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]

BILLING CODE 4140–01–P

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

collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

DATES: *Comment Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Dale Sandler, Ph.D., Chief, Epidemiology Branch, National Institute of Environmental Health Sciences, NIH, 111 T.W. Alexander Drive, P.O. Box 12233, MD A3–05, Research Triangle Park, NC 27709, or call non-toll-free number 919–541–4668, or email your request, including your address to: *sandler@niehs.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Agricultural Health Study: A Prospective Cohort Study of Cancer and Other Diseases Among Men and Women in Agriculture, 0925–0406 (Expiration Date 9/30/2016, REVISION), National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this information collection is to request new components as part of the ongoing Study of Biomarkers of Exposures and Effects in Agriculture (BEEA), as well as continue and complete phase IV (2013–2016) of the Agricultural Health Study (AHS) and continue buccal cell collection. Phase IV will continue to update the occupational and environmental exposure information as well as medical history information for licensed pesticide applicators and their spouses enrolled in the AHS. The new BEEA components are a control respondent group, and a smartphone application (app), along with new sample collection (buccal cell and air monitoring samples). The new components will use similar procedures to ones already employed on the BEEA study, as well as other NCI studies. The primary objectives of the study are to determine the health effects resulting from occupational and environmental exposures in the agricultural environment. Secondary objectives include evaluating biological markers that may be associated with agricultural exposures and risk of certain types of cancer. Phase IV questionnaire data are collected by using self-administered computer assisted web survey (CAWI); self-administered paper-and-pen (Paper/pen); or an interviewer administered computer assisted telephone interview (CATI) and in-person interview (CAPI) systems for telephone screeners and home visit interviews, respectively. Some respondents are also asked to participate in the collection of biospecimens and environmental samples, including blood, urine, buccal cells (loose cells from the respondent's mouth), and vacuum dust. The findings will provide valuable information concerning the potential link between agricultural exposures and cancer and other chronic diseases among Agricultural Health Study cohort members, and this information may be generalized to the entire agricultural community.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 11,440.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Private and Commercial Applicators and Spouses.	IA/NC Scripts for Verbal Consent for Buccal	100	1	3/60	5
Private and Commercial Applicators and Spouses.	IA/NC Written Consent for Buccal	100	1	5/60	8
Private and Commercial Applicators and Spouses.	Buccal Follow-up Scripts (as needed): Reminder, Missing Consent, or Damaged/Missing Sample.	30	1	2/60	1
Private Applicators	BEEA CATI Screening Script for RSG, REG or AMG Eligibility.	480	1	20/60	160
Private Applicators	IA/NC BEEA Consent for RSG Home Visit or REG Home Visit or AMG Home Visit.	196	1	5/60	16
Private Applicators	IA/NC BEEA RSG Pre-Visit Show Card	160	1	5/60	13
Private Applicators	IA/NC BEEA RSG Paper/Pen Dust Questionnaire.	160	1	10/60	27
Private Applicators	BEEA RSG Pre-Home Visit Script	160	1	2/60	5
Private Applicators	BEEA RSG Home Visit CAPI, Blood, Buccal cell, Urine & Dust.	160	1	90/60	240
Private Applicators	IA/NC BEEA REG Pre-Visit Show Card	20	3	5/60	5
Private Applicators	IA/NC BEEA REG Paper/Pen Dust Questionnaire.	20	3	10/60	10
Private Applicators	BEEA REG Pre-Home Visit Script	20	3	2/60	2
Private Applicators	BEEA REG Home Visit CAPI, Blood, Buccal cell, Urine & Dust.	20	3	90/60	90
Private Applicators	IA/NC BEEA REG Post-Exposure Scheduling Script.	20	1	2/60	1
Private Applicators	IA/NC BEEA AMG Pre-Visit Show Card	16	2	5/60	3
Private Applicators	IA/NC BEEA AMG Paper/Pen Dust Questionnaire.	16	2	10/60	5
Private Applicators	BEEA AMG Pre-Home Visit Script	16	2	2/60	1
Private Applicators	BEEA AMG Home Visit CAPI, Blood, Urine, Buccal cell & Dust.	16	2	90/60	48

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Private Applicators	IA/NC BEEA Consent for AMG Farm Visit	16	1	5/60	1
Private Applicators	BEEA Pre-Farm Visit Script	16	2	2/60	1
Controls	BEEA CATI Control Eligibility Script	215	1	20/60	72
Controls	IA/NC BEEA Control Home Visit Consent	67	1	5/60	6
Controls	IA/NC BEEA Pre-Visit Show Card	67	1	5/60	6
Controls	IA/NC BEEA Paper/Pen Dust Questionnaire	67	1	10/60	11
Controls	BEEA REG Pre-Visit Script	67	1	2/60	2
Controls	BEEA Control Home Visit CAPI, Blood, Buccal cell, Urine, & Dust.	67	1	90/60	101
Private Applicators	'Life in a Day' Smartphone App Consent and Setup.	78	1	20/60	26
Private Applicators	'Life in a Day' Smartphone Application	78	30	10/60	390
Private Applicators	Phase IV Follow-up CAWI, CATI, or Paper/pen.	13,855	1	25/60	5,773
Spouses	Phase IV Follow-up CAWI, CATI, or Paper/pen.	10,201	1	25/60	4,250
Proxy	Phase IV Follow-up CAWI, CATI, or Paper/pen.	635	1	15/60	159
Total		27,139	29,641		11,438

Dated: April 18, 2016.

Jane M. Lambert,

Project Clearance Liaison, NIEHS.

[FR Doc. 2016–09296 Filed 4–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; 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 Cancer Institute Initial Review Group; Subcommittee F—Institutional Training and Education.

Date: June 14, 2016.

Time: 12:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850, (Telephone Conference Call).

Contact Person: Timothy C. Meeker, M.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W624, Bethesda, MD 20892–9750, 240–276–6464, *meekert@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel, Comprehensive Partnerships to Advance Cancer Health Equity (CPACHE) (U54).

Date: June 15–16, 2016.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Yisong Wang, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W240, Bethesda, MD 20892–9750, 240–276–7157, *yisong.wang@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 18, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–09315 Filed 4–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0123]

Agency Information Collection Activities: Regulations Relating to Recordation and Enforcement of Trademarks and Copyrights

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Regulations Relating to Recordation and Enforcement of Trademarks and Copyrights (Part 133 of the CBP Regulations). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before May 23, 2016 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to