ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
45 CFR Part 1301	2,500	2	2	10,000

Estimated Total Annual Burden Hours: 10,000.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 3, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–23798 Filed 10–7–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0521]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning the establishment and operation of clinical trial data monitoring committees.

DATES: Submit written or electronic comments on the collection of information by December 8, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees—(OMB Control Number 0910–0581)—Extension

Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (21 CFR 312.50 and 312.56 for drugs and biologics, and 21 CFR 812.40 and 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One such group is a Data Monitoring Committee (DMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from an

ongoing clinical trial. The DMC advises the sponsor regarding the continuing safety of current participants and those yet to be recruited, as well as the continuing validity and scientific merit of the trial.

FDA's guidance document is intended to assist sponsors of clinical trials in determining when a DMC is needed for monitoring a study, and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs, describes certain reporting and recordkeeping responsibilities, including the following: (1) Sponsor notification to the DMC regarding waivers, (2) DMC reports of meeting minutes to the sponsor, (3) sponsor reports to the FDA on DMC recommendations related to safety, (4) standard operating procedures (SOPs) for DMCs, and (5) DMC meeting records.

1. Sponsor Notification to the DMC Regarding Waivers

The sponsor must report to FDA serious unexpected adverse events in drugs and biologics trials (§ 312.32 (21 CFR 312.32)) and unanticipated adverse events in the case of device trials under (§ 812.150(b)(1) (21 CFR 812.150(b)(1))). The agency recommends in the guidance that sponsors notify DMCs about any waivers granted by FDA for expedited reporting of certain serious events.

2. DMC Reports of Meeting Minutes to the Sponsor

The agency recommends in the guidance that the DMC issue a written report to the sponsor based on the DMC meeting minutes. Reports to the sponsor should include only those data generally available to the sponsor. The sponsor may convey the relevant information in this report to other interested parties, such as study investigators. Meeting minutes or other information that include discussion of confidential data would not be provided to the sponsor.

3. Sponsor Reporting to FDA on DMC Recommendations Related to Safety

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (§ 312.32(c)) would not apply when the DMC recommendation is related to an excess of events not classifiable as serious. Nevertheless, the agency recommends in the guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of ''serious.''

4. Standard Operating Procedures for DMCs

In the guidance, we recommend that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;
- Ensure that those with serious conflicts of interest are not included in the DMC;
- Provide disclosure to all DMC members of any potential conflicts that are not thought to impede objectivity and, thus, would not preclude service on the DMC;
- Identify and disclose any concurrent service of any DMC member on other DMCs of the same, related or competing products;
- Ensure separation, and designate a different statistician to advise on the management of the trial, if the primary study statistician takes on the responsibility for interim analysis and reporting to the DMC; and
- Minimize the risks of bias that arise when the primary study statistician takes on the responsibility for interim analysis and reporting to the DMC, if it appears infeasible or highly impractical for any other statistician to take over responsibilities related to trial management.

5. DMC Meeting Records

The agency recommends in the guidance that the DMC or the group preparing the interim reports to the DMC maintain all meeting records. This information should be submitted to FDA with the clinical study report (§ 314.50(d)(5)(ii) (21 CFR 314.50(d)(5)(ii))).

Description of Respondents: The submission and data collection recommendations described in this document affect sponsors of clinical trials and DMCs.

Burden Estimate: Table 1 of this document provides the burden estimate of the annual reporting burden for the information to be submitted in accordance with the guidance. Table 2 of this document provides the burden estimate of the annual recordkeeping burden for the information to be maintained in accordance with the guidance.

Reporting and Recordkeeping Burdens

Based on information from FDA review divisions, FDA estimates there are approximately 740 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 370 clinical trials. Because FDA has no information on which to project a change in the use of DMCs, FDA estimates that the number of clinical trials with DMCs will not change significantly in the next few years. For purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 37 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. FDA receives very few requests for waivers regarding expedited reporting of certain serious events; therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two DMC reports of meeting minutes to the sponsor. One set of both meeting records should be maintained per clinical trial.

The ''Hours per Response'' and ''Hours per Record'' are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The ''Hours per Response'' include the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC, FDA, or the sponsor. The ''Hours per Record'' include the time to record, gather, and maintain the information.

The information collection provisions in the guidance for §§ 312.30 (21 CFR 312.30), 312.32, 312.38 (21 CFR 312.38), 312.55 (21 CFR 312.55), and 312.56 have been approved under OMB Control No. 0910–0014; § 314.50 has been approved under OMB Control No. 0910–0001; and §§ 812.35 (21 CFR 812.35) and 812.150 have been approved under OMB Control No. 0910–0078.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of Guidance/Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
4.4.1.2. Sponsor notification to the DMC regarding waivers	1	1	1	.25	.25
4.4.3.2. DMC reports of meeting minutes to the sponsor	370	2	740	1	740
5. Sponsor reporting to FDA on DMC recommendations related to safety	37	1	37	.5	18.5
Total					758.75

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Recordkeeping Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: September 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23833 Filed 10–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Information Program on Clinical Trials: Maintaining a Registry and Results Databank

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Information Program on Clinical Trials: Maintaining a Registry and Results Databank; *Type of Information Collection Request:* Revision of currently approved collection [OMB No. 0925–0586, expiration date 01/31/2009], *Form Number:* NA; *Need and Use of Information Collection:* The National Institutes of Health is modifying the clinical trial registry databank established under previous law [FDAMA, Section 113] to comply with provisions of Title VIII of Public Law 110–85 (Food and Drug Administration Amendments Act of 2007). The databank collects specified registration and results information on certain clinical trials identified in the law, with the objective of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical trials, to the benefit of public health. The databank is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research studies. Public Law 110–85 expands the scope of clinical trials that must be registered in ClinicalTrials.gov, increases the clinical trial information that must be submitted as part of each registration, and requires the submission of basic results information for registered trials of approved drugs, biologics and devices. *Frequency of Response:* Responsible parties must submit the required registration information not later than 21 days after enrolling the first subject. Results information is to be reported not later than 12 months after the completion date (as defined in the law), but can be delayed under certain circumstances. Updates to submitted information are required at least once a year, unless there are no changes to report. Changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. *Description of Respondents:* Respondents are referred to in the law as ''responsible parties,'' and are defined as: (1) The sponsor of the clinical trial (as defined in 21 CFR 50.3) or (2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, provided that ''the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements'' for submitting information under the law. *Estimate of Burden:* The burden associated with this information collection consists of two parts: the burden associated with registration of clinical trials; and the burden associated with the reporting of results information. In both cases, the burden includes the time necessary to extract information from the study protocol or results record, reformat it, enter it into the databank, and provide necessary updating over the course of the study. It is estimated that registration information will be required