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: *hastingw@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.*