

Dated: June 24, 2016.

Elizabeth A. Fowler,
Deputy Director for Management Operations,
Indian Health Service.

[FR Doc. 2016-16008 Filed 7-5-16; 8:45 am]

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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 co-owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 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 and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD 20850-9702, Tel. 240-276-5515 or email ncitechtransfer@mail.nih.gov. A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Technology description follows.

Title of Invention: Shark Antibodies that Target Tumor and Viral Antigens.

Description of Technology: Shark V-NAR (Variable New Antigen Receptor) antibodies are an emerging class of therapeutic candidates. As single domain (heavy chain) antibodies with an extensive antigen-binding repertoire, shark V-NAR antibodies may provide advantages over traditional antibodies. Specifically, the smaller size of shark V-NAR antibodies may provide increased solubility, thermal stability, refolding capacity, and the ability to recognize

epitopes that are sterically hindered from recognition by larger antibodies, but without loss of specificity in antigen-binding.

Researchers at the National Cancer Institute's Laboratory of Molecular Biology (NCI LMB) have developed an immunological platform that includes the development of a shark V-NAR antibody phage display library, isolation of specific antibodies that bind to several tumor and viral antigens from the library, and the development of the specific antibodies for treatment of cancer or viral infection. Specific antibody targets for binders include tumor-specific antigens (GPC3 [*Clone F1*], PD1 [*Clone A1*], HER2 [*Clones A6/A7*]), and viral antigens (MERS [*Clones A3, A7, A8, B4, and B5*] and SARS [*Clone O1*]).

Anti-glypican 3 (GPC3) V-NAR, Clone F1, is an antibody of immediate interest since it has already shown specific binding to GPC3-expressing tumor cells *in vitro*. Thus, anti-GPC3 V-NAR represents a viable candidate for development of an antibody-toxin/drug conjugate (ADC and immunotoxin), a bispecific antibody or a chimeric antigen receptor (CAR) against GPC3-expressing tumor cells.

Potential Commercial Applications:

- Therapeutic Uses
 - Use as unconjugated antibodies
 - Use as targeting moieties for immunoconjugates such as CARs, ADCs, Immunoconjugates, bispecific antibodies, etc.
 - Diagnostic agent for detecting and monitoring target-expressing malignancies
- Value Proposition:*
- Potential to be first to market with high specificity and binding to targets resulting in less non-specific cell killing, therefore fewer potential side-effects for the patient
 - Small size of antibodies enhances stability, solubility, and target recognition

Development Stage:

- *In-vitro* data—Shark/Human anti-GPC3 chimera can bind to GPC3-positive tumor cells
 - *In-vivo* testing
- Inventor(s):* Mitchell Ho (NCI), *et al.*
Intellectual Property: US Provisional Application 62/334,194 (HHS Reference No. E-113-2016/0-US-01) filed May 10, 2016 entitled "Variable New Antigen Receptor (VNAR) Antibodies and Antibody Conjugates Targeting Tumor and Viral Antigens".

Collaboration Opportunity:

Researchers at the NCI seek parties interested in licensing or co-developing shark V-NAR antibodies and/or conjugates for cancer therapeutics and/or diagnostics.

Contact Information: Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Dated: June 28, 2016.

John D. Hewes,

Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016-15898 Filed 7-5-16; 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 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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; Opportunities for Collaborative Research at the NIH Clinical Center (U01).

Date: August 2, 2016.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Rockville, MD 20892-9823, (240) 669-5023, fdesilva@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: June 29, 2016.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-15883 Filed 7-5-16; 8:45 am]

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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 (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Topics in Non-HIV Microbial Diagnostic and Detection Research.

Date: July 11, 2016.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301-435-1167, pandyaga@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(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: June 29, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-15880 Filed 7-5-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences (NCATS); Notice of Organizational Change

SUMMARY: The National Center for Advancing Translational Sciences (NCATS), of the National Institutes of Health (NIH), is seeking public comment regarding its proposal to reorganize its Office of Policy, Communications, and Strategic Alliances.

DATES: Any interested person may file written comments by sending an email to NCATSReorgComments@nih.gov by July 22, 2016. The statement should include the individual's name, and when applicable, professional affiliation. NCATS will respond to comments by email no later than July 29, 2016.

ADDRESSES: The following email address has been established for questions and/or comments on the reorganization: NCATSReorgComments@nih.gov.

FOR FURTHER INFORMATION CONTACT: Nicole Martino, Management Analyst, National Center for Advancing Translational Sciences, NCATSReorgComments@nih.gov, 301-443-8358

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), NCATS will launch public Web site information at <https://ncats.nih.gov/about/center/org/reorg> on July 8, 2016, to encourage further public discussion of the proposal to reorganize its Office of Policy, Communications and Strategic Alliances. NCATS also will provide information via its Facebook page (<https://www.facebook.com/ncats.nih.gov>) and Twitter account (https://twitter.com/ncats_nih_gov). The proposal is aimed at better reflecting NCATS' alignment and priorities while ensuring the Center remains a leader in public education and community involvement related to translational science.

Dated: June 28, 2016.

Keith Lamirande,

Associate Director for Administration, NCATS, NIH.

[FR Doc. 2016-15865 Filed 7-5-16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Diseases and Microbiology.

Date: July 28-29, 2016.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Grand Chicago Riverfront, 71 East Wacker Drive, Chicago, IL 60601.

Contact Person: Alexander D. Politis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435-1150, politisa@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Review of National Center for Advanced ESR Technology (ACERT).

Date: August 4-6, 2016.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Statler Hotel, 130 Statler Drive, Ithaca, NY 14853.

Contact Person: Nuria E. Assa-Munt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451-1323, assamunu@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: June 29, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

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