

While many clinical studies are registered and submit results information 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.

This extension request does not include any changes to the information submission requirements for ClinicalTrials.gov that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 and for which the public comment period closed on March 23, 2015 (79 FR 225, Nov. 21, 2014). The

NIH is continuing to review submitted public comments as it prepares the final rule. The NIH will make any corresponding changes to the ClinicalTrials.gov information collection via separate procedure.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 682,535.

ESTIMATED ANNUALIZED BURDEN HOURS

Submission type	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
PRS Account	5,700	1	15/60	1,425
Initial Registration	23,000	1	7	161,000
Updates	23,000	8	2	368,000
Initial Results	3,700	1	25	92,500
Updates	3,700	2	8	59,200
Certification to Delay Results	700	1	30/60	350
Extension Request	30	1	2	60

Dated: August 13, 2015.

David Sharlip,

Project Clearance Liaison, NLM, NIH.

[FR Doc. 2015-20473 Filed 8-18-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; National Toxicology Program (NTP) Level of Concern Categories Study (NIEHS)

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 of Environmental Health Sciences (NIEHS), 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: Dr. Kristina Thayer, Director of the Office of Health Assessment and Translation, Division of National Toxicology Program, NIEHS, P.O. Box 12233, Mail Drop K2-04, Research Triangle Park, NC 27709, or call non-toll-free number (919) 541-5021, or Email your request, including your address to: thayer@niehs.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: National Toxicology Program Level of Concern Categories, 0925-NEW, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Toxicology Program (NTP) has used a 5-point level of concern (LoC) framework to communicate NTP's assessment of the degree of concern regarding the potential human health effects of selected substances given what is known about their toxicity, level of human exposure, and pharmacokinetics. As part of its systematic review methodologies, the NTP is updating its LoC framework to enhance transparency in what the LoC categories mean, describing the factors considered in reaching conclusions and identifying strategies for improving their use as a risk communication tool. This study will use expert solicitation from five NTP stakeholder sectors (academia, industry, non-government organizations, and federal and state agencies) to aid in determining the optimal number of LoC categories for an updated LoC framework.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 300.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
LoC "Cards"	Experts	200	2	90/60	600

Dated: August 11, 2015.

Joellen M. Austin,

Associate Director for Management, NIEHS, NIH.

[FR Doc. 2015-20474 Filed 8-18-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

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 meeting.

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

Name of Committee: National Institute on Aging Initial Review Group; Neuroscience of Aging Review Committee.

Date: October 1-2, 2015.

Time: 8 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jeannette L. Johnson, Deputy Review Branch Chief, National Institutes of Health, National Institute on Aging, Gateway Building, Bethesda, MD 20892, 301-402-7705, johnsonj9@nia.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 13, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-20453 Filed 8-18-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Inherited Disease Research Access Committee.

Date: September 17-18, 2015.

Time: 5 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Camilla E. Day, Ph.D., Scientific Review Officer, CIDR, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Suite 4075, Bethesda, MD 20892, 301-402-8837, camilla.day@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: August 13, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Integrative Perspectives in Early Life.

Date: September 21, 2015.

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

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carmen Moten, Ph.D., MPH., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7703, cmoten@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 13, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-20452 Filed 8-18-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should