located within the state that hold valid permits are in compliance with CLIA requirements.

Our branch location in New York has conducted validation inspections of a representative sample (approximately 5 percent) of the laboratories inspected by the New York State Office of Laboratory Quality Assurance (LQA). The validation inspections were primarily of the concurrent type; that is, our surveyors accompanied New York State's inspectors, each inspecting against his or her agency's respective regulations. Analysis of the validation data revealed no significant differences between the State and Federal findings. The validation surveys verified that the State of New York CLEP inspection process covers all CLIA conditions applicable to each laboratory being inspected and also verified that the CLEP requirements meet or exceed CLIA condition-level requirements. Our validation surveys found the State inspectors highly skilled and qualified. The LQA inspected laboratories in a timely fashion; that is, all laboratories were inspected within the required 24-month cycle. All parameters monitored by our branch location in New York, to date, indicate that the State of New York is meeting all requirements for approval of CLIA exemption. This Federal monitoring will continue as an ongoing process.

C. Conclusion

Based on review of the documents submitted by the New York State licensure program, CLEP, pursuant to the requirements of subpart E of part 493, as well as the outcome of the validation inspections conducted by our branch location in New York, we find that the State of New York's licensure program meets the requirements of § 493.551(a), and that, as a result, we may exempt from CLIA program requirements all State-licensed or -approved laboratories.

Approval of the CLIA exemption for laboratories located within and permitted by the State of New York is subject to removal if we determine that the outcome of a comparability review or a validation review inspection is not acceptable, as described under §§ 493.573 and 493.575, or if the State of New York fails to pay the required fee every 2 years as required under § 493.646(b).

D. Laboratory Data

In accordance with our regulations at § 493.557(b)(8), the approval of this exemption for laboratories located within and permitted by the State of New York is conditioned on the State of New York's continued compliance with the assertions made in its application, especially the provision of information to us about changes to a laboratory's specialties or subspecialties based on the State's survey, and changes to a laboratory's certification status, such as a change from a CLIA certificate of compliance to a CLIA certificate of waiver.

E. Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by laboratories is intended to cover the cost of the development and administration of the program. However, when a state's application for exemption is approved, we do not charge a fee to laboratories in the state. The state's share of the costs associated with CLIA must be collected from the state, as specified in § 493.645(a).

The State of New York must pay for the following:

- Costs of Federal inspections of laboratories in the State to verify that New York State's laboratory licensure program requirements are equivalent to or more stringent than those in the CLIA program, and that they are enforced in an appropriate manner. The average Federal hourly rate is multiplied by the total hours required to perform Federal validation surveys within the State.
- Costs incurred for Federal surveys, including investigations of complaints that are substantiated. We will bill the State of New York on a semiannual basis.
- The State of New York's proportionate share of the costs associated with establishing, maintaining, and improving the CLIA computer system, based on the portion of those services from which the State of New York received direct benefit or which contributed to the CLIA program in the State. Thus, the State of New York is being charged for a portion of our direct and indirect costs of administering the CLIA program. Such costs will be incurred by CMS, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA) and contractors working on behalf of these respective agencies.

To estimate the State of New York's proportionate share of the general overhead costs to develop and implement CLIA, we determined the ratio of laboratories in the State to the total number of laboratories nationally. Approximately 1.5 percent of the registered laboratories are in the State of New York. We determined that a corresponding percentage of the applicable CMS, CDC, FDA, and their respective contractor costs should be borne by the State of New York.

The State of New York has agreed to pay the State's pro rata share of the anticipated overhead costs and costs of actual validation (including complaint investigation surveys). A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

II. Approval

In light of the foregoing, we grant approval of the State of New York's laboratory licensure program (CLEP) under subpart E. All laboratories that are located within the State of New York and hold valid CLEP permits are CLIA-exempt for all specialties and subspecialties until March 26, 2027.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Acting Administrator of the Centers for Medicare & Medicaid Services (CMS), Elizabeth Richter, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 25, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–06499 Filed 3–26–21; 4:15 pm]

BILLING CODE 4120–01–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; New Investigator Gateway Awards for Collaborative T1D Research Special Emphasis Panel.

Date: April 6, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Video Meeting).

Contact Person: Peter J. Kozel, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7009, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–4721, *kozelp@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. 93.847, 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)

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–06470 Filed 3–29–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Chimeric Antigen Receptors Targeting CD56

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 Memorial Sloan Kettering Cancer Center, (''MSKCC''), a non-profit research center located in New York, 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 April 14, 2021 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 at Telephone: (301) 624–8775 or 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 MSKCC: U.S. Provisional Patent Application No. 62/199,775, filed July 31, 2015 entitled ''Antigen-Binding Proteins Targeting CD56 And Uses Thereof,'' (HHS Ref. No. E–142–2014–0–US–01); PCT Application No. PCT/US16/045027, filed August 2, 2016 entitled ''Antigen-binding proteins targeting CD56 and uses thereof'' (HHS Ref. No. E–142–2014–0–PCT–02); U.S. Patent No. 10,730,941, granted on August 4, 20201, corresponding to U.S. Patent Application No. 15/884,608, filed January 31, 2018, entitled ''Antigen-binding proteins targeting CD56 and uses thereof'' (HHS Ref. No. E–142–2014–0–US–03); Canadian Patent Application No. 2994412, filed January 31, 2018, entitled ''Antigen-binding proteins targeting CD56 and uses thereof'' (HHS Ref. No. E–142–2014–0–CA–04); Australian Patent Application No. 16833684.0, filed January 31, 2018, entitled ''Antigen-binding proteins targeting CD56 and uses thereof'' (HHS Ref. No. E–142–2014–0–AU–05); U.S. Patent Application No. 16/912,291, filed June 25, 2020, entitled ''Methods of treatments using antigen-binding proteins targeting CD56'' (HHS Ref. No. E–142–2014–0–US–06).

The patent rights in these inventions have been assigned to the Government of the United States of America and Memorial Sloan Kettering Cancer Center. The prospective patent license will be for the purpose of consolidating the patent rights to MSKCC, 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 MSKCC 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 CD56 or NCAM, a glycoprotein that is highly expressed in a variety of cancerous cells. Based on current available data, the intended use for the invention is anti-CD56 CARs for the treatment of CD56 positive cancers such as multiple myeloma.

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; March 10, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2021–06474 Filed 3–29–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for