

**C. Annual Burden**

Respondents: 10,275.

Recordkeepers: 8,391.

Total Annual Responses: 342,019.

Total Burden Hours: 627,162 (123,702 reporting hours + 503,460 recordkeeping hours).

**Obtaining Copies:** Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202-501-4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov).

Please cite OMB Control No. 9000-0018, Federal Acquisition Regulation Part 3: Improper Business Practices and Personal Conflicts of Interest.

**William F. Clark,**

Director, Federal Acquisition Policy Division,  
Office of Governmentwide Acquisition Policy,  
Office of Acquisition Policy, Office of  
Governmentwide Policy.

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BILLING CODE 6820-EP-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Supplemental Evidence and Data Request on Models of Care That Include Primary Care for Adult Survivors of Childhood Cancer

**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 on *Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer*, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 December 28, 2020.

**ADDRESSES:**

Email submissions: [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice

Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Jenae Benms, Telephone: 301-427-1496 or Email: [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov).

**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 *Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer*, including those that describe adverse events. The entire research protocol is available online at: <https://effectivehealthcare.ahrq.gov/products/pediatric-adolescent-cancer-survivorship/protocol>.

This is to notify the public that the EPC Program would find the following information on *Models of Care that Include Primary Care for Adult Survivors of Childhood Cancer* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: Study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use

instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

*The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.*

#### Contextual and Key Questions

We have developed contextual questions to guide our preliminary discussions with the stakeholders, as well as the specific review questions (or key questions) to be addressed.

#### Contextual Questions (CQ)

CQ1. How is effectiveness defined and measured for survivorship care models for adult survivors of childhood cancer?

CQ2. What are the models of survivorship care for adult survivors of childhood cancer?

- a. Which of these models include primary care?

- i. What is the evidence of effectiveness of the different models that include primary care?

CQ3. What survivorship care resources are available for adult survivors of childhood cancer and their families?

- a. What are the intended outcomes of the different resources available for adult survivors of childhood cancer and their families?

- b. What is the evidence of effectiveness of the different resources available for adult survivors of childhood cancer and their families?

- c. What are the monetary costs to access these resources?

CQ4. What survivorship care resources are available to providers who care for adult survivors of childhood cancer?

a. What are the intended outcomes of the different resources available to care providers?

b. What is the evidence of effectiveness of the different resources available to care providers?

c. What are the monetary costs to access these resources?

#### *Key Questions (KQs) for the Realist Review*

KQ1. For whom and under what circumstances could different survivorship care models for adult survivors of childhood cancer that include primary care be effective?

a. What are the key mechanisms by which these models could be effective?

b. What are important contexts that determine whether different mechanisms could be effective?

KQ2. For whom and under what circumstances could different survivorship care resources for adult survivors of childhood cancer be effective in achieving their intended outcomes?

a. For survivors and their families  
i. What are the key mechanisms by which these resources could lead to their intended outcome?

ii. What are important contexts that determine whether different mechanisms could lead to outcomes?

b. For care providers

i. What are the key mechanisms by which these resources could lead to their intended outcome?

ii. What are important contexts that determine whether different mechanisms could lead to outcomes?

#### **PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)**

We will adapt the PICOTS framework (populations, interventions, comparators, outcomes, timing, and setting) to inform our realist review. The PICOTS include but are not limited to the following.

#### *Population(s)*

- Adult survivors of childhood cancer (cancer diagnosed prior to age 21 years old) with no evidence of clinical disease; and their families
- Care providers of adult survivors of childhood cancer

#### *Interventions*

- Models of childhood cancer survivorship care for use in adult survivors
  - Models of childhood cancer survivorship care for use in adult survivors that include primary care
- Survivorship resources available to adult survivors of childhood cancer and their families
- Survivorship resources available to care providers of adult survivors of childhood cancer

#### *Comparators*

- Optional (will not require a comparison)

#### *Outcomes*

List of outcomes will be informed by contextual questions but may include:

- Intermediate patient health outcomes
- Morbidity
- Mortality
- Relapse
- Quality of life
- Psychosocial outcomes
- Mental health outcomes
- Caregiver burden
- Satisfaction with care
- Educational attainment
- Adherence with care
- Cost and resource utilization
- Unintended consequences
- Additional burdens
- Late effects—new cancers, cardiac or respiratory issues, etc. from original treatment

#### *Timing*

- After the transition from childhood cancer care

#### *Settings*

- All care settings

Dated: November 19, 2020.

**Marquita Cullom,**  
*Associate Director.*

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**BILLING CODE 4160–90–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

#### **Administration for Children and Families**

#### **Submission for OMB Review; ORR Serious Medical Procedure Request (SMR) Form (New Collection)**

**AGENCY:** Office of Refugee Resettlement, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new data collection, *the Serious Medical Procedure Request (SMR) Form*.

**DATES:** *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

#### **SUPPLEMENTARY INFORMATION:**

*Description:* Children with complex medical/dental conditions may require surgical intervention or procedures in order to maintain and promote their health while in ORR custody. Procedures requiring general anesthesia, surgeries, and invasive diagnostic procedures (e.g., cardiac catheterization, invasive biopsy, amniocentesis) require advance ORR approval. Before a decision can be rendered by ORR, data on clinical indications, risks and benefits of the surgery/procedure, potential adverse outcomes if services are not rendered, timeframe for recovery, follow-up care, and points of contact must be collected and submitted to ORR. The form is not required for emergency procedures, procedures performed during hospitalization, or procedures resulting from complication of a previously approved procedure.

*Respondents:* Healthcare providers, ORR grantee staff.

*Annual Burden Estimates:*