regulated services to reflect external costs. Regulated cable operators submit this form to local franchising authorities or the Commission, in situations where the FCC has assumed jurisdiction. FCC Form is filed by cable operators quarterly.

FCC Form 1240 is filed by cable operators seeking to adjust maximum permitted rates for regulated cable services to reflect changes in external costs. Cable operators submit FCC Form 1240 to their respective local franchising authorities (''LFAs'') to justify rates for the basic service tier and related equipment or with the Commission, in situations where the Commission has assumed jurisdiction. FCC Form 1240 is a filing alternative to FCC Form 1210. FCC Form 1240 is filed by cable operators annually.

Federal Communications Commission.

**Avis Mitchell,**

*Federal Register Liaison, Office of the Secretary, Office of Managing Director.*

[FR Doc. 2011–21986 Filed 8–26–11; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* Formative Data Collections for Informing Policy Research.

*OMB No.:* 0970–0356.

*Description:* The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), intends to request approval from the Office of Management and Budget (OMB) for a generic clearance that will allow OPRE to conduct a variety of qualitative data collections. Over the next three years, OPRE anticipates undertaking a variety of new research projects in the fields of cash welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, and child welfare. In order to inform the development of OPRE research, to maintain a research agenda that is rigorous and relevant, and to ensure that research products are as current as possible, OPRE will engage in a variety of qualitative data collections in concert with researchers and practitioners throughout the field. OPRE envisions using a variety of techniques including semi-structured discussions, focus groups, telephone interviews, and in-person observations and site visits, in order to integrate the perspectives of program operators, policy officials and members of the research community.

Following standard Office of Management and Budget (OMB) requirements, OPRE will submit a change request to OMB individually for every group of data collection activities undertaken under this generic clearance. OPRE will provide OMB with a copy of the individual instruments or questionnaires (if one is used), as well as other materials describing the project.

*Respondents:* Administrators or staff of State and local agencies or programs in the relevant fields; academic researchers; and policymakers at various levels of government.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|---|---|---|---|---|
| Semi-Structured Discussion and Information-Gathering Protocol ..... | 2400 | 1 | .5 | 1200 |

*Estimated Total Annual Burden Hours:* 1200.

*Additional Information:* Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: OPREinfocollection@acf.hhs.gov.*

*OMB Comment:* OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: August 22, 2011.

**Steven M. Hanmer,**

*Reports Clearance Officer.*

[FR Doc. 2011–21868 Filed 8–26–11; 8:45 am]

**BILLING CODE 4184–22–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* Pre-testing of Evaluation Surveys.

*OMB No.:* 0970–0355.

*Description:* The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), intends to request approval from the Office of Management and Budget (OMB) for a generic clearance that a will allow OPRE to conduct a variety of data gathering activities aimed at identifying questionnaire and procedural problems in survey administration. Over the next three years, OPRE anticipates undertaking a variety of new surveys as part of research projects in the fields of cash welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, and child welfare, among others. In order to improve the development of its research and evaluation surveys, OPRE envisions using a variety of techniques including field tests, respondent debriefing questionnaires, cognitive interviews and focus groups in order to identify questionnaire and procedural problems, suggest solutions, and measure the relative effectiveness of alternative survey solutions.

Following standard OMB requirements, OPRE will submit a change request to OMB individually for every data collection activity undertaken under this generic clearance. OPRE will provide OMB with a copy of the individual instrument or questionnaire, as well as other materials describing the project and specific survey pretest.

*Respondents:* The respondents will be identified at the time that each change request is submitted to OMB. Generally they will be individuals who are representative of the target groups for the public assistance research or evaluation project in question.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|---|---|---|---|---|
| Survey development field tests, respondent debriefing questionnaires, cognitive interviews and focus groups | 6000 | 1 | .5 | 3000 |

*Estimated Total Annual Burden Hours:* 3000.

*Additional Information:* Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. *E-mail address: OPREinfocollection@acf.hhs.gov.*

*OMB Comment:* OMB is required to make a decision concerning 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.

*Written comments and recommendations for the proposed information collection should be sent directly to the following:* Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: August 22, 2011.

**Steven M. Hanmer,**

*Reports Clearance Officer.*

[FR Doc. 2011–21863 Filed 8–26–11; 8:45 am]

**BILLING CODE 4184–07–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–D–0597]**

### Draft Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring.'' This guidance is intended to assist sponsors in developing risk-based monitoring strategies and plans for clinical investigations of human drugs, biologics, medical devices, and combinations thereof. The overarching goal of this guidance is to enhance human subject protection and the quality of clinical trial data. The guidance is intended to make clear that sponsors can use a variety of approaches to meet their monitoring responsibilities when conducting investigational new drug (IND) or investigational device exemption (IDE) studies.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 28, 2011.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448; or the Office of Communication, Education and Radiation Programs, Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Ann Meeker-O'Connell, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5339, Silver Spring, MD 20993–0002, 301–796–3150; or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Chrissy Cochran, Center for Devices and Radiological Health (HFZ–311), Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 66, rm. 3453, Silver Spring, MD 20993–0002, 301–796–5490.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring.'' FDA is publishing this new draft guidance to assist sponsors of clinical investigations in developing risk-based monitoring strategies and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. This guidance is intended to make clear that sponsors can use a variety of approaches to meet their monitoring responsibilities during clinical investigations. This guidance describes a modern, risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to effectively oversee a study. For example, the guidance encourages greater use of centralized monitoring methods where appropriate. The guidance also makes recommendations about how to develop monitoring plans and document monitoring activities.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will