Medical Devices; Exception from General Requirements for Informed Consent
0910-0586
RIN 0910-AC25
SUPPORTING STATEMENT

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Abstract

The interim final rule amends FDA's informed consent regulation to provide an exception to the general requirement to obtain informed consent from the subject of an investigation involving an unapproved or not cleared in vitro diagnostic device intended to identify a chemical, biological, radiological, or nuclear agent. This regulation was issued under the statutory authority provided in section 520(g)(3)(D) of the act, which outlines the criteria under which an exemption from informed consent may be permissible. It amends 21 CFR 50.23, to add paragraph (e). Section 50.23(e)(1) and (e)(2), require the investigator and an independent licensed physician to make the determination and certify in writing certain facts concerning the need for use of the investigational in vitro diagnostic device without informed consent. The investigator would submit this written certification to the institutional review board (IRB). Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities. The investigator must provide the IRB with the information required by § 50.25 and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

This information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information

FDA is requiring this information disclosure in order to assure that exceptions to the informed consent requirement occur only in cases in which the investigator may not obtain informed consent in sufficient time to protect the health of the subject.

The prospective respondents are investigators who are using investigational in vitro diagnostic devices intended to identify a chemical, biological, radiological, or nuclear agent. These investigators may be private sector laboratory directors and physicians who have their own business or are affiliated with business entities such as hospitals or device manufacturers. Respondents may also include investigators affiliated with federal or local government institutions such as public health laboratories and state health departments.

3. Use of Information Technology and Burden Reduction

Respondents can use any appropriate technology to develop, maintain, and/or disseminate the required certification information. Use of computers and word processors has greatly reduced the time needed to compile, submit, and maintain the required documents. FDA estimates that 98% of the respondents will use electronic means to fulfill the agency's requirement.

4. Efforts to Identify Duplication and Use of Similar Information

The Food and Drug Administration is the only agency charged with the responsibility of regulating the investigation of in vitro diagnostic manufacture devices that are not approved or cleared for introduction into interstate commerce. Therefore, no similar information is available that can be used or modified for the purpose described.

5. Impact on Small Businesses or Other Small Entities

The FDA has established a Division of Small Manufacturers International and Consumer Assistance (DSMICA). DSMICA provides technical and nonfinancial assistance through a comprehensive program, which includes seminars and educational conferences, informational materials and use of a toll-free number which may be used by firms that require information or assistance. Additional Center for Devices and Radiological Health staff are available for consultation on request. The percentage of respondents that may be considered small business is estimated to be 20%.

6. Consequences of Collecting the Information Less Frequently

Data will be submitted occasionally. FDA requires a certification within five days of each use of investigational in vitro diagnostic device subject to this rule without obtaining informed consent in order to assure adequate protection for subjects of such investigations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This collection of information is consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In the Federal Register of February 18, 2010 (75 FR7278), FDA solicited comments on the collection of information. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

The regulation does not provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondent

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. All records and other information submitted to FDA are releasable under 21 CFR Part 20. However, FOIA provides certain exemptions from mandatory public disclosures of government records (5 U.S.C. 522(b)(1-9). One such exemption, personnel, medical, and similar files, disclosure of which would constitute a clearly unwarranted invasion of personal privacy applies to patient information that may be included in the information collection provisions of this rule.

11. Justification for Sensitive Questions

The information required does not include questions about sexual behavior, attitude, religious beliefs, or any other matters, which are commonly considered private or sensitive in nature.

12. Estimates of Hour Burden Including Annualized Hourly Costs

12 a. Estimates of Annualized Burden Estimate

From its knowledge of the in vitro diagnostic device investigations, FDA estimates that there are approximately 150 investigators who could perform this type of testing and, as investigators, are required to comply with information collection and recordkeeping. FDA estimates that there are approximately 450 naturally occurring cases of this type each year. Based on its knowledge of similar types of submissions, FDA estimates that it will take about two hours to prepare each certification required by § 50.23(e)(1) and (2). FDA also estimates that it will take each investigator approximately one hour to make each of the disclosures required by § 50.23(e)(4). The respondents to this collection of information are expected to be clinical laboratory directors and physicians.

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

Estimated Average Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per response	Total hours
50.23(e) (1)&(2)	150	3	450	2	900
50.23(e)(4)	150	3	450	1	450

Total					1350

12 b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Laboratory Director	1000	$75.00	$75,000
Physician	350	$75.00	$26,250
Total			$105,250

13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

The operating and maintenance costs of $100 are for copying and mailing.

14. Annualized Cost to the Federal Government

There are no anticipated costs to the Federal Government, since this information need not be submitted to the FDA. Inspections of clinical investigators may include reviews of certification statements required by this rule, will be conducted under the auspices of the bioresearch monitoring program.

15. Explanation for Program Changes or Adjustments

There is no change in burden.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Currently, CDRH is not requesting an exemption for display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Currently, CDRH is not requesting an exemption to Certification for the Paperwork Reduction Act Submissions.

B. Collection of Information Employing Statistical Methods

There are no statistical methods being employed in this collection of information.