complete the program as well as increase their intent to practice in underserved areas.

D. *Criterion four:* The fourth criterion requires designated health professions schools to have made a significant recruitment effort to increase the number of URM individuals serving in faculty or administrative positions at the school. A major COE program focus is to improve the capacity of the school to train, recruit, and retain URM faculty and administrative personnel. A health professions school should demonstrate over a 5-year period a ''significant effort'' to recruit and retain URM faculty and administrative positions based on the number of URM faculty and new URM hires.

[FR Doc. 2012–2933 Filed 2–8–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request: Information Program on Clinical Trials; Maintaining a Registry and Results Databank

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), 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.

Proposed Collection

Title: Information Program on Clinical Trials: Maintaining a Registry and Results Databank.

Type of Information Collection Request: Revision of OMB No. 0925–0586, expiration date April 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 and to facilitate the registration of patient registries.

Frequency of Response: For clinical trials that are subject to FDAAA, responsible parties must submit the required registration information not later than 21 days after enrolling the first subject. 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. Updates to most submitted information are required at least once a year, if there are changes to report, but changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. Other clinical studies register once, at their inception, and are requested to update information annually, as necessary.

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 consists of the burden associated with registration of clinical studies and the burden associated with the submission of results information (including adverse events). These information collections will occur at different times, but submitted information is integrated into a single record for each clinical trial. 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.

FOR FURTHER INFORMATION CONTACT: 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.*

DATES: *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.

Dated: February 2, 2012.

David H. Sharlip,

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

[FR Doc. 2012–3048 Filed 2–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 of General Medical Sciences Initial Review Group Biomedical Research and Research Training Review Subcommittee A.

Date: March 8, 2012.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Carole H. Latker, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–2848, *latkerc@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: February 2, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–3035 Filed 2–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, 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 Heart, Lung, and Blood Institute Special Emphasis Panel; Technologies for Lipoprotein Subfraction Analyses.

Date: March 2, 2012.

Time: 10 a.m. to 1 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Charles Joyce, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892–7924, 301–435–0288, *cjoyce@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: February 2, 2012.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–3044 Filed 2–8–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 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