## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

*Title:* Formative Data Collections for Policy Research.

*OMB No.:* 0970–0356.

*Description:* The Office of Planning, Research and Evaluation (OPRE), in the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) intends to request approval from the Office of Management and Budget (OMB) for renewal of a generic clearance to allow OPRE to conduct a variety of formative data collections with more than nine respondents. The data collections will inform future research but will not be highly systematic nor intended to be statistically representative.

OPRE conducts research on a wide variety of policy and programmatic areas. OPRE's research serves to provide further understanding of current programs and service populations, explore options for program improvement, and assess alternative policy and program designs. OPRE uses this formative data collection generic clearance to employ a variety of information collection techniques, including semi-structured discussions, focus groups and interviews. These activities inform the development of OPRE research, help OPRE maintain a research agenda that is rigorous and relevant, and ensure that research products are as current as possible.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OPRE requests OMB review within 10 days of receiving each change request.

Respondents: Key stakeholder groups involved in ACF projects, state or local government officials or service providers, or experts in fields pertaining to ACF research.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|---|
| Semi-Structured Discussion and Information-Gathering Protocols | 1,600 | 533 | 1 | 1 | 1,600 | 533 |

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Karl Koerper,**

*Reports Clearance Officer.*

[FR Doc. 2014–21917 Filed 9–12–14; 8:45 am]

**BILLING CODE 4184–79–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

*Title:* Pre-testing of Evaluation Surveys.

*OMB No.:* 0970–0355.

*Description:* The Office of Planning, Research and Evaluation (OPRE), in the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) intends to request approval from the Office of Management and Budget (OMB) for renewal of a generic clearance to allow OPRE to pre-test data collection instruments with more than nine participants to identify and resolve any question or procedural problems in survey administration.

OPRE studies ACF programs, and the populations they serve, through rigorous research and evaluation projects. These include evaluations of existing programs, evaluations of innovative approaches to helping low-income children and families, research syntheses and descriptive and exploratory studies. To improve the development of its research and evaluation surveys, OPRE uses the pre-testing of evaluation surveys generic clearance to employ a variety of techniques including cognitive and usability laboratory and field techniques, behavior coding, exploratory interviews, respondent debriefing questionnaires, split sample experiments, focus groups, and pilot studies/pre-tests. These activities allow OPRE to identify if and when a survey may be simplified for respondents, respondent burden may be reduced, and other possible improvements.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OPRE requests OMB review within 10 days of receiving each change request.

Respondents: Participants in ACF programs being evaluated; participants in ACF demonstrations; comparison group members; and other relevant populations, such as individuals at risk of needing ACF services.

ANNUAL BURDEN ESTIMATES

| Instrument | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours | Annual burden hours |
|---|---|---|---|---|---|---|
| Survey development field tests, respondent debriefing questionnaires, cognitive interviews, split sample experiments, focus groups | 5100 | 1700 | 1 | .75 | 3,825 | 1,275 |

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

**Karl Koerper, Reports**

*Clearance Officer.*

[FR Doc. 2014–21918 Filed 9–12–14; 8:45 am]

**BILLING CODE 4184–79–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0649]**

### Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: External Pacemaker Pulse Generator; Withdrawal of Draft Guidance

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

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of the draft guidance entitled ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator,'' dated October 2011, in response to the requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA) and new input received during a panel meeting.

**DATES:** The withdrawal is effective September 15, 2014.

**FOR FURTHER INFORMATION CONTACT:** Hina Pinto, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 1652, Silver Spring, MD 20993, 301–796–6351.

**SUPPLEMENTARY INFORMATION:**

In a notice published in the **Federal Register** of October 17, 2011 (76 FR 64228), FDA announced the availability of a draft special controls guidance document that, if finalized, would serve as a special control if FDA reclassified these devices. FDA believed that the special controls described in the draft guidance entitled, ''Class II Special Controls Guidance Document: External Pacemaker Pulse Generator'' would be sufficient to mitigate the risks to health associated with the external pacemaker pulse generator (EPPG) (Ref. 1).

On July 9, 2012, FDASIA (Pub. L. 112–144) was enacted. Section 608(a) of FDASIA amended section 513(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(a)) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting to discuss the classification of this device type. On September 11, 2013, a meeting of the Circulatory System Devices Panel (the Panel) was held to discuss whether EPPG devices should be reclassified or remain as class III devices (Ref. 2). The Panel recommended that EPPG devices be reclassified to class II with special controls when intended for cardiac rate control or prophylactic arrhythmia prevention.

FDA provided an opportunity for interested parties to comment on the special control guidance on EPPG. FDA did not receive any comments to the docket. As a result of the Panel recommendation and the amendment to section 513(e) of the FD&C Act, FDA will now include the special controls for EPPG devices in a proposed order published elsewhere in this issue of the **Federal Register** and withdraw the draft guidance through this notice.

**References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Class II Special Controls Draft Guidance Document: External Pacemaker Pulse Generator, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM275703.pdf.*

2. The transcript and other meeting materials for the September 11, 2013, Circulatory System Devices Panel are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/*