Design and Implementation Study is complete; data collection related to the Performance Analysis Study will be complete in late summer 2017. This notice is specific to data collection activities for the Impact and In-Depth Implementation Study, which is being conducted in four sites. The proposed extension is necessary to complete ongoing follow-up data collection. The resulting data will be used in a rigorous program impact analysis to assess the effectiveness of each program in reducing teen sexual activity and associated risk behaviors.

Respondents: Youth participants who agreed to participate in the study upon enrollment in the four impact study sites.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondents	Average burden hours per response	Total/annual burden hours
Second follow-up survey	325	1	.75	244

Estimated Total/Annual Burden Hours: 244

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, 330 C Street SW., Washington, DC 20201, 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.

Mary Jones,

ACF/OPRE Reports Clearance Officer.

[FR Doc. 2017–16843 Filed 8–9–17; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Variations in Implementation of Quality Interventions (VIQI) Project: Data Collection.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF), Office of Planning, Research and Evaluation (OPRE) proposes to collect information as part of the Variations in Implementation of Quality Interventions (VIQI): Examining the Quality-Child Outcomes Relationship in Child Care and Early Education Project.

The VIQI Project will inform policymakers, practitioners, and stakeholders about effective ways to support the quality and effectiveness of early care and education (ECE) centers for promoting young children's learning and development. In partnership with ECE centers across the United States that serve young children with diverse economic backgrounds, the VIQI Project aims to (1) identify dimensions of quality within ECE settings that are key levers for promoting children's outcomes; (2) inform what levels of quality are necessary to successfully support children's developmental gains; (3) identify drivers that facilitate and inhibit successful implementation of interventions aimed at strengthening quality; and (4) understand how these relations vary across different ECE settings, staff, and children. To achieve these aims, the VIQI Project will include a year-long pilot study that will pilot up to three curricular and professional development models, followed by a year-long impact evaluation and process study that involve testing the effectiveness of two curricular and professional development models that aim to strengthen teacher practices, the quality of classroom processes, and children's outcomes. The study will include up to 189 community-based and Head Start ECE centers spread across seven different metropolitan areas in the United States.

To test the effectiveness of the curricular and professional development models, the VIQI project will consist of a 3- or 4-group experimental design in the pilot study and a 3-group experimental design in the impact evaluation and the process study in which the initial quality and other characteristics of ECE centers are measured. The centers then will be stratified based upon select information collected—by setting type (*e.g.,* Head Start and community-based ECE centers) and initial levels of quality—and randomly assigned to one of the intervention conditions where they will be offered curricular and professional development supports aimed at strengthening the quality of classroom and teacher practices, or to a business-as-usual comparison condition.

In the pilot study, 24 centers in one metropolitan area will participate in the VIQI Project. Information about center and staff characteristics and classroom and teacher practices will be collected (1) to stratify and randomly assign centers; (2) to describe how the different interventions are implemented and are experienced by centers and teachers; and (3) to document the treatment differentials across research conditions. The information will then be used to adjust and to refine the research design and measures that will be used in the impact evaluation and process study.

In the impact evaluation and process study, 165 centers in seven metropolitan areas will participate in the VIQI Project. Information about center and staff characteristics and classroom and teacher practices will be collected (1) to stratify and randomly assign centers; (2) to identify subgroups of interest; (3) to describe how the interventions are implemented and are experienced by

centers and teachers; (4) to document the treatment differentials across research conditions; and (5) to assess the impacts of each of the interventions on different dimensions of quality and teacher practices when compared to a business-as-usual comparison condition for the impact evaluation sample and separately for subgroups of interest. In addition, information about the background characteristics of families and children being served in the centers will be collected, as well as measures of children's skills at the beginning and end of the year-long impact evaluation for a subset of children in these centers. This information will also be used (1) to define subgroups of interest defined by family and child characteristics, and (2) to assess the impacts of each of the interventions on children's skills for the full impact evaluation sample and separately for subgroups of interest. Lastly, the information on quality, teacher practices and children's skills will be used in a set of analyses that will rigorously examine the nature of the quality-to-child outcomes relationship by exploring the effects of different dimensions and thresholds (or levels) of quality on child outcomes for the full impact evaluation sample and separately for subgroups of interest.

The data collection instruments for the VIQI Project include the following:

(1) Instruments for Screening and Recruitment of ECE Centers will be used in the pilot study, impact evaluation, and process study to assess ECE centers' eligibility, to inform the sampling strategy, and to recruit ECE centers to participate in the VIQI Project;

(2) Baseline Instruments for the Pilot Study, Impact Evaluation, and Process Study will be used to collect background information about centers, classrooms, center staff, and families and children being served in the centers. All of the instruments will be administered at the beginning of the pilot study, impact evaluation, and process study, with the exception of the baseline survey administered to parents of children enrolled in participating ECE centers and the protocol for baseline assessments of children's skills at the beginning of the impact evaluation and process study;

(3) Follow-Up Instruments for the Pilot Study, Impact Evaluation, and Process Study will be used to inform how centers, classrooms, teachers, and children changed and to assess the impacts of each of the interventions over the course of the pilot study, impact evaluation, and process study. All of the instruments will be administered at the end of the pilot study, impact evaluation, and process study, with the exception of the protocol for follow-up assessments of children's skills at the end of the impact evaluation and process study; and,

(4) Fidelity of Implementation Instruments for Pilot Study and Process Study will be used to document how the curricular and professional development models are delivered and experienced by staff, to document treatment differentials across research conditions, and to provide context for interpreting the findings of the impact evaluation.

Respondents: The target population of the VIQI Project will include staff members working in Head Start grantee and community-based child care oversight agencies, staff members working in 189 ECE centers in seven metropolitan areas across the United States, and parents and children being served in these centers.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Instruments for Screening and Recruitment of ECE Centers					
Landscaping protocol with Stakeholder Agencies (staff burden in Head Start (HS) *grantee* and community-based child care *agencies*)	100	33	1	1.50	50
Screening protocol for phone calls (staff burden in HS *grantees* and community-based child care *agencies*)	110	37	1	2	74
Screening protocol for phone calls (HS and community-based child care *center* staff burden)	280	93	1	1.20	112
Protocol for in-person visits for screening and recruitment activities (staff burden in HS *grantees* and community-based child care *agencies*)	488	163	1	1.50	245
Protocol for in-person visits for screening and recruitment activities (HS and community-based child care *center* staff burden)	760	253	1	1.20	304
Baseline Instruments for the Pilot Study, Impact Evaluation, and Process Study					
Baseline administrator survey	236	79	1	0.60	47
Baseline coach survey	223	74	1	0.60	44
Baseline teacher/assistant teacher survey	1358	453	1	0.60	272
Baseline parent/guardian information form in Impact Evaluation only	8,568	2,856	1	0.20	571
Baseline classroom observation protocol (teacher burden)	543	181	1	0.30	54
Baseline protocol for child assessments in Impact Evaluation only (child burden)	1980	660	1	0.50	330
Follow-Up Instruments for Pilot Study, Impact Evaluation, and Process Study					
Follow-up administrator survey	189	63	1	0.50	32
Follow-up coach survey	178	59	1	0.50	30
Follow-up teacher/assistant teacher survey	1086	362	1	0.75	272
Teacher reports to questions about children in classroom (administered as part of the follow-up teacher survey)	543	181	1	0.67	121

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Follow-up classroom observation protocol (teacher burden)	543	181	2	0.30	109
Follow-up protocol for child assessments in Impact Evaluation only (child burden)	1980	660	1	1	660
Fidelity of Implementation Instruments for Pilot Study and Process Study					
Coach Log	117	39	55	0.25	536
Teacher/assistant teacher Log	1086	362	36	0.25	3258
Implementation fidelity observation protocol (teacher burden)	72	24	1	0.30	7
Interview/Focus group protocol (administrator, teacher/assistant teacher and coach burden)	322	107	1	1.5	161

Estimated Total Annual Burden Hours: 7,289.

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, 330 C Street SW., Washington, DC 20201, 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.

Mary Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2017–16854 Filed 8–9–17; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1279]

Qualification of Medical Device Development Tools; Guidance for Industry, Tool Developers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Qualification of Medical Device Development Tools (MDDT).'' This document formalizes the MDDT program and provides guidance to FDA staff, industry, healthcare providers, researchers, and patient and consumer groups on a new voluntary process within the Center for Devices and Radiological Health (CDRH) for qualification of medical device development tools (MDDT) for use in device development and evaluation programs. In addition, the guidance discusses the framework of an MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, considerations for qualification, and the contents of a qualification package. FDA considered comments on the draft guidance and revised the guidance as appropriate.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''