SUPPORTING STATEMENT

Part A

"Systematic Review Data Repository (SRDR) 2.0 for Digitally Enabling Systematic Review Data" Contract No. HHSA2902015000021_HHSA29032012T

Version: September 10, 2019

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.

In 1997, AHRQ launched an initiative to promote evidence-based practice in everyday care through establishment of the Evidence-based Practice Center (EPC) Program. Since then, the EPCs have been reviewing all relevant scientific literature on a wide spectrum of clinical and health services topics to produce various types of evidence reports. This program directly addresses AHRQ's abovementioned mission to promote health care quality improvement by conducting synthesis and dissemination of existing scientific evidence for use by various stakeholders.

Majority of these evidence reports are systematic reviews (SRs), which are used as evidence bases for clinical practice guidelines, research agenda, healthcare coverage, and other health related policies. Performing SRs is costly in time, labor, and money. Moreover, there is an increasing expectation of quicker turnaround in producing SRs to accommodate the fast moving pace of innovations and new scientific discoveries in healthcare. Some SRs overlap or are replicated; independent teams of SR producers often extract data from the same studies, resulting in replication of work. Current methodology makes it difficult to harness and reuse previous work when updating SRs. An open-access

repository of extracted data from primary studies could improve the efficiency of conducting SRs by sharing this extracted data for SR updates or new SRs. A repository of such data would also greatly facilitate methodological research to improve the conduct of SR and primary research. It can foster collaboration, transparency, and reliability among research groups who contribute data. It can also provide valuable information to patients and stakeholders who view the deposited data.

In an effort to reduce the economic burden of conducting SRs, the EPC program undertook development of a collaborative, Web-based repository of systematic review data called the Systematic Review Data Repository (SRDR). This resource serves as both an archive and data extraction tool, shared among organizations and individuals producing SRs worldwide, enabling the creation of a central database of SR data. This database is collaboratively vetted, freely accessible, and integrates seamlessly with reviewers' existing workflows, with the ultimate goal of facilitating the efficient generation and update of evidence reviews, and thus speeding and improving policy-making with regards to health care.

The SRDR project aims to achieve the following goals:

1) Create online easy-to-use Web-based tools for conducting systematic reviews to facilitate extraction of data from primary studies;
2) Develop an open-access searchable archive of key questions addressed in systematic reviews;
3) Maintain a public repository of primary study data including provision of technical support for repository users; and
4) Develop a process for making summary data from systematic reviews digitally shareable to end-users.

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

1) Collect registration information on SRs from SR producers who populate will populate the SRDR system, which will achieve all of the above goals.

AHRQ proposes the collection of registration data. SRDR uses a three-tiered categorization of users and collection of registration data will depend on the type of user: (1) *"Contributors"* are SR producers who use SRDR as a tool to support production of the SR and share scientific data from their SRs. Registration data will be collected from these users; (2) *"Commentators"* provide comments (i.e. opinions) on publicly available scientific data in SRDR. Registration data will be collected from these users; (3) *"General public"* users only view scientific data publicly available in SRDR. No data will be collected from these type of users.

All *Contributors* and *Commentators* will undergo a simple self-registration process by providing a username, password, email address, and institution. Collection of registration data from *Contributors* and *Commentators* are required due to the technical nature of using SRDR both as a database and a tool for assisting in the production of a SR including providing comments in the various sections of a particular project on SRDR. In addition, provision of an email address and institution information allows the

administrators of SRDR to confirm that requests are being made by actual people and not potentially malicious software code such as bots and other cybersecurity threats.

This study is being conducted by AHRQ through its contractor, Brown University, 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 SRDR is to provide a readily available open-access repository of extracted data from primary studies to improve the efficiency of conducting SRs by sharing this extracted data for SR updates or new SRs. A repository of such data would greatly facilitate methodological research to improve the conduct of SR and primary research. It will foster collaboration, transparency, and reliability among research groups such as the AHRQ EPCs and Cochrane Collaboration who contribute data. It will also provide valuable information to patients and stakeholders who can view the deposited scientific data. Examples of these include CMS, CDC, and NIH – AHRQ's sister agencies in HHS who have commissioned SRs from the EPC program to inform coverage decisions, disease control programs, and research agenda, respectively. The scientific information being collected in SRDR is visible to the public visiting the SRDR website, and is readily available for public use.

User registration will be used for administrative purposes only including communication between SRDR administrators and registrant users. This type of information will not be made publicly available.

The SRDR is an ongoing data collection initiative.

3. Use of Improved Information Technology

The SRDR is web-based, and does not require users to submit any type of paper forms. It allows users to enter their registration information manually into the web-based system.

4. Efforts to Identify Duplication

The SRDR registration system can only accept email addresses from registrants that do not currently exist in the system thereby preventing duplication of efforts and accounts for previously registered users.

5. Involvement of Small Entities

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

6. Consequences if Information Collected Less Frequently

The success of the SRDR project depends on wide use of this resource for systematic review production to aid in health policy decision-making. It is also dependent to contributors willing to share data from systematic reviews that they have conducted. Without ongoing collection of registration information from repository users especially from prospective contributors, intended growth and expansion of data available for re-use within SRDR will be hampered and federal funding, manpower, and other resources which the government has invested in SRDR would be wasted.

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 27780 on June 14, 2019 for 60 days (see Attachment A). AHRQ did not receive comments from the public.

8.b. Outside Consultations

To ensure that the SRDR project will meet the needs of its intended end-users, a governance board comprising experts representing various government and non-government stakeholder viewpoints are relied upon for guidance by SRDR administrators. Non-government board members include representatives from academia, NGOs, industry, and medical societies/guideline creators and disseminators.

9. Payments/Gifts to Respondents

Participation in the SRDR is voluntary. As such, there is no payment or remuneration offered to registrants of users the SRDR.

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act. 42 U.S.C. 299c-3(c). That law requires that information collected for research conducted or supported by AHRQ that identifies individuals or establishments be used only for the purpose for which it was supplied.

For the self-registration pathway, users are required to enter an email address that will be associated with the account as well as a username and password. First and last names as well as institution information is required to make sure that an actual human is attempting to register and not bots or other malicious software applications which can negatively impact cybersecurity for the project and AHRQ. All information is mandatory but is not made public. It is only used for administrative purposes such as communicating information about password updates and resets or for providing technical assistance when requested by the users.

Other information that can directly identify the respondent, such as social security numbers will not be collected.

Registrants to SRDR are told the purposes for which this information (e.g., e-mail) is collected, in accordance with the Privacy Act, not to be used, or disclosed for any other purpose than for the SRDR. To this effect, a disclaimer statement is clearly stated on the registration form: *"Your responses will be kept confidential to the extent permitted by law, including AHRQ's confidentiality statute, 42 USC 299c-3(c)."*

11. Questions of a Sensitive Nature

The SRDR does not collect any information of a sensitive nature including social security numbers or Medicare/Medicaid numbers.

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 SRDR. In 2017, 176 users registered as Commentators and 206 users registered as Contributors. Registration will take approximately 2 minutes per user. We, thus calculate the total burden hours required for registration for all users annually is 12.73 hours.

Exhibit 1. Estimated annualized burden hours

Form Name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Registration of users as Commentators or Contributors	382	1	2/60	12.73
Total	382			12.73

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the SRDR. The total cost burden to respondents is estimated at an average of $501.82 annually.

Exhibit 2. Estimated annualized cost burden

Form Name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Registration of users as Commentators or Contributors	382	12.73	$39.42[a]	$501.82
Total	382	12.73		$501.82

* National Compensation Survey: Occupational wages in the United States May 2018, "U.S. Department of Labor, Bureau of Labor Statistics." Available at: https://www.bls.gov/oes/current/oes290000.htm

[a] Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29-0000

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

A project manager provides user support throughout the registration process along with other account maintenance tasks as necessary to maintain SRDR system functions accessed by registered users by AHRQ's contractor, Brown University.

Per Exhibit 3a, the estimated total annual cost of Project Management is $110,335.45.

Exhibit 3a. Estimated Total and Annualized Cost

Cost Component	Total Cost	Annualized Cost
Project Management	$169,746.85	$67,898.74
Overhead	$106,091.77	$42,436.71
Total	$275,838.62	$110,335.45

Exhibit 3b. Federal Government Personnel Cost

Activity	Federal Personnel	Hourly Rate	Estimated Hours	Cost
Project Oversight	Physician (COR) GS 14, Step 9	$71.13	104	$7,397.52
Total				$7,397.52

Annual salaries based on 2019 OPM Pay Schedule for Washington/DC area: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2019/DCB_h.pdf

15. Changes in Hour Burden

This is an ongoing collection of information. As user registration is only required for Contributor and Commentator accounts and General Public users do not need to register to use SRDR, it is anticipated that the reported respondent burden will not change over time.

16. Time Schedule, Publication and Analysis Plans

There are no plans to publish or analyze user registration information collected in the SRDR.

17. Exemption for Display of Expiration Date

AHRQ does not seek this exemption.

List of Attachments:

Attachment A: Federal Register Notice

Attachment B: Data Collection Instrument