

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.

[FR Doc. 2015–23575 Filed 9–18–15; 8:45 am]

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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).

Method of Collection

To achieve the goals of this project, the following data collection will be implemented: Collect information from users who populate the RoPR database system, which will achieve all of the above goals.

The purpose and the use of the RoPR is to provide a readily available public resource strictly for patient registries, following the model of ClinicalTrials.gov, allowing for the increased availability and efficacy of patient registries. The information being collected in the RoPR Record is visible to the public visiting the RoPR Web site, and is readily available for public use. The RoPR is an ongoing data collection initiative.

Estimated Annual Respondent Burden

Between July 2014 and June 2015, 59 respondents entered their RoPR record manually.

Each respondent need enter his or her new RoPR record only once. The RoPR system sends an automated reminder to any registry owner who has not updated his or her RoPR record in the past year. Approximately, 57.25% of RoPR records were estimated to have been eligible for updates between July 2014 and June 2015, either on the registry owner’s own initiative, or prompted by the automated reminder. As the RoPR continues to grow and more patient registry records are added over time, this percentage represents a growing, cumulative number.

Prior to the deployment of the live RoPR system, Quintiles conducted six (6) usability sessions with RoPR stakeholders using a web-based prototype.

In February 2015, Quintiles conducted a knowledge transfer webinar for registry contacts to learn how to enter new records into the RoPR. As a result of the knowledge gained during these processes, it is estimated that it takes users 45 minutes to manually enter a new RoPR record; and 15 minutes to upload a new RoPR record (an average of 30 minutes using either method). It takes 15 minutes for a user to review and make updates to an existing RoPR record.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response (average)	Total burden hours (average)
New RoPR Record (manually—entered or uploaded electronically method)	59	1	30/60	29.5
Review/update existing RoPR Record	79	1	15/60	19.75
Total	138	49.25

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate †	Total cost burden
New RoPR Record (manually—entered or uploaded electronically method)	59	29.5	\$36.54	\$1,077.93
Review/update existing RoPR Record	79	19.75	36.54	721.67
Total	138	44.25	\$1,799.60

† * Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29-0000. National Compensation Survey: Occupational wages in the United States May 2014, “U.S. Department of Labor, Bureau of Labor Statistics.” Available at: http://www.bls.gov/oes/current/oes_nat.htm#b29-0000..

In order to highlight patient registry concerns about using the RoPR system and turning user feedback into future system maintenance and upgrade initiatives (increasing the usability of the RoPR and lowering the burden of entering patient registry information), plans for a voluntary user satisfaction survey is being considered for development and deployment in 2Q 2016. Its full nature and design is still in the concept stage and so this survey is not part of the Estimated Annualized Respondent Hourly/Cost Burden noted in Exhibits 1 and 2.

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 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

Centers for Disease Control and Prevention

[60 Day-15-15BFV; Docket No. CDC-2015-0085]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).