Supporting Statement for
Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that Are Not Individually Identifiable
OMB # 0910-0582

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Abstract

The Food and Drug Administration has notified the public, in a guidance document of the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations (as required by section 520(g) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 50) for *in vitro* diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from the Investigational Device Exemption (IDE) regulation at 21 CFR 812.2(c) (3), as long as subject privacy is protected by using only specimens that are not individually identifiable. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=37d0b05067c9473305705375339348a&rgn=div5&view=text&node=21:8.0.1.1.9&idno=21

In the guidance document, FDA recommends that sponsors of studies that meet the factors/circumstances described in the guidance maintain documentation of how these factors were met and of the types of human subject protection procedures followed by the specimen provider to ensure that the subject cannot be identified. The agency developed this guidance because it became aware that the requirement to obtain informed consent for IVD studies (including those using leftover human specimens) was bringing to a halt a class of very valuable investigations used to evaluate the performance of potentially valuable diagnostic tests. FDA believes these requirements do not, in the circumstances described above, appreciably add protection for human subjects, which is the purpose of having informed consent requirements in the first place.

The agency included this information collection and record keeping in the guidance document because IVD manufacturers that embrace this enforcement discretion policy should have documentation to demonstrate that their product met the factors/circumstances described in the guidance.

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

2. Purpose and Use of the Information Collection

FDA has announced the availability of a guidance entitled, "Guidance on Informed Consent for *In Vitro* Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable." The guidance defines when the agency intends to exercise enforcement discretion

regarding informed consent requirements (21 CFR parts 812, 50) with regard to leftover human specimens that are not individually identifiable that are used in certain *in vitro* diagnostic studies.

The guidance document recommends that sponsors (investigators, IVD manufacturers or federal government agencies that develop and evaluate IVD tests) that meet the factors described in the guidance maintain records of how these factors were met. Sponsors that wish to take advantage of this policy will substitute use of records to demonstrate conformance to this enforcement discretion policy in place of the more detailed and patient specific records for obtaining and document informed consent. Most fundamentally, this means collecting and maintaining information about the protections that are in place to prevent the identification of the specimens, since making sure that the specimens are not identifiable is key to obtaining FDA's enforcement discretion.

FDA intends to exercise enforcement discretion when all of the following are true: the investigation meets the IDE exemption criteria at 21 CFR 812.2(c)(3), http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=00086154372b2f56d151558d73df36d4&rgn=div8&view=text&node=21:8.0.1.1.13.1.1.2&idno=21

-the study uses leftover specimens, that is, remnants of specimens collected for routine clinical care or analysis that would have been discarded. The study may also use specimens obtained from specimen repositories or leftover specimens that were previously collected for other research purpose may also be used;

-the specimens are not individually identifiable;

-the specimens may be accompanied by clinical information as long as this information does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor;

-the individuals caring for the patients are different from and do not share information with those conducting the investigation;

-the specimens are provided to the investigator(s) without identifiers and the supplier of the specimens has established policies and procedures to prevent the release of personal information; and

-the study has been reviewed by an IRB in accordance with 21 CFR part 56.

3. Use of Improved Information Technology and Burden Reduction

Companies are free to use whatever forms of information technology may best assist them in utilizing this guidance document. FDA estimates that 95% of the respondents will use electronic means to fulfill the agency’s requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

As this is a guidance document, no firm is required by regulation to take advantage of this policy. There should be no duplicative information collection as a result of this guidance.

5. Impact on Small Businesses or Other Small Entities

This guidance document offers clinical investigators and sponsors (including small businesses) a pathway for using leftover human specimens that are not individually identifiable (short forms are not applicable). This will be an alternative to existing requirements for sponsors to obtain informed consent, which could be extraordinarily time-consuming and costly, if not impossible. This pathway is not currently available; thus the policy expressed in the guidance document should help facilitate important research in a cost-effective way. FDA estimates that 70% of respondents are businesses.

6. Consequences of Collecting the Information Less Frequently

This guidance may reduce the information collection burden on clinical investigators and sponsors by requesting only that they meet the factors in the guidance, rather than keeping the records and satisfying other information collection requirements related to obtaining informed consent. The clinical investigators and sponsors need to maintain written documentation demonstrating that they meet the factors in the guidance only if they choose to take advantage of the policy expressed in the guidance. Respondents will respond to the date collection only once per investigation.

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

There are no special circumstances associated with this information collection.

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

In a **Federal Register** of October 20, 2009 (74 FR 53749), FDA published a 60 day notice requesting comments on the information collection provisions. In response to this notice, FDA did not receive any comments. http://edocket.access.gpo.gov/2009/pdf/E9-25178.pdf
Before publishing this guidance document FDA discussed its content with members of the Trans-HHS Taskforce on Harmonization of Ethical and Legal Policies Related to Use of Human Specimens and Data in Research (HELPS), which is coordinated by NIH with representation from other federal agencies. This group was very supportive.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for payment or gifts to respondents.

10. Assurance of confidentiality Provided to Respondents

This information collection will be used only to assist clinical investigators, sponsors, and IRBs in

conducting research with leftover specimens that are not individually identifiable. All human specimens that are part of this information collection will be not individually identified. The guidance document explains what constitutes a not individually identifiable specimen.

11. Justification for Sensitive Questions

This information collection does not include any questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

FD&C Act	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
520(g)	700	1	700	4	2,800

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

FDA bases its estimate on FDA's experience with the documentation burden required under Good Manufacturing Practices.

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 812.2 (c)(3) have been approved under OMB control number 0910-0078.

12b. Annualized Hour Cost to Respondents

FDA estimates that cost of developing standard operating procedures for each record keeper is $300. (6 hours of work at $50/Hr.) This results in a total cost to industry of $210,000.

13. Estimates of Other Total Annual Cost Burden to Respondents

There are no capital, start-up or operating and maintenances associated with this collection of information.

14. Annualized Cost to Federal Government

There are no annualized costs to the Federal Government as a result of this guidance.

15. Explanation for Program changes or Adjustments

There is no change in burden.

16. Plans for Tabulation and Publication and Project Time Schedule

The agency has no plans for publication of information from this information collection.

17. Reasons(s) Display of OMB Approval Date is Inappropriate

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in item 19 of OMB Form 83-I.