SUPPORTING STATEMENT

Part A

American Recovery and Reinvestment Act
"Developing a Registry of Registries"

Version: January 17th, 2012

Agency for 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. However, the FDA Amendments Act of 2007 only mandates the registration of certain controlled, interventional studies in ClinicalTrials.gov. While ClinicalTrials.gov supports the listing of observational studies, it is not required.

Patient registries are a distinct type of observational study. Patient registries may be designed for many purposes, such as to observe the natural history of disease, examine comparative effectiveness, or fulfill post-approval commitments. Patient registries have specific characteristics that are not currently captured on ClinicalTrials.gov. To date, some registry sponsors have attempted to leverage the observational study model to post patient registry-type records on ClinicalTrials.gov; however, stakeholders have noted that the system does not fully meet their needs.

Patient registries have received significant attention and funding in recent years. Similar to controlled interventional 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, there are no legal mandates or policies at present that require the registration of patient registries 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 creating a central point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) helps to further AHRQ's goals by making information regarding quality, appropriateness, and effectiveness of health services (and patient registries in particular) more readily available and centralized.

The purpose of the RoPR is to create a readily available public resource in the model of ClinicalTrials.gov to share information on existing patient registries. Specifically, the system will meet 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 goals of this project the following data collections will be implemented:

1) Collect information from registry holders, defining a patient registry profile via a web-based interface, to populate the RoPR database system. This will achieve all of the above goals (see Attachment A for a listing of the data elements comprising a patient registry profile).

This study is being conducted by AHRQ through its contractor, the Outcome DEcIDE Center, 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 quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

The purpose of the RoPR is to create a readily available public resource in the model of ClinicalTrials.gov to share information on existing patient registries to promote collaboration, reduce redundancy, and improve transparency in registry research. Patient registry research has become more prevalent and, based on stakeholder feedback, is not adequately served by ClinicalTrials.gov at present. The information being collected in the RoPR record will be visible to the public visiting the RoPR website and will be available for public use in this capacity. At this time there is no plan for the data to be used by AHRQ or any other Federal agency.

3. Use of Improved Information Technology

The RoPR will be web-based with an intended primary URL of www.patientregistries.ahrq.gov, and will not require users to submit any type of paper forms. The RoPR will allow for the collection of data in two ways: users will be 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 upload feature will allow users to pre-populate information into an XML file, thereby eliminating the time burden involved in manual data entry. The XML files can be created from existing databases, using a provided template/schema.

Additionally, the RoPR system will send 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 will help 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, some patient registries are currently registered in ClinicalTrials.gov. However, registration in ClinicalTrials.gov is not currently mandated for patient registries and observational studies, and the information that ClinicalTrials.gov collects during voluntary registration of patient registries is not completely sufficient at present. At a high level, the data points not reflected on ClinicalTrials.gov include: the registry's classification and purpose; the conditions, services of interest and categories addressed by the registry; and reasons for accessing the registry or its data. Refer to Attachment A for a listing of RoPR data elements which are not available on ClinicalTrials.gov.

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 will only request information from users which is not already collected 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 will be held to the absolute minimum required for the intended use, as described in Section 4.

6. Consequences if Information Collected Less Frequently

If the RoPR is not built, or is built but does not collect the registry information it is intended to collect, then information about registries will 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 will provide notification to registry holders informing them on a regular basis of the need to update basic data and contact information, but it is the responsibility of the registry holder to update the information. If this does not occur as frequently as anticipated, it is possible that contact information and registry data may become obsolete.

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 February 23rd, 2012 for 60 days and again on July 11th, 2012 for 30 days (see Attachment B). Three comments were received; see Attachment C for a summary of the comments and AHRQ's response, and Attachments D, E and F for the full comments.

8.b. Outside Consultations

AHRQ and its contractor, the Outcome DEcIDE Center, 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, policies, and procedures of a RoPR. The views and opinions of these stakeholders were taken into consideration during the design and development of the RoPR.

AHRQ and the Outcome DEcIDE Center also worked closely with the team at ClinicalTrials.gov and the National Library of Medicine to determine the technical infrastructure of the RoPR and its relationship to ClinicalTrials.gov.

9. Payments/Gifts to Respondents

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

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 934(c) of the Public Health Service Act, 42 USC 299c-3(c). They will be told the purposes for which the information is collected and that, in accordance with this statute, any identifiable information about them will not be used or disclosed for any other purpose. The RoPR registration interface will collect the e-mail address of the registry holder. The e-mail address will only be used for the generation of e-mails pertaining to the maintenance of RoPR patient registry data. A disclaimer to this effect will be clearly stated within the system.

11. Questions of a Sensitive Nature

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

12. Estimates of Annualized Burden Hours and Costs

Exhibit 1 shows the estimated annualized burden for the respondent's time to participate in the RoPR. Because the RoPR is a voluntary system available to any entity conducting a patient registry, it is not possible to determine the number of potential respondents. We do know that over 3,800 newly registered records designated as "observational studies" were entered into ClinicalTrials.gov in 2010. Only a subset of this number (which we will estimate at a maximum of 40%) would qualify as patient registries and would likely be registered in the RoPR. Therefore, we use 1,520 (3,800*0.40) in Exhibits 1 and 2 below as a very rough, but high, estimation of the potential number of respondents who will enter registries into the RoPR annually. The actual number of respondents will depend on a variety of factors and could vary widely. It should be remembered that mandates could evolve making registration in the RoPR mandatory. Our estimates therefore attempt to factor an upper threshold for volume.

Each respondent will enter a new RoPR record only once and is estimated to take 45 minutes. An estimated 50% (760 records) of RoPR records will be updated once a year and will take about 15 minutes. This estimate is based on a query of ClinicalTrials.gov which showed that about 50% of observational studies registered in ClinicalTrials.gov had been updated in the past year. The total respondent burden is estimated to be 1,330 hours annually.

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden is estimated to be $45,579 annually.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
New RoPR Record	1,520	1	45/60	1,140
Review/update RoPR Record	760	1	15/60	190
Total	2,280	na	na	1,330

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate†	Total cost burden
New RoPR Record	1,520	1,140	$34.27	$39,068
Review/update RoPR Record	760	190	$34.27	$6,511
Total	2,280	1,330	na	$45,579

†Based upon the mean average wage for Healthcare Practitioners and Technical Occupations, May 2010 National Occupational Employment and Wage Estimates, U.S. Department of Labor, Bureau of Labor Statistics. Available at: http://www.bls.gov/oes/current/oes_nat.htm#29-0000.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

Capital and maintenance costs include the purchase of equipment, computers, computer software or services, or storage facilities for records as a result of complying with this data collection. There are no direct costs to respondents other than their time to participate in the study.

14. Estimates of Annualized Cost to the Government

Exhibit 3 shows the estimated total and annualized cost to the government to create and maintain the RoPR for 3 years. The total cost is estimated to be $3,184,333.

Exhibit 3. Estimated Total and Annualized Cost

Cost Component	**Total Cost**	**Annualized Cost**
Project Development	$2,318,509	$772,836
Project Management	$409,149	$136,383
Overhead	$456,675	$152,225
Total	**$3,184,333**	**1,061,444**

15. Changes in Hour Burden

The RoPR represents a new collection of information. Therefore, there is no change in hour burden.

16. Time Schedule, Publication and Analysis Plans

The project schedule has a launch date of the RoPR system of September 2012, following a pre-launch of a testing system in March/April 2012. 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: RoPR Data Collection Instrument
Attachment B: Federal Register Notice
Attachment C: Comments Summary and Response
Attachment D: Public Comment -- Western CT Health Network
Attachment E: Public Comment -- AHA Comments
Attachment F: Public Comment -- CNIPS Comments