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]

**BILLING CODE 4150–38–P**

## 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.