

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Instrument	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Annual burden hours
Clinical Trials	Initial Registration	5,500	1	2	11,000
	Amendment	5,500	4	1	22,000
	Accrual Updates	5,500	4	15/60	5,500
Total	16,500	38,500

Dated: January 25, 2013.
Vivian Horovitch-Kelley,
NCI Project Clearance Liaison, National Cancer Institute (NCI), National Institutes of Health (NIH).
 [FR Doc. 2013-02123 Filed 1-31-13; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Human Monoclonal Antibodies Against DR4

AGENCY: National Institutes of Health, Public Health Service, 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 evaluation option license to practice the inventions embodied in PCT Patent Application No. PCT/US2011/040750 and foreign equivalents thereof entitled "Agonistic Human Monoclonal Antibodies Against DR4" (HHS Ref. No. E-158-2010/0) to Customized Biosciences, Inc., which is located in Pasadena, CA. The patent rights in these inventions have been assigned to the United States of America.

The prospective start-up exclusive commercial license territory may be worldwide and the field of use may be limited to "use of the Licensed Patent Rights to develop therapeutic agents for the treatment of lymphomas, leukemias, hepatocellular cancer, colorectal cancer, ovarian cancer, lung cancer, rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, amyotrophic lateral sclerosis, and Alzheimer's disease".

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 19, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments,

and other materials relating to the contemplated exclusive evaluation option license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; Email: *hastingsw@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: The tumor necrosis factor (TNF)-related apoptosis-inducing ligand (TRAIL) and its functional receptors, DR4 and DR5, have been recognized as promising targets for cancer treatment. Therapeutics targeting TRAIL and its receptors are not only effective in killing many types of tumors but they also synergize with traditional therapies, and show efficacy against tumors that are otherwise resistant to conventional treatments.

The above identified patent application relates to the development of two human monoclonal antibodies (mAbs) that bind to death receptor 4 ("DR4"). The two mAbs were selected from a human phage displayed Fab library by panning against a recombinant DR4 extracellular domain. Therefore the two mAbs are fully human. These antibodies could have considerable potential as cancer therapeutics alone or in combination with other drugs. Further, these antibodies could be used as a research tool for the study of DR4.

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

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 start-up exclusive commercial 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: January 24, 2013.
Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.
 [FR Doc. 2013-02152 Filed 1-31-13; 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 (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: Center for Scientific Review Special Emphasis Panel, RFA Panel: Studies in Neonatal Resuscitation.

Date: February 27-28, 2013.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Gary Hunnicutt, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, 301-435-0229, *gary.hunnicutt@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Dermatology, Rheumatology and Inflammation.

Date: February 27, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Aruna K Behera, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4211, MSC 7814, Bethesda, MD 20892, 301-435-6809, beheraak@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR-11-100: Alzheimer's Disease Pilot Clinical Trials.

Date: February 27, 2013.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mark Lindner, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7770, Bethesda, MD 20892, 301-435-0913, mark.lindner@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflict: Societal and Ethical Issues in Research.

Date: February 27, 2013.

Time: 2:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Lisa Steele, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3139, MSC 7770, Bethesda, MD 20892, 301-594-6594, steeleln@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Par Panel: Biobehavioral pathways of physical activity and weight control on Cancer prognosis and survival.

Date: February 27, 2013.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Fungai Chanetsa, MPH, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3135, MSC 7770, Bethesda, MD 20892, 301-408-9436, fungai.chanetsa@nih.hhs.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Healthcare Delivery and Methodologies Academic Research Enhancement Review.

Date: February 27, 2013.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

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

Contact Person: Melinda Jenkins, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3156, MSC 7770, Bethesda, MD 20892, 301-437-7872, jenkinsml2@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships: Neurodevelopment, Synaptic Plasticity and Neurodegeneration.

Date: February 28–March 1, 2013.

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

Agenda: To review and evaluate grant applications.

Place: The St. Regis Hotel, 923 16th & K Streets NW., Washington, DC 20006.

Contact Person: Mary Schueler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7846, Bethesda, MD 20892, 301-451-0996, marygs@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PA12-006: Academic Research Enhancement Award.

Date: February 28, 2013.

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

Agenda: To review and evaluate grant applications.

Place: The Westin Riverwalk, 420 W Market Street, San Antonio, TX 78205.

Contact Person: Rebecca Henry, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3222, MSC 7808, Bethesda, MD 20892, 301-435-1717, henryrr@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Small Business: Drug Discovery for Aging, Neuropsychiatric and Neurologic Disorders.

Date: February 28–March 1, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Chevy Chase Pavilion, 4300 Military Rd. NW., Washington, DC 20015.

Contact Person: Yuan Luo, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207 MSC 7846, Bethesda, MD 20892-7846, 301-827-7915.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowships: Genes, Genomes, and Genetics.

Date: February 28, 2013.

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

Agenda: To review and evaluate grant applications.

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

Contact Person: Ross D Shonat, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6172, MSC 7892, Bethesda, MD 20892, 301-435-2786, ross.shonat@nih.hhs.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Review of Neuroscience AREA Grant Applications.

Date: February 28–March 1, 2013.

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

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Carole L Jelsema, Ph.D., Chief and Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7850, Bethesda, MD 20892, (301) 435-1248, jelsemac@csr.nih.gov.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group, Social Sciences and Population Studies B Study Section.

Date: February 28–March 1, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Valerie Durrant, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, (301) 827-6390, durrantv@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts: Epidemiology and Genetics of Cancer.

Date: February 28, 2013.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Julia Krushkal, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3148, MSC 7770, Bethesda, MD 20892, 301-435-1782, krushkalj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 25, 2013.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-02153 Filed 1-31-13; 8:45 am]

BILLING CODE 4140-01-P

ADVISORY COUNCIL ON HISTORIC PRESERVATION

Proposed Alterations to Pawtucket Dam on the Merrimack River in Lowell, MA; Public Meeting

AGENCY: Advisory Council on Historic Preservation.

ACTION: Notice of public meeting.

Overview Information: Public meeting to inform the drafting of formal