A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001:

1. *Arthur L. Loomis, II, Patricia A. Loomis, Genevieve E. Loomis, and Julia P. Loomis, all of Niskayuna, New York; Florence Porter Loomis, Frederick S. Loomis, Anne M. Loomis, and J. Porter Loomis, all of Pratt, Kansas; Howard K. Loomis, Jr., Karen P. Loomis, Katherine P. Loomis, Margaret P. Loomis, and Victoria K. Loomis, all of Los Gatos; California, as individuals and/or trustees of the 2011 Arthur L. Loomis, II Gift Trust, the Julia P. Loomis Revocable Trust, the Arthur L. Loomis, II Revocable Trust, the Genevieve E. Loomis Revocable Trust, all of Niskayuna, New York; the Howard K. Loomis Revocable Trust, the 2010 Howard K. Loomis Irrevocable Family Trust, the Porter Legacy Trust, Florence Porter Loomis Trust, the 2010 Florence Porter Loomis Irrevocable Family Trust, the 2011 Frederick S. Loomis Gift Trust, the 2011 J. Porter Loomis Gift Trust, all of Pratt, Kansas; the 2011 Howard K. Loomis Jr. Gift Trust, The Loomis 1993 Revocable Trust, both of Los Gatos, California; and Flopper, L.P., How-Kan, L.P., and Driftwood, LLC, all of Pratt, Kansas; and all as members of the Loomis Family Group,* to retain control of Krey Co. Ltd., and thereby indirectly retain control of The Peoples Bank, both in Pratt, Kansas.

Comments on this application must be received by April 20, 2012.

Board of Governors of the Federal Reserve System, April 11, 2012.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2012–9033 Filed 4–13–12; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Information Program on Clinical Trials: Maintaining a Registry and Results Databank

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Library of Medicine (NLM), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 9, 2012 (Vol. 77, No. 27, p. 6808) and allowed 60-days for public comment. A single public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. 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.

Proposed Collection: Title: Information Program on Clinical Trials: Maintaining a Registry and Results Databank; *Type of Information Collection Request:* Revision of currently approved collection [OMB No. 0925–0586, expiration date 04/30/2012], *Form Number:* NA; *Need and Use of Information Collection:* The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (e.g., observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies, to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered voluntarily, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events. As the existing PRA clearance for this information collection nears expiration, we are making a limited number of revisions to include additional data elements that may be voluntarily submitted to describe and aid in the interpretation of any submitted adverse event information, to facilitate the registration of patient registries, and to account for the burden of establishing an account with the ClinicalTrials.gov Protocol Registration System (PRS). *Frequency of Response:* For clinical trials that are subject to FDAAA, responsible parties must register once, not later than 21 days after enrolling the first subject. Updates to submitted information are required at least once a year, if there are changes to report, although changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. Results information is to be submitted not later than 12 months after the completion date (as defined in the law), but can be delayed under certain circumstances. Other clinical studies also register once, at their inception, and are requested to update information annually, as necessary. An organization must establish a PRS account one time in order to register studies (and submit results) with ClinicalTrials.gov.

Description of Respondents: Respondents include sponsors or principal investigators of clinical studies. Those subject to FDAAA are referred to as ''responsible parties,'' which are defined as sponsors of the clinical trial (as defined in 21 CFR 50.3) or designated principal investigators who meet requirements specified in the law. *Estimate of Burden:* The burden associated with this information collection is calculated in three parts: the burden associated with the one-time process of applying for a PRS account at ClinicalTrials.gov; the burden associated with registration; and the burden associated with the submission of results information, including adverse events. These information collections will occur at different times, but the registration and results information will be integrated into a single record for each clinical trial, which is entered through the PRS account. Based on data from 2011, we estimate that 5,500 new PRS account applications will be submitted annually. The time necessary to collect the required information and enter it into a new application form is estimated at 15 minutes. Using these figures, we estimate the total annual burden of submitting an application for a new PRS account to be 1,375 hours (5,500 applications per year times 0.25 hours per application). To estimate the annual reporting burden for registration, we examined the number of clinical studies registered annually with ClinicalTrials.gov and found an average of 17,000 registrations per year since the enactment of FDAAA. From this total, we estimate that approximately 5,000 studies would be applicable clinical trials of drugs (including biological products) and 500 would be applicable trials of devices subject to FDAAA. The remaining 11,500 studies would be registered voluntarily. We estimate the time to complete an initial registration

to be 7 hours (including time to extract, reformat and submit information which has already been produced for other purposes). This estimate is consistent with that used on the previous PRA clearance and incorporates 4 hours for data extraction and 3 hours for reformatting. Based on previous experience, we estimate that each registration record will be updated an average of eight times and that each update takes approximately 2 hours. Applying these figures to the estimated number of trials to be registered per year produces an annual burden estimate of 391,000 hours. Of this total, 126,500 hours are associated with the mandatory registration of trials subject to FDAAA, and 264,500 hours are associated with voluntary registrations. The burden of results submission consists of the time and effort needed to summarize information from a clinical trial, format it, and enter it into the databank. We estimate that of the 5,500 applicable clinical trials that are registered each year, approximately 1,845 will be required to submit results each year (1,500 trials of drugs and biological products, and 345 trials of devices). We estimate that each results record will submitted once and updated twice to reflect changes in the data analysis, additional results of subsequent pre-specified outcome measures, or additional adverse event information. Based on information available from various organizations about results submission times, comments made at a public meeting held in April 2009, responses to estimates in previous OMB clearance documents (73 FR 58972, Oct. 8, 2008), and feedback from respondents who have submitted results to ClinicalTrials.gov, we have increased our estimate of the average response time to 25 hours from the 10 hour estimate included in the previous OMB clearance request. We estimate that updates take 8 hours, an increase over the 5 hour estimate included in the previous OMB clearance request for adverse event information. In addition, we estimate that 3,655 trials per year will submit certifications to ClinicalTrials.gov indicating that they qualify for delayed results submission, and another 200 trials will request extensions to the submission deadline for good cause, as permitted by FDAAA. We expect that it would take no more than 30 minutes for a responsible party to determine that a certification is required and to submit the necessary information through ClinicalTrials.gov. For extension requests, we estimate that the time to prepare a request and submit it to ClinicalTrials.gov would be no more than 2 hours. Using these figures, we estimate the annualized hourly burden for submitting results information, certifications, and extension requests to be 77,872.5 hours. There are no capital costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance 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.

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: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301–402–9680 or email your request to *sharlipd@mail.nih.gov.*

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.

Dated: April 10, 2012.

David H. Sharlip,

NLM Project Clearance Liaison, National Library of Medicine, National Institutes of Health.

[FR Doc. 2012–9083 Filed 4–13–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 USC, as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel E-Technology Tools for Extending the Reach of Prevention Interventions in Rural and Remote Locations (5567)

Date: April 30, 2012.

Time: 1:30 p.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Nadine Rogers, Ph.D., Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Blvd., Room 4229, MSC 9550, Bethesda, MD 20892–9550, 301–402–2105, *rogersn2@nida.nih.gov*.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel Rapid Portable Devices to Measure Drug Use (1206).

Date: May 1, 2012.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, *lf33c.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 10, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–9055 Filed 4–13–12; 8:45 am]

BILLING CODE 4140–01–P