

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Application Waiver/Supplemental A Research	HHS 426	45	1	10	450
Application Waiver/Supplemental B Clinical Care	HHS 426	35	1	10	350
Total	800

Terry Clark,
Office of the Secretary, Asst Paperwork Reduction Act Reports Clearance Officer.
 [FR Doc. 2020-00717 Filed 1-16-20; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; Early Phase Clinical Trials for Psychosocial Interventions.

Date: February 11, 2020.

Time: 9:00 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: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, *dsommers@mail.nih.gov*.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Early Phase Clinical Trials—Pharma/Device.

Date: February 20, 2020.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center Building (NSC), 6001

Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6154, MSC 9606, Bethesda, MD 20892, 301-443-7861, *dsommers@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: January 13, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020-00688 Filed 1-16-20; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of Regulatory T-Cell Therapies for the Treatment of Hemophilia A (HA)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the **SUPPLEMENTARY INFORMATION** section of this notice to TeraImmune, Inc. (“TeraImmune”) located in Rockville, Maryland.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases’ Technology Transfer and Intellectual Property Office on or before February 3, 2020 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Dr. Yogikala Prabhu,

Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC9804, Rockville, MD 20852-9804; Telephone: (301) 496-2644; Facsimile: (240) 627-3117; Email: *prabhuyo@niaid.nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- U.S. Patent 9,481,866—issued November 1, 2016, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells” [HHS Reference No. E-279-2011/0-US-02]
- U.S. Divisional Application No.15/284,840—filed October 4, 2016, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells”. [HHS Reference No. E-279-2011/0-US-03]

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory will be the United States and the field of use will be limited to: “Human cell-based therapeutics for the treatment of Hemophilia A in patients that have inhibitory Factor VIII antibodies.”

The technology is directed to a method for producing or growing cell populations that are enriched for stable, highly suppressive regulatory T cells (Tregs). Tregs are critical in regulating immune system processes that maintain tolerance to self-antigens and prevent immune mediated diseases. The method takes a population of cells comprising stable, regulatory T cells and enriched for specific CD markers, cultures these cells in the presence of interleukin-2, an anti-CD3 antibody, an anti-CD28 antibody, and oligodeoxynucleotides of specified length having a phosphorothioate backbone, and yields the expansion of the initial population of regulatory T-cells. The expanded Tregs may then be used for the treatment of immune-mediated diseases.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.

The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this notice will be presumed to contain business confidential information, and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: January 6, 2020.

Wade W. Green,

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

[FR Doc. 2020-00721 Filed 1-16-20; 8:45 am]

BILLING CODE 4140-01-P

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 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Clinical Neuroscience and Neurodegeneration Study Section.

Date: February 10–11, 2020.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Alessandra C. Rovescalli, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Rm. 5205 MSC 7846, Bethesda, MD 20892, (301) 435-1021, rovescalia@mail.nih.gov.

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Biomedical Computing and Health Informatics Study Section.

Date: February 12–13, 2020.

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

Agenda: To review and evaluate grant applications.

Place: AC Hotel by Marriott National Harbor, 156 Waterfront Street, National Harbor, MD 20745.

Contact Person: Karen Nieves Lugo, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, Bethesda, MD 20892, (301) 594-9088, karen.nieveslugo@nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Cellular and Molecular Technologies Study Section.

Date: February 12–13, 2020

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

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Tatiana V. Cohen, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5213, Bethesda, MD 20892, 301-455-2364, tatiana.cohen@nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Biostatistical Methods and Research Design Study Section.

Date: February 13–14, 2020.

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

Agenda: To review and evaluate grant applications.

Place: San Francisco Marriott Fisherman's Wharf, 1250 Columbus Ave., San Francisco, CA 94133.

Contact Person: Chittari V. Shivakumar, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301-408-9098, chittari.shivakumar@nih.gov.

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section

Date: February 13–14, 2020.

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

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

Contact Person: Kenneth Ryan, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3218, MSC 7717, Bethesda, MD 20892, 301-435-0229, kenneth.ryan@nih.hhs.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Clinical and Integrative Diabetes and Obesity Study Section.

Date: February 13–14, 2020.

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

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW, Washington, DC 20036.

Contact Person: Hui Chen, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive Bethesda, MD 20892, 301-435-1044, chenhui@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Integrative Physiology of Obesity and Diabetes Study Section

Date: February 13–14, 2020.

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

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Metro Center, 775 12th Street NW, Washington, DC 20005.

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, MSC, Bethesda, MD 20892, (301) 451-6319, rojasr@mail.nih.gov.

Name of Committee: Vascular and Hematology Integrated Review Group; Atherosclerosis and Inflammation of the Cardiovascular System Study Section.

Date: February 13–14, 2020.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Catamaran Resort, 3999 Mission Boulevard, San Diego, CA 92109.

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301-435-1206, komissar@mail.nih.gov.

Name of Committee: Cell Biology Integrated Review Group; Membrane Biology and Protein Processing Study Section.

Date: February 13–14, 2020.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301-806-2765, larkinja@csr.nih.gov

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Biophysics of Neural Systems Study Section.

Date: February 13–14, 2020.

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