

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Jenish Patel, Ph.D., 240-669-2894; jenish.patel@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Monoclonal Antibodies Against Bacillus Anthracis Antigens

Description of Technology: Anthrax, whether resulting from natural or bioterrorist-associated exposure, is a constant threat to human health. *Bacillus anthracis* is the causative agent of anthrax. It is surrounded by a polypeptide capsule of poly-gamma-D-glutamic acid (gamma-D-PGA), which is essential for virulence, is poorly immunogenic and has anti-phagocytic properties. Antibodies to the capsule have been shown to enhance phagocytosis and killing of encapsulated bacilli. The lethality of anthrax is primarily the result of the effects of anthrax toxin, which has 3 components: A receptor-binding protein known as “protective antigen” (PA) and 2 catalytic proteins known as “lethal factor” (LF) and “edema factor” (EF). Although production of an efficient anthrax vaccine is an ultimate goal, the benefits of vaccination can be expected only if a large proportion of the population at risk is immunized. The low incidence of anthrax suggests that

large-scale vaccination may not be the most efficient means of controlling this disease. In contrast, passive administration of neutralizing human or chimpanzee monoclonal antibody to a subject at risk for anthrax or exposed to anthrax could provide immediate efficacy for emergency prophylaxis against or treatment of anthrax.

Several monoclonal antibodies (mAbs) against gamma-D-PGA, PA, LF and EF of anthrax were isolated from a phage display library generated from immunized chimpanzees. Two anti-PA, and two anti-LF mAbs efficiently neutralized the cytotoxicity of lethal toxin in a macrophage lysis assay. One anti-EF mAb efficiently neutralized edema toxin in cell culture. All of these five neutralizing mAbs protected animals from anthrax toxin challenge. There are two anti-gamma-D-PGA mAbs that showed strong opsonophagocytic killing of bacilli in vitro assays. These two mAbs were also tested for protection of mice challenged with virulent anthrax spores and results showed that both mAbs provided full or nearly full protection. Since chimpanzee immunoglobulins are virtually identical to human immunoglobulins, these chimeric chimpanzee mAbs may have clinically useful applications.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications:

- Prophylaxis, therapeutics or diagnostics against *B. anthracis* antigens

Competitive Advantages:

- Strongly neutralizing antibodies
- Known regulatory pathway
- Potential for use as both a prophylaxis and therapy

Development Stage:

- In vivo (animal)

Inventors:

Anti-PGA mAbs: Zhaochun Chen (NIAID), Robert Purcell (NIAID), Rachel Schneerson (NIACHD), Joanna Kublerkiel (NICHHD), Lily Zhongdong Dai (NICHHD).

All other mAbs: Zhaochun Chen (NIAID), Stephen Leppla (NIAID), Suzanne Emerson (NIAID), Robert Purcell (NIAID), and Mahtab Moayeri (NIDCR).

Publications:

- Z Chen et al. Efficient neutralization of anthrax toxin by chimpanzee monoclonal antibodies against protective antigen. *J Infect Dis.* 2006 Mar 1;193(5): 625-633.
- Z Chen et al. *Bacillus anthracis* Capsular Conjugates Elicit Chimpanzee

Polyclonal Antibodies That Protect Mice from Pulmonary Anthrax. *Clin Vaccine Immunol.* 2015 Aug; 22(8): 902-908.

Intellectual Property: HHS Reference Nos. E-146-2004, E-123-2007 and E-125-2008.

Licensing Contact: To license this technology, please contact Jenish Patel, Ph.D., 240-669-2894; jenish.patel@nih.gov.

Dated: February 7, 2020.

Wade W. Green,

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

[FR Doc. 2020-03443 Filed 2-20-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; 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 Drug Abuse Special Emphasis Panel; The National Drug Abuse Treatment Clinical Trials Network (UG1 Clinical Trial Required).

Date: March 5, 2020.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building, 6001 Executive Blvd., Rockville, MD 20852.

Contact Person: Gerald L. McLaughlin, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, 6001 Executive Blvd., Room 4235, MSC 9550, Bethesda, MD 20892-9550, 301-827-5819, gm145a@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: February 14, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-03444 Filed 2-20-20; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2020-0043]

National Commercial Fishing Safety Advisory Committee; Initial Solicitation for Members

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The Coast Guard is requesting applications from persons interested in serving in membership on the National Commercial Fishing Safety Advisory Committee ("Committee"). This recently established Committee will advise the Secretary of the Department of Homeland Security on matters relating to national commercial fishing safety. Please read this notice for a description of the 18 Committee positions we are seeking to fill.

DATES: Your completed application should reach the Coast Guard on or before April 21, 2020.

ADDRESSES: Applicants should send a cover letter expressing interest in an appointment to the National Commercial Fishing Safety Advisory Committee and a resume detailing the applicant's experience. We will not accept a biography. Applications should be submitted via one of the following methods:

- *By Email:* CGfishsafe@uscg.mil (preferred).
- *By Mail:* Commandant (CG-CVC-3), Attn: CFSAC ADFO, U.S. Coast Guard Stop 7501, 2703 Martin Luther King Jr. Avenue SE, Washington, DC 20593-7501.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Wendland, Alternate Designated Federal Officer of the National Commercial Fishing Safety Advisory Committee; Telephone 202-372-1245 or Email at CGfishsafe@uscg.mil.

SUPPLEMENTARY INFORMATION: The National Commercial Fishing Safety Advisory Committee is a federal advisory committee. It will operate under the provisions of the *Federal Advisory Committee Act*, 5 U.S.C. Appendix, and the administrative

provisions contained in Section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018* (specifically, 46 U.S.C. 15109).

The Committee was established on December 4, 2018, by the *Frank LoBiondo Coast Guard Authorization Act of 2018*, which added section 15102, National Commercial Fishing Safety Advisory Committee, to Title 46 of the U.S. Code (46 U.S.C. 15102). The Committee will advise the Secretary of Homeland Security on matters relating to national commercial fishing safety.

In accordance with 46 U.S.C section 15109(a), the Committee is required to hold meetings at least once a year, but it may meet more frequently as needs may require. The meetings are held at a location selected by the U.S. Coast Guard.

All members will serve at their own expense and receive no salary or other compensation from the Federal Government, with the exception that members may be reimbursed for travel and per diem in accordance with Federal Travel Regulations.

Under 46 U.S.C. 15109 (f) (6), membership terms expire on December 31 of the third full year after the effective date of your appointment. The Secretary may require an individual to have passed an appropriate security background examination before appointment to the Committee, 46 U.S.C. 15109(f)(4). In this initial solicitation for Committee members, we will consider applications for all 18 positions:

(A) Ten members shall represent the commercial fishing industry and—

(i) as a group, shall together reflect a regional and representational balance; and (ii) as individuals each shall have experience—

(I) in the operation in which chapter 45 of this title applies; or

(II) as a crew member or processing line worker on a fish processing vessel.

(B) One member shall represent naval architects and marine engineers.

(C) One member shall represent manufacturers of equipment for vessels to which

Chapter 45 of this title applies.

(D) One member shall represent education and training professionals related to fishing vessels, fish processing vessels, and fish tender vessels safety and personnel qualifications.

(E) One member shall represent underwriters that insure vessels to which chapter 45 of this title applies.

(F) One member shall represent owners of vessels to which chapter 45 of this title applies.

(G) Three members shall represent the general public and to the extent possible, shall include—

(i) an independent expert or consultant in maritime safety,

(ii) a marine surveyor who provides services to vessels to which chapter 45 of this title applies; and

(iii) a person familiar with issues affecting fishing communities and the families of fishermen.

Each member of the Committee must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on matters related to national commercial fishing safety.

If you are selected as a member drawn from the general public, you will be appointed and serve as a Special Government Employee as defined in 18 U.S.C. 202(a). Applicants for appointment as a Special Government Employee are required to complete a Confidential Financial Disclosure Report (OGE Form 450) for new entrants and if appointed as a member must submit Form 450 annually. The Coast Guard may not release the reports or the information in them to the public except under an order issued by a Federal Court or as otherwise provided under the Privacy Act (5 U.S.C 552a). Only the Designated U.S. Coast Guard Ethics Official or his or her designee may release a Confidential Financial Disclosure Report. Applicants can obtain this form by going to the website of the Office of Government Ethics (www.oge.gov), or by calling or emailing the individual listed above in the **FOR FURTHER INFORMATION CONTACT** section.

Applications for member drawn from the general public must be accompanied by a completed OGE Form 450.

Registered lobbyists are not eligible to serve on Federal Advisory Committees in an individual capacity. See "Revised Guidance on Appointment of Lobbyists to Federal Advisory Committees, Boards and Commissions" (79 FR 47482, August 13, 2014). Registered lobbyists are "lobbyists," as defined in 2 U.S.C. 1602, who are required by 2 U.S.C. 1603 to register with the Secretary of the Senate and the Clerk of the House of Representatives.

The Department of Homeland Security does not discriminate in selection of Committee members on the basis of race, color, religion, sex, national origin, political affiliation, sexual orientation, gender identity, marital status, disabilities and genetic information, age, membership in an employee organization, or any other non-merit factor. The Department of Homeland Security strives to achieve a