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 Necessitating Information Collection

The Food and Drug Administration has developed a guidance document that addresses an immediate need of the research community. The guidance identifies circumstances when the agency intends to exercise enforcement discretion regarding informed consent requirements. FDA intends to apply enforcement discretion to studies of *in vitro* diagnostic devices that are conducted using leftover specimens -- remnants of specimens collected for routine clinical purposes that would otherwise have been discarded --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. (Attachment A) This exercise of enforcement discretion regards the requirements for informed consent that normally apply to all FDA-regulated clinical studies (as required by section 520(g) of the Federal Food, Drug, and Cosmetic Act and 21 CFR part 50). The agency developed this guidance because the existing requirements are bringing a halt to a class of very valuable research that can produce new 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 has received information that numerous studies have been rejected because of the existing rules. These new products have potential to improve the public health by providing new tools for diagnosing many diseases or conditions, some of which may at present have no established means of lab diagnosis. Without this policy, valuable research is at best slowed considerably by the need to gather a prospective group of subjects (as opposed to using leftover materials already at hand) and at worse may become prohibitively expensive and not undertaken. This is contrary to the agency's mission, and to its commitment to removing unnecessary obstacles to product development. In addition to the impact on the development of new diagnostic devices, this requirement also has a negative impact on development of new drugs and biological products, many of which rely on the results of diagnostic tests to identify the patients for whom they are suitable.

FDA has notified the public, in a level one guidance document issued pursuant to the Good Guidances Practices regulation, 21 CFR 10.115, of the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and institutional review boards (IRBs). In the guidance document, FDA recommends that sponsors of studies that meet the factors 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.

2. How, by Whom, Purpose of 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 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 the following are true:

-the investigation meets the IDE exemption criteria at 21 CFR 812.2(c)(3), (Attachment A);

-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. Consideration Given to Information Technology

Companies are free to use whatever forms of information technology may best assist them in utilizing this guidance document.

4. Identification of Duplicative 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. Small Businesses

This guidance document offers clinical investigators and sponsors a pathway for using leftover human specimens that are not individually identifiable. 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.

6. Less Frequent Collection

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.

7. Special Circumstances

There are no special circumstances associated with this information collection.

8. Federal Register Notice/Outside Consultation

In a **Federal Register** of May 19, 2006 (71 FR 29158), FDA published a 6o day notice requesting comments on the information collection provisions. In response to this notice, FDA did not receive any comments.

9.Payment or Gift to Respondent

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

10. Confidentiality Provisions

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.

11. Sensitive Questions

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

12. Burden of Information Collection

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

Table 1. – Estimated Annual Recordkeeping Burden[1]

No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Operating and Maintenance Costs
700	1	700	4	2,800	$210,000	$420,000

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

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. ($300 multiplied by 700 record keepers) FDA estimates that operating costs for collecting this information is $300 per record keeper. (6 hours of work at $50/Hr.) This results in a total operational and maintenance cost to industry of $210,000. ($300 multiplied by 700 record keepers) The total cost of this recordkeeping, capital plus operational and maintenance cost is estimated to be $420,000.

13. Estimate of Other Total Annual Cost Burden to Respondents

There are no other cost burden incurred by the respondent(s).

14.Cost to Federal Government

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

15, Reason for Change

FDA made an adjustment in the number of respondents from 600 to 700 thereby increasing the burden hours from 2400 to 2800 due to expansion of the scope of the guidance which meant an increase in the number of studies.

16. Publication and Tabulation Dates

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

17 .Display of OMB Approval Date

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.

Attachment:

Attachment A: 21 CFR 812.2.