

in this draft FPL is intended to enable the Council to most effectively meet these fundamental commitments. The

Council looks forward to hearing from the public on this proposal.

APPENDIX A—COUNCIL COMPREHENSIVE PLAN COMMITMENTS

Topic	Commitment	Page No.
Development of Funded Priority Lists.	Take a holistic approach to restoration	13, 14
	Continue to improve Submission Guidelines	17
	The Council adopted the watershed/estuary-based approach as a strategic planning principle for future FPL development.	22
	Healthy and sustainable ecosystems are essential for thriving and resilient coastal communities.	23
	Encourage partnerships and additional public and private financial and technical support to maximize outcomes and impacts.	23
	Identify and leverage new sources of funding to support current and future restoration work by exploring creative conservation funding.	25
	The Council will refine its processes for considering public input on draft FPLs before finalizing changes to the final FPL.	25
	Project evaluation and selection will be conducted in the most open manner feasible	25
	Will update and improve the process for applying BAS to FPL proposals, including exploring the use of one or more science review panels.	27
	Collaboration and Coordination	Sponsor and participate in meetings and workshops in 2017 and into 2018
Facilitate meaningful engagement with range of stakeholders		17
Maximize outcomes by leveraging funds and expertise		17
Coordination and collaboration among members and our restoration partners is critical to the success of Gulf restoration.		24
Coordinate regulatory efforts across Council membership		26
Science	Decisions made pursuant to the FPL will be based on the best available science	6, 17, 27
	The Council recognizes the importance of measuring outcomes and impacts in order to achieve tangible results and ensure that funds are invested in a meaningful way.	27

Document Availability: Copies of the draft CPS FPL are available at the following office during regular business hours: Gulf Coast Ecosystem Restoration Council, Hale Boggs Federal Building, 500 Poydras Street, Suite 1117, New Orleans, LA 70130. The draft CPS FPL can also be viewed and downloaded at www.restorethegulf.gov.

Legal Authority: The statutory program authority for the draft FPL is found at 33 U.S.C. 1321(t)(2).

Will D. Spoon,
Program Analyst, Gulf Coast Ecosystem Restoration Council.

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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 August 14, 2017.

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 Web site, 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 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 <i>ClinicalTrials.gov</i> 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 <i>ClinicalTrials.gov</i> pathway	132	1	15/60	33
Total	246			107.42

Exhibit 2 shows the estimated cost time to participate in the RoPR. The estimated at an average of \$4,017.51 burden associated with the respondent's total cost burden to respondents is 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 <i>ClinicalTrials.gov</i> 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 <i>ClinicalTrials.gov</i> 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update

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

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update*, which is currently being conducted by the AHRQ’s Evidence-based Practice Centers (EPC) Program. Access to

published and unpublished pertinent scientific information will improve the quality of this review.

DATES: Submission Deadline on or before August 14, 2017.

ADDRESSES:

Email submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.):

Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 51723 or Email: *SEADS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Stroke Prevention in Atrial Fibrillation Patients: A Systematic Review Update*. AHRQ is conducting