SUPPORTING STATEMENT

Part A

American Recovery and Reinvestment Act
"Developing a Registry of Registries"
Contract No. HHSA290200500351

Version: March 11, 2016

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ) set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care; and

2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ shall conduct and support research and evaluations, and support demonstration projects, with respect to (A) the delivery of health care in inner-city areas, and in rural areas (including frontier areas); and (B) health care for priority populations, which shall include (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

The US Food and Drug Administration (FDA) Modernization Act of 1997 provided for the creation of the ClinicalTrials.gov system to improve transparency in clinical research.

Since its launch in 2000, the ClinicalTrials.gov system has registered over 90,500 trials. The large volume of studies currently listed in ClinicalTrials.gov and the high usage numbers suggest that the system has been successful at improving access to information about clinical studies. Current mandates, however, only require the registration of controlled, experimental studies in ClinicalTrials.gov. Observational studies, such as patient registries, are not required to be listed in ClinicalTrials.gov.

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) furthers AHRQ's goals by enhancing patient registry information, extracted from ClinicalTrials.gov, to further describe the quality, appropriateness, and effectiveness of health services (and patient registries in particular) in a more readily available, central location.

This research has the following goals:

1) Engage stakeholders in the design and development of a RoPR database system that is compatible with ClinicalTrials.gov and meets 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);
    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.

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

1) Collect information on registries from users who populate the RoPR database system, which will achieve all of the above goals.

This study is being conducted by AHRQ through its contractor, L&M Policy Research and partner Quintiles, pursuant to AHRQ's statutory authority to conduct and support research on healthcare 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).

2. Purpose and Use of Information

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.

3. Use of Improved Information Technology

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

The RoPR allows for the collection of data in two (2) ways: users are able to enter information into the web-based system manually, or use an automated upload feature. The manual data entry system utilizes an intuitive and logical step-by-step data entry process. The automated uploader feature allows users to pre-populate information into an XML file, thereby eliminating the time burden involved in manual data entry. The XML files are created from existing databases, using a provided template/ schema.

Additionally, the RoPR system sends an automated e-mail notification to registry holders if no change has been made to their RoPR record in the past year, reminding them to ensure that their registry information is up-to-date. This automated reminder system helps to ensure the timeliness of the information entered in the RoPR, while reducing the burden on registry holders to remember to update information they entered in the RoPR.

4. Efforts to Identify Duplication

As mentioned in Section 1, patient registries are currently registered in ClinicalTrials.gov. These patient registries may appear in RoPR information searches. However, because registration in ClinicalTrials.gov is not currently mandated for registries and observational studies, the information that ClinicalTrails.gov collects is not completely sufficient for the needs of users registering information about existing patient registries.

As part of the background research and development activities for this project, meetings were held with the ClinicalTrials.gov team at the National Library of Medicine. It was determined that many aspects of the current ClinicalTrials.gov system adequately serve the needs of a RoPR, therefore the RoPR only requests information that is not already collected from patient registry users, on ClinicalTrials.gov.

5. Involvement of Small Entities

While small businesses and other small entities may use the RoPR to enter information, participation is not compulsory. The information being requested by the RoPR is held to the absolute minimum required for the intended use, as described in Section 4. It is not expected that small businesses need to provide less information than any other business or entity registering a registry in the RoPR. The burden is voluntary and minimal, and therefore should not be taken into consideration.

6. Consequences if Information Collected Less Frequently

If the RoPR ceases to collect the registry information it is intended to collect, then information about registries will continue to be stored and accessed as it is currently: in a fragmented and inconsistent way which does not facilitate collaboration among researchers; reduced redundancy in research, and improved transparency in registry practice.

Because participation in the RoPR is not obligatory, it is possible that collection from a given entity may only occur once, or less frequently than recommended. Registry holders may choose to only post information regarding their registry one time, expecting users to seek them out for updated data.

The RoPR system provides notification to registry holders informing them on a regular, or annual, basis of the need to update basic statistics and contact information, but 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 considered to be archived.

Archived Registry Profiles are displayed by default on the RoPR search site. However, a selection option on the Search Web site allows for archived records to be hidden from search results.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

As required by 5 CFR 1320.8(d), notice was published in the Federal Register on Page 56992 of Federal Register, September 21, 2015 for 60 days (see Attachment A).

No comments were received.

8.b. Outside Consultations

AHRQ and its contractor, Quintiles, consulted with representatives from varied backgrounds (including the pharmaceutical industry, government agencies, academia, patient/consumer advocates, Federal funding agencies, provider/physician associations, and others) to garner their perspectives on the expected scope and policies and

procedures of the RoPR. The views and opinions of these stakeholders were taken into consideration during the design and development of the RoPR.

AHRQ and Quintiles also worked closely with the team at ClinicalTrials.gov and the National Library of Medicine (NLM) to determine the technical infrastructure of the RoPR and the nature of its relationship to ClinicalTrials.gov.

9. Payments/Gifts to Respondents

Participation in the RoPR is voluntary. As such, there is no payment or remuneration offered to users for registering a registry in the RoPR.

10. Assurance of Confidentiality

Individuals and organizations are to be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c), which requires that information that is obtained in the course of AHRQ-supported activities and that identifies individuals or establishments be used only for the purpose for which it was supplied. Information that is obtained in the course of AHRQ-supported activities and that identifies an individual may be published or released only with the consent of the individual who supplied the information or is described in it.

The RoPR registration interface collects the e-mail address of the RoPR record owner This information is mandatory and is not made public. It is used only for periodic auto-generation of e-mail reminders pertaining to the maintenance of RoPR patient registry data. There is no human administrator that is pulling this information for the purpose of sending out e-mails. Therefore, individuals registering patient registries via the RoPR are told the purposes for which this information (e.g., e-mail) is collected is, in accordance with the Privacy Act, not to be used, or disclosed for any other purpose than for the RoPR. To this effect, a disclaimer statement is clearly stated within the RoPR system: *"This email will only be used by RoPR and will not be distributed."*

The RoPR record owner has the option to select "Do not contact" on the RoPR. This selected option does not exempt the RoPR user from having to complete these "mandatory" fields: *Reasons for being contacted; Organization; E-mail and Phone.*

PII (First/Last Name) and Title fields are non - mandatory entries, which are indicated as optional fields as a user completes the RoPR profile. This information is available publically for intended uses as identified by the accompanying categories detailing the sponsor's reasons for being contacted. In this case, the Privacy Act is not applicable, however the collection of PII is deemed necessary for collection on the RoPR, for the following reasons:

The RoPR is an information repository which connects patient registries with individuals interested in learning more about them and how they advance healthcare. Many patient

registries find it mutually beneficial to provide primary contact information to facilitate dialogue between them and interested parties. Patient registries comprise a highly specialized field. Only a subset of the general public would be interested in pursuing dialogue with a particular patient registry, motivated by interest in specific medical conditions being examined. Extra security measures have been taken so that PII is not searchable on the RoPR, in the live or administrative environments.

Registration burden is reduced by clearly indicating that the submission of PII, First Name/Last Name, of the primary contact person purely voluntary, for the purpose of knowledge exchange between the patient registry and concerned members of the public.

11. Questions of a Sensitive Nature

The RoPR does not collect any information of a sensitive nature, or information that can directly identify the respondent, such as a social security number or Medicare/Medicaid number.

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the RoPR. Between July 2014 and June 2015, 59 new respondents had entered their RoPR record, utilizing either a manual or electronic upload data entry method.

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 their RoPR record in the past year. Approximately, 79, or 57.25% of all RoPR records were eligible for updates between July 2014 and June 2015, either by the registry owner's initiative, or when prompted by the automated RoPR reminder. As the RoPR continues to grow and more patient registry records are added over time, this percentage represents a growing, cumulative number.

In February 2015, Quintiles conducted a knowledge transfer webinar for registry contacts 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, on average, to manually enter a new RoPR record; 15 minutes to upload a new RoPR record (an average of 30 minutes using either upload or manual method). It takes 15 minutes for a person to review and make updates to an existing RoPR record.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses	Minutes per	Total burden

		per respondent	response	hours
New RoPR Record (manually - entered or uploaded electronically method)	59	1	45/60	44.25
Review/update existing RoPR Record	79	1	15/60	19.75
Total	138			64.0

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 $1,799.60 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 (manually - entered or uploaded electronically method)	59	44.25	$36.54	$1,617
Review/update existing RoPR Record	79	19.75	$36.54	$721.67
Total	138	64	-	$2,339

* 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

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Total and Annualized Cost to the Government

The RoPR project is in the fourth phase, where ongoing RoPR user support is provided, along with the need for occasional system maintenance and performing necessary system upgrades as necessary by AHRQ's contractor, L&M Policy Research; and L&M's sub-contractor, Quintiles.

Per Exhibit 3a, the estimated total annual cost of Project Management and system maintenance/updates is $129,124.

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Management	$90,156.93	$30,052.31
Maintain & update the system	$297,215.07	$99,071.69
Total	**$387,372.00**	**$129,124.00**

Per exhibit 3b, the Federal Government Personnel Cost (at approximately 5%, or 104 hours, of an FTE Project Officer, GS 15, Step 5) is estimated at $7,154.00 on an annual basis.

Exhibit 3b. Federal Government Personnel Cost

Activity	Federal Personnel*	Annual Rate	Estimated Hours	Annual Cost
Project Oversight	Project Officer, GS 15, Step 5	$143,079	104	$7,154
Total				**$7,154**

Annual salaries based on 2015 OPM Pay Schedule for Washington/DC area:
http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2015/DCB.pdf

15. Changes in Hour Burden

This is an ongoing collection of information. While user participation burden remains voluntary and minimal, with continued marketing of the RoPR as knowledge repository for patient registries, it is anticipated that the number of respondents will increase over time. The total burden hours, however, will remain the same as previously stated in Exhibit 2.

16. Time Schedule, Publication and Analysis Plans

There are no plans to publish or analyze the information collected in the RoPR Record.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Federal Register Notice

Attachment B: New RoPR Record

Attachment C: Privacy Impact Assessment