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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 changes to the currently approved information collection project: ***"Developing a Registry of Registries."***

In accordance with the Paperwork Reduction Act, AHRQ invites the public to comment on this proposed information collection. This proposed information collection was previously published in the Federal Register on April 28, 2017, and allowed 60 days for public comment. AHRQ did not receive any substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by (insert date 30 days after date of publication).

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 email at OIRA_submission@omb.eop.gov (attention: AHRQ's desk 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 Revision of a Currently Approved Collection Project: "Developing a Registry of Registries." OMB Control Number 0935-0203

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ is extending the comment period for this this proposed information collection on the

development of a registry of patient registries. 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 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 to patients and to ensure that resources are used in the most efficient manner, registries need to be listed in a manner similar to that of trials in ClinicalTrials.gov.

By providing a centralized point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) enhances patient registry information, extracted from ClinicalTrials.gov, building on AHRQ's efforts to describe the quality, appropriateness, and effectiveness of health services (and patient registries in particular) in a more readily available, central location.

The RoPR database system aims to achieve the following objectives:

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

2) Facilitate the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);

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

4) Offer a search tool to locate existing data that researchers can request for use in new studies; and

5) Serve as a recruitment tool for researchers and patients interested in participating in patient registries.

To achieve the objectives of this project, the following data collections will be implemented:

1) Collect information on registries from users who populate the RoPR database system.

AHRQ is proposing to add a self-registration option to the RoPR database so that registry owners do not need a National Library of Medicine Protocol Registration System (PRS) account to contribute. The current OMB-approved RoPR system requires users to have a PRS account. In the current data entry process, registry owners enter most of the registry information using the ClinicalTrials.gov PRS. If a user defines the ClinicalTrials.gov record as a patient registry, that user will have the option of following a link to the RoPR submission page to input additional information about the registry. Patient registry data entered in the PRS is uploaded to the RoPR system daily and is accessible (along with information entered directly into RoPR) to the public via the RoPR search function. Under the AHRQ proposal, these users could complete a simple registration on the RoPR site, which would be less burdensome than the PRS registration process, and then enter all registry information directly on RoPR. The rationale behind this alternative registration pathway is that many registries are created for quality reporting, outcome tracking, and quality improvement purposes, rather than for research purposes. Registering in ClinicalTrials.gov implies a research purpose, so it is not necessarily appropriate for non-research registries to register in ClinicalTrials.gov, and many have expressed that they do not wish to do so. AHRQ anticipates that more than 75 percent of registries would still register through the ClinicalTrials.com. However, the remaining registries are extremely important for health policy, and providing them with a registration pathway furthers the goal of creating a central place where stakeholders can find information on research and non-research registries pertinent to a specific clinical topic.

The new self-registration pathway is being developed by AHRQ through its contractor, L&M Policy Research and subcontractor Truven Health Analytics, an IBM Company, 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 health care services and with respect to database development. 42 U.S.C. 299a(a)(1) and (8).

AHRQ, in collaboration with the Centers for Medicare & Medicaid Services (CMS), is also proposing to add three fields to the self-registration pathway related to the CMS initiative to create a Centralized Repository for Public Health Agencies and Clinical Data Registry Reporting. The purpose of the repository is to assist eligible professionals, eligible hospitals, and critical access hospitals in finding entities that accept electronic public health data. By adding these fields to the existing RoPR database, AHRQ will further the goal of creating a central place where stakeholders can find all pertinent information on registries.

Method of Collection

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 website, and is readily available for public use.

The RoPR is an ongoing data collection initiative.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the RoPR. In 2016, 65 respondents manually entered a new RoPR record. It is expected that more than 75% of patient registries are research-focused and will continue to use the original ClinicalTrials.gov pathway described above. Thus, it is estimated that once the self-registration pathway is available, approximately 65 respondents will enter RoPR records through the ClinicalTrials.gov link annually, and an

additional 16 respondents (roughly 25% of 65), representing non-research registries, will enter RoPR records through the new self-registration pathway.

Each respondent would to 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. In 2016, 132 RoPR entries were updated and released. Using the same logic as above, it is estimated that an additional 33 entries (25% of 132) might be updated annually once the self-registration pathway is available.

In January 2017, Truven Health Analytics used a sample of existing ClinicalTrials.gov registry entries to estimate the time needed to enter all additional fields added through the self-registration process. The sample included records representing a range of depth and complexity. For example, one registry record contained only one primary outcome measure. Another record contained three more detailed outcome measures (one primary, one secondary, and one other.)

As a result of the knowledge gained during these processes, it is estimated that it will take users 10 minutes, on average, to manually enter the additional fields added through the self-registration process. Adding this time to the estimated burden of completing the original RoPR fields (45 minutes), it is estimated that it will take users 55 minutes to complete all fields through the self-registration pathway.

It is estimated that it will take users 5 minutes to review and update the fields added through the self-registration pathway. Adding this time to the estimated burden of reviewing and updating the original RoPR fields (15 minutes), it is estimated that it will take 20 minutes for a person to review and make updates to an existing RoPR record created through the self-registration pathway.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
New RoPR Record entered manually through self-registration process	16	1	55/60	14.67
New RoPR Record entered through ClinicalTrials.gov pathway	65	1	45/60	48.75
Review/update existing RoPR Record created through self-registration process	33	1	20/60	11
Review/update existing RoPR Record created through ClinicalTrials.gov pathway	132	1	15/60	33
Total	246			107.42

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden to respondents is estimated at an average of $4,017.51 annually.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate†	Total cost burden
New RoPR Record entered manually through self-registration process	16	14.67	$37.40	$548.66
New RoPR Record entered through ClinicalTrials.gov pathway	65	48.75	$37.40	$1,823.25
Review/update existing RoPR Record created through self-registration process	33	11	$37.40	$411.40
Review/update existing RoPR Record created through ClinicalTrials.gov pathway	132	33	$37.40	$1,234.20

Total	246	107.42	$37.40	$4,017.51

* Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29-0000. National Compensation Survey: Occupational wages in the United States May 2015, "U.S. Department of Labor, Bureau of Labor Statistics." Available at: https://www.bls.gov/oes/current/oes290000.htm

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 B. Arnold

Deputy Director

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