hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $13,536. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $24,675 + $13,536 = $38,211. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2019 will be $38,211.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2019

Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications and certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2019, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2019 based on the fully supported FTE hourly rates for FY 2019 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2019
Renewal application fee for recognized accreditation body ...	$21,350
Renewal application fee for directly accredited certification body	28,999
Annual fee for certification body directly accredited by FDA	21,056

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application.

For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the invoice date. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: August 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18802 Filed 8–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting.

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: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel, NIBIB Team-based R25 Review (2019/01).

Date: September 24, 2018.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Blvd., Suite 920, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, 6707 Democracy Blvd., Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail@nih.gov.*

Dated: August 23, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–18769 Filed 8–29–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is by webcast only and is open to the public. Registration is requested for oral comment and is required to access the webcast. Information about the meeting and registration are available at *http://ntp.niehs.nih.gov/go/165*.

DATES:

Meeting: October 9, 2018; 1:00—4:00 p.m. (EDT).

Written Public Comment Submissions: Deadline is October 1, 2018.

Oral Comments: Deadline is October 1, 2018.

Registration to view the webcast: Deadline October 9, 2018.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Webpage: The preliminary agenda, registration, and other meeting materials are at *http://ntp.niehs.nih.gov/go/165*.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Mary Wolfe, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2–03, Research Triangle Park, NC 27709. Phone: 984–287–3209, Fax: 301–451–5759, Email: *wolfe@niehs.nih.gov*. Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

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*. 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*) 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*. 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 (*C*omplement *H*yperactivation, *A*ngiopathic thrombosis, and *P*rotein-*L*osing *E*nteropathy), 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