

Human Monoclonal and Bispecific Antibodies Targeting SARS-CoV-2 Coronavirus

Description of Technology

SARS-CoV-2 is a virus of the Coronavirus family that has emerged as a major public health concern. The first cases of SARS-CoV-2 were reported in China and rapidly spread worldwide leading to a global pandemic. The highest morbidity and mortality have been reported in the elderly and immunocompromised. Antibody therapeutics have great importance for advanced cases of SARS-CoV-2 where a vaccine would not be effective and may be more effective than a vaccine in certain high-risk populations.

Scientists at NIAID have developed recombinant monoclonal antibodies that are effective *in vitro* and *in vivo* at neutralizing SARS-CoV-2. Based on whether they are mono-specific or bi-specific and where they bind to the SARS-CoV-2 virus, these antibodies can be subdivided into four groups that target (A) the receptor-binding-domain (RBD) of the SARS-CoV-2 spike protein, (B) the N-terminal domain (NTD) of the SARS-CoV-2 spike protein, (C) dual locations on the RBD, or (D) both the RBD and NTD. Crucially, these antibodies effectively neutralize the emerging B.1.1.7 and B.1.351 SARS-CoV-2 variants of concern.

These recombinant monoclonal antibodies can be used alone, in combination, or with other therapeutics for the treatment of SARS-CoV-2. In addition to their potential as therapeutics, these antibodies against SARS-CoV-2 can be used as prophylactics and in assay development. They can contribute to the surveillance, diagnosis, and prevention of SARS-CoV-2. Furthermore, the specific antibody sequences and targets will inform vaccine development and establishment of long-term immunity.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Prophylaxis or therapeutics against SARS-CoV-2.
- Diagnostics and surveillance of SARS-CoV-2.
- Vaccine research.

Competitive Advantages

- Potent neutralizing activity against SARS-CoV-2, including against B.1.1.7 and B.1.351 variants.

- Prophylactic usage against SARS-CoV-2 in normal or high-risk populations.

- Therapeutic treatment, alone or in combination, in patients with SARS-CoV-2 infection.
- Assay development for surveillance, diagnostic, and prevention measures.
- Identification of vaccine candidates which elicit protective antibodies against SARS-CoV-2 infections.

Development Stage

- Pre-clinical.

Inventors: Joshua Tan, Ph.D., Peter Crompton, M.D., Hyeseon Cho, Ph.D., Mary Peterson, Kristina Kay Gonzales-Wartz, Ph.D., all of NIAID.

Publications: Cho, Hyeseon, et al. "Ultrapotent bispecific antibodies neutralize emerging SARS-CoV-2 variants." *bioRxiv* 2021.04.01.437942;

Intellectual Property: HHS Reference No. E-030-2021-0; US provisional application No. 63/127,077 filed on December 17, 2020.

Licensing Contact: To license this technology, please contact Dawn Taylor-Mulneix 301-767-5189 or dawn.taylor-mulneix@nih.gov, and reference E-030-2021-0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Dawn Taylor-Mulneix at 301-767-5189 or dawn.taylor-mulneix@nih.gov.

Dated: April 7, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-07709 Filed 4-14-21; 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 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 Child Health and Human Development Initial Review Group; Biobehavioral and Behavioral Sciences Subcommittee.

Date: June 28, 2021.

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

Agenda: To review and evaluate grant applications.

Place: NICHD Offices, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Clay Mash, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131A, Bethesda, MD 20892, (301) 496-6866, mashc@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 12, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-07735 Filed 4-14-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: June 17-18, 2021.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kee Forbes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, 301-272-4865, pyonkh2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 12, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-07746 Filed 4-14-21; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2021-0016]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, Department of Homeland Security (DHS).

ACTION: Committee management; notice of Federal Advisory Committee meeting.

SUMMARY: The DHS Data Privacy and Integrity Advisory Committee will meet on Friday, May 14, 2021, via virtual conference. The meeting will be open to the public.

DATES: The DHS Data Privacy and Integrity Advisory Committee will meet on Friday, May 14, 2021, from 1:00 p.m. to 3:00 p.m. Please note that the virtual conference may end early if the Committee has completed its business.

ADDRESSES: The meeting will be held via a virtual forum (conference information will be posted on the Privacy Office website in advance of the meeting at www.dhs.gov/privacy-advisory-committee), or call (202) 343-1717, to obtain the information. For information on services for individuals with disabilities, or to request special assistance during the meeting, please contact Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, as soon as possible.

To facilitate public participation, we invite public comment on the issues to be considered by the Committee as listed in the **SUPPLEMENTARY**

INFORMATION section below. A public comment period will be held during the meeting, and speakers are requested to limit their comments to three minutes. If you would like to address the Committee at the meeting, we request that you register in advance by contacting Nicole Sanchez at the address provided below. The names and affiliations of individuals who address the Committee will be included in the public record of the meeting. Please note that the public comment period may end before the time indicated, following the last call for comments. Advanced written comments or comments for the record, including from persons who wish to submit comments and who are unable to participate or speak at the meeting, should be sent to Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, by May 7, 2021. All submissions must include the Docket Number (DHS-2021-0016) and may be submitted by any *one* of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.

- **Email:** PrivacyCommittee@hq.dhs.gov. Include the Docket Number (DHS-2021-0016) in the subject line of the message.

- **Fax:** (202) 343-4010.

- **Mail:** Nicole Sanchez, Designated Federal Officer, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, 245 Murray Lane SW, Mail Stop 0655, Washington, DC 20528.

Instructions: All submissions must include the words "Department of Homeland Security Data Privacy and Integrity Advisory Committee" and the Docket Number (DHS-2021-0016). Comments received will be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

The DHS Privacy Office encourages you to register for the meeting in advance by contacting Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, at PrivacyCommittee@hq.dhs.gov. Advance registration is voluntary. The Privacy Act Statement below explains how DHS uses the registration information you may provide and how you may access or correct information retained by DHS, if any.

Docket: For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Advisory Committee, go to <http://www.regulations.gov> and search for docket number DHS-2021-0016.

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FOR FURTHER INFORMATION CONTACT:

Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, Department of Homeland Security, 245 Murray Lane SW, Mail Stop 0655, Washington, DC 20528, by telephone (202) 343-1717, by fax (202) 343-4010, or by email to PrivacyCommittee@hq.dhs.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Title 5, U.S.C. The DHS Data Privacy and Integrity Advisory Committee provides advice at the request of the Secretary of Homeland Security and the DHS Chief Privacy Officer on programmatic, policy, operational, administrative, and technological issues within DHS that relate to personally identifiable information, as well as data integrity and other privacy-related matters. The Committee was established by the Secretary of Homeland Security under the authority of 6 U.S.C. 451.

Proposed Agenda

During the meeting, the Committee will provide updates on its response to the latest taskings from the DHS Chief Privacy Officer. The Tasking Memorandum is available at: <https://www.dhs.gov/publication/dpiac-meeting-october-27-2020>. If you wish to submit written comments, you may do so in advance of the meeting by forwarding them to the Committee at the locations listed under **ADDRESSES**. The final agenda will be posted on or before May 7, 2021, on the Committee's website at www.dhs.gov/dhs-data-privacy-and-integrity-advisory-committee-meeting-information.

Privacy Act Statement: DHS's Use of Your Information

Authority: DHS requests that you voluntarily submit this information under its following authorities: The Federal Records Act, 44 U.S.C. 3101; the FACA, 5 U.S.C. appendix; and the Privacy Act of 1974, 5 U.S.C. 552a.

Principal Purposes: When you register to attend a DHS Data Privacy and Integrity Advisory Committee meeting, DHS collects your name, contact information, and the organization you represent, if any. We use this information to contact you for purposes related to the meeting, such as to confirm your registration, to advise you of any changes in the meeting, or to assure that we have sufficient materials to distribute to all attendees. We may also use the information you provide for public record purposes such as posting