ORDER

The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent for Emergency Research; Availability.”

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled “Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent for Emergency Research.” This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors in the development, conduct, and oversight of research involving FDA-regulated products (e.g., drugs, biological products, devices) in emergency settings when an exception from the informed consent requirements is requested under the Code of Federal Regulations (CFR). FDA determined that
guidance is needed in interpreting and complying with these regulations, particularly in the areas of planning and conducting community consultation and public disclosure activities, and the establishment of informed consent procedures to be used when feasible. The guidance announced in this notice finalizes the draft guidance of the same title, dated July 2006.

DATES: Submit either electronic or written comments on Agency guidance at any time.

ADDRESS: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6320 or 301–796–3400), or the Office of Communication, Outreach and Development (HF–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448 (1–800–638–4709 or 301–827–1800); or the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist the office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sara Goldkind, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance entitled “Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception From Informed Consent for Emergency Research.” This guidance is intended to assist IRBs, clinical investigators, and sponsors in the development, conduct, and oversight of research involving FDA-regulated products (e.g., drugs, biological products, devices) in emergency settings when an exception from the informed consent requirements is requested under title 21 of the CFR (21 CFR 50.24). The exception applies to investigations to determine the safety and/or effectiveness of FDA-regulated products used in emergency settings (emergency research). These investigations involve human subjects who have a life-threatening medical condition (for which available treatments are unproven or unsatisfactory), and who, because of their condition (e.g., traumatic brain injury), cannot give informed consent. The research involves an investigational product that, to be effective, must be administered before informed consent from the subjects’ legally authorized representatives can be obtained.

In the Federal Register of August 29, 2006 (71 FR 51198), FDA announced the availability of the draft guidance of the same title, dated July 2006. The same Federal Register (71 FR 51143) announced a public hearing, held on October 11, 2006, on emergency research conducted without informed consent under FDA’s emergency research regulations. FDA received numerous comments on the draft guidance. All comments received during the comment period, questions received by Agency staff related to implementation of the regulations, and information presented at the public hearing have been carefully reviewed and, where appropriate, incorporated into the guidance. A summary of changes includes the following: (1) Additional discussion of the goals and purpose of community consultation and public disclosure, information that should be included, and how community consultation and public disclosure activities may be implemented; (2) clarification of “unproven” and “unsatisfactory” with respect to available therapy; and (3) discussion of trial design issues (e.g., study endpoints, therapeutic window). This guidance incorporates comments received on earlier drafts of the guidance document, questions received by Agency staff related to implementation of the regulations, and information presented at the October 11, 2006, public meeting on emergency research studies.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. 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 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 21 CFR part 56 have been approved under OMB control number 0910–0130, the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014, and the collections of information in 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) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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


Dated: March 29, 2011.

Leslie Kux,
Acting Assistant Commissioner for Policy.

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