research uses, they should not be required and instead should be optional.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA and OHRP on ''Considerations for Including Tissue Biopsies in Clinical Trials.'' It does not establish any rights for any person and is not binding on FDA, OHRP, 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information related to the protection of human subjects under 21 CFR part 50 and the IRB under 21 CFR part 56 have been approved under OMB control number 0910–0130; the collection of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 312, including Form FDA 1572, have been approved under OMB control number 0910–0014 and the collections of information in the guidance document, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program'' have been approved under OMB control number 0910–0756. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303. The collections of information in 45 CFR part 46 and the final rule entitled, ''Federal Policy for the Protection of Human Subjects'' (known as the Common Rule), have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31536 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; A Solicitation of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) for Small Business Innovation Research (SBIR) Contract Proposals (PHS 2025–1), NIH/NIAID 142—Adjuvant Development for Vaccines.

Date: January 30–31, 2025.

Time: 9:00 a.m. to 6:00 p.m.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G22, Rockville, MD 20892 (Video Assisted Meeting).

Agenda: To review and evaluate contract proposals.

Contact Person: Michael M. Opata, 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 3G22, Rockville, MD 20892, 240–627–3319, *michael.opata@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–00099 Filed 1–6–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 1009 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 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 Institute of Allergy and Infectious Diseases Special Emphasis Panel; HHS–NIH–CDC–SBIR PHS 2025–1 Phase I and Fast Track: Devices and Materials-Based Platforms for the Delivery of Broadly Neutralizing Antibodies (Topic 138).

Date: January 24, 2025.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3E71, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Samita S. Andreansky, 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 3E71, Rockville, MD 20892, 240–669–2915, *samita.andreansky@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: January 2, 2025.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

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