mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when the PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Verge Patient Safety Organization, a component entity of Verge Solutions, LLC, PSO number P0118, to voluntarily relinquish its status as a PSO. Accordingly, Verge Patient Safety Organization was delisted effective at 12:00 Midnight ET (2400) on February 2, 2016.

Verge Patient Safety Organization has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification to providers that have reported to the PSO. In addition, according to sections 3.108(c)(2)(ii) and 3.108(b)(3) of the Patient Safety Rule regarding disposition of PSWP, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.ahrq.gov/*.

Sharon B. Arnold,

AHRQ Deputy Director.

[FR Doc. 2016–03034 Filed 2–12–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2015–0049]

Notice of Availability of the Final Environmental Assessment and a Finding of No Significant Impact for HHS/CDC Lawrenceville Campus Proposed Improvements 2015–2025, Lawrenceville, Georgia

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is issuing this notice to advise the public that HHS/CDC has prepared and signed on February 9, 2016 a Finding of No Significant Impact (FONSI) based on the Final Environmental Assessment (Final EA) for the HHS/CDC Lawrenceville Campus Proposed Improvements 2015–2025 on the HHS/CDC Lawrenceville Campus, Lawrenceville, Georgia. The Final EA has been prepared in accordance with the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality (CEQ) implementing regulations (40 CFR 1500–1508) and the HHS General Administration Manual (GAM) Part 30 Environmental Procedures, dated February 25, 2000.

DATES: The FONSI and Final EA are available as February 16, 2016.

FOR FURTHER INFORMATION CONTACT: Copies of the FONSI and/or the Final EA or additional information may be obtained by contacting Angela Wagner, Portfolio Manager, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–K96, Atlanta, GA 30329. Telephone: (770) 488–8170.

SUPPLEMENTARY INFORMATION: The Centers for Disease Control and Prevention (CDC) within the U.S. Department of Health and Human Services (HHS), has prepared an Environmental Assessment (EA), to assess the potential impacts associated with the undertaking of proposed improvements on the HHS/CDC's Lawrenceville Campus located at 602 Webb Gin House Road in Lawrenceville, Georgia. The proposed improvements include: (1) Building demolition; (2) new building construction, including an approximately 12,000 gross square feet (gsf) Science Support Building, a new Transshipping and Receiving Area at approximately 2,500 gsf and two new small Office Support Buildings at 8,000 gsf and 6,000 gsf; (3) expansion and relocation of parking on campus; and (4) the creation of an additional point of access to the campus. The proposed improvements would be undertaken between the time period of 2015 and 2025 and are contingent on receipt of funding. The proposed improvements are needed to maintain an appropriate facilities quality level on the Lawrenceville Campus.

On August 14, 2015, HHS/CDC published a notice in the **Federal Register** (80 FR 48863) announcing the availability of a Draft EA and requesting public comment. The comment period ended on September 28, 2015. No substantive comments were received that raised specific issues or concerns with the methodology, analysis, conclusion or accurateness of the EA.

Based on the analysis of environmental impacts in the EA and in accordance with NEPA, HHS/CDC has determined that the proposed action will not significantly affect the human or natural environment and therefore does not require the preparation of an environmental impact statement.

Dated: February 10, 2016.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2016–03059 Filed 2–12–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–15–0573]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of

the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov*. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

National HIV Surveillance System (NHSS) (OMB Control No. 0920–0573, Expires 02/29/2016)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Data collected as part of the National HIV Surveillance System (NHSS) are the primary data used to monitor the impact of HIV infection in the United States. The NHSS provides critical data that are used to describe the incidence and prevalence of HIV disease and the characteristics of infected persons. HIV surveillance data are used widely at the local, state and national levels for planning, evaluation and allocation of funding for HIV prevention and care programs.

The NHSS has been updated periodically as science, technology, and our understanding of HIV has evolved. CDC in collaboration with health departments in the 50 states, the District of Columbia, and U.S. dependent areas, conducts national surveillance for cases of HIV infection that includes critical data across the spectrum of HIV disease from HIV diagnosis, to stage 3 (AIDS), the end-stage disease caused by infection with HIV, and death. In addition, this national system provides essential data to estimate HIV incidence and monitor patterns in HIV drug resistance and genetic diversity, as well as provide information on perinatal exposures in the United States.

The CDC surveillance case definition has been modified periodically to accurately monitor disease in adults, adolescents and children and reflect use of new testing technologies and changes in HIV treatment. Information is then updated in the case report forms and reporting software as needed.

In 2014, following extensive consultation and peer review, CDC and the Council of State and Territorial Epidemiologists (CSTE) revised and combined the surveillance case definitions for human immunodeficiency virus (HIV) infection into a single case definition for persons of all ages. Laboratory criteria for defining a confirmed case now accommodate new multi-test algorithms, including criteria for differentiating between HIV–1 and HIV–2 infection and for recognizing early HIV infection. Clinical (non-laboratory) criteria for defining a case for surveillance purposes have been made more practical by eliminating the requirement for information about laboratory tests. The surveillance case definition is intended primarily for monitoring the HIV infection burden and planning for prevention and care on a population level, not as a basis for clinical decisions for individual patients. CDC and CSTE recommend that all states and territories conduct case surveillance of HIV infection using this revised surveillance case definition.

Modifications to data elements to accommodate the 2014 HIV case surveillance definition were approved in the last renewal of OMB Control No. 0920–0573. The revisions requested in this extension include modifications to currently collected data elements and forms to accommodate new testing technologies as well as clinical practice guidelines. Specifically, the HIV Testing and Antiretroviral Use History section will be revised on the adult/adolescent and pediatric case report forms to include new laboratory tests, additional information on use of antiretrioviral (ARV) medications for pre-exposure prophylaxis (PrEP), post-exposure prophylaxis (PEP), prevention of mother-to-child-transmission among HIV infected women during pregnancy, and hepatitis B virus (HBV) treatment. Other changes include addition of dates to the address and patient ID fields to better track residence information and minor formatting changes to the form used for Perinatal HIV Exposure Reporting (PHER).

The revisions to this request also include the addition of burden hours for annual reporting by health departments for the Standards Evaluation Report (SER) and Annual Performance Report (APR). Findings from these reports are used to improve data quality and ensure the accuracy, timeliness, and completeness of the national HIV surveillance, as well as to monitor performance and progress in achieving both state and national HIV surveillance program objectives. Fifty-nine health departments funded for HIV surveillance will report a Standards Evaluation Report (SER) and APR annually.

CDC provides funding for 59 health departments to conduct adult and pediatric HIV case surveillance and report information to CDC. Health department staff compile information from laboratories, physicians, hospitals, clinics and other health care providers to complete adult and adolescent and pediatric HIV confidential case reports. Updates to case reports are also entered into an electronic database by health departments, as additional information may be received from laboratories, vital statistics offices, or additional providers. Evaluations are also conducted by health departments on a subset of case reports (*e.g.,* re-abstraction/validation activities and routine interstate de-duplication) in all jurisdictions.

Supplemental surveillance data are collected in a subset of areas to provide additional information necessary to estimate HIV incidence, to better describe the extent of HIV viral resistance and quantify HIV subtypes among persons infected with HIV and to monitor and evaluate perinatal HIV prevention efforts. Health departments funded for these supplemental data collections obtain this information from laboratories, health care providers, and medical records. CDC estimates that 25 health departments will be reporting data elements containing HIV Incidence Surveillance (HIS) data, 53 health departments will report additional data elements on HIV nucleotide sequences as part of Molecular HIV Surveillance (MHS), and 35 areas will be reporting data as part of 35 health departments will be reporting data collected as part of Perinatal HIV Exposure Reporting (PHER) annually. The total estimated annual burden hours are 50,504.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Departments	Adult HIV Case Report	59	1,061	20/60
Health Departments	Pediatric HIV Case Report	59	5	20/60
Health Departments	Case Report Evaluations	59	107	20/60
Health Departments	Case Report Updates	59	1,576	2/60
Health Departments	Laboratory Updates	59	6,303	1/60
Health Departments	HIV Incidence Surveillance (HIS)	25	2,288	10/60
Health Departments	Molecular HIV Surveillance (MHS)	53	829	5/60
Health Departments	Perinatal HIV Exposure Reporting (PHER)	35	114	30/60
Health Departments	Annual Reporting: Standards Evaluation Report (SER).	59	1	8
Health Departments	Annual Reporting: Annual Performance Report (APR).	59	1	42

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–03046 Filed 2–12–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Food and Drug Administration Clinical Trial Requirements, Regulations, Compliance, and Good Clinical Practices; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Educational Conference Co-Sponsored With the Society of Clinical Research Associates (SOCRA).'' The public workshop on FDA's clinical trial requirements is designed to aid the Clinical Research Professional's understanding of the mission, responsibilities, and authority of FDA and to facilitate interaction with FDA representatives. The program will focus on the relationships among FDA, clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process and informed consent documents; regulations relating to drugs, devices, and biologics; as well as inspections of clinical investigators, of IRBs, and of research sponsors.

DATES: The public workshop will be held on March 9 and 10, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the Holiday Inn San Diego Bayside, 4875 North Harbor Dr., San Diego, CA 92106, 619–224–3621.

FOR FURTHER INFORMATION CONTACT: Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510–287–2708, FAX: 510–287–2739, or Society of Clinical Research Associates (SOCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, telephone: 800–762–7292 or 215–822–8644, FAX: 215–822–8633, *Office@socra.org,* Web site: *www.socra.org.* (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

SUPPLEMENTARY INFORMATION:

I. Background

The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by Government Agencies to small businesses.

II. Topics for Discussion at the Public Workshop

Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working With FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings With FDA—Why, When, and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

Registration: The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of the registration is as follows: SOCRA member—$575, SOCRA nonmember (includes membership)—$650, Federal Government member—$450, Federal