Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301–435–0484, *mohsenim@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–AI–18–057: Long-acting Drug Delivery Systems for ART Optimization in HIV–1 Infected Children.

Date: August 9, 2019.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Rockledge II 6701 Rockledge Drive Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 8, 2019.

Natasha M. Copeland,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–14805 Filed 7–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

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 July 29, 2019 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an 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

United States Provisional Patent Application No. 62/732,263, filed 17 September 2018 and entitled ''Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20 and Their Uses'' [HHS Reference No. E–205–2018–0–US–01]; and U.S. and foreign patent applications claiming priority to the aforementioned application.

The patent rights in these inventions have been assigned and/or exclusively licensed 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 following:

''The development, production and commercialization of an anti-CD19 anti-CD20 dual targeting chimeric antigen receptor (CAR)-based immunotherapy using allogeneic (where the donor and the recipient are different) immune cells, wherein the genome editing is meditated only by zinc-finger nucleases, and where the CAR has at least:

(1) A dual antigen specificity;

(2) the complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;

(3) the complementary determining region (CDR) sequences of the anti-CD20 antibody known as 2.1.2; and

(4) a T cell signaling domain;

for the treatment of B-cell derived human cancers.''

This technology discloses the development of chimeric antigen receptors that recognize both the CD19 and CD20 cell surface proteins. CD19 and CD20 are expressed on the cell surface of several hematological malignancies, including Non-Hodgkins Lymphoma (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). Although the FDA has recently approved CAR-based therapies which target only CD19 (Yescarta, Kymriah), tumors are capable of undergoing tumor antigen escape (the downregulation of target antigen expression on tumor cells), which results in gradual resistance to ''single target therapies.'' As a result, patients receiving single target CAR therapies are susceptible to relapse. This has prompted investigators to pursue dual targeting CAR therapies to provide as a means of overcoming tumor antigen escape, thereby providing a more comprehensive therapeutic alternative. The development of a new therapeutic targeting both CD19 and CD20 will benefit public health by offering up an improved treatment for patients that would otherwise be subject to relapse due to tumor antigen escape.

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: July 2, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–14822 Filed 7–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director)

AGENCY: National Institutes of Health, HHS.

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 Office of Clinical Research (OCR), Office of the Director (OD), National Institutes of Health, will publish periodic summaries of proposed 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: Dr. Anne Zajicek, M.D., Pharm.D., Deputy Director, Office of Clinical Research, NIH Office of the Director, Building 1, Room 208A, MSC–0155, Bethesda, Maryland 20892 or call non-toll-free number (301) 480–9913 or Email your request, including your address to: *zajiceka@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 minimizes 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.

Proposed Collection Title: Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research, Office of Clinical Research, (OCR), 0925–NEW, expiration date XX/XX/XXXX, National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: The purpose of this survey is to assess the long-term impact and outcomes of clinical research training programs provided by the Office of Clinical Research located in the NIH Office of the Director (OD) over a ten-year follow-up period. The information received from respondents will provide insight on the following: Impact of the courses on (a) promotion of professional competence, (b) research productivity and independence, and (c) future career development within clinical, translational and academic research settings. These surveys will provide preliminary data and guidance in (1) developing recommendations for collecting outcomes to assess the effectiveness of the training courses, and (2) tracking the impact of the curriculum on participants' ability to perform successfully in academic, non-academic, research, and non-research settings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,589.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Estimated number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
OCR Learning Portal Registration	Healthcare Professionals	2,000	1	10/60	333
	Students	1,000	1	10/60	167
	General Public	500	1	10/60	83
IPPCR Lecture Evaluation	Healthcare Professionals	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
IPPCR Final Course Evaluation	Healthcare Professionals	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
PCP Lecture Evaluation	Healthcare Professionals	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
PCP Final Course Evaluation	Healthcare Professionals	750	1	10/60	125
	Students	500	1	10/60	83
	General Public	250	1	10/60	42
NIH Summer Course in Clinical and Translational Research Course Evaluation.	Healthcare Professionals	20	1	10/60	3
Sabbatical in Clinical Research Management Course Evaluation.	Healthcare Professionals	20	1	10/60	3
Total			9,540		1,589

Dated: July 3, 2019.

Lawrence A. Tabak,

Principal Deputy Director, National Institutes of Health.

[FR Doc. 2019–14821 Filed 7–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

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 July 29, 2019 will be considered.

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SUPPLEMENTARY INFORMATION:

Intellectual Property

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(1) A dual antigen specificity;

(2) the complementary determining region (CDR) sequences of the anti-CD19 antibody known as Hu19;

(3) the complementary determining region (CDR) sequences of the anti-CD20 antibody known as 2.1.2; and

(4) a T cell signaling domain;

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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: July 2, 2019.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2019–14823 Filed 7–11–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

All of Us Research Program, Tribal Consultation Meetings and Listening Sessions; Correction

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on June 3, 2019. That Notice requires a correction in the **DATES** and **SUPPLEMENTARY INFORMATION** sections.

FOR FURTHER INFORMATION CONTACT: The *All of Us* Tribal Engagement team by phone at 240–515–5317, by email at *AOUTribal@nih.gov,* or by mail at 6011 Executive Boulevard, Suite 214, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: On June 3, 2019, the Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on pages 25551–25552 (84 FR 25551) that provided two dates for the HHS Regional Consultation, Regions 1–4 (Washington, DC) session to take place on July 16, 2019 and August 21, 2019. The purpose of this Notice is to correct the date within the Dates and Supplemental Information sections for the Regional Washington DC consultation session to read: July 17, 2019. A full schedule of consultations and listening sessions will be made available on the *All of Us* Tribal Engagement web page at *https://AllofUs.nih.gov/All-Us-Tribal-Engagement.*