

**SUPPLEMENTARY INFORMATION:** The BSC will provide input to the NTP on programmatic activities and issues. Preliminary agenda topics include discussions on strategic realignment of NTP and updates on peer reviews. Please see the preliminary agenda for information about the specific presentations. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting website (<http://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting website.

**Meeting and Registration:** The meeting is open to the public with time scheduled for oral public comments. Registration to view the webcast is by October 9, 2018, at <http://ntp.niehs.nih.gov/go/165>. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

**Written Public Comments:** NTP invites written and oral public comments on the agenda topics. Guidelines for public comments are available at [https://ntp.niehs.nih.gov/ntp/about\\_ntp/guidelines\\_public\\_comments\\_508.pdf](https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf). The deadline for submission of written comments is October 1, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

**Oral Public Comments:** Registration for oral comments is on or before October 1, 2018, at <http://ntp.niehs.nih.gov/go/165>. Oral comments will be received only during the formal public comment periods indicated on the preliminary agenda. Oral comments may be by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Each organization is allowed one time slot, and five minutes will be allotted to each time slot.

**Meeting Materials:** The preliminary meeting agenda is available on the meeting web page (<http://>

[ntp.niehs.nih.gov/go/165](http://ntp.niehs.nih.gov/go/165)) and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

**Background Information on the BSC:** The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, biochemistry, epidemiology, risk assessment, carcinogenesis, mutagenesis, molecular biology, behavioral toxicology, neurotoxicology, immunotoxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets biannually. The authority for the BSC is provided by 42 U.S.C. 217a, section 222 of the Public Health Service Act (PHS), as amended.

The BSC is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

Dated: August 20, 2018

**Brian R. Berridge,**

*Associate Director, National Toxicology Program.*

[FR Doc. 2018-18778 Filed 8-29-18; 8:45 am]

**BILLING CODE 4140-01-P**

## 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:** Yogikala Prabhu, Ph.D., 301-761-7789; [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov). Licensing information and copies of the patent applications 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.

#### Methods of Diagnosing and Treating CHAPLE, a Newly Identified Orphan Disease Description of Technology

This technology is directed towards a potential treatment for a new disease, CHAPLE (Complement Hyperactivation, Angiopathic thrombosis, and Protein-Losing Enteropathy), identified by NIAID researchers. CHAPLE is associated with GI symptoms and vascular thrombosis and is caused by loss-of-function variants in the gene encoding the complement regulatory protein CD55. The disease is caused by enhanced activation of the complement pathway and complement-mediated induction of intestinal lymphangiectasia and protein-losing enteropathy. There is no current therapy for the newly described heritable genetic disorder and the symptoms are poorly controlled. CHAPLE is similar to other complement activating diseases that can be fatal, particularly for patients who develop severe thrombosis. Recent off-label use of a complement inhibiting drug, eculizumab (CD55 inhibitor) was shown to provide a dramatic benefit in patients with CHAPLE disease with an immediate correction of gastrointestinal protein loss. Thus, identification of CD55 deficiency in CHAPLE patients, and the possibility to use complement inhibitory drugs provide opportunities for treatment.

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

- Diagnostic.
- Therapeutic.

#### Competitive Advantages

- There is no therapy currently approved for CHAPLE disease, and

patients face a debilitating and often time fatal course of the disease.

- Anti-complement drugs (including eculizumab) has the potential to treat CHAPLE disease.

#### Development Stage

- Pre-clinical.
- Clinical.

#### Inventors

Dr. Michael J. Lenardo (NIAID), Dr. Helen Su (NIAID), Ahmet Ozen (NIAID), William A. Comrie (NIAID), Mr. Rico C. Ardy (CeMM, Austria), and Dr. Kaan Boztug (CeMM, Austria).

#### Intellectual Property

HHS Reference No. E-251-2016/0, U.S. Provisional Patent Application Number 62/394,630, filed September 14, 2016, and PCT/US2017/051413 filed September 13, 2017.

#### Licensing Contact

Yogikala Prabhu, Ph.D., 301-761-7789; [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov).

#### 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 the use of Eculizumab or other complement inhibitory drugs for the treatment of CHAPLE. For collaboration opportunities, please contact Yogikala Prabhu, Ph.D., 301-761-7789; [prabhuyo@niaid.nih.gov](mailto:prabhuyo@niaid.nih.gov).

Dated: August 18, 2018.

#### Suzanne M. Frisbie,

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

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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, 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 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 contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Shared and High-end Mass Spectrometers.

*Date:* September 20-21, 2018.

*Time:* 11:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hotel Nikko San Francisco, 222 Mason Street, San Francisco, CA 94102.

*Contact Person:* Sudha Veeraraghavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301-435-1504, [sudha.veeraraghavan@nih.gov](mailto:sudha.veeraraghavan@nih.gov).

*Name of Committee:* Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Surgery, Anesthesiology and Trauma Study Section.

*Date:* September 26-27, 2018

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

*Agenda:* To review and evaluate grant applications

*Place:* Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Weihua Luo, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5114, MSC 7854, Bethesda, MD 20892, (301) 435-1170, [luow@csr.nih.gov](mailto:luow@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; PAR Panel: Neural regulation of Cancer.

*Date:* September 26, 2018.

*Time:* 12:00 p.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301-495-1718, [jakobir@mail.nih.gov](mailto:jakobir@mail.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: August 23, 2018.

#### David D. Clary,

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-18772 Filed 8-29-18; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel CTSA.

*Date:* September 13-14, 2018.

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

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, Brookside Conference Rooms A & B, 5701 Marinelli Road, Rockville, MD 20852.

*Contact Person:* Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1080, Bethesda, MD 20892-4878, 301-435-0813, [henriqvu@mail.nih.gov](mailto:henriqvu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Research Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 23, 2018.

#### David D. Clary,

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2018-18773 Filed 8-29-18; 8:45 am]

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