++ Obtain TCT's agreement to provide CMS with a copy of the most current accreditation survey, together with any other information related to the survey as we may require, including corrective action plans.

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the December 21, 2023, proposed notice also solicited public comments regarding whether TCT's requirements met or exceeded the Medicare Conditions for Certification (CfCs) for RHCs. CMS did not receive any public comments.

V. Provisions of the Final Notice

A. Differences Between TCT's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared TCT's RHC accreditation requirements and survey process with the Medicare conditions set forth at 42 CFR part 491, subpart A, the survey and certification process requirements of parts 488 and 489, and survey process as outlined in the State Operations Manual (SOM). Our review and evaluation of TCT's RHC application, which was conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, TCT has completed revising its standards and certification processes in order to—

• Meet the Medicare CfC requirements for all of the following regulations:

++ Section 488.5(a)(4)(ii), to provide documentation demonstrating the comparability of the organization's survey process and surveyor guidance to those required for State survey agencies conducting federal Medicare surveys for the same provider or supplier type to ensure levels of triaging will not negatively impact patient care and outcomes.

++ Section 488.5(a)(12) to specify a triage process for responding to and investigating complaints against accredited facilities, including policies and procedures regarding referrals when applicable to appropriate licensing bodies and ombudsman programs.

++ Section 488.26(b) to ensure citation level of deficiencies are cited appropriately, by conducting additional review of standards and RHC Medicare CfCs, provide a process for ensuring a thorough understanding of manner and degree of deficiency, and surveyor training.

++ Section 491.5(a)(1) to explicitly demonstrate RHC is located in a rural area, through policies and procedures, ensure surveyor's documentation exhibits the RHC physical name and address where services are provided.

++ SOM Chapter 2, Section 2700A to establish a policy and procedure to protect the integrity and intent of unannounced surveys when surveys are conducted at multiple locations and in close proximity.

++ SOM Chapter 2, Section 2728B, is to clarify an acceptable plan of correction that includes the RHC completing the organizational plan of correction template and documentation implementing the plan for future compliance and monitoring.

++ SOM Chapter 5 Section 5075, to ensure the administrative review and offsite investigation that are generally not permitted is consistent with the compliant policies found in Chapter 5.

++ Provide a revised plan of correction policy comparable to Chapter 2 of the SOM.

In addition to the standards review, CMS reviewed TCT's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, TCT has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Removing TCT's policies to allow patient and staff identifiers to be kept together. Such identifiers need to be kept separately from the surveyor's notes and findings to keep patients and staff private.

++ Revising language prohibiting Protected Health Information from being taken from the clinic. TCT language is inconsistent with CMS policy, which allows surveyors to photocopy documents needed to support deficient findings.

++ Clarifying TCT's policy that gives surveyors the discretion to conduct interviews privately. This policy is inconsistent with CMS policy governing private interviews with patients, staff, and visitors; it is a requirement and not discretionary unless the interviewee refuses.

++ Specifying TCT's policy to allow facilities to audio tape exit conferences, require facilities to provide two tapes and tape recorders and a recording of the meeting simultaneously, and then permitting the surveying team to select one of the tapes at the conclusion of the exit conference.

B. Term of Approval

Based on our review and observations described in section III. and section V. of this final notice, we approve TCT as a national accreditation organization for RHCs that request participation in the Medicare program. The decision announced in this final notice is effective July 17, 2024, to July 17, 2028 (4 years).

VI. 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. chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–10250 Filed 5–9–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 1009 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 Environmental Health Sciences Special Emphasis Panel: NIEHS Support for Conferences and Scientific Meeting R13.

Date: June 11, 2024.

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

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, 530 Davis Drive, Keystone Building, Durham, NC 27713 (Virtual Meeting).

Contact Person: Murali Ganesan, Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, Room 3097, Research Triangle Park, NC 27713, (984) 287–4674, *murali.ganesan@nih.gov*.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: Career Development in K Applications.

Date: June 20–21, 2024.

Time: 10:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Science, 530 Davis Drive, Keystone Building, Durham, NC 27713 (Virtual Meeting).

Contact Person: Beverly W. Duncan, Ph.D., Scientific Review Officer, Keystone Building, 530 Davis Drive, Room 3130, Durham, NC 27713, (240) 353–6598, *beverly.duncan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: May 6, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–10200 Filed 5–9–24; 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: Antibody-Drug Conjugates (ADCs) for Targeting CD56-Positive Tumors

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 McSAF Inside Oncology SAS (''McSAF Inside Oncology'') located in Tours, France.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before May 28, 2024 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 Freel, Ph.D., Unit Supervisor, NCI Technology Transfer Center, Telephone: (301) 624–1257; Email: *rose.freel@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/199,707 filed July 31, 2015, entitled ''Antibody-drug conjugates for targeting CD56-positive tumors'' [HHS Reference No. E–221–2015–0–US–01];

2. International Patent Application No. PCT/US2016/044777 filed July 29, 2016, entitled ''Antibody-drug conjugates for targeting CD56-positive tumors'' [HHS Reference No. E–221–2015–0–PCT–02]; and

3. United States Patent No. 10,548,987 issued February 02, 2020 (corresponding to United States Patent Application No. 15/747,620 filed January 25, 2018), entitled ''Antibody-drug conjugates for targeting CD56-positive tumors'' [HHS Reference No. E–221–2015–0–US–03].

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 use, development, and commercialization of an antibody-drug conjugate (ADC) for the treatment of Merkel cell carcinoma, wherein the ADC utilizes any technology for attachment of the cytotoxic payload and has:

(1) The CDR sequences of the m906 antibody; and

(2) a cytotoxic payload.''

and

''The use, development, and commercialization of an antibody-drug conjugate (ADC) for the treatment of CD56-positive cancers except glioblastoma, wherein the ADC:

(1) has the CDR sequences of the m906 antibody;

(2) has a cytotoxic payload; and

(3) utilizes solely McSAF Inside Oncology's proprietary or exclusively in-licensed bioconjugation technologies for attachment of the linker-payload(s) to the m906 antibody.

The E–221–2015 patent family is directed to ADCs utilizing the CD56-specific monoclonal antibody known as m906 and conjugated to a drug. The technology is intended to be used as a therapeutic for CD56-positive cancers such as neuroblastoma, multiple myeloma, ovarian cancer, acute myeloid leukemia, and small cell lung cancer. The exclusive field of use which may be granted to McSAF Inside Oncology applies to only ADCs which either (1) treat Merkel Cell Carcinoma; or (2) use McSAF Inside Oncology's proprietary bioconjugation platform for attachment of the antibody to the linker-payload. Accordingly, the proposed scope of rights which may be conveyed under the license covers only a portion of the total scope of the E–221–2015 patent family and only a subset of the possible ADCs that incorporate the m906 antibody as well as the possible therapeutic applications of the ADCs.

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 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: May 6, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–10198 Filed 5–9–24; 8:45 am]

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