Any collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future; personally identifiable information (PII) is collected only to the extent necessary and is not retained; information gathered will be used only internally for general service improvement and program management purposes and is not intended for release outside of the agency; information gathered will not be used for the purpose of substantially informing influence policy decisions; and information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: The target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, information collections will not result in any new quantitative results. Depending on the type of study, including the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Current Actions: Extension of approval for a collection of information.

Type of Review: Extension.

Affected Public: Individuals, households, professionals, public/private sector.

Estimated Number of Respondents: Below we provide projected average estimates for the next three years:

- Average Expected Annual Number of activities: 7.
- Average number of Respondents per Activity: 350.
- Annual responses: 4,158.
- Frequency of Response: Once per request.
- Average minutes per response: 5.
- Burden hours: 1,041.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

All written comments will be available for public inspection Regulations.gov.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Terry S. Clark.
Asst. Information Collection Clearance Officer.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer

AGENCY: National Institutes of Health

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the SUPPLEMENTARY INFORMATION section of this notice to Kite Pharma, Inc. (“Kite”) located in Santa Monica, CA.

DATES: Only written comments and/or complete applications for a license which are received by the National Cancer Institute’s Technology Transfer Center on or before January 4, 2018 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240)–276–5530; Facsimile: (240)–276–5504; Email: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

The prospective exclusive license territory may be worldwide and the field of use may be limited to the following:

"The development of a CD30 chimeric antigen receptor (CAR)-based..."
immunotherapy using autologous (meaning one individual is both the donor and the recipient) T cells transfected with a retroviral vector (including lentiviral vectors), wherein the vector expresses a CAR having:
1. a single antigen specificity; and
2. comprising at least:
   a. the complementary determining region (CDR) sequences of the anti-CD30 antibody known as 5F11; and
   b. a T cell signaling domain;
for the prophylaxis and treatment of CD30-expressing human cancers."

This technology discloses the development of chimeric antigen receptors that recognize the CD30 protein (also known as tumor necrosis factor receptor superfamily member 8 (TNFRSF8)). CD30 is expressed on the cell surface of several rare forms of cancer, including Hodgkin lymphoma (HL), Non-Hodgkin’s Lymphoma (NHL), diffuse large B cell lymphoma (DLBCL), peripheral T cell lymphoma not otherwise specified (PTCL–NOS), anaplastic large cell lymphoma (ALCL), and anaplastic large cell lymphoma (AITL). The development of a new therapeutic targeting CD30 will benefit public health by offering up a new therapeutic targeting CD30.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 8, 2017.

Richard U. Rodriguez,
Associate Director, Technology Transfer Center, National Cancer Institute.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
National Institute of Neurological Disorders and Stroke Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Institute of Neurological Disorders and Stroke Technologies for Large-Scale Recording and Modulation in the Nervous System.

Date: January 18–19, 2018.
Time: 8:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Ernest Lyons, Ph.D., Scientific Review Officer; Scientific Review Branch; NINDS/NIH/DHHS; Neuroscience Center; 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529; 301–496–0456; Lyonses@ninds.nih.gov.

Name of Committee: Neurological Sciences Training Initial Review Group; NST–1 Subcommittee.

Date: January 29–30, 2018.
Time: 8:00 a.m. to 6:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: William Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529; 301–496–0660, benzingwe@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)


Sylvia L. Neal,
Program Analyst, Office of Federal Advisory Committee Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Proposed Collection; 60-Day Comment Request Division of Cancer Epidemiology and Genetics Fellowship Program and Summer Student Applications (DCEG) (National Cancer Institute)

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 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: Jackie Lavigne, Ph.D., M.P.H., Chief, Office of Education, Division of Cancer Epidemiology and Genetics, 9609 Medical Center Drive, MSC, Bethesda, Maryland 20892 or call non-toll-free number 240.276.7237or Email your request, including your address to: lavignej@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: 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) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to 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