I. Background

FDA is announcing the availability of a document entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus From Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Guidance for Industry.'' The guidance document provides establishments that make donor eligibility determinations for donors of HCT/Ps with recommendations for testing living donors for WNV. The guidance does not provide recommendations regarding testing of cadaveric HCT/P donors for WNV. FDA believes that the use of an FDA-licensed NAT will reduce the risk of transmission of WNV from living donors of HCT/Ps and therefore recommends that you use an FDA-licensed NAT for testing living donors of HCT/Ps for infection with WNV as set forth in the guidance. The 2007 Donor Eligibility Guidance indicated that FDA may recommend routine use of an appropriate, licensed donor screening test(s) to detect acute infections with WNV using NAT technology, once such tests were available.

In the **Federal Register** of December 15, 2015 (80 FR 77645), FDA announced the availability of the draft guidance entitled ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Draft Guidance for Industry'' dated December 2015 (December 2015 draft guidance). FDA received several comments on the draft guidance and those comments were considered as the guidance was developed.

In the **Federal Register** of February 28, 2007 (72 FR 9007), FDA announced the availability of the 2007 Donor Eligibility Guidance. FDA issued a revised version of this guidance under the same title, dated August 2007 (2007 Donor Eligibility Guidance).

The guidance announced in this notice finalizes the December 2015 draft guidance and supplements sections IV.E. (recommendations 15 and 16) and IV.F. (recommendation 5), and supersedes the ''West Nile Virus (WNV)'' section in Appendix 6 of the 2007 Donor Eligibility Guidance.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Living Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21969 Filed 9–12–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Healthy Start Evaluation and Quality Improvement

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than October 13, 2016.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Healthy Start Evaluation and Quality Improvement OMB No. 0915–0338—Revision

Abstract: The National Healthy Start Program, funded through HRSA's Maternal and Child Health Bureau (MCHB), has the goal of reducing disparities in infant mortality and adverse perinatal outcomes. The program began as a demonstration project with 15 grantees in 1991 and has expanded over the past 2 decades to 100 grantees across 37 states and Washington, DC. Healthy Start grantees operate in communities with rates of infant mortality at least 1.5 times the U.S. national average and high rates for other adverse perinatal outcomes. These communities are geographically, racially, ethnically, and linguistically diverse low-income areas. Healthy Start covers services during the perinatal period (before, during, after pregnancy) and follows the woman and infant through 2 years after the end of the pregnancy. The Healthy Start program has five approaches including: (1) Improving women's health; (2) promoting quality services; (3) strengthening family resilience; (4) achieving collective impact; and (5) increasing accountability through quality assurance, performance monitoring, and evaluation.

MCHB seeks to implement a uniform set of data elements for monitoring and conducting a mixed-methods evaluation to assess the effectiveness of the program on individual, organizational, and community-level outcomes. Data collection instruments will include a National Healthy Start Program Survey; Community Action Network Survey; Healthy Start Site Visit Protocol; Healthy Start Participant Focus Group Protocol—these instruments have not been changed. The Preconception, Pregnancy and Parenting (3Ps) Information Form will also be used as a data collection instrument; however the 3Ps Information Form has been redesigned from one form into six forms. The six forms include: (1) Demographic Intake Form; (2) Pregnancy Status/History; (3) Preconception; (4) Prenatal; (5) Postpartum; and (6) Interconception/Parenting. The purpose of this redesign is to enhance the 3Ps Information Form to ensure collected data is meaningful for monitoring and evaluation, as well as screening and care coordination, and streamline previously separate data systems. The 3Ps Information Form was also redesigned to allow questions to be administered in accordance with the participant's enrollment/service delivery status and perinatal period. In addition to redesigning the 3Ps Information Form, HRSA deleted questions that are neither critical for

evaluation nor programmatic purposes. HRSA also added questions to the 3Ps Information Form to allow the Form to be used as an all-inclusive data collection instrument for MCHB and Healthy Start grantees. The additional questions extend and refine previously approved content, allowing for the collection of more granular and/or in-depth information on existing topics. Adding these questions allows Healthy Start grantees to better assess risk, identify needed services, provide appropriate follow-up activities to program participants, and improve overall service delivery and quality.

Need and Proposed Use of the Information: The purpose of the data collection instruments is to obtain consistent information across all grantees about Healthy Start and its outcomes. The data will be used to: (1) Conduct ongoing performance monitoring of the program; (2) provide credible and rigorous evidence of program effect on outcomes; (3) assess the relative contribution of the five program approaches to individual and community-level outcomes; (4) meet program needs for accountability, programmatic decision-making, and ongoing quality assurance; and (5) strengthen the evidence-base, and identify best and promising practices for the program to support sustainability, replication, and dissemination of the program.

Likely Respondents: Respondents include project directors and staff for the National Healthy Start Program Survey; representatives from partner organizations for the Community Action Network Survey; program staff, providers, and partners for the Healthy Start Site Visit Protocol; and program participants for the Healthy Start Participant Focus Group Protocol. Respondents for the redesigned 3Ps Information Form (*i.e.,* (1) Demographic Intake; (2) Pregnancy Status/History; (3) Preconception; (4) Prenatal; (5) Postpartum; and (6) Interconception/Parenting) are pregnant women and women of reproductive age who are served by the Healthy Start Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
3Ps Information Form:					
1. Demographic Intake Form	*+40,675	1	40,675	0.08	3,254
2. Pregnancy Status/History	40,675	1	40,675	0.17	6,915
3. Preconception	*+20,337	1	20,337	1.00	20,337
4. Prenatal	20,337	1	20,337	1.00	20,337
5. Postpartum	20,337	1	20,337	1.00	20,337
6. Interconception/Parenting	20,337	1	20,337	1.00	20,337
National Healthy Start Program Web Survey	+100	1	100	2.00	200
CAN member Web Survey	+225	1	225	0.75	169
Healthy Start Site Visit Protocol	+15	1	15	6.00	90
Healthy Start Participant Focus Group Protocol	+180	1	180	1.00	180
Total	61,532	.....	61,532	.....	92,156

*The same individuals (40,675) complete the Demographic Intake and Pregnancy Status/History forms, and a subset of these same individuals (20,337) also complete the Preconception, Prenatal, Postpartum, and Interconception/Parenting forms for total of 61,532 respondents and responses.

+These are the numbers included in the total respondent count.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–21889 Filed 9–12–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the Fogarty International Center Advisory Board was renewed for an additional two-year period on August 31, 2016.

It is determined that the Fogarty International Center Advisory Board is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail code 4875), Telephone (301) 496–2123, or *spaethj@od.nih.gov.*

Dated: September 6, 2016.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–21899 Filed 9–12–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as