

Supporting Statement
PROTECTION OF HUMAN SUBJECTS
RECORDKEEPING REQUIREMENTS
FOR INSTITUTIONAL REVIEW BOARDS
Docket No. 2004N-0114
OMB Control Number 0910-0130

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

FDA is continuously seeking ways to reduce burden through advances in information technology. Utilization of computer equipment and computerized IRB records management has greatly reduced the time needed to compile, arrange, and update the documentation maintained by IRBs; it has also expanded the

capability to review and respond to the problems found during inspections of IRBs.

4. Efforts to Identify Duplication

There is no duplication resulting from these requirements.

5. Involvement of 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 if Information Collected 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. Consistency with 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. Consultations Outside the Agency

In the Federal Register of March 17, 2004 (69 FR 12700), the agency requested comments on the proposed collection of information. FDA received one comment. The comment strongly disagreed with the estimate of the time required to transcribe and type the minutes of IRB meetings, to maintain records of continuing review activities, and to make copies of all correspondence between the IRB and investigative member records and of written IRB procedures. The comment explained

that the burden estimate should include the time required to keep membership lists current, distribute educational materials to members, orient new members, instruct researchers and their staffs about IRB requirements, provide information to institutions, attend IRB meetings, transcribe discussions, incorporate all revisions into typed minutes and into the official IRB correspondence that is issued to investigators, collate materials, stamp, file, keypunch database entry, and other responsibilities. FDA has considered the comment and has revised the burden estimate to 100 hours.

Efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions, record-keeping and on the data elements to be recorded and reported have been made at several Institutional Review Board Regional Conferences held nationwide each year, national conferences of IRB professional associations, and FDA national conferences on IRB issues. Additionally, FDA staff frequently are contacted by IRB members and administrative staff regarding questions on the interpretation and application of the regulatory requirements. Such questions often address recordkeeping requirements and provide FDA with information on the amount of time IRBs devote to recordkeeping.

9. Remuneration of Respondents

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

10. Assurance of Confidentiality

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. Questions of a Sensitive Nature

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.

12. Estimates of Annualized Hour Burden

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	5,000	14.6	73,000	100	7,300,000
Total					7,300,000

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

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 5,000 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.

13. Estimates of Annualized Cost Burden to Respondents

Assuming an average of \$50 per hour (labor plus overhead) to comply with the requirements, the cost would be approximately \$25,000,000.

14. Estimates of Annualized Cost Burden to the Government

The cost to the Federal Government of the IRB recordkeeping requirements results from FDA inspections and follow-up. FDA estimates that it expends approximately 28 FTEs to inspect IRBs and 8.5 FTEs to review inspection reports, issue regulatory correspondence to IRBs, and conduct related planning, evaluation, and oversight activities. The annual cost is expected to be approximately \$2,754,436 based on an average grade level of 12 step 5 (a salary of \$67,211), and an estimated \$8,253 per person-year for related overhead expenses [$\$67,211 + \$8,253 = \$75,464$; $\$75,464 \times 36.5 = \$2,754,436$].

15. Changes in Burden

The total burden hours have increased because of a recalculation of the number of IRBs - an increase from 2,000 to 5,000. This calculation is consistent with the number of IRBs used in the Paperwork Reduction Act section of the proposed rule entitled "Institution Review Boards; Registration Requirements." In addition, as a result of the comment (see number 8 above), the burden hours have increased to 100 hours.

16. Time Schedule, Publication, and Analysis Plans

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

17. Displaying of OMB Expiration Date

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 "Certification for Paperwork Reduction Act Submissions"

There are no exceptions to "Certification for Paperwork Reduction Act Submissions" for this recordkeeping requirement.

