

for health care services performed by such providers; and to serve as a legal document for health and medical care authorized by IHS and rendered by health care providers under contract with the IHS. *Affected Public:* Patients,

health and medical care providers or Tribal Governments. *Type of Respondents:* Health and medical care providers.

*Burden Hours:* The table below provides: Types of data collection

instruments, Estimated number of respondents, Number of responses per respondent, Average burden hour per response, and Total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hours
IHS 843-1A .....	7,977	52	3/60	20,740
Total .....	.....	.....	.....	20,740

\*For ease of understanding, burden hours are also provided in actual minutes.

The total estimated burden for this collection is 20,740 hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

*Request for Comments:* Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the IHS processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (this is the amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct your comments to OMB: Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection, or to obtain a copy of the data collection instruments and/or instruction(s) contact: Tamara Clay, Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852, call non-toll free (301) 443-4750, send via facsimile to (301) 443-2316, or send your email requests, comments, and return address to: [Tamara.Clay@ihs.gov](mailto:Tamara.Clay@ihs.gov).

**DATES:** *Comment Due Date:* March 4, 2013. Your comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: January 23, 2013.

**Yvette Roubideaux,**

*Director, Indian Health Service.*

[FR Doc. 2013-02140 Filed 1-31-13; 8:45 am]

**BILLING CODE 4165-16-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; Comment Request (60-Day FRN); The Clinical Trials Reporting Program (CTRP) Database (NCI)

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to

respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. To submit comments in writing, request more information on the proposed project, or to obtain a copy of the data collection plans and instruments, contact: Jose Galvez, Office of the Director, National Cancer Institute, 2115 East Jefferson Street, Rockville, MD 20852 or call non-toll-free number 301-443-6141 or Email your request, including your address to: [jose.galvez@nih.gov](mailto:jose.galvez@nih.gov).

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

*Proposed Collection:* The Clinical Trials Reporting Program (CTRP) Database, 0925-0600, Expiration Date 3/31/2013—EXTENSION, National Cancer Institute (NCI), National Institutes of Health (NIH).

*Need and Use of Information Collection:* The Clinical Trials Reporting Program (CTRP) is an electronic resource that serves as a single, definitive source of information about all NCI-supported clinical research. This resource allows the NCI to consolidate reporting, aggregate information and reduce redundant submissions. Information is submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. The designees can electronically access the CTRP Web site to complete the initial trial registration. Subsequent to registration, four amendments and four study subject accrual updates occur per trial annually.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The estimated annualized burden hours are 38,500.

## 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](mailto: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](mailto:gary.hunnicutt@nih.gov).