



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0560]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0582. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable--(OMB Control Number 0910-0582)--

Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see

21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document, entitled “Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable,” issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours ($700 \times 4 = 2,800$).

In the Federal Register of June 12, 2012 (77 FR 34954), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Recordkeeping Burden¹

Federal Food, Drug, and Cosmetic Act Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
520(g) (21 U.S.C. 360j(g))	700	1	700	4	2,800

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: February 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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