DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Antibody-Based Therapeutics and Chimeric Antigen Receptors Targeting Glypican-2

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Stanford University, (''Stanford''), a non-profit university located in California, in its rights to the inventions and patents listed in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center February 10, 2020 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Rose M. Freel, Ph.D., Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 8490 Progress Drive, Suite 400, Frederick MD 21701 (for business mail), Telephone: (301) 624–8775; Facsimile: (301) 631–3027; Email: *rose.freel@nih.gov*.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to Stanford: United States Provisional Patent Application No. 62/844,695, filed May 7, 2019 and entitled ''CHIMERIC ANTIGEN RECEPTORS TARGETING GLYCIPAN–2'' [HHS Reference No. E–064–2019/0–US–01].

The patent rights in these inventions have been assigned to the Government of the United States of America, Stanford University, and Children's Hospital of Philadelphia. The prospective patent license will be for the purpose of consolidating the patent rights to Stanford, one of the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by Stanford will be subject to the provisions of 37 CFR part 401 and 404.

The invention pertains to novel antibody binders and chimeric antigen receptors (CARs) that target glypican-2 (GPC–2), a cell surface heparin sulfate proteoglycan with very restricted expression in normal tissue but with expression on many hard-to-treat pediatric and adult solid tumors such as glioblastoma, small cell lung cancer, uterine carcinoma, neuroblastoma, and medulloblastoma. Based on current available data, the intended use for the invention is as a therapeutic for the treatment of GPC–2 expressing solid tumors.

This notice is made pursuant to 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive patent license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights and 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 that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a 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 from 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: January 15, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020–01154 Filed 1–23–20; 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; Information Program on Clinical Trials: Maintaining a Registry and Results Databank (National Library of Medicine)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with 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.

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

ADDRESSES: 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: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, Office of Administrative and Management Analysis Services, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 827–6361, or Email your request, including your address to: *sharlipd@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on November 19, 2019, pages 63884–5 (84 FR 63884) 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 Library of Medicine (NLM), 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.

In compliance with 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.

Proposed Collection: Information Program on Clinical Trials: Maintaining a Registry and Results Databank, 0925–0586, Expiration Date 02/29/2020—EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and by the Clinical Trials Registration and Results Information Submission regulations at 42 CFR part 11. ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (*e.g.,* observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research. While many clinical studies are registered and results information submitted voluntarily, 42 CFR part 11 requires the registration and submission of results information for certain applicable clinical trials of drug, biological, and device products whether or not they are approved, licensed, or cleared by the Food and Drug Administration.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 1,072,306.

ESTIMATED ANNUALIZED BURDEN HOURS

Submission type	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hours
Registration—attachment 2:				
Initial	7,400	1	8	59,200
Updates	7,400	8	2	118,400
Triggered, voluntary	88	1	8	704
Initial, non-regulated, NIH Policy	657	1	8	5,256
Updates, non-regulated, NIH Policy	657	8	2	10,512
Initial, voluntary and non-regulated	11,244	1	8	89,952
Updates, voluntary and non-regulated	11,244	8	2	179,904
Results Information Submission—attachment 5:				
Initial	7,400	1	40	296,000
Updates	7,400	2	10	148,000
Triggered, voluntary—also attachment 2	30	1	45	1,350
Initial, non-regulated, NIH Policy	657	1	40	26,280
Updates, non-regulated, NIH Policy	657	2	10	13,140
Initial, voluntary and non-regulated	2,000	1	40	80,000
Updates, voluntary and non-regulated	2,000	2	10	40,000
Other:				
Certification to delay results—attachment 6	5,150	1	30/60	2,575
Extension request—attachment 7	250	1	2	500
Initial, expanded access—attachment 3	213	1	2	426
Updates, expanded access—attachment 3	213	2	15/60	107
Total	64,660	210,037	.....	1,072,306

Dated: January 21, 2020.

David H. Sharlip,

Project Clearance Liaison, National Library of Medicine, National Institutes of Health.

[FR Doc. 2020–01157 Filed 1–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA–DK–19–505: Limited Competition for the Accelerating Medicines Partnership (AMP) in Type 2 Diabetes Knowledge Portal (UM1 Clinical Trial Not Allowed).

Date: March 12, 2020.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–7682, *campd@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)