

Notice that announces Board and Subcommittee meetings.

**Contact Person for More Information:** Theodore Katz, Designated Federal Officer, NIOSH, CDC, 1600 Clifton Road NE., MS E-20, Atlanta, Georgia 30329, telephone: (513)533-6800, toll free: 1-800-CDC-INFO, email: [dcas@cdc.gov](mailto:dcas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Claudette Grant,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 2016-26571 Filed 11-2-16; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.564]

#### Announcement of the Award of a Single-Source Program Expansion Supplement Grant to the Washington State Department of Social and Health Services in Lacey, WA

**AGENCY:** Office of Child Support Enforcement, ACF, HHS.

**ACTION:** Notice of the award of a single-source program expansion supplement grant to the Washington State Department of Social and Health Services in Lacey, WA, to support the development of additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the Evaluation of Behavioral Interventions for Child Support Services of the Behavioral Interventions for Child Support Services (BICS) Demonstration.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Child Support Enforcement (OCSE), Division of Program Innovation, announces the award of a single-source program expansion supplement grant in the amount of \$200,000 to the Washington State Department of Social and Health Services in Lacey, WA, to support the development of additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the Evaluation of Behavioral Interventions for Child Support Services of the

Behavioral Interventions for Child Support Services (BICS) Demonstration.

**DATES:** The period of support for this supplement is September 30, 2016 through September 29, 2017.

#### FOR FURTHER INFORMATION CONTACT:

Michael Hayes, Senior Programs Manager, Office of Child Support Enforcement, 330 C Street SW., 5th Floor, Washington, DC 20201. Telephone: 202-401-5651; Email: [Michael.Hayes@acf.hhs.gov](mailto:Michael.Hayes@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In FY 2014, OCSE competitively awarded a cooperative agreement to the Washington State Department of Social and Health Services to conduct a 5-year evaluation of OCSE's national demonstration called Behavioral Interventions for Child Support Services (BICS).

This supplement will allow the Washington State Department of Social and Health Services to develop additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the evaluation of Behavioral Interventions for Child Support Services Demonstration.

The cost of the BICS evaluation is higher than originally budgeted because the process mapping and project design phase has been significantly slower than anticipated for the grantees. This led to the need for increased technical assistance to the BICS grantees by the evaluation grantee. Additionally, as a result of the mapping and design phase, OCSE anticipates an increased number of interesting findings that will be of benefit to the greater child support field.

The supplemental funds will allow Washington State Department of Social and Health Services to provide increased technical assistance to the BICS demonstration sites, and support the development of additional dissemination tools such as reports and web-based trainings on the lessons learned and early findings from the Evaluation of BICS.

Specifically, the Washington State Department of Social and Health Services will explore the development of innovative, user-friendly tools such as podcasts and infographics that will provide research findings and learning to the child support community in a way that is easily accessible to interested program administrators and policy officials. These tools will also continue to build the evidence-base in what works in the delivery of child support services.

**Statutory Authority:** Section 1115 of the Social Security Act authorizes funds for experimental, pilot, or demonstration

projects that are likely to assist in promoting the objectives of Part D of Title IV.

**Christopher Beach,**

*Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.*

[FR Doc. 2016-26563 Filed 11-2-16; 8:45 am]

**BILLING CODE 4184-42-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

[CFDA Number: 93.564]

#### Announcement of the Award of a Single-Source Expansion Supplement Grant to the Wisconsin Department for Children and Families in Madison, WI

**AGENCY:** Office of Child Support Enforcement, ACF, HHS.

**ACTION:** Notice of the award of a single-source expansion supplement grant to the Wisconsin Department of Children and Families to support the evaluation of the Child Support Noncustodial Parent Employment Demonstration.

**SUMMARY:** The Administration for Children and Families (ACF), Office of Child Support Enforcement, Division of Program Innovation announces the award of a cooperative agreement in the amount of \$200,000 to the Wisconsin Department for Children and Families in Madison, WI to support the evaluation of the Child Support Noncustodial Parent Employment Demonstration.

In FY 2012, the Office of Child Support Enforcement (OCSE) competitively awarded a cooperative agreement to the Wisconsin Department of Children and Families to conduct a 5-year evaluation of OCSE's national demonstration called Child Support Noncustodial Parent Employment Demonstration (CSPED) under Funding Opportunity Announcement (FOA) number HHS-2012-ACF-OCSE-FD-0537. Under this FOA, a total of \$4.5 million of 1115 funds were made available to the Wisconsin Department of Children and Families to conduct this evaluation.

The award of \$200,000 the Wisconsin Department of Children and Families is required to cover the unanticipated costs of conducting the CSPED evaluation. The CSPED evaluation includes an impact evaluation using random assignment, an implementation study and a benefit-cost analysis. The evaluator is also providing evaluation-related technical assistance to the grantees implementing CSPED. A baseline and 12 month follow-up survey

are being conducted. Administrative data from multiple sources are also being collected and evaluated. A grants management information system was developed for grantees to use to conduct random assignment, enroll individuals into the project, and document service delivery.

**DATES:** The period of support for this supplement is September 30, 2016 through September 29, 2017.

**FOR FURTHER INFORMATION CONTACT:** Elaine Sorensen, Office of Child Support Enforcement, 330 C Street SW., 5th Floor, Washington, DC 20201. Telephone: 202-401-5099; Email: [Elaine.sorensen@acf.hhs.gov](mailto:Elaine.sorensen@acf.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Given the importance of child support outcomes for the evaluation of CSPED, OCSE has asked the Wisconsin Department of Children and Families to expand the child support outcomes included in the evaluation, requiring additional collection of child support administrative data and additional analyses of these data. In addition, the Wisconsin Department of Children and Families provided OCSE with preliminary impact findings using child support administrative data, which uncovered further unexpected complications with the child support administrative data. OCSE has asked the Wisconsin Department of Children and Families to go back and collect additional child support administrative data to further understand these complications and report their findings to OCSE. Finally, given the strong focus on child support outcomes for this evaluation, OCSE has asked the evaluator to add a second impact report that focuses exclusively on child support outcomes.

**Statutory Authority:** Section 1115 of the Social Security Act authorizes funds for experimental, pilot, or demonstration projects that are likely to assist in promoting the objectives of Part D of Title IV.

**Christopher Beach,**  
*Certifying Official, Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-N-0403]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects: Informed Consent; Institutional Review Boards

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by December 5, 2016.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0755. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Protection of Human Subjects: Informed Consent; Institutional Review Boards OMB Control Number 0910-0755—Extension

Part 50 (21 CFR part 50) applies to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color

additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 50 is intended to protect the rights and safety of subjects involved in investigations filed with FDA under sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513-516, 518-520, 721, and 801 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 352, 353, 355, 360, 360c-360f, 360h-360j, 379e, and 381, respectively) and sections 351 and 354-360F of the Public Health Service Act.

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (see § 50.20). In seeking informed consent, each subject must be provided with certain elements of informed consent. Those elements are listed in § 50.25. Informed consent shall be documented in writing as described in § 50.27.

An institutional review board (IRB) may approve emergency research without requiring the informed consent of all research subjects provided the IRB finds and documents that certain criteria are met as required in § 50.24. We estimate that about eight times per year an IRB is requested to review emergency research under § 50.24. We estimate, of the 8 yearly requests for IRB review under § 50.24, a particular IRB will take about an hour during each of three separate fully convened IRB meetings to review the request under § 50.24 (one meeting occurring after community consultation). The total annual reporting burden for IRB review of emergency research under § 50.24 is estimated at 24 hours (see table 1).

The information requested in the regulations for exception from the general requirements for informed consent for medical devices (21 CFR 812.47), and the information requested in the regulations for exception from the general requirements of informed consent in § 50.23, paragraphs (a) through (c) and (e), is currently approved under OMB control number 0910-0586. The information requested in the investigational new drug (IND) regulations concerning exception from informed consent for emergency research under § 50.24 is currently approved under OMB control number 0910-0014. In addition, the information requested in the regulations for IND safety reporting requirements for human drug and biological products and safety reporting requirements for bioavailability and bioequivalence studies in humans (21 CFR 320.31(d))