cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On November 13, 2013, the committee will meet in open session to hear an overview of the research programs in the Laboratory of Retroviruses and Laboratory of Immunoregulation, Division of Viral Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Review, FDA.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On November 13, 2013, from 12:30 p.m. to approximately 3:10 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 6, 2013. Oral presentations from the public will be scheduled between approximately 2:10 p.m. and approximately 3:10 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 29, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 30, 2013.

Closed Committee Deliberations: On November 13, 2013, between approximately 3:10 p.m. and approximately 3:45 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 26, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–24025 Filed 10–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Notice Request: Application Process for Clinical Research Training and Medical Education at the Clinical Center and Its Impact on Course and Training Program Enrollment and Effectiveness

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 application information collection, the Clinical Center (CC), 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 to address 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) 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: Robert M. Lembo, MD, Deputy Director, Office of Clinical Research Training and Medical Education, NIH Clinical Center, 10 Center Drive, MSC 1158, Bethesda, MD 20892–1352, or call non-toll-free number (301)–594–4193, or Email your request, including your address to: *lembor@mail.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: Application Process for Clinical Research Training and Medical Education at the Clinical Center and its Impact on Course and Training Program Enrollment and Effectiveness, 0925–NEW, Clinical Center, National Institutes of Health (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The primary objective of the application process is to allow OCRTME to evaluate applicants' qualifications to determine applicants' eligibility for courses and training programs managed by the office. Applicants must provide the required information requested in the respective applications to be considered a candidate for participation. Information submitted by candidates for training programs is reviewed initially by OCRTME administrative staff to establish eligibility for participation. Eligible candidates are then referred to the designated training program director or training program selection committee for review and decisions regarding

acceptance for participation. A secondary objective of the application process is to track enrollment in courses and training programs over time.

OMB approval is requested for 3 years. There are capital, operating, and/or maintenance costs of $98,022. The total estimated annualized burden hours are 2,210.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of applicants	Estimated number of applicants	Estimated number of applications per applicant	Maximum burden hours per application	Estimated total annual burden hours requested
Doctoral Level	6,488	1	20/60	2,163
Students	82	1	20/60	27
Other	59	1	20/60	20

Dated: September 25, 2013.

Laura Lee,

Project Clearance Liaison, Clinical Center, National Institutes of Health.

[FR Doc. 2013–24074 Filed 10–1–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Drug Abuse (NIDA), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on March 29, 2013, Vol.78, No.61, pages 19273–19274, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute on Drug Abuse (NIDA), the National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Steve Gust, National Institute on Drug Abuse, 6001 Executive Blvd., Bethesda, MD 20892, or call non-toll-free number (301) 443–6480 or Email your request, including your address to: *sgust@nida.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Quantification of Behavioral and Physiological Effects of Drugs Using a Mobile Scalable Device, 0925-New, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: This study will examine the effectiveness of a mobile scalable device to detect the impairing effects of different drugs. The primary purpose of the data collected is to determine eligibility in a driving simulation study and to verify the effectiveness of the experimental manipulations. The findings will provide valuable information concerning the utility and effectiveness of mobile, smartphone/tablet-based neurocognitive assessment that can provide a multifactorial evaluation of cognitive functioning associated with impaired driving.

OMB approval is requested for 18 months. There are no costs to respondents other than their time. The total estimated annualized burden hours are 859.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Per annual hour burden
Phone Screening	Adults	100	1	10/60	17
Consent Process, In-Person Screening Adderall	Adults	.....	.....	45/60	75
Consent Process, In-Person Screening Xanax	Adults	100	.....	45/60	75
Consent Process, In-Person Screening Cannabis	Adults	.....	.....	45/60	75
Driving Survey	Adults	.....	1	15/60	18
Realism Survey	Adults	.....	1	3/60	4
Sleep and Intake Questionnaire	Adults	.....	2	3/60	7
Stanford Sleepiness Scale	Adults	72	6	1/60	7
Wellness Survey	Adults	.....	2	2/60	5
Dosing/Driving/Waiting	Adults	.....	2	4	576