

be submitted to CBER if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information including, but not limited to, manufacturing records, certain test records, and identity test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to the CBER Director at the time of initial distribution of each lot.

Section 660.46(a) contains requirements as to the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) contains the requirements as to the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by FDA, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to

CBER if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of a product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (e.g., Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 80

manufacturers submitted samples and protocols in fiscal year (FY) 2014, under the regulations cited previously in this document. FDA estimates that approximately 76 manufacturers submitted protocols under § 610.2 and 2 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under § 660.36 or § 660.46, however FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

In the **Federal Register** of March 27, 2015 (80 FR 16393), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

The estimated total annual responses are based on FDA's final actions completed in FY 2014 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 to 5.5 hours. Under § 610.2, the average burden per response is based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) since more information is generally required to be submitted in the other protocols than under § 610.2. FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2 Lot Release Information Submission .....	76	84.54	6,197	3	18,591
660.6(b) Lot Release Information Submission .....	2	9	18	5	90
660.36(a)(2) and (b) Lot Release Information Submission .....	1	1	1	6	6
660.46(b) Lot Release Information Submission .....	1	1	1	5	5
Total .....	80	.....	6,217	.....	18,692

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: September 16, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-24028 Filed 9-21-15; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Eunice Kennedy Shriver National Institute of Child Health and Human Development; 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 section 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 Child Health and Human Development Initial Review Group Developmental Biology Subcommittee.

*Date:* November 12, 2015.

*Time:* 8:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Cathy J. Wedeen, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892-9304, (301) 435-6878, [wedeenc@mail.nih.gov](mailto:wedeenc@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: September 16, 2015.

**Michelle Trout,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-23641 Filed 9-21-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; 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 would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Cerebrovascular Disease and Aging II.

*Date:* October 22, 2015.

*Time:* 1:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute On Aging, Gateway Building, Suite 2C212, 7201

Wisconsin Ave., Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Ramesh Vemuri, Ph.D., Chief, Scientific Review Branch, National Institute On Aging, National Institutes Of Health, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-402-7700, [rv23r@nih.gov](mailto:rv23r@nih.gov).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Lifespan Connectome.

*Date:* November 9, 2015.

*Time:* 1:00 p.m. to 3:00 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:* Alexander Parsadonian, Ph.D., Scientific Review Officer, National Institute On Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, [PARSADANIANA@NIA.NIH.GOV](mailto:PARSADANIANA@NIA.NIH.GOV).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Biomarkers For AD: The Adult Children Study.

*Date:* November 12, 2015.

*Time:* 12:00 p.m. to 4:00 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:* Alexander Parsadonian, Ph.D., Scientific Review Officer, National Institute On Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, [PARSADANIANA@NIA.NIH.GOV](mailto:PARSADANIANA@NIA.NIH.GOV).

*Name of Committee:* National Institute on Aging Special Emphasis Panel; Vascular Contribution to AD and Genetic Risk Factors.

*Date:* November 16, 2015.

*Time:* 12:00 p.m. to 3:30 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:* Alexander Parsadonian, Ph.D., Scientific Review Officer, National Institute On Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, [PARSADANIANA@NIA.NIH.GOV](mailto:PARSADANIANA@NIA.NIH.GOV).

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

Dated: September 17, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-24035 Filed 9-21-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Nursing Research; 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 would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Institute of Nursing Research Initial Review Group.

*Date:* October 19-20, 2015.

*Time:* 8:00 a.m. to 12:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Weiqun Li, MD, Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd. Ste. 710, Bethesda, MD 20892 (301) 594-5966 [wli@mail.nih.gov](mailto:wli@mail.nih.gov).

*Name of Committee:* National Institute of Nursing Research Special Emphasis Panel; Institutional Training Grants

*Date:* October 20, 2015.

*Time:* 12:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

*Contact Person:* Weiqun Li, MD, Scientific Review Administrator National Institute of Nursing Research National Institutes of Health, 6701 Democracy Blvd. Ste. 710, Bethesda, MD 20892 (301) 594-5966 [wli@mail.nih.gov](mailto:wli@mail.nih.gov).

*Name of Committee:* National Institute of Nursing Research Special Emphasis Panel; Community Partnerships to Advance Research.

*Date:* October 21, 2015.

*Time:* 11:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 703, 6701 Democracy Boulevard Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Tamizchelvi Thyagarajan, Ph.D. Scientific Review Officer, National Institute of Nursing Research, National Institutes of Health, Bethesda, MD 20892 (301) 594-0343 [tamizchelvi.thyagarajan@nih.gov](mailto:tamizchelvi.thyagarajan@nih.gov).

*Name of Committee:* National Institute of Nursing Research Special Emphasis Panel;