance document provides guidance on the development and conduct of community consultation and public disclosure activities; the establishment of informed consent procedures to be used when feasible; the need for the concurrence of a licensed physician; use of data monitoring committees; use of independent

IRB's; documentation of efforts to contact a subject's legally authorized representative or family member regarding the subject's participation in the study; and other aspects of the emergency research regulations.

This draft Level 1 guidance document is being issued consistent with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on ways to effectively implement its emergency research regulations in order to protect the rights and welfare of human subjects participating in that research. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information contained in the guidance document may be applicable to all situations.

## **II. Request for Comments**

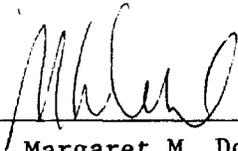
Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

Persons with access to the Internet may obtain the document using the Internet at [http://www.fda.gov/ora/compliance\\_\\_ref/bimo/default.html](http://www.fda.gov/ora/compliance__ref/bimo/default.html).

Dated: 3/21/00  
March 21, 2000.



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**

