

patterns, devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

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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, HHS.

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) approve the proposed information collection project “AHRQ Research Reporting System (ARRS).” The purpose of this notice is to allow 60 days for public comment.

DATES: Comments on this notice must be received by May 30, 2023.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

AHRQ Research Reporting System (ARRS)

AHRQ has developed a systematic method for its grantees to report project progress and important preliminary findings for grants funded by the Agency. This system, the AHRQ Research Reporting System (ARRS),

previously known as the Grants Reporting System (GRS), was last approved by OMB on August 31, 2020. The system addressed the shortfalls in the previous reporting process and established a consistent and comprehensive reporting solution for grants in AHRQ. The ARRS provides a centralized repository of grants research progress and additional information that can be used to support initiatives within the Agency. This includes future research planning and support for administrative activities such as performance monitoring, budgeting, and knowledge transfer, as well as for strategic planning.

This Project has the following goals:

(1) To promote the transfer of critical information more frequently and efficiently and enhance the Agency’s ability to support research designed to improve the outcomes and quality of health care, reduce its costs, and broaden access to effective services.

(2) To increase the efficiency of the Agency in responding to ad-hoc information requests.

(3) To support Executive Branch requirements for increased transparency and public reporting.

(4) To establish a consistent approach throughout the Agency for information collection regarding grant progress and a systematic basis for oversight and for facilitating potential collaborations among grantees.

(5) To decrease the inconvenience and burden on grantees of unanticipated ad-hoc requests for information by the Agency in response to particular (one-time) internal and external requests for information.

This project is being conducted by AHRQ through its contractor, Science Applications International Corporation, Inc, pursuant to AHRQ’s statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness, and value of healthcare services and with respect to quality

measurement and improvement. 42 U.S.C 299a(a)(1) and (2)

Method of Collection

Grantees use the ARRS system to report project progress and important preliminary findings for grants funded by the Agency. Grantees submit progress reports on a monthly or quarterly basis, which are reviewed by AHRQ personnel. All users access the ARRS system through a secure online interface which requires a user id and password entered through the ARRS Login screen. When status reports are due AHRQ notifies Principal Investigators (PI) via email.

The ARRS is an automated user-friendly resource that is utilized by AHRQ staff for preparing, distributing, and reviewing reporting requests to grantees for the purpose of information sharing. AHRQ personnel are able to systematically search the information collected and stored in the ARRS database. Personnel will also use the information to address internal and/or external requests for information regarding grant progress, preliminary findings, and other requests, such as Freedom of Information Act requests, and producing responses related to federally mandated programs and regulations.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents. It will take grantees an estimated 15 minutes to enter the necessary data into the ARRS System. Frequency of reporting varies from monthly to once a year. The total number of responses submitted for the past year is considered for this estimation. Based on that, the total annualized burden hours are estimated to be 125 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents. The total estimated cost burden for respondents is \$5,475.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of responses	Hours per response	Total burden hours
Data entry into ARRS	500	15/60	125
Total	500	N/A	125

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of responses	Total burden hours	Average hourly wage rate *	Total cost burden
Data entry into ARRS	500	125	\$43.80	\$5,475
Total	500	125	N/A	5,475

*Based upon the average wages for Healthcare Practitioner and Technical Occupations (29-0000), "National Compensation Survey: Occupational Wages in the United States, May 2021," U.S. Department of Labor, Bureau of Labor Statistics, http://www.bls.gov/oes/current/oes_nat.htm#29-0000.

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, 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’s 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: March 21, 2023.

Marquita Cullom,
Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0488]

Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled “Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k) Submissions.” This draft guidance document provides recommendations for information to include in 510(k) submissions for non-resorbable bone plate, screw, and washer devices. The scope of this draft guidance includes devices that are indicated for orthopedic bone fixation but does not include devices indicated for spinal, mandibular, maxillofacial, cranial, and orbital fracture fixation. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 30, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the

public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2023–D–0488] for “Orthopedic Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k) Submissions.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- *Confidential Submissions—*To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this