diseases, and the donor (and product/source material) test results for relevant disease agents are negative or nonreactive. To prevent transmission of disease when manufacturing ACTPs, it is necessary to determine that donors are healthy and free from relevant disease agents. Transmission of relevant disease agents by an ACTP may be the result of the presence of relevant disease agents in the donated cells/tissues (either within the cells/tissues, within other accompanying cells/tissues, or in the extracellular components of the product).

The CGMP requirements for new animal drugs are found in Title 21 parts 210 and 211 of the Code of Federal Regulations (21 CFR parts 210 and 211). These regulations are broad in scope, and FDA recognizes that they do not specifically or fully address some aspects of the manufacture of ACTPs, including donor eligibility determinations. This guidance offers FDA's recommendations for determining that a donor is free from relevant disease agents and is an eligible source of cells, tissues, or both, used in the manufacture of allogeneic or xenogeneic ACTPs. We encourage sponsors and manufacturers of ACTPs to contact CVM early in the product development process to discuss considerations specific to approval of a new animal drug product.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on donor eligibility for animal cells, tissues, and cell- and tissue-based products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: September 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–20517 Filed 9–22–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–XXXX]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: SHIP COVID–19 Testing and Mitigation Program Data Collection—New, Emergency

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 4, 2021.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: SHIP COVID–19 Testing and Mitigation Program Data Collection, OMB No. 0906–XXXX—New, Emergency.

Abstract: The American Rescue Plan Act of 2021 (Pub. L. 117–2) provided one-time funding for awards that will be carried out under Section 711 of the Social Security Act (42 U.S.C. 912(b)(5)). The Small Rural Hospital Improvement Program (SHIP) is requesting approval of an emergency ICR. State grantees will improve health care in rural areas by using the funding to provide support to eligible rural hospitals to increase COVID–19 testing efforts, expand access to testing in rural communities, and expand the range of mitigation activities.

Need and Proposed Use of the Information: The terms and conditions for this program specify that, ''hospitals will be required to report on the number of tests provided and categories in which the funding is spent.'' The data will allow HRSA to ensure SHIP COVID–19 recipients are meeting the terms and conditions of their funding, while providing HRSA with information on the effectiveness of funds distributed through this program.

Likely Respondents: The respondents will be hospital staff and designated representatives.

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	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
SHIP COVID–19 Testing and Mitigation Data Reporting.	1,540: Number of unique organizations funded through the program.	6: Reported on a quarterly basis during the 18 month program or the end of the public health emergency (whichever is first).	9,240	.25	2,310: Total hours spent on responses for all funded organizations over a 2-year period.
Total	1,540		9,240		2,310.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–20601 Filed 9–22–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 Minority Health and Health Disparities Special Emphasis Panel; Impact of Structural Racism and Discrimination on Minority Health and Health Disparities.

Date: November 15–17, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Karen Nieves-Lugo, M.P.H., Ph.D., Scientific Review Officer, Office of Extramural Research Activities, National Institute on Minority Health and Health Disparities, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 480–4727, *karen.nieveslugo@nih.gov*.

Dated: September 17, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–20583 Filed 9–22–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel; Exploratory Data Science Methods and Algorithm Development, Early-Stage Development of Data Science Technologies, and Enhancement or Sustainment of Data Science Tools for Infectious and Immune-Mediated Diseases (R21, U01, U24).

Date: October 26–28, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Sandip Bhattacharyya, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G42, Rockville, MD 20852, 240–292–0189, *sandip.bhattacharyya@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: September 17, 2021.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–20585 Filed 9–22–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.