

information. Available study registries and databases may not be complete to sufficiently inform the Program’s research.

The purpose of SEADS requests is not to collect generalizable data, but to supplement the published and grey literature searches EPC investigators are conducting. Furthermore, considering the evidence and data included in responses collected from industry stakeholders, an assessment pertaining to the completeness of the evidence-base will be produced. This, AHRQ believes, will increase the value of AHRQ’s research reviews to end users and potentially provide stakeholders a

better understanding of how their submissions are used.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on pilot testing of materials and what can reasonably be requested of respondents. The number of respondents listed in “Number of respondents per SEADS request” of Exhibit 1 reflects a projected 80% response rate.

Online Submission Form: A form for submitting scientific evidence and data related to medical interventions

sponsored by organizations and individuals such as pharmaceutical companies and independent researchers. The form has three required fields: The organization’s name, the intervention in question, and whether the information they provide is all the information they know to exist. They may upload documents and they are also provided a data entry form if they wish to offer greater details on their studies.

An Optional Data Entry Form is available as an alternative to the Online Submission form. The time requirements for response would be same as the Online Submission Form.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents per SEADS request	Number of responses per respondent	Hours per response	Total burden hours per SEADS
Online Submission Form (OSF)	70	1	15/60	17.5
Total	70	1	15/60	17.5

EXHIBIT 2—ESTIMATED ANNUALIZED COST HOURS

Form name	Number of SEADS requests	Total burden hours per SEADS	Average hourly wage rate*	Total cost burden
OSF	70	17.5	\$55.48 ^a	\$970.90
Total	70	17.5	55.48	970.90

*Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.

^aBased on the mean wages for *Public Relations and Fundraising Managers, 11–2031*, the occupational group most likely tasked with completing the OSF.

Request for Comments

In accordance with the Paperwork Reduction Act, 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.

Sharon Arnold,

Deputy Director,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Five AHRQ Subcommittee Meetings.

SUMMARY: The subcommittees listed below are part of AHRQ’s Health Services Research Initial Review Group Committee. Grant applications are to be reviewed and discussed at these meetings. Each subcommittee meeting will commence in open session before

closing to the public for the duration of the meeting. These meetings will be closed to the public in accordance with 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6).

DATES: See below for dates of meetings:

1. *Healthcare Effectiveness and Outcomes Research (HEOR)*
Date: October 7, 2015 (Open from 8:30 a.m. to 9:00 a.m. on October 7th and closed for remainder of the meeting)
2. *Health System and Value Research (HSVR)*
Date: October 7, 2015 (Open from 8:30 a.m. to 9:00 a.m. on October 7th and closed for remainder of the meeting)
3. *Healthcare Safety and Quality Improvement Research (HSQR)*
Date: October 14–15, 2015 (Open from 8:00 a.m. to 8:30 a.m. on October 14th and closed for remainder of the meeting)
4. *Health Care Research and Training (HCRT)*
Date: October 15–16, 2015 (Open from 8:00 a.m. to 8:30 a.m. on October 15th and closed for remainder of the meeting)

5. *Healthcare Information Technology Research (HITR)*

Date: October 22–23, 2015 (Open from 8:30 a.m. to 9:00 a.m. on October 22nd and closed for remainder of the meeting)

ADDRESSES: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD 20878.

FOR FURTHER INFORMATION CONTACT: (To obtain a roster of members, agenda or minutes of the non-confidential portions of the meetings.)

Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research Education and Priority Populations, AHRQ, 540 Gaither Road, Suite 2000, Rockville, Maryland 20850, Telephone (301) 427–1554.

SUPPLEMENTARY INFORMATION: In accordance with section 10 (a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), AHRQ announces meetings of the scientific peer review groups listed above, which are subcommittees of AHRQ's Health Services Research Initial Review Group Committees. Each subcommittee meeting will commence in open session before closing to the public for the duration of the meeting. The subcommittee meetings will be closed to the public in accordance with the provisions set forth in 5 U.S.C. App. 2 section 10(d), 5 U.S.C. 552b(c)(4), and 5 U.S.C. 552b(c)(6). The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Agenda items for these meetings are subject to change as priorities dictate.

Sharon B. Arnold,
Deputy Director.

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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:

“*Developing a Registry of Registries.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by November 20, 2015.

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

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

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 Renewal of an Existing Project: “Developing a Registry of Registries.” OMB Control Number 0935–0203

Patient registries have received significant attention and funding in recent years. Similar to controlled studies, patient registries represent some burden to patients (e.g., time to complete patient reported outcome measures, risk of loss of privacy), who often participate voluntarily in hopes of improving the public's and medical community's knowledge about a disease or condition. Patient registries also represent a substantial investment of health research resources. Despite these factors, patient registries are not required to be registered in ClinicalTrials.gov, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To fulfill the obligation of advancing the quality and specificity of patient healthcare, and to ensure that resources are used in the most efficient manner, patient registries need to be listed in a manner similar to that of trials in ClinicalTrials.gov.

By creating a central point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) furthers AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available, in a central location.

This research has the following goals:

(1) Maintaining and updating the RoPR database system to be compatible with ClinicalTrials.gov; meeting the following objectives:

a. Providing a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);

b. Facilitating the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage) and free-text search field for highlighting information specific to an individual registry;

c. Providing a public repository of searchable summary results (including results from registries that have not yet been published in the peer-reviewed literature);

d. Offering a search tool to locate existing data that researchers can request for use in new studies; and

e. Serving as a recruitment tool for researchers and patients interested in participating in patient registries.

The RoPR is a web-based application, and does not require users to submit any type of paper form.

The RoPR collects patient registry data in two ways: users are able to enter information into the web-based system manually, or use an automated upload feature.

Information being collected in the RoPR Record is visible to the public and patient registries visiting the RoPR Web site, and is available for public use in this capacity.

The RoPR system provides email notification to registry holders informing them on an annual basis of the need to update basic statistics and contact information. It is the responsibility of the registry holder to update the information.

If a Registry Profile has not been reviewed and updated to the RoPR search site within four (4) years, it is archived.

As of August 8, 2015, the RoPR has 138 patient registries listed.

This study is being conducted by AHRQ through its contractor L&M Policy Research and sub-contractor to L&M, Quintiles, pursuant to AHRQ's statutory authority to conduct and support research and disseminate information 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 health care services and with respect to database development. 42 U.S.C. 299a(a)(1) and (8).