

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
DCFS Biological Parent Interview	173	2	.25	86
DCFS Youth and Foster Parent Study Contact Form	1	228	.1	23
DCFS Foster Parent Interview	228	2	.75	342
DCFS Youth Interview	228	2	.75	342
DCFS burden				810
RISE Staff Pre-Test	157	1	.25	39
RISE Staff Post-Test	157	1	.25	39
RISE burden				78

Estimated Total Annual Burden Hours: 888

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. Email 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, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Steven M. Hanmer,

OPRE Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Parents and Children Together (PACT) Evaluation.

OMB No.: 0970-0403.

Description: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing data collection activity as

part of the Parents and Children Together (PACT) Evaluation. The objective of the PACT evaluation is to document and provide initial assessment of selected Responsible Fatherhood and Healthy Marriage grant programs that were authorized under the 2010 Claims Resolution Act. This information will be critical to informing decisions related to future investments in programming as well as the design and operation of such services.

PACT is utilizing three major, interrelated evaluation strategies: Impact evaluation; implementation evaluation; and qualitative evaluation. To collect data for these strategies, four instruments have been approved to-date, and 14 new instruments are under review as of the publish date of this notice.

Instruments approved to-date:

(1) Selecting Study Grantees (discussions with program and partner organization staff)—APPROVED April 20, 2012.

(2) Introductory Script (for RF program staff to discuss with program applicants)—APPROVED October 31, 2012.

(3) Baseline Survey (for RF study participants)—APPROVED October 31, 2012.

(4) RF study Management Information System (MIS)—APPROVED October 31, 2012.

Instruments under review at publish date of this notice:

(5) Introductory Script (for HM program staff to discuss with program applicants).

(6) Baseline Survey (for HM study participants).

(7) HM study Management Information System (MIS) (8) Semi-structured interview topic guide (for program staff).

(9) On-line survey (for program staff).

(10) Telephone interview guide (for program staff at referral organizations).

(11) On-line Working Alliance Inventory (for program staff and participants).

(12) Focus group discussion guide (for program participants).

(13) Telephone interview guide (for program dropouts).

(14) In-person, in-depth interview guide (for program participants).

(15) Telephone check-in guide (for program participants).

(16) Semi-structured interview topic guide (for program staff).

(17) Focus group discussion guide (for program participants).

(18) Questionnaire (for program participants in focus groups).

This 60-Day **Federal Register** Notice covers two new instruments:

(19) Follow-up Survey (for RF study participants).

(20) Follow-up Survey (for HM study participants).

Respondents: Program applicants, program participants, program staff, and staff at referral agencies.

Annual Burden Estimates

Some burden has already been approved for this study, and the instruments are still in use.

ANNUAL BURDEN—ALREADY APPROVED

Evaluation component	Total annual burden hours
Site Selection	50
Impact Study	4235
Total	4285

Some burden is currently under review, as of the date of this publication.

ANNUAL BURDEN—CURRENTLY UNDER REVIEW

Evaluation component	Total annual burden hours
Impact Study	8731
Implementation/Qualitative Study	1000
Total	8831

This current 60-Day **Federal Register** Notice covers two new instruments:

ANNUAL BURDEN: CURRENT REQUEST

Activity/respondent	Annual number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden hours
IMPACT				
Responsible Fatherhood Grantee Impact Evaluation				
(19) Follow-up survey: Study participants	1,600	1	0.75	1,200
Healthy Marriage Grantee Impact Evaluation				
(20) RF study MIS: Study participants	1,600	1	0.75	1,200
Total				2,400

Estimated Total Annual Burden Hours (for instruments previously approved and currently in use, instruments currently under review, and those associated with this 60-Day Notice): 15,516.

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.

Steven M. Hanmer,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-0558]

Draft Guidance for Industry on Contract Manufacturing Arrangements for Drugs: Quality Agreements; 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 "Contract Manufacturing Arrangements for Drugs: Quality Agreements." This guidance describes our current thinking on defining, establishing, and documenting the responsibilities of each party (or all parties) involved in the contract manufacturing of drugs subject to Current Good Manufacturing Practice (CGMP). In particular, we describe how parties involved in the contract manufacturing of drugs can utilize Quality Agreements to delineate their responsibilities and assure drug quality, safety, and efficacy.

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 July 29, 2013.

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; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448; or Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. 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:

Paula Katz, Center for Drug Evaluation and Research, Bldg. 51, Rm. 4314, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6972; 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 Jonathan Bray, Center for Veterinary Medicine (HFV-232),