

*Estimated Total Annual Burden Hours:* 630,960.

**Authority:** 42 U.S.C. 601, 607, 609, 611, 613, and 1302.

**Mary B. Jones,**  
*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Cost Study of Trauma-Specific Evidence-Based Programs Used in the Regional Partnership Grants Program (New Collection)**

**AGENCY:** Children’s Bureau, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Children’s Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new descriptive study—the Cost Study of Trauma-Specific Evidence-Based Programs used in the Regional Partnership Grants (RPG) Program.

**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:* Since 2006, CB has awarded multiple rounds of competitive grants to state and local agencies and service providers under the RPG Program. Grants are awarded to organizations such as child welfare agencies, substance abuse treatment providers, or family court systems to develop interagency collaborations and provide services designed to increase well-being, improve permanency, and enhance the safety of children who are in or are at risk of being placed in out-of-home care as a result of a parent’s or caretaker’s substance abuse. Thirty-five grantees are participating in the ongoing RPG national cross-site evaluation, which examines implementation, partnerships, outcomes, and impacts. All grantees collect data on a uniform set of performance measures and report them to CB on a semi-annual basis

through a web-based system. These ongoing data collection activities are approved under OMB #0970–0527. All grantees are also required to use a portion of their funding to conduct their own “local” program impact evaluation.

This proposed cost study adds a new and unique contribution to CB’s portfolio of evaluation activities. Although the RPG cross-site evaluation will provide evidence for the effectiveness of some interventions to address the emotional effects of trauma, more information is needed about the cost of implementing these Evidence-Based Programs (EBPs).

The cost study has the key objective to determine the cost of implementing three select Trauma-Specific EBPs: Parent-Child Interaction Therapy, Seeking Safety, and Trauma-Focused Cognitive Behavioral Therapy. To carry out this objective, the study team will collect detailed cost information from nine RPG round four and five grantees who are implementing these selected EBPs. For each grantee, the study team will administer two data collection instruments: (1) A Cost Workbook used to collect comprehensive information on the cost of implementing each select program (Instrument #1), and (2) a Staff Survey and Time Log used to collect information on how program staff allocate their time (Instrument #2).

*Respondents:* Grantee staff.

*Annual Burden Estimates:* Data collection will take place within a one year period.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
Cost Workbook .....	9	1	8	72
Staff Survey and Time Log .....	90	1	3.6	330

*Estimated Total Annual Burden Hours:* 402.

**Authority:** The Child and Family Services Improvement and Innovation Act (Pub. L. 112–34).

**Emily Ball Jabbour,**  
*ACF/OPRE Certifying Officer.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA–2020–D–1564]**

**Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability**

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing the availability of the draft guidance entitled “Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.” The FDA encourages the collection, analysis, and integration of patient perspectives in the development, evaluation, and surveillance of medical devices, including digital health technologies. Patient-reported outcome (PRO) instruments facilitate the systematic collection of patient perspectives as scientific evidence to support the regulatory and healthcare decision-making process. This draft guidance describes principles that should be considered when using PRO