

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) allow the renewal of the generic information collection project: "Voluntary Customer Surveys Generic Clearance for the Agency for Healthcare Research and Quality" In accordance with the Paperwork Reduction Act of 1995, Public Law 104-13 (44 U.S.C. 3506(c)(2)(A)), AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on August 3, 2007 and allowed 60 days for public comment. No

comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by November 13, 2007.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395-6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from AHRQ's Report Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ, Reports Clearance Officer, (301) 427-1477.

SUPPLEMENTARY INFORMATION:

Proposed Project

Voluntary Customer Surveys Generic Clearance for the Agency for Healthcare Research and Quality

In response to Executive Order 12862, the Agency for Healthcare Research Quality (AHRQ) plans to conduct voluntary customer surveys to assess strengths and weaknesses in agency program services. Customer surveys to

be conducted by AHRQ may include readership surveys from individuals using AHRQ automated and electronic technology databases to determine satisfaction with the information provided or surveys to assess effect of the grants streamlining efforts. Results of these surveys will be used in future program planning initiatives and to redirect resources and efforts, as needed, to improve AHRQ program services. The current clearance will expire January 31, 2008. This is a request for a generic approval from OMB to conduct customer surveys over the next three years.

Methods of Collection

The data will be collected using a combination of methodologies appropriate to each survey. These methodologies include:

- Evaluation forms;
- Mail surveys;
- Focus groups;
- Automated and electronic technology (e.g., e-mail, Web-based surveys, instant fax, AHRQ Publications Clearinghouse customer feedback) and,
- Telephone surveys.

Estimated Annual Respondent Burden

Type of survey	No. of respondents	Average hour burden response	Total hours of burden
Mail/Telephone Surveys	51,200	0.15	7,680
Automated/Web-based	52,000	0.163	8,476
Focus Groups	200	1.0	200
Totals	103,400	NA	16,356

This information collection will not impose a cost burden on the respondents beyond that associated with their time to provide the required data. There will be no additional costs for capital equipment, software, computer services, etc.

Estimated Annual Costs to the Federal Government

The mail and telephone surveys and focus groups will in some cases be carried out under contract. Assuming the contract cost per survey is \$50,000-\$100,000, and for each focus group is \$20,000, total contract costs could be \$720,000 per year.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of

AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: October 2, 2007.

Carolyn M. Clancy,
Director.

[FR Doc. 07-5009 Filed 10-10-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned committee:

Times and Dates:
9 a.m.-5 p.m., November 13, 2007.
9 a.m.-4 p.m., November 14, 2007.

Place: Department of Health and Human Services Building, 395 East

Street, SW., Suite 9100, Washington, DC 20201.

Status: Open to the public, limited only by the space available.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, the Assistant Secretary for Health, the Director, CDC, and the Director, National Center for Preparedness, Detection, and Control of Infectious Diseases (NCPDCID), regarding (1) The practice of hospital infection control; (2) strategies for surveillance, prevention, and control of infections (e.g., nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Discussed: Agenda items will include: IT Standards Update; White Paper Updates; and Updates on the Disinfection and Sterilization Guideline. Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Angela B. Scott, Committee Management Specialist, HICPAC, Division of Healthcare Quality Promotion, NCPDCID, CDC, 1600 Clifton Road, NE., Mailstop A-45, Atlanta, Georgia 30333. Telephone: (404) 639-1526.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 4, 2007.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0241]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 13, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0130.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4816.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Institutional Review Boards—21 CFR 56.115 (OMB Control Number 0910-0130)—Extension

When reviewing clinical research studies regulated by FDA, institutional review boards (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 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.

In the **Federal Register** of June 28, 2007 (72 FR 35492), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
56.115	5,000	14.6	73,000	100	7,300,000
Total					7,300,000

¹There 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 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.