

Dated: April 18, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-09314 Filed 4-21-16; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

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 meeting.

The meeting 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 Institute of General Medical Sciences Special Emphasis Panel; Research Centers in Trauma, Burn and Perioperative Injury.

Date: May 6, 2016.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3An. 12N, 45 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301-594-3907, pikbr@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 18, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016-09316 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 Framingham Heart Study (NHLBI)

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 12/31/2015, pages 81830-81832. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Heart, Lung and Blood Institute (NHLBI), 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.

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, submit comments in writing, or request more information on the proposed project, contact: Ms. Deshree Belis, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Dr., Suite 6185A, Bethesda,

MD 20892, or call non-toll-free number 301-435-1032, or Email your request, including your address to deshree.belis@nih.gov. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: The Framingham Heart Study, 0925-0216, Revision, National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH).

Need and Use of Information Collection: This proposal is to extend the Framingham Study to examine the Generation Three Cohort, New Offspring Spouses and Omni Group 2 Cohort, as well as to continue to monitor the morbidity and mortality which occurs in all Framingham Cohorts. The contractor, with the collaborative assistance of NHLBI Intramural staff, will invite study participants, schedule appointments, administer examinations and testing, enter information into computer databases for editing, and prepare scientific reports of the information for publication in appropriate scientific journals. All participants have been examined previously and thus the study deals with a stable, carefully described group. Data are collected in the form of an observational health examination involving such components as blood pressure measurements, venipuncture, electrocardiography and a health interview, including questions about lifestyles and daily living situations. The National Heart, Lung, and Blood Institute uses the results of the Framingham Study to: (1) Characterize risk factors for cardiovascular and lung diseases so that national prevention programs can be designed and implemented; (2) evaluate trends in cardiovascular diseases and risk factors over time to measure the impact of overall preventive measures; and (3) understand the etiology of cardiovascular and lung diseases so that effective treatment and preventive modalities can be developed and tested. Most of the reports of study results have been published in peer reviewed medical journals and books.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 8,382.

Estimated Annualized Burden Hours

TABLE A.12–1.1—ESTIMATE OF RESPONDENT BURDEN, ORIGINAL COHORT ANNUALIZED

| Type of respondent | Number of respondents | Number of responses per respondent | Average time per response (in hours) | Total annual burden hour |
|--|-----------------------|------------------------------------|--------------------------------------|--------------------------|
| I. Participant Components Annual Follow-Up: | | | | |
| a. Records Request (Attach #5) | 30 | 1 | 15/60 | 8 |
| b. Health Status Update (Attach #3) | 30 | 1 | 15/60 | 8 |
| Sub-Total: Participant Components | * 30 | | | 15 |
| II. Non-Participant Components: | | | | |
| A. Informant Contact (Pre-exam and Annual Follow-up) (Attach #3—pages 3–7) | 15 | 1 | 10/60 | 3 |
| B. Health Care Provider Records Request (Annual follow-up) (Attach #5) | 30 | 1 | 15/60 | 8 |
| Sub-Total: Non-Participant Components | 45 | | | 10 |
| Total: Participant and Non-Participant Components | 75 | 75 | | 25 |

* Number of participants as reflected in Row I.b. above.

TABLE A.12–1.2—ESTIMATE OF RESPONDENT BURDEN, OFFSPRING COHORT AND OMNI GROUP 1 COHORT ANNUALIZED

| Type of respondent | Number of respondents | Number of responses per respondent | Average time per response (in hours) | Total annual burden hour |
|--|-----------------------|------------------------------------|--------------------------------------|--------------------------|
| I. Participant Components Annual Follow-Up: | | | | |
| a. Records Request (Attach #5) | 1500 | 1 | 15/60 | 375 |
| b. Health Status Update (Attach #3) | 1700 | 1 | 15/60 | 425 |
| Sub-Total: Participant Components | *1700 | | | 800 |
| II. Non-Participant Components: | | | | |
| A. Informant contact (Pre-exam and Annual Follow-up) (Attach #3—pages 3–7) | 150 | 1 | 10/60 | 25 |
| B. Health Care Provider Records Request (Annual follow-up) (Attach #5) | 1500 | 1 | 15/60 | 375 |
| Sub-Total: Non-Participant Components | 1650 | | | 400 |
| Total: Participant and Non-Participant Components | 3350 | 3350 | | 1200 |

* Number of participants as reflected in Row I.b. above.

TABLE A.12—1.3—ESTIMATE OF RESPONDENT BURDEN, GENERATION 3 COHORT, NOS AND OMNI GROUP 2 COHORT ANNUALIZED

| Type of respondent | Number of respondents | Number of responses per respondent | Average time per response (in hours) | Total annual burden hour |
|--|-----------------------|------------------------------------|--------------------------------------|--------------------------|
| I. Participant Components: | | | | |
| A. Pre-Exam | | | | |
| 1. Telephone contact for appointment | 1,450 | 1 | 10/60 | 242 |
| 2. Exam appointment, scheduling, reminder and instructions (Attach #6) | 1,270 | 1 | 35/60 | 741 |
| B. Exam Cycle 3 | | | | |
| 1. Exam at study center (Attach #1) | 1,200 | 1 | 90/60 | 1,800 |
| 2. Consent (Attach #10) | 1,200 | 1 | 20/60 | 400 |
| 2. Home or nursing home visit (Attach #1—partial as respondent is capable) | 35 | 1 | 1 | 35 |
| C. Post-Exam | | | | |
| eFHS Mobile Technology for Collection of CVD Risks (Attach #2) | 1,100 | 18 | 9/60 | 2,970 |
| D. Annual Follow-Up | | | | |
| 1. Records Request (Attach #5) | 1,200 | 1 | 15/60 | 300 |
| 2. Health Status Update (Attach #3) | 1,400 | 1 | 15/60 | 350 |
| Sub-Total: Participant Components | * 2,850 | | | 6,830 |
| II. Non-Participant Components—Annual Follow-Up: | | | | |
| A. Informant Contacts (Attach #3—pages 3–7) | 180 | 1 | 10/60 | 30 |
| B. Health Care Provider Record Request (Attach #5) | 1,155 | 1 | 15/60 | 289 |
| Sub-Total: Non-Participant Components | 1,335 | | | 319 |
| Total: Participant and Non-Participant Components | 4,185 | 28,890 | | 7,157 |

* Number of participants as reflected in Rows I.A.1 and I.D.2 above.

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