PROTECTION OF HUMAN SUBJECTS RECORDKEEPING REQUIREMENTS
FOR INSTITUTIONAL REVIEW BOARDS
OMB Control Number 0910-0130
Supporting Statement

A. Justification

1. Circumstances of Information Collection

The Food and Drug Administration is requesting approval from the Office of Management and Budget (OMB) for the following information collection requirements:

21 CFR 56.115 -- Recordkeeping

When reviewing clinical research studies regulated by FDA, IRBs are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods that the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by the FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

2. Purpose and Use of Information

The IRB must maintain documentation of its activities as provided in § 56.115. If the information were not maintained, the IRB could not show that it has fulfilled its responsibility to protect the rights and welfare of human research subjects. The records are maintained by IRBs to document that these responsibilities have been fulfilled.

3. Use of Improved Information Technology and Burden Reductions

The Food and Drug Administration Modernization Act of 1997 (FDAMA) and the Prescription Drug User Fee Act (PDUFA) II reauthorization mandate that the agency develop and update its information management infrastructure to allow the paperless receipt and processing of investigational new drug applications and new drug applications, as defined in PDUFA, and related submissions. In the Federal Register of December 11, 2003, FDA issued a final rule requiring the submission of labeling for human prescription drugs and biologics in electronic

format. FDA has also issued several guidances describing how to make voluntary electronic submissions to the agency, including a guidance on general considerations for electronic submissions entitled "Providing Regulatory Submissions in Electronic Format--General Considerations." The general considerations guidance included a description of the types of electronic file formats that we are able to accept for processing, reviewing, and archiving electronic documents. This guidance and more recent related guidances can be found at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances.

4. Efforts to Identify Duplication

There is no duplication resulting from these requirements.

5. Impact on Small Businesses or Other Small Entities

A substantial majority of IRB reviews are conducted at large institutions such as universities, medical schools, and research and teaching hospitals. The documentation requirements require only minimum documentation necessary for a committee to function in accord with good management practices, for FDA to conduct its inspections, and to ensure the integrity and accuracy of information submitted to the Agency in support of marketing permits. FDA has developed and widely distributed a series of information sheets to assist IRBs and others concerned with the protection of research subjects to conform with the requirements contained in FDA regulations. FDA continues to participate in regional workshops with the National Institutes of Health (NIH), the purpose of which is to describe the requirements of the FDA and DHHS regulations. FDA, in its information sheets and through its participation in workshops, has continually offered its assistance to any IRB that desires it. Other FDA offices are also available to discuss any regulatory requirement and to provide clarification and direction to small businesses.

6. Consequences of Collecting the Information Less Frequently

Recordkeeping occurs with each convened meeting of the IRB, and it is not considered feasible to conduct accurate recordkeeping on a less frequent basis.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5(d)(2)

There are no special circumstances that require the information to be collected in a manner inconsistent with the guidelines set forth in 5 CFR 1320.5.

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

In the Federal Register of August 17, 2010 (75 FR 50766), the Agency requested comments on the proposed collection of information. No comments were received on the information collection burden estimates.

9. Explanation of Any Gift to Respondents

No payment or gift is contemplated under the terms of this recordkeeping.

10. Assurance of Confidentiality Provided to Respondents

The documentation obtained during IRB inspections rarely contains any sensitive or confidential information that has not been submitted to FDA (e.g., copies of research protocols which may be considered confidential and contain trade secret information). The material is kept confidential in accordance with 18 U.S.C. 1905, 21 U.S.C. 331(j), and 21 U.S.C. 520(c), as well as sections 301(j) and 520(c) of the Federal Food, Drug and Cosmetic Act.

11. Justification for Sensitive Questions

The documentation maintained and collected does not contain questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature. Such data are more commonly contained in behavioral research, which FDA does not regulate. The identity of study subjects is rarely collected. Such sensitive information is treated as confidential and not released to third parties unless required by law or requested by Congress.

12a. Estimates of Annualized Burden Hours and Costs

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

Estimated Annual Recordkeeping Burden					
CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,500	14.6	36,500	100	3,650,000
Total					3,650,000

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 2,500 IRBs. The IRBs meet on an average of 14.6 times annually. The Agency estimates that approximately 100 hours of person-time per meeting are required to meet the requirements of the regulation.

12b. Estimated Cost to Respondents

FDA's Economics Staff estimates an average industry wage rate of $75 per hour (averaged from wages for upper management, middle management, and clerical support, plus overhead and personnel benefits) for preparing and submitting the information requested. Using the averaged wage rate of $75 per hour, and multiplied times the total hour burden estimated above (3,650,000), the total cost burden to respondents is approximately $273,750,000.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

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

14. Estimates of Annualized Cost Burden to the Government

Periodically FDA investigators conduct bioresearch monitoring inspections of IRBs. Before conducting these inspections, FDA staff ensures that the IRBs are registered with FDA. The annual cost to the government to check this information is negligible.

15. Explanation for Program Changes or Adjustments

In the previous information collection, FDA estimated that there were 5,000 IRBs, resulting in the current OMB inventory of 7,300,000 hours. The total hours requested in this submission is 3,650,000. This significant difference is due to a more accurate calculation in the number of IRBs registered with FDA.

16. Plans for Tabulation and Publication and Project Time Schedule

The records maintained under this regulation are not expected to be published.

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

This request does not seek approval to exempt display of the OMB approval date on any documents that are associated with this recordkeeping requirement.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

Not applicable.