

and Users to ensure it does not result in an activity prohibited by any U.S. export regulations, or other restriction. Before taking further action, to ensure full compliance with all the terms and conditions of the restrictions placed on the parties on this list, the Provider must check the official publication of restricted parties in the **Federal Register**. They should also check the official lists of restricted parties maintained on the websites of the Departments of Commerce, State, and the Treasury.

Following up with the U.S. Government in Cases Where Malintent is Suspected by Providers or Third-Party Vendors: If sequence or Customer screening raises concerns that are not alleviated through follow-up screening, Providers and Third-Party Vendors are encouraged to contact the nearest FBI Field Office Weapons of Mass Destruction (WMD) Coordinator. Institutions are encouraged to work with their Principal Users and End Users to help them understand that only individuals with legitimate, bona fide, and peaceful need should obtain oligonucleotides containing SOC's.

Records Retention: The Revised Guidance recommends that Providers, Third-Party Vendors, and Manufacturers:

- Using responsible business practices, retain records of Customer orders for at least 8 years.
- Archive the following information: Customer information (point-of contact name, organization, address, email, and phone number), order sequence information (nucleotide sequences ordered, vector used), and order information (date placed and shipped, shipping address, receiver name).
- Develop and document protocols for sequence screening and for determining whether a sequence hit qualifies as a SOC and maintain records of these protocols—even if no longer current—for at least 8 years.
- Retain screening documentation of all hits for at least 8 years, even if the order was deemed acceptable.
- Retain records of any follow-up screening, even if the order was ultimately filled, for at least 8 years.

Periodic Review, Evaluation, and Improvement of This Guidance: This Revised Guidance is addressing biosecurity risks that have emerged in a dynamic and rapidly developing technological landscape. It is likely that new risks will emerge and that new technological approaches will also appear to address biosecurity risks. As such, this Revised Guidance encourages the further development of mechanisms to detect SOC's and screening strategies

for sequences that contribute to pathogenicity and toxicity. For instance, strategies may be used by malicious Customers to obfuscate SOC's, including engineering pathogenic or toxic proteins with completely novel sequences. In such cases, synthetic oligonucleotide orders may contain 50 bp windows that are not a match to any known sequence. Although there are likely several legitimate explanations for orders of sequences with no matches in nature (e.g., oligonucleotides to populate microarrays or to store digital information), in such cases, it may be possible to use predictive bioinformatic algorithms to screen sequences that are not a match to any known sequences to determine if they could produce proteins that are structurally and functionally identical to SOC's. This Revised Guidance encourages Providers to continue to develop these methods to best ensure the safety of the synthetic oligonucleotide research enterprise. Likewise, while there is not a comprehensive and curated database available presently for sequences that may contribute to pathogenicity or toxicity by enabling the circumvention of medical countermeasures (MCM), such as therapeutics or vaccines, such information may become increasingly available in coming years. This Revised Guidance encourages the identification of such MCM-evasive sequences and may revisit the definition of SOC's in the future, given advances in this field.

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

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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 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; NIAID Investigator Initiated Program Project Applications (P01 Clinical Trial Not Allowed).

Date: May 31, 2022.

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 3G41, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Tara Capece, Ph.D., MPH, 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 3G41, Rockville, MD 20852, 240-191-4281, capecet2@niaid.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: April 25, 2022.

Tyeshia M. Roberson-Curtis,

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 Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Drug Abuse Special Emphasis Panel; NIDA Animal Genomics Program.

Date: May 25, 2022.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).