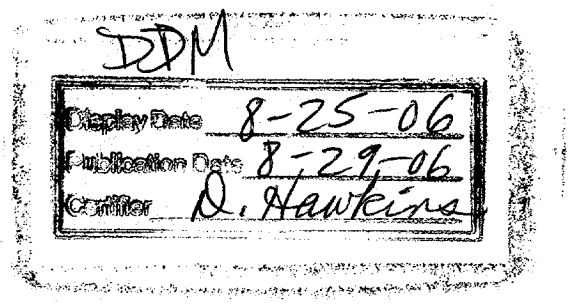
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0331]




# Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research

**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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research." This draft guidance, when finalized, is intended to assist Institutional Review Boards (IRBs), clinical investigators, and sponsors in the development and conduct of emergency research.The draft guidance also describes the additional specific human subject protection requirements for emergency research. Elsewhere in this issue of the **Federal Register**, FDA is announcing a public hearing on emergency research conducted without informed consent under FDA regulations.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Policy (HF–11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-

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addressed adhesive label to assist that office in processing your requests. Submit phone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Carolyn Hommel, Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20857, 301–827–3340.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a draft guidance entitled "Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors; Exception from Informed Consent Requirements for Emergency Research." This draft guidance was developed to assist IRBs, clinical investigators, and sponsors in the development and conduct of emergency research, that is, research in emergency settings when an exception from the informed consent requirements is requested under FDA's emergency research regulation. Further, the draft guidance describes the additional specific human subject protection requirements for emergency research, such as community consultation and public disclosure activities, the need for the concurrence of a licensed physician, use of data monitoring committees, use of independent IRBs, and the documentation of efforts to contact a subject's legally authorized representative or family member regarding the subject's participation in the study.

In addition to the draft guidance, FDA is holding a public hearing on emergency research conducted without informed consent under FDA regulations. The public hearing is designed to solicit the views of individuals and groups affected by challenges encountered in the conduct of emergency research in the absence of informed consent, including patient advocacy groups, individuals who have participated in clinical trials, IRB members, sponsors, clinical investigators, medical societies, ethicists, and other interested parties. FDA will consider comments and suggestions received at the hearing together with any comments received on the draft guidance to determine whether the current framework is adequate for the ethical conduct of emergency research, or whether modifications would be appropriate.

Under the regulations in 21 CFR 50.24, and the conforming amendments contained in 21 CFR parts 56, 312, 314, 601, 812, and 814, an exception may be requested from the requirement to obtain informed consent from each subject, or the subject's legally authorized representative, prior to enrollment in a clinical investigation. The narrow exception applies to emergency research for which, among other things, the following conditions exist: (1) An investigational new drug application (IND) or investigational device exemption application (IDE) is required; (2) that involves human subjects who have a life-threatening medical condition (for which available treatments are unproven or unsatisfactory); (3) that involves subjects who because of their medical condition (e.g., unconsciousness) cannot give informed consent; and (4) where, to be effective, the intervention must be administered before informed consent from the subjects' legally authorized representative is feasible. Studies involving an exception from the general requirement of informed consent may

proceed only after a sponsor has received prior written permission from FDA, and the IRB has found and documented that specific conditions have been met.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the exception from informed consent requirements for emergency 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.

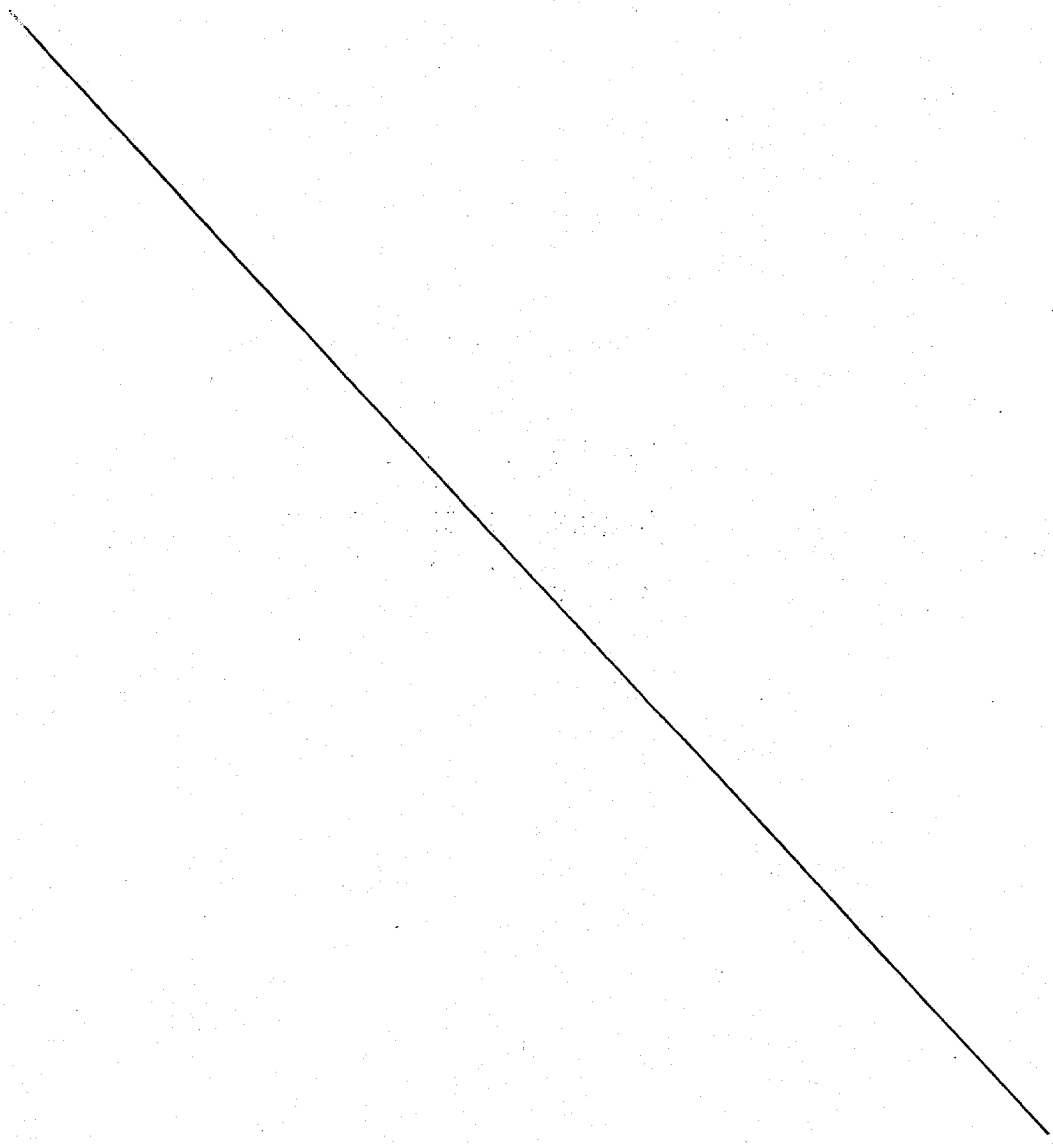
**II. The Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 56 (21 CFR part 56) have been approved under OMB control number 0910–0130, the collections of information in part 312 (21 CFR part 312) have been approved under OMB control number 0910–0014, and the collections of information in part 812 (21 CFR part 812) have been approved under OMB control number 0910–0078. Modifications to these approved information collection requirements are underway or will be made at the time that each information collection is renewed. The agency believes that this is appropriate because this guidance has only a minor impact on these existing collections of information.

**III. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed

comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



## IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: AUG 2 1 2006

August 21, 2006.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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