

Estimates of annualized total hour burden are summarized in Table A.12–1.4 Below.

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Participants	4580	1	90/60	7,653
Non-Participants	3030	1	15/60	729
Totals	7610	2		8,382

(Note: reported and calculated numbers differ slightly due to rounding.)

Dated: April 18, 2016.

Valery Gheen,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2016–09313 Filed 4–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Anti-CD70 Chimeric Antigen Receptors (CARs) for the Treatment of Chronic Myelogenous Leukemia

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Dedalus Pharma, LLC (“Dedalus”) located in Maryland, USA.

Intellectual Property

United States Provisional Patent Application No. 62/088,882, filed December 8, 2014, entitled “Anti-CD70 Chimeric Antigen Receptors” [HHS Reference No. E–021–2015/0–US–01]; and PCT Application No. PCT/US2015/025047 filed April 9, 2015 entitled “Anti-CD70 Chimeric Antigen Receptors” [HHS Reference No. E–021–2015/0–PCT–02].

The patent rights in these inventions have been assigned to the government of the United States of America.

The patent rights in these inventions have been assigned to the government of the United States of America. The prospective exclusive license territory may be worldwide and the field of use may be limited to the development and commercialization of CD70 chimeric antigen receptor (CAR)-based autologous peripheral blood T cell

therapy products as set forth in the Licensed Patent Rights for the treatment of chronic myelogenous leukemia in humans.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer Center at the National Cancer Institute on or before May 9, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Andrew Burke, Ph.D., Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, MSC 9702, Rockville, MD 20852; Telephone: (240) 276–5484; Email: andy.burke@nih.gov.

SUPPLEMENTARY INFORMATION: The present invention describes chimeric antigen receptors (CARs) targeting CD70. CARs are hybrid proteins comprised of extracellular antigen binding domains and intracellular signaling domains designed to activate the cytotoxic functions of CAR-transduced T cells upon antigen stimulation.

CD70 is a co-stimulatory molecule that provides proliferative and survival cues to competent cells upon binding to its cognate receptor, CD27. Its expression is primarily restricted to activated lymphoid cells; however, recent research has demonstrated that several cancers, including renal cell carcinoma, glioblastoma, non-Hodgkin’s lymphoma, and chronic myelogenous leukemia also express CD70 under certain circumstances. Due to its limited expression in normal tissues, CARs targeting CD70 may be useful in adoptive cell therapy protocols for the treatment of select cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NCI 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 part 404.

Complete applications for a license in an appropriate field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive 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 18, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–09324 Filed 4–21–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture (NIEHS)

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on November 27, 2015, Pages 74115–74116, and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information