analytical approaches integrating multiple sources of data and in using the results for impact monitoring, planning, and HIV/AIDS policy-making; (7) supports and strengthens global and country capacity to monitor and evaluate HIV/AIDS prevention, care, treatment programs, health system strengthening, other related global health programs, and health systems through the development of standards, guidelines, curricula, and other tools; (8) coordinates, oversees, or assists in the formulation of M&E funding/budgets and in the execution of extramural awards; and (9) collaborates with other DGHT branches, other CDC and HHS programs and offices, other USG agencies, and other national and international organizations.

James Seligman,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2015–30968 Filed 12–8–15; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Strengthening Relationship Education and Marriage Services (STREAMS) Evaluation

OMB No.: New Collection

Description: The Office of Family Assistance (OFA) within the Administration for Children and Familes (ACF) at the U.S. Department of Health and Human Services has issued grants to 46 organizations to provide healthy marriage and relationship education (HMRE) services. The Office of Planning, Research, and Evaluation (OPRE) within ACF proposes data collection activity in six HMRE grantees as part of the Strengthening Relationship Education and Marriage Services (STREAMS) evaluation. The purpose of STREAMS is to measure the effectiveness and quality of HMRE programs designed to strengthen intimate relationships. In particular, the evaluation will examine HMRE programs for youth in high school, at-risk youth, and adults. The study will fill knowledge gaps about the effectiveness of HMRE programming for youth and adults and strategies for improving program delivery and participant engagement in services. The STREAMS evaluation will include two components, an impact study and a process study.

1. Impact Study. The goal of the impact study is to provide rigorous estimates of the effectiveness of program services and interventions to improve program implementation. The impact study will use an experimental design. Eligible program applicants will be randomly assigned to either a program group that is offered program services or a control group that is not. Grantee staff will use an add-on to an existing program MIS (the nFORM system, OMB no. 0970–0460) to conduct random assignment in sites enrolling at-risk youth and adults. STREAMS will use classroom-level or school-level random assignment for programs serving youth in high school. STREAMS will collect baseline information from eligible program applicants prior to random assignment and administer a follow-up survey to all study participants 12 months after random assignment.

2. Process study. The goal of the process study is to support the interpretation of impact findings and document program operations to support future replication. STREAMS will conduct semi-structured interviews with program staff and selected community stakeholders, conduct focus groups with program participants, administer a paper-and-pencil survey to program staff, and collect data on adherence to program curricula through an add on to an existing program MIS (nForm, OMB no. 0970–0460).

This 60-Day Notice includes the following data collection activities: (1) Introductory script that program staff will use to introduce the study to participants, (2) the MIS functions for conducting random assignment, (3) a baseline survey for youth, (4) a baseline survey for adults, (5) a follow-up survey for youth, (6) a follow-up survey for adults, (7) a topic guide for semi-structured interviews with program staff and community stakeholders, (8) focus group guides for program participants, (9) a staff survey, and (10) the MIS functions for collecting data on adherence to program curricula.

Respondents: Program applicants, study participants, grantee staff, and local stakeholders (such as staff at referral agencies).

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
Impact Study, Introductory Script and Random Assignment					
1. Grantee staff	24	12	313	.08	301
2. Program applicants	7,500	3,750	1	.08	300
3. Study MIS for grantee to conduct random assignment	16	8	313	.08	200
Impact Study, Baseline Surveys					
4. Baseline Survey for Youth	3,100	1,550	1	.5	775
5. Baseline Survey for Adults	4,000	2,000	1	.5	1,000
6. Follow-up Survey for Youth	2,790	1,395	1	.5	698
7. Follow-up Survey for Adults	3,200	1,600	1	.75	1,200
Process Study					
8. Topic guide for process study staff and stakeholder interviews	150	75	1	1	75
9. Focus group guide for adults	90	45	1	1.5	68
10. Focus group guide for youth in schools	60	30	1	1.5	45
11. Focus group guide for youth out of schools	30	15	1	1.5	23
12. Staff survey	120	60	1	.5	30

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
13. Study MIS nFORM for grantees to report session adherence to curriculum	48	24	312	.08	599

Estimated Total Annual Burden Hours: 5,314

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.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2015–30994 Filed 12–8–15; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2881]

Standards-Based Approach to Analytical Performance Evaluation of Next Generation Sequencing in Vitro Diagnostic Tests; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of a public workshop that appeared in the **Federal Register** of September 9, 2015. In the notice of the public workshop, FDA requested comments on the workshop topics about the proposed standards-based regulatory strategy for next-generation sequencing (NGS) tests that produce results on variation in the human genome. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice of the public workshop published September 9, 2015. Submit either electronic or written comments by December 24, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–2881 for ''Standards-Based Approach to Analytical Performance Evaluation of Next-Generation Sequencing In Vitro Diagnostic Tests.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information