

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0406]

Draft Information Sheet Guidance for Sponsors, Clinical Investigators, and Institutional Review Boards on Frequently Asked Questions—Statement of Investigator (Form FDA 1572); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft information sheet guidance entitled “Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572).” This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of investigational drugs and biologics in completing the Statement of Investigator form (Form FDA 1572). FDA developed this draft information sheet guidance in response to numerous questions from the research community regarding Form FDA 1572. This draft information sheet guidance provides FDA’s responses to the most frequently asked questions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft information sheet guidance by *[insert date 60 days after date of publication in the Federal Register]*.

SDM
Display Date

7-28-08

Publication Date

7-29-08

Certifier

D. Hawkins

ADDRESSES: Submit written comments on this draft information sheet 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft information sheet guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Office of Science and Health Coordination/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 information sheet guidance for sponsors, clinical investigators, and IRBs entitled “Frequently Asked Questions—Statement of Investigator (Form FDA 1572).” This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of investigational drugs and biologics in complying with the requirement that each investigator complete and sign a Form FDA 1572 before participating in an investigation. It describes how to complete the Statement of Investigator form (Form FDA 1572).

FDA developed this draft information sheet guidance in response to numerous questions from the research community regarding Form FDA 1572. In this draft guidance, we provide answers to frequently asked questions concerning the purpose of this form, when this form needs to be completed and signed by the investigator, how to best complete the various blocks within the form, and when the form might need to be updated. In addition, we clarify questions related to the use of Form FDA 1572 by clinical investigators

participating in studies conducted outside the United States that may or may not be under an investigational new drug application.

This information sheet guidance is part of the Information Sheet Guidance Initiative announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as "Information Sheets," these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA since the early 1980s. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidances that address current issues, and develop new Information Sheet Guidances as needed.

This draft information sheet guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The draft information sheet guidance, when finalized, will represent the agency's current thinking on completing Form FDA 1572. 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 for Form FDA 1572 have been approved under OMB Control No. 0910–0014.

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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/oc/gcp/draft.html> or <http://www.regulations.gov>.

Dated: 7/21/08

July 21, 2008.



Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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Dawn P. Hawkins