

massively paralleled multiplexed screening method using next generation sequencing (NGS). This method uses sample-specific barcoded indexes that detect both SARS-CoV-2 virus and the host's transcriptional response to infection simultaneously. By matching existing laboratory protocols for PCR-based sample processing, this assay is easily incorporated into existing CLIA-certified facilities. This testing approach provides the capability for testing tens of thousands of patient samples in a large bolus, allowing accurate and fast-turnaround SARS-CoV-2 testing capacity at population scale, and permits massive scale monitoring of at-risk individuals with minimal processing delay.

Potential Commercial Applications: Diagnostic test for detecting infectious organisms, including SARS-CoV-2.

Competitive Advantages

- Reduction in reagents needed to perform a test, reducing test cost and bottleneck of critical reagents used during nucleic acid amplification.
- Simultaneously detect the pathogen and a host's transcriptional response to infection by the pathogen.
- Gene expression information from the donor can be used to predict disease severity.

Development Stage:

- Early stage.
- Data from tests of human samples available.

Inventors: Oswaldo Alonso Lozoya (NIEHS), and Brian Papas (NIEHS).

Intellectual Property: HHS Reference No. E-241-2020-0; U.S Provisional Patent Application 63/116,031 filed November 19, 2020.

Licensing Contact: Vidita Choudhry, Ph.D.; 301-594-4095; vidita.choudhry@nih.gov. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Dated: January 8, 2021.

Bruce D. Goldstein,

Director, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2021-00825 Filed 1-14-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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/or 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 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 Special Emphasis Panel; Maternal and Pediatric HIV/AIDS Research.

Date: March 12, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Child Health and Human Development, 6710B Rockledge Drive, Bethesda, MD 20817 (Video-Assisted Meeting).

Contact Person: Luis E. Dettin, Ph.D., M.S., M.A., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131B, Bethesda, MD 20892, (301) 827-8231, luis_dettin@nih.gov.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Centers to Advance Research in Endometriosis (CARE) (P01 Clinical Trial Not Allowed).

Date: March 16-17, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6710B Rockledge Drive, Rockledge Drive, Bethesda, MD 20817 (Video-Assisted Meeting).

Contact Person: Derek J. McLean, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2125B, Bethesda, MD 20892-7002, Derek.McLean@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: January 12, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-00918 Filed 1-14-21; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2020-0016]

Meeting To Implement Pandemic Response Voluntary Agreement Under the Defense Production Act

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Announcement of meetings.

SUMMARY: The Federal Emergency Management Agency (FEMA) held a series of meetings to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic.

DATES: The first meeting took place on Wednesday, January 6, 2021, from 2 to 4 p.m. Eastern Time (ET). The second meeting took place on Thursday, January 7, 2021, from 2 to 4 p.m. ET. The third meeting took place on Friday, January 8, 2021, from 2 to 3:30 p.m. ET.

FOR FURTHER INFORMATION CONTACT: Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at OB3I@fema.dhs.gov or via phone at (202) 212-1666.

SUPPLEMENTARY INFORMATION: Notice of these meetings is provided as required by section 708(h)(8) of the Defense Production Act (DPA), 50 U.S.C. 4558(h)(8), and consistent with 44 CFR part 332.

The DPA authorizes the making of "voluntary agreements and plans of action" with, among others, representatives of industry and business to help provide for the national defense.¹ The President's authority to facilitate voluntary agreements was delegated to the Secretary of Homeland Security with respect to responding to the spread of COVID-19 within the United States in Executive Order 13911.² The Secretary of Homeland Security has further delegated this authority to the FEMA Administrator.³

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission, FEMA completed and published in the **Federal Register** a "Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to

¹ 50 U.S.C. 4558(c)(1).

² 85 FR 18403 (Apr. 1, 2020).

³ DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).

Respond to a Pandemic” (Voluntary Agreement).⁴ Unless terminated prior to that date, the Voluntary Agreement is effective until August 17, 2025, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Agreement may be used to prepare for or respond to any pandemic, including COVID-19, during that time.

On December 7, 2020, the first plan of action under the Voluntary Agreement—the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 (Plan of Action)—was finalized.⁵ The Plan of Action established several subcommittees under the Voluntary Agreement, focusing on different aspects of the Plan of Action.

The meetings were chaired by the FEMA Administrator or his delegate, and attended by the Attorney General or his delegate and the Chairman of the Federal Trade Commission or his delegate. In implementing the Voluntary Agreement, FEMA adheres to all procedural requirements of 50 U.S.C. 4558 and 44 CFR part 332.

Meeting Objectives: The objectives of the meetings were to:

(1) Establish priorities for COVID-19 PPE under the Voluntary Agreement;

(2) Identify tasks that should be completed under specific subcommittees; and

(3) Identify information gaps and areas that merit sharing (from both FEMA to private sector and vice versa).

Meetings Closed to the Public: By default, the DPA requires meetings held to implement a voluntary agreement or plan of action be open to the public.⁶ However, attendance may be limited if the Sponsor⁷ of the voluntary agreement finds that the matter to be discussed at a meeting falls within the purview of matters described in 5 U.S.C. 552b(c). The Sponsor of the Voluntary Agreement, the FEMA Administrator, found that these meetings to implement

the Voluntary Agreement involved matters which fell within the purview of matters described in 5 U.S.C. 552b(c) and were therefore closed to the public.⁸

Specifically, the meetings to implement the Voluntary Agreement could have required participants to disclose trade secrets or commercial or financial information that is privileged or confidential. Disclosure of such information is a basis for closing meetings pursuant to 5 U.S.C. 552b(c)(4). In addition, the success of the Voluntary Agreement depends wholly on the willing and enthusiastic participation of private sector participants. Failure to close these meetings could have had a strong chilling effect on participation by the private sector and caused a substantial risk that sensitive information would be prematurely released to the public, resulting in participants withdrawing their support from the Voluntary Agreement and thus significantly frustrating the implementation of the Voluntary Agreement. Frustration of an agency’s objective due to premature disclosure of information allows for the closure of a meeting to pursuant to 5 U.S.C. 552b(c)(9)(B).

Pete Gaynor,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2021-00893 Filed 1-14-21; 8:45 am]

BILLING CODE 9111-19-P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS-2021-0004]

Agency Information Collection Activities: COVID-19 Contact Tracing, COVID-19 Contact Tracing Scripts, COVID-19 Contact Tracing Form

AGENCY: Department of Homeland Security (DHS).

ACTION: 60-day notice and request for comments; extension without change of a currently approved collection, 1601-0027.

SUMMARY: The Department of Homeland Security, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in

⁸ Under 50 U.S.C. 4558(h)(8), the Sponsor generally must publish in the **Federal Register** prior notice of any meeting held to carry out a voluntary agreement or plan of action. However, when the Sponsor finds that the matters to be discussed at such meeting fall within the purview of matters described in 5 U.S.C. 552b(c), notice of the meeting may instead be published in the **Federal Register** within ten days of the date of the meeting. See 50 U.S.C. 4558(h)(8).

accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted until March 16, 2021. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: You may submit comments, identified by docket number Docket # DHS-1601-0027, at:

○ *Federal eRulemaking Portal:* <http://www.regulations.gov>. Please follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number Docket # DHS-1601-0027. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

COVID-19 Contact Tracing information is necessary to support the President’s National Guidelines for all phases of *Opening Up America Again*. The Office of Management and Budget (OMB) M-20-23 Memorandum for Heads of Executive Department requires employers to develop and implement policies and procedures for workforce contact tracing following an employee’s COVID-19 positive test. The M-20-23 Memorandum requires symptomatic Federal employees and contractors to follow their Agency’s process if they are symptomatic or test positive for COVID-19. It specifies that the agency processes should protect the anonymity and privacy of Federal employees and contractors, to the extent possible, while disclosing only the information necessary for agencies to take appropriate actions of notifying potentially affected employees and cleaning the facility. Additionally, per the Centers for Disease Control and Prevention guidance entitled *Get and Keep America Open*, COVID-19 Contact Tracing is essential to reduce the spread of COVID-19. Furthermore, in response to the Coronavirus Pandemic, public health leaders are calling for communities around the country to ramp up capacity and implement a massive contact tracing effort to control spread of the Coronavirus. The response and recovery from the effect of COVID-19 will continue to present Federal agencies with unprecedented challenges, as well as opportunities for improvement, that require new processes and practices such as COVID-19 Contact Tracing to keep the workforce and the public safe. As DHS plans to reconstitute the workforce, it is

⁴ 85 FR 50035 (Aug. 17, 2020). The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the voluntary agreement may not reasonably be achieved through an agreement having less anticompetitive effects or without any voluntary agreement and published the finding in the **Federal Register** on the same day. 85 FR 50049 (Aug. 17, 2020).

⁵ See 85 FR 78869 (Dec. 7, 2020). See also 85 FR 79020 (Dec. 8, 2020).

⁶ See 50 U.S.C. 4558(h)(7).

⁷ “[T]he individual designated by the President in subsection (c)(2) [of section 708 of the DPA] to administer the voluntary agreement, or plan of action.” 50 U.S.C. 4558(h)(7).