INSTITUTIONAL REVIEW BOARDS –
Recordkeeping Requirements
OMB Control Number 0910-0130
Supporting Statement

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) regulations governing Institutional Review Boards (IRBs). As promulgated under 21 CFR Part 56, the regulations explain the provisions and requirements regarding the composition, operation, and responsibilities of IRBs, including recordkeeping requirements. While the agency maintains a related information collection request in support of regulations regarding specific IRB documents and the protection of human subjects (see also OMB Control No. 0910-0755), this information collection covers the general requirements under 21 CFR Part 56; Subpart D. Under the regulations, respondents must create and maintain records and make those records available for FDA inspection when requested. The recordkeeping should describe the structure and membership of the IRB; methods that the IRB will use in performing its functions; and other documentation relating to research protocols, informed consent, progress reports, and reports of injuries to subjects submitted by investigators to the IRB. Also included in the recordkeeping are 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. Finally, the information collection is applicable to any other information collection described in 21 CFR Part 56 Subpart D: *Records and Reports*.

2. Purpose and Use of the Information Collection

The information is used by 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. The IRB must maintain documentation of its activities as required under 21 CFR 56.115 to fulfill 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 and must be made available to FDA when requested.

3. Use of Improved Information Technology and Burden Reductions

The regulations impose no technological burdens nor require standardized formats for respondents, and we encourage the use of automated technology.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

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 recordkeeping requires what FDA believes is the minimal documentation necessary to ensure both the effective operation of IRBs and implementation of human subject protection. To assist respondents, FDA has developed an "*Institutional Review Board Frequently Asked Questions Information Sheet,*" available on its website at: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm. Information is available regarding the agency's bioresearch monitoring program as well, which respondents may also find helpful.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with existing laws and regulations under 21 CFR Part 56; Subpart D: *Records and Reports*.

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

There are no special circumstances for this collection of information.

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

In the Federal Register of November 1, 2016 (81 FR 75826), we published a 60 day notice requesting comments on this proposed collection of information. No comments were received regarding the information collection.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

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.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

Respondents to the collection are sponsors, members, or other individuals subject to the requirements of 21 CFR Part 56; Subpart D; specifically, 21 CFR 56.115. We estimate the annual burden for the collection of information as follows:

Table 1 – Estimated Annual Recordkeeping Burden[1]

21 CFR 56 – Institutional Review Boards	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Subpart D; 56.115 – IRB Records	2,520	14.6	36,792	100	3,679,200

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

Based on our review, we estimate there are approximately 2,520 IRBs that meet an average of 14.6 times annually. We further estimate approximately 100 hours of burden per meeting would be required to fulfill the regulatory requirements regarding recordkeeping.

12b. *Annualized Estimated Cost Burden Estimate*

Using 2016 wage data from the Bureau of Labor Statistics, we estimate $85 per hour (mean salary of upper plus middle management, and clerical support, plus overhead and personnel benefits) for preparing and submitting the information requested. When multiplied by the total number of burden hours discussed above (3,679,200), we estimate $312,732,000 as the total cost burden to respondents for the collection of information.

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

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

14. Annualized Cost to the Federal Government

Periodically FDA investigators conduct bioresearch monitoring inspections of IRBs. Funding is allocated from existing bioresearch monitoring allocations and therefore we estimate no cost to the Federal government for the collection of information.

15. Explanation for Program Changes or Adjustments

The information collection reflects an adjustment in the agency's estimate. We have increased the number of responses by **292** with a corresponding increase in burden hours by **29,200**. We attribute the adjustment to an increase in the number of respondents based on our review of available data.

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

Display of OMB Expiration Date is appropriate.

18. Exceptions to the Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.