

Dated: April 3, 2013.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, NCI, NIH.*

[FR Doc. 2013-08270 Filed 4-8-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Advancing Translational Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

*Date:* April 30, 2013.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mohan Viswanathan, Ph.D., Acting Director, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1084, Bethesda, MD 20892-4874, 301-435-0829, [mv10f@nih.gov](mailto:mv10f@nih.gov).

*Name of Committee:* National Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

*Date:* May 1, 2013.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mohan Viswanathan, Ph.D., Acting Director, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1084, Bethesda, MD 20892-4874, 301-435-0829, [mv10f@nih.gov](mailto:mv10f@nih.gov).

*Name of Committee:* National Center for Advancing Translational Sciences Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings.

*Date:* May 3, 2013.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Mohan Viswanathan, Ph.D., Acting Director, Office of Grants Management & Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1084, Bethesda, MD 20892-4874, 301-435-0829, [mv10f@nih.gov](mailto:mv10f@nih.gov).

Dated: April 2, 2013.

**David Clary,**

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

[FR Doc. 2013-08149 Filed 4-8-13; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of An Exclusive Evaluation Option License: Pre-clinical Evaluation of Anti-tyrosine Kinase-like Orphan Receptor 1 Immunotoxins for the Treatment of Human Cancers

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Application 61/172,099 entitled "Anti-human ROR1 Antibodies" [HHS Ref. E-097-2009/0-US-01], U.S. Patent Application 60/703,798 entitled "Mutated *Pseudomonas* Exotoxins with Reduced Antigenicity" [HHS Ref. E-262-2005/0-US-01], U.S. Patent Application 60/969,929 entitled "Deletions in Domain II of *Pseudomonas* Exotoxin A that Remove Immunogenic Epitopes with Affecting Cytotoxic Activity" [HHS Ref. E-292-2007/0-US-01], U.S. Patent Application 61/241,620 entitled "Improved *Pseudomonas* Exotoxin A with Reduced Immunogenicity" [HHS Ref. E-269-2009/0-US-01], U.S. Patent Application 61/483,531 entitled "Recombinant Immunotoxin Targeting Mesothelin" [HHS Ref. E-117-2011/0-US-01], U.S. Patent Application 61/

495,085 entitled "*Pseudomonas* Exotoxin A with Less Immunogenic T-Cell/or B-Cell Epitopes" [HHS Ref. E-174-2011/0-US-01], U.S. Patent Application 61/535,668 entitled "*Pseudomonas* Exotoxin A with Less Immunogenic B-Cell Epitopes" [HHS Ref. E-263-2011/0-US-01], and all related continuing and foreign patents/patent applications for the technology family, to SPEED BioSystems, LLC. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to pre-clinical evaluation of lead therapeutic candidates for the development and use of anti-tyrosine kinase-like orphan receptor 1 (ROR1) targeted immunotoxins for the treatment of human ROR1 expressing cancers, wherein the immunotoxin comprises an anti-ROR1 antibody designated as 2A2 and *Pseudomonas* exotoxin A (PE). Upon expiration or termination of the exclusive evaluation option license, SPEED will have the right to execute an exclusive patent commercialization license which will supersede and replace the exclusive evaluation option license with no broader territory than granted in the exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 24, 2013 will be considered.

**ADDRESSES:** Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4633; Facsimile: (301) 402-0220; Email: [wongje@od.nih.gov](mailto:wongje@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** This invention concerns anti-ROR1 immunotoxin comprising an anti-ROR1 antibody designated as 2A2 and PE as a treatment for human ROR1 expressing cancers. The immunotoxin will comprise a chimeric mouse anti-human receptor tyrosine kinase-like orphan receptor 1 monoclonal antibody whereas the immunotoxin will have a toxin domain derived from PE. PE toxin's domain have been modified in

various ways in order to reduce the immunogenicity of the molecule to improve its therapeutic value while at the same time maintaining the toxin's ability to trigger cell death. The immunotoxin provides targeted cytotoxic delivery to cancer cells while sparing normal cells thereby resulting in therapies with fewer side effects.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation option license, and a subsequent exclusive patent commercialization license, may be granted unless within fifteen (15) days from the date of this published notice, the NIH 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 404.7.

Any additional, properly filed, and complete applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive evaluation option license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: April 2, 2013.

**Richard U. Rodriguez,**

*Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 2013-08148 Filed 4-8-13; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Substance Abuse and Mental Health Services Administration**

**Agency Information Collection Activities: Submission for OMB Review; Comment Request**

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of

information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

**Project: Protection and Advocacy for Individuals With Mental Illness (PAIMI) Final Rule, 42 CFR Part 51 (OMB No. 0930-0172)—Extension**

These regulations meet the directive under 42 U.S.C. 10826(b) requiring the Secretary to promulgate final regulations to carry out the PAIMI Act. The regulations contain information collection requirements. The Act authorizes funds to support activities on behalf of individuals with significant (severe) mental illness (adults) or emotional impairment (children/youth) [42 U.S.C. 10802 (4)]. Only entities designated by the governor of each State, including American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, the Mayor of the District of Columbia, and the tribal councils for the American Indian Consortium (the Hopi and Navajo Nations in the Four Corners region of the Southwest), to protect and advocate the rights of persons with developmental disabilities are eligible to receive PAIMI Program grants [the Act at 42 U.S.C. at 10802 (2)]. These grants are based on a formula prescribed by the Secretary [42 U.S.C. at 10822(a)(1)(A)].

On January 1, each eligible State protection and advocacy (P&A) system is required to prepare a report that describes its activities, accomplishments, and expenditures to protect the rights of individuals with mental illness supported with payments from PAIMI Program allotments during the most recently completed fiscal year. The PAIMI Act [at 42 U.S.C. 10824(a)] requires that each P&A system transmit a copy of its annual report to the Secretary (via SAMHSA/CMHS) and to the State Mental Health Agency where the system is located. These annual PAIMI Program Performance Reports (PPR) to the Secretary must include the following information:

- The number of (PAIMI-eligible) individuals with mental illness served;

- A description of the types of activities undertaken;
- A description of the types of facilities providing care or treatment to which such activities are undertaken;
- A description of the manner in which the activities are initiated;
- A description of the accomplishments resulting from such activities;
- A description of systems to protect and advocate the rights of individuals with mental illness supported with payments from PAIMI Program allotments;
- A description of activities conducted by States to protect and advocate such rights;
- A description of mechanisms established by residential facilities for individuals with mental illness to protect such rights; and,
- A description of the coordination among such systems, activities and mechanisms;
- Specification of the number systems that are public and nonprofit systems established with PAIMI Program allotments;
- Recommendations for activities and services to improve the protection and advocacy of the rights of individuals with mental illness and a description of the need for such activities and services that were not met by the State P&A systems established under the PAIMI Act due to resource or annual program priority limitations.

\*\* The PAIMI Rules [42 CFR Part 51] mandate that each State P&A system may place restrictions on either its case or client acceptance criteria developed as part of its annual PAIMI priorities. Each P&A system is required to inform prospective clients of any such restrictions when they request a service [42 CFR 51.32(b)].

This PAIMI PPR summary must include a separate section, prepared by the PAIMI Advisory Council (PAC) that describes the council's activities and its assessment of the State P&A system's operations [42 U.S.C. 10805(7)].

The burden estimate for the annual State P&A system reporting requirements for these regulations is as follows.

42 CFR Citation	Number of respondents	Responses per respondent	Burden per response (Hrs.)	Total annual burden
51.(8)(a)(2) Program Performance Report .....	57	1	26.0	11,482
51.8(8)(a)(8) Advisory Council Report .....	57	1	10.0	1570
51.10 Remedial Actions:				
Corrective Action Plans .....	7	1	8.0	56
Implementation Status Report .....	7	3	2.0	42
51.23(c) Reports, materials and fiscal data provided to the PAC .....	57	1	1.0	57