

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 be 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.

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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.

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