

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Post-Baccalaureate Supplemental Application.	Post-Baccalaureate (Including Post-Master's) Individuals.	50	1	30/60	25
Graduate Student Application	Graduate Students	30	1	2	60
Postdoctoral Fellowship Application	Postdoctoral Candidates	50	1	2	100
Reference Letter	PIs, professors, supervisors	240	1	30/60	120
Totals	370	370	305

Dated: October 2, 2018.

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2018-22319 Filed 10-12-18; 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, 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; Genomic Centers for Infectious Diseases (U19 Clinical Trial Not Allowed).

Date: November 8-9, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Eleazar Cohen, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G62A, National Institute of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20899823, (240) 669-5081, ecohen@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: October 5, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-22311 Filed 10-12-18; 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 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 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; NIAID Peer Review Meeting.

Date: November 5, 2018.

Time: 9:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

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

Contact Person: Lee G. Klinkenberg, Ph.D., Scientific Review Program, DEA/NIAID/NIH/DHHS, 5601 Fishers Lane, MSC-9823, Bethesda, MD 20892-9834, 301-761-7749, lee.klinkenberg@nih.gov.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Sexually Transmitted Infections CRC; Vaccine Development (U19).

Date: November 8-9, 2018.

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

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Annie Walker-Abbey, Ph.D., Scientific Review Officer, Scientific Review Program, AID/NIH/DHHS, 5601 Fishers Lane, Room 3E70A, Rockville, MD 20852, 240-627-3390, aabbey@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: October 5, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-22312 Filed 10-12-18; 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 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 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; NIH Pathway to Independence Award (K99/R00).

Date: October 17, 2018.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, (301) 827-5817, m McGuire@mail.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Device-Based Treatments for Substance Use Disorders (UG3/UH3) (Clinical Trial Optional).

Date: October 22, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Julia Berzhanskaya, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4234, MSC 9550, Bethesda, MD 20892, 301-827-5840, julia.berzhanskaya@nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Cutting-Edge Basic Research Awards (CEBRA) (R21-Clinical Trial Optional).

Date: October 24, 2018.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, (301) 827-5817, m McGuire@mail.nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Development of Medications to Prevent and Treat Opioid Use Disorders and Overdose (UG3/UH3) (Clinical Trials Optional).

Date: November 15, 2018.

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

Agenda: To review and evaluate cooperative agreement applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Ivan K. Navarro, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, Room 4242, MSC 9550, Bethesda, MD 20892, 301-827-5833, ivan.navarro@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: October 5, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-22309 Filed 10-12-18; 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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-402-5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

High Density Lipoprotein (HDL) Targeting Protease Inhibitor

Available for licensing and commercial development is intellectual property covering a class of lipoproteins targeting protease inhibitors and methods of their use for treating a protease-mediated disease. Alpha-1-antitrypsin (A1AT) deficiency occurs in about 1 in 2500 individuals in the United States and Europe. Persons with this condition develop severe liver disease and emphysema/chronic obstructive pulmonary disease (COPD). The current treatment for A1AT deficiency includes intravenous infusion of purified human A1AT protein. This treatment strategy is expensive and only moderately effective. A recent study demonstrated improvement in the treatment of A1AT deficiency in a mouse model of emphysema by pre-incubating A1AT with high density lipoprotein (HDL) particles prior to infusion. This resulted in improvements in lung morphology and inflammatory markers in the lung

compared to A1AT treatment alone. The mechanism for this improvement in function of A1AT when bound to HDL is believed to be increased trafficking of A1AT to the lung. The lipoprotein targeting protease inhibitory peptide of the present invention represents provides advances upon these existing methods. First, it replaces the need for full length A1AT protein with a known small peptide inhibitor of elastase (the natural target protease of A1AT; a small tetra-peptide with the sequence Ala-Ala-Pro-Val-chloromethylketone). Second, the peptide can be conjugated by amine reactive chemistry to a lipoprotein targeting motif. The inventors have data linking the peptide to a Vitamin E with a polyethylene glycol spacer arm to distance the functional AAPV peptide from the targeting moiety and to provide improved solubility. Third, the approach promises improved efficacy over the current standard of care (A1AT infusion) because the overall molecule is small molecule, 2.5 kDa versus 52 kDa for the full length A1AT protein. An HDL particle can generally accommodate only one molecule of A1AT, whereas many copies of our VitE-PEG-AAPV peptide can reside on an HDL particle providing a significant increase in potency.

Potential Commercial Applications

- Alpha-1-antitrypsin deficiency
- severe liver disease
- emphysema/chronic obstructive pulmonary disease

Development Stage

- Early stage

Inventors: Alan Remaley and Scott Maxwell Gordon (both of NHLBI)

Relevant Publications: Gordon, *et al.* Molecular & Cellular Proteomics 14: 10.1074/mcp.M115.054031, 3247-3257, 2015.

Intellectual Property: HHS Reference No. E-155-2016; U.S Patent Application 15/297,054 filed October 18, 2016.

Licensing Contact: Michael Shmilovich, Esq. CLP; 301-435-5019; shmilovm@mail.nih.gov.

Dated: September 24, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018-22316 Filed 10-12-18; 8:45 am]

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