Respondents: The respondents will be identified at the time that each change request is submitted to OMB. Generally they will be individuals who are representative of the target groups for the public assistance research or evaluation project in question.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Survey development field tests, respondent debriefing questionnaires, cognitive interviews and focus groups	6000	1	.5	3000

Estimated Total Annual Burden Hours: 3000.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, *Attn:* OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail address: OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: August 22, 2011.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2011–21863 Filed 8–26–11; 8:45 am]

BILLING CODE 4184–07–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Draft Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring.'' This guidance is intended to assist sponsors in developing risk-based monitoring strategies and plans for clinical investigations of human drugs, biologics, medical devices, and combinations thereof. The overarching goal of this guidance is to enhance human subject protection and the quality of clinical trial data. The guidance is intended to make clear that sponsors can use a variety of approaches to meet their monitoring responsibilities when conducting investigational new drug (IND) or investigational device exemption (IDE) studies.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 28, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or the Office of Communication, Education and Radiation Programs, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ann Meeker-O'Connell, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5339, Silver Spring, MD 20993–0002, 301–796–3150; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Chrissy Cochran, Center for Devices and Radiological Health (HFZ–311), Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 66, rm. 3453, Silver Spring, MD 20993–0002, 301–796–5490.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring.'' FDA is publishing this new draft guidance to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. This guidance is intended to make clear that sponsors can use a variety of approaches to meet their monitoring responsibilities during clinical investigations. This guidance describes a modern, risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to effectively oversee a study. For example, the guidance encourages greater use of centralized monitoring methods where appropriate. The guidance also makes recommendations about how to develop monitoring plans and document monitoring activities.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will

represent the Agency's current thinking on implementing a risk-based approach to the oversight of clinical investigations. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, FDA invites comments on the following 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 estimated 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 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.

Title: Draft Guidance for Industry: Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring.

Description of Respondents: Respondents to this collection of information are sponsors that monitor clinical investigations.

Burden Estimate: The draft guidance is intended to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for investigational studies of medical products, including human drug and biological products, medical devices, and combinations thereof. The guidance is intended to make clear that sponsors can use a variety of approaches to fulfill their responsibilities related to monitoring investigator conduct and the progress of IND or IDE studies. The guidance describes strategies for monitoring activities performed by a sponsor, or contract research organizations (CROs), that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance specifically encourages greater reliance on centralized monitoring methods, where appropriate.

Sponsors are required to provide appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality and integrity of the resulting data submitted to FDA.[1] As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations.[2] [3] The regulations are not specific about how sponsors are to conduct monitoring of clinical investigations and, therefore, are compatible with a range of approaches to monitoring. FDA currently has OMB approval for the information collection required under part 812 (OMB control number 0910–0078) and part 312, including certain provisions under subpart D (OMB control number 0910–0014).

However, the collections of information associated with this draft guidance that are not currently approved under OMB control numbers 0910–0014 or 0910–0078 are as follows:

Development of Comprehensive Monitoring Plan: Section IV.D of the draft guidance recommends that sponsors develop a prospective, detailed monitoring plan that describes the monitoring methods, responsibilities, and requirements for each clinical trial. The plan should provide those involved in monitoring with adequate information to effectively carry out their duties. All sponsor and CRO personnel who may be involved with monitoring, including those who review and/or determine appropriate action regarding potential issues identified through monitoring, should review the monitoring plan. The components of a monitoring plan are described in the draft guidance, including monitoring plan amendments (*i.e.,* the review and revision of monitoring plans and processes for timely updates). FDA understands that sponsors currently develop monitoring plans; however, not all monitoring plans contain all the elements described in the guidance. Therefore, our following burden estimate provides the additional time that a sponsor would expend in developing a comprehensive monitoring plan based on the recommendations in the guidance. We estimate that approximately 88 sponsors will develop approximately 132 comprehensive monitoring plans in accordance with the draft guidance, and that the added burden for each plan will be approximately 4 hours to develop, including the time needed for preparing monitoring plan amendments when appropriate (a total of 528 hours).

Voluntary Submission of Monitoring Plans to FDA: Section IV.D of the draft guidance permits sponsors to voluntarily and prospectively submit their monitoring plans to the appropriate CDER review division and request input from the division's clinical trial oversight component (sponsors of significant risk device studies are already required under § 812.25(e) to submit and maintain written procedures for monitoring). We estimate that approximately 22 sponsors will submit approximately 33 monitoring plans to CDER for feedback and that each submission will take approximately 2 hours to complete (a total of 66 hours).

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

[1] Part 312 (21 CFR part 312), subpart D, generally (Responsibilities of Sponsors and Investigators) and part 812 (21 CFR part 812), subpart C, generally (Responsibilities of Sponsors).

[2] Section 312.50 requires a sponsor to, among other things, ensure ''proper monitoring of the investigation(s)'' and ''that the investigations(s) is conducted in accordance with the general investigational plan and protocols contained in the IND.''

[3] Also see §§ 312.53(d), 312.56(a), 812.40, and 812.43(d).

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Draft guidance on monitoring clinical investigations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Development of Comprehensive Monitoring Plan	88	1.5	132	4	528
Voluntary Submission of Monitoring Plans to FDA	22	1.5	33	2	66
Total	N/A	N/A	N/A	6	594

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

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatory Information/default.htm, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm,* or *http://www.regulations.gov.*

Dated: August 23, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–21972 Filed 8–26–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Partner and Customer Satisfaction Surveys

SUMMARY: Under the provisions of Section 3507(a)(l)(D) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the Center for Scientific Review (CSR), National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 22, 2011 (Vol. 76, No. 141, p. 44020) and allowed 60-days for public comment. There was one public comment received during this time.

The purpose of this notice is to allow 30 days for public comment. The National Institutes of Health may not conduct or sponsor and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: Extension of Generic Clearance for Voluntary Partner and Customer Satisfaction Surveys.

Type of Information Collection Request: Extension.

Need and Use of Information Collection: The information collected in these surveys will be used by the Center for Scientific Review management and personnel: (1) To assess the quality of the modified operations and processes now used by CSR to review grant applications; (2) To assess the quality of service provided by CSR to our customers; (3) To enable identification of the most promising biomedical research that will have the greatest impact on improving public health by using a peer review process that is fair unbiased from outside influence, timely, and (4) To develop new modes of operation based on customer need and customer feedback about the efficacy of implemented modifications. These surveys will almost certainly lead to quality improvement activities to enhance and/or streamline CSR's operations. The major mechanism by which CSR will request input is through surveys. The major initiatives ongoing at the present time include: Shortening the review and application process, shortening the grant application, recruiting the best reviewers by developing additional review modes, improving study section alignment to ensure the best reviews, and others. Surveys will be collected via Internet. Information gathered from these surveys will be presented to, and used directly by, CSR management to enhance the operations, processes, organization of, and services provided by the Center.

Frequency of Response: The participants will respond once, unless there is a compelling reason for a subsequent survey. *Affected public:* Universities, not-forprofit institutions, business or other forprofit, small businesses and organizations, and individuals. *Type of Respondents:* Adult scientific professionals.

ESTIMATES OF ANNUALIZED HOUR BURDEN

[Totals rounded off to the nearest hour]

Type of respondent	Number of respondents	Frequency of response	Average time per response (Hr)	Total annual hour burden
Adult scientific professionals (via Mail/Telephone/Internet)	5000	1	0.25	1250
Adult scientific professional (via focus groups)	75	1	1	188
Total	5075	.....	.....	1438