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Maria G. Button,

Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; the Stem Cell Therapeutic Outcomes Database, OMB No. 0915-0310-Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 23, 2019.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915-0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109-129, as amended by the Stem Cell Therapeutic and Research Reauthorization Act of 2015, Public Law 114-104 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. HRSA's Healthcare Systems Bureau has established the Stem Cell Therapeutic Outcomes Database. Operation of this database necessitates certain recordkeeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation under contract to HHS. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using a standardized, electronic format. Data is collected from transplant centers, under contract, by the Medical College of Wisconsin's Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes. Over time, there is an expected increase in the number of recipients for whom data are reported as an increasing number of transplants are

performed annually and survivorship after transplantation improves.

A 60-day notice was published in the **Federal Register** on March 7, 2019, vol. 84, No. 45; pp. 8334-8335. There were no public comments.

Need and Proposed Use of the Information: HRSA uses the information to carry out its statutory responsibilities. Information is needed to monitor the clinical status of transplantation and provide the Secretary of HHS with an annual report of transplant center specific survival data. Modifications of these forms fall into several categories: Consolidating questions and removing duplicate questions across the forms, implementing 'check all that apply' formatting to reduce data entry time, and removing items no longer clinically significant (e.g., drugs). These modifications reduced the overall hours of burden inventory.

Likely Respondents: Transplant Centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents ¹	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Baseline Pre-Transplant Essential Data (TED)	200	48	9,600	² 0.68	6,560
Disease Classification	200	48	9,600	³ 0.43	4,160
Product Form (includes Infusion, HLA, and Infectious Disease Marker inserts)	200	45	9,000	1.00	9,000
100-day Post-TED	200	48	9,600	0.85	8,160
6 month Post-TED	200	43	8,600	0.85	7,310
1 year Post-TED	200	40	8,000	0.65	5,200
2 year Post-TED	200	34	6,800	0.65	4,420
3+ years Post-TED	200	172	34,400	⁴ 0.52	17,773
Total	200		95,600		62,583

¹ The total of 200 is the number of centers completing the form; the same group will complete all of the forms.

² The decimal is rounded down, and the actual number is .683333333.

³ The decimal is rounded down, and the actual number is .433333333.

⁴ The decimal is rounded up, and the actual number is .516667.

Maria G. Button,

Director, Division of the Executive Secretariat.

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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, 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; AD Centers Review.

Date: September 19–20, 2019.

Time: 1:30 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Rockville, MD 20852.

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Gateway Building, Suite 2W200, Bethesda, MD 20892, 301-496-9374, grimaldim2@mail.nih.gov.

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

Dated: August 16, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-18079 Filed 8-21-19; 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, 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; Aging and Mobility.

Date: September 13, 2019.

Time: 4:30 p.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892.

Contact Person: Anita H. Undale, MD, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-827-7428, anita.undale@nih.gov.

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

Dated: August 16, 2019.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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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, 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: NIGMS Initial Review Group Training and Workforce Development Subcommittee—D Review of MARC and RISE applications

Date: October 24–25, 2019.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Tracy Koretsky, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, MSC 6200, Room 3AN.12F, Bethesda, MD 20892, 301 594 2886, tracy.koretsky@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; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 16, 2019.

Miguelina Perez,

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, 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; Neuroimaging of AD and Related Dementias.

Date: September 24, 2019.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892.

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, parsadaniana@nia.nih.gov.