For those without Internet access, please contact Denise Pica-Branco (see *Contact*) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Denise Pica-Branco (see *Contact*) at least 7 days in advance.

II. Transcripts

Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and at *http://www.regulations.gov* approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301–827–9267.

Dated: January 31, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–02552 Filed 2–5–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICE

National Institutes of Health

Proposed Information Collection; 60-day Comment Request: Population Assessment of Tobacco and Health (PATH) Study

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) The approaches used to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received by April 7, 2014.

FOR FURTHER INFORMATION CONTACT: *To Submit Comments and for Further Information:* To obtain a copy of the data collection plans and instruments, submit comments in writing or request more information on the proposed project, contact: Kevin P. Conway, Ph.D., Deputy Director, Division of Epidemiology, Services, and Prevention Research, National Institute on Drug Abuse, 6001 Executive Boulevard, Room 5185; or call non-toll-free number (301) 443–8755; or Email your request, including your address to: *PATHprojectofficer@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION:

Proposed Collection: Population Assessment of Tobacco and Health (PATH) Study—Second Wave of Data Collection–0925–0664–Revision—National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), in partnership with the Food and Drug Administration (FDA).

Need and Use of Information Collection: This is a revision request (OMB 0925–0664, expires 11/30/2015) for the Population Assessment of Tobacco and Health (PATH) Study to conduct the second wave of data collection. The PATH Study is a large national longitudinal cohort study on tobacco use behavior and health among the U.S. household population of adults age 18 and older and youth ages 12 to 17. The PATH Study conducts annual interviews and collects biospecimens from adults to help inform the development, implementation, and evaluation of tobacco-product regulations by FDA in meeting its mission under the Family Smoking Prevention and Tobacco Control Act (TCA) to regulate tobacco products, including tobacco-product advertising, labeling, marketing, constituents, ingredients, and additives. The longitudinal design of the PATH Study provides it with the capacity to measure and report within-person changes and between-person differences in tobacco product use behaviors and health effects within the cohort over time. These data will help to inform regulatory decisions and actions by FDA and FDA's evaluations of associations between its regulations and tobacco use behaviors and health indicators in the population.

OMB approval is requested for 3 years. There are no capital, operating, or maintenance costs to report. There are no costs to respondents other than their time. The total estimated annualized burden hours are 75,124.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent and instrument	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response (in hours)	Estimated total annual burden hours requested
Adults—Extended Interview	38,740	1	1	38,740
Adults—Baseline youth respondents who age into adult cohort—Consent for Extended Interview	2,717	1	2/60	91
Adults—Baseline youth respondents who age into adult cohort—Extended Interview	2,500	1	68/60	2,833
Adults—Adult respondents who refused biospecimen collection at Baseline but who consent for Wave 2—Consent for Biological Samples	1,452	1	4/60	97
Adults—Baseline youth respondents who age into the adult cohort—Consent for Biological Samples	2,500	1	4/60	167
Adults—Biospecimen Collection: Urine	12,387	1	10/60	2,065
Adults—Biospecimen Collection: Buccal Cell	2,387	1	18/60	716

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent and instrument	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response (in hours)	Estimated total annual burden hours requested
Adults—Biospecimen Collection: Blood	2,303	1	18/60	691
Adults—Tobacco Use Form	17,077	1	4/60	1,138
Adults—Follow-up/Tracking Participant Information Form	41,239	2	8/60	10,997
Youth—Extended Interview	12,392	1	32/60	6,609
Youth—Shadow youth who age into youth cohort—Assent for Extended Interview	2,734	1	2/60	91
Youth—Shadow youth who age into youth cohort—Extended Interview	2,515	1	42/60	1,761
Adult—Parent Interview	12,392	1	14/60	2,891
Adults—Parents of Shadow youth who age into youth cohort—Parent Permission and Consent for Parent Interview	2,734	1	2/60	91
Adults—Parents of Shadow youth who age into youth cohort—Parent Interview	2,515	1	17/60	713
Adults—Follow-up/Tracking Participant Information Form for Youth (completed by parents)	14,907	2	8/60	3,975
Adults—Follow-up/Tracking Participant Information Form for sample Shadow youth (completed by parents)	5,468	2	8/60	1,458

Dated: January 31, 2014.

Glenda J. Conroy,

Executive Officer (OM Director), National Institute on Drug Abuse, NIH.

[FR Doc. 2014–02603 Filed 2–5–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

HIV–1 BED: A Simple Serological Assay for Detecting Recent Infection and Estimating Incidence of Multiple, Worldwide HIV–1 Subtypes

Description of Technology: This CDC developed invention is a simple enzyme immunoassay that detects increasing levels of anti-HIV-IgG after seroconversion and can be used for detection of HIV–1 infection. The assay, termed IgG-Capture BED–EIA, incorporates a branched peptide derived from 3 different subtypes to allow equivalent detection of antibodies of different subtypes. The competitive format of the assay allows detection of increasing proportion of HIV–1 IgG for almost 2 years after seroconversion. This is different from what is normally observed in a conventional EIA (with antigen coated plates) that plateaus soon after seroconversion. This assay will be important for HIV prevention activities, targeting resources, and evaluation of ongoing interventions.

Potential Commercial Applications:

- HIV clinical serodiagnostics
- Informing clinical decision-making
- Public health/HIV monitoring programs and incidence surveillance

Competitive Advantages:

- Ready for commercialization
- Simple and high-throughput capable
- Detects HIV–1 subtypes prevalent in N. America, Europe, Japan, Thailand, Australia, and also central and E. Africa

Development Stage: In vitro data available

Inventors: Bharat S. Parekh and J. Steven McDougal (CDC)

Publications:

1. Parekh BS, *et al.* Determination of mean recency period for estimation of HIV type 1 Incidence with the BED-capture EIA in persons infected with diverse subtypes. AIDS Res Hum Retroviruses. 2011 Mar;27(3):265–73. [PMID 20954834]
2. Dobbs T, *et al.* A comprehensive evaluation of the proficiency testing program for the HIV–1 BED incidence assay. J Clin Microbiol. 2011 Oct;49(10):3470–3. [PMID 21832016]
3. Parekh BS, *et al.* Quantitative detection of increasing HIV type 1 antibodies after seroconversion: a simple assay for detecting recent HIV infection and estimating incidence. AIDS Res Hum Retroviruses. 2002 Mar 1;18(4):295–307. [PMID 11860677]
4. Dobbs T, *et al.* Performance characteristics of the immunoglobulin G-capture BED-enzyme immunoassay, an assay to detect recent human immunodeficiency virus type 1 seroconversion. J Clin Microbiol. 2004 Jun;42(6):2623–8. [PMID 15184443]
5. Nesheim S, *et al.* Temporal trends in HIV Type 1 incidence among inner-city childbearing women in Atlanta: use of the IgG-capture BED-enzyme immunoassay. AIDS Res Hum Retroviruses. 2005 Jun;21(6):537–44. [PMID 15989458]

Intellectual Property: HHS Reference No. E–555–2013/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technologies:

- HHS Reference No. E–357–2013/0—Research Tool. Patent protection is not being pursued for this technology.
- HHS Reference No. E–358–2013/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Whitney Blair, J.D., M.P.H.; 301–435–4937; *whitney.blair@nih.gov*

Improved Botulism, Botulinum Neurotoxin Type-E Diagnostics

Description of Technology: CDC researchers have improved upon a prior,