data by demographic subgroups including sex, age, race, and ethnicity, is included in applications submitted to the FDA,'' and provide such publication to Congress. The report, entitled ''Reporting of Inclusion of Demographic Subgroups in Clinical Trials and Data Analysis in Applications for Drugs, Biologics, and Devices,'' was posted on FDA's Internet Web site in August 2013 and is available at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.*

Section 907(b) of FDASIA further requires the Secretary, again acting through the Commissioner, to publish an action plan on FDA's Internet Web site and provide such publication to Congress. The action plan is to contain recommendations, as appropriate, to improve the completeness and quality of analyses of data on demographic subgroups in summaries of product safety and effectiveness and in labeling; on the inclusion of such data, or the lack of availability of such data in labeling; and on ways to improve public availability of such data to patients, health care providers, and researchers. These recommendations are to include, as appropriate, a determination that distinguishes between product types and applicability. The action plan is due not later than 1 year after the publication of the report described previously. The action plan entitled ''FDA Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data'' was published in August 2014 and is available at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FDASIA/ucm356316.htm.*

Priority three of the action plan aims to make demographic data more available and transparent by, amongst other things, posting demographic composition and analysis by subgroup in pivotal clinical studies for FDA-approved medical products. The first iteration of FDA's publication of this data is available at *www.fda.gov/drugtrialssnapshot.*

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

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

Dated: November 19, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–27732 Filed 11–21–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Assessing an Online Process To Study the Prevalence of Drugged Driving in the U.S.: Development of the Drugged Driving Reporting System

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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways 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.

To Submit Comments and for Further Information: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Harold Perl, Ph.D., Chief, Prevention Research Branch, Division of Epidemiology, Services & Prevention Research, NIDA, 6001 Executive Blvd., Rockville, MD 20852 or call this non-toll-free number (301) 443–6504, or email your request, including your address to: *hperl@nida.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Proposed Collection: Assessing an Online Process to Study the Prevalence of Drugged Driving in the U.S: Development of the Drugged Driving Reporting System. Type of Information Collection Request: 0925–NEW. National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: The study seeks to provide an improved understanding of the prevalence of drugged driving among adult drivers in the U.S and will assess the effectiveness of the online survey implementation process. The primary objectives of the study are to: (a) To provide comprehensive data on drugged driving; (b) determine if the Drugged Driving Survey Instrument (DDS) is an effective and accurate measure of drugged driving among licensed U.S. Drivers aged 18 and older; and, (c) to assess the effectiveness of the survey implementation process, including various levels of incentives for participation to determine the appropriate/optimal incentive amount needed to obtain the desired number of total survey respondents within the timeframe within which survey data will be collected. The findings will provide valuable information concerning various aspects of substance use and driving behavior, including: (1) Demographic information about drivers who do and do not drive while impaired by medication and/or drugs (*e.g.* age, zip code, type of driver's license); (2) which drugs/medications are most likely to be used while driving; (3) drivers' beliefs and attitudes toward drugged driving. OMB approval is requested for 2 years. There are no direct costs to respondents other than their time. The total annualized estimated burden hours are 750.

Study material	Type of respondent	Number of respondents	Responses per respondent	Hours per response	Annual hour burden
Drugged Driving Survey	Drivers (18 years of age or older) ...	3,750	1	12/60	750

Dated: November 18, 2014.

Genevieve deAlmeida,

Project Clearance Liaison, National Institute on Drug Abuse.

[FR Doc. 2014–27760 Filed 11–21–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Electronic Prior Approval Submission System (ePASS) (NHLBI)

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 Heart, Lung and Blood Institute (NHLBI), 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways 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.

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: Ms. Suzanne White, 6701 Rockledge, Office of Grants Management, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Dr., MSC 7926, Bethesda, MD 20892–7926, or call non-toll-free number 301–435–0166, or Email your request, including your address to *whitesa@nhlbi.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Electronic Prior Approval Submission System (ePASS), 0925—New, National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose and use of the information collection for this project is to collect and track certain requests (such as budget modifications or undertaking particular activities) from NIH grantees in an electronic format. This new electronic system, ePASS (electronic Prior Approval Submission System), will enable grantees to have a standard way to submit requests for their projects per NIH policy. The grantee will initiate a request for a certain action as required by NIH policy: Use of unobligated balances/carryover, change of PI, change of effort, Training Grant (NRSA) waivers, significant rebudgeting, 2nd and 3rd no cost extensions, and change of scope. These are all prior approvals as required by the NIH Grants Policy, and need to be reviewed and approved by the NHLBI. ePASS will provide a template to ensure that all specific points are addressed and documented in the official grant file. All information is submitted via the internet, tracked in ePASS, and the documentation will automatically be forwarded to the official grant file. The system will ensure that individuals authorized by the grantee are submitting requests and that the appropriate NIH staff is receiving the requests. The requests will be template driven so that the grantee is including the minimally required information, thus eliminating the usual back and forth to obtain missing information. Forms will have automatic fill-in capability that will reduce typos in grant numbers and PI names, further reducing approval time. Reminders will be sent to NIH staff within ePASS based on roles to ensure timely responses to the grantee. The system will facilitate email communication with applicants by automatic notifications when applications are received and when NIH has made a determination regarding a request (approval issued or request denied with explanation for denial).

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 470.

A.12–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
NHLBI Grantees	940	1	30/60	470

Dated: November 12, 2014.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–27762 Filed 11–21–14; 8:45 am]

BILLING CODE 4140–01–P