

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Teaching Health Center Costing Instrument	56	1	56	10	560
Total	56	56	560

Maria G. Button,
Director, Executive Secretariat.
 [FR Doc. 2020–17729 Filed 8–12–20; 8:45 am]
BILLING CODE 4165–15–P

Authority: 42 U.S.C. 1395.
Alex M. Azar II,
Secretary.
 [FR Doc. 2020–17748 Filed 8–12–20; 8:45 am]
BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Delegation of Authority

Notice is hereby given that I have delegated jointly to the Administrator, Centers for Medicare & Medicaid Services (CMS), and to the Director, National Institutes of Health (NIH), the authorities vested in the Secretary under Section 1881(c)(7)(B)–(E) [42 U.S.C. 1395rr(c)(7)(B)–(E)] of the Social Security Act (the Act), as amended, to assemble and analyze data reported by network organizations, transplant centers, and other sources on all end-stage renal disease (ESRD) patients.

Limitations

This delegation of authorities under Section 1881(c)(7)(B)–(E) [42 U.S.C. 1395rr(c)(7)(B)–(E)] of the Act shall be shared between CMS and NIH as these authorities relate to their respective programs. CMS and NIH will implement proactive collaborative measures such as ongoing status checks to discuss progress and resolve any potential disputes.

This delegation supersedes any prior delegations under this section, including the delegation dated September 6, 1984 (49 FR 35247).

This delegation of authority may be re-delegated.

This delegation of authority is effective immediately.

I hereby affirm and ratify any actions taken by the Administrator, CMS, and the Director, NIH, or their subordinates, which involved the exercise of authority under Section 1881(c)(7)(B)–(E) [42 U.S.C. 1395rr(c)(7)(B)–(E)] of the Act, as amended, delegated herein prior to the effective date of this delegation of authority.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[Assistance Listing Number 93.933]

Awards Unsolicited Proposal for the Health Communication Initiative Program

AGENCY: Office of Clinical and Preventive Services, Indian Health Service, Department of Health and Human Services.

ACTION: Notice of award of a single-source unsolicited grant to Johns Hopkins University in Baltimore, Maryland.

Recipient: Johns Hopkins University, Baltimore, Maryland.

Purpose of the Award: Cooperative agreement to collect, develop, package and distribute information to American Indian and Alaska Native (AI/AN) communities to address the coronavirus disease 2019 (COVID–19)-specific recommendations on healthcare, in a culturally sensitive way.

Amount of Award: \$127,644 in Fiscal Year (FY) 2020.

Period of Performance: April 24, 2020–August 24, 2020.

SUMMARY: The Office of Clinical and Preventive Services (OCPS) announces the award of a single-source cooperative agreement in response to an unsolicited proposal from Johns Hopkins University, Baltimore, Maryland. The proposal submitted was not solicited either formally or informally by any federal government official.

OCPS performed an objective review of the unsolicited proposal from Johns Hopkins University (JHU) to develop information on proper actions to mitigate the spread of COVID–19, in a culturally sensitive way. The Johns Hopkins Bloomberg School of Public Health (JHSPH) Center for American

Indian Health (CAIH) mission is to work in partnerships with AI/AN communities to raise their health status, self-sufficiency, and health leadership to the highest possible level. This mission is accomplished through research, training and education, and service. The CAIH has more than nine facilities and approximately 100 staff in the Southwestern tribal communities to assist the Indian Health Service (IHS) in containing and mitigating COVID–19, while building a response model and set of communication materials for all IHS regions nationwide. The CAIH can draw on broad expertise from JHU for additional guidance and recommendations on best practices as the situation evolves.

The materials will be developed from the Centers for Disease Control and Prevention (CDC) and the Substance Abuse and Mental Health Services Administration (SAMHSA) guidance. Based on an internal review of the proposal and the immediate response of the IHS to address the COVID–19 public health emergency, OCPS determined that the proposal has merit.

The long history between the federal government and Native American Tribes and people has often been less than ideal. There are still barriers to the Native American community accepting instruction or direction from the federal government. There is great value in having a third party that has a good history with the community to gather, package and deliver recommendations, in a culturally sensitive way, on staying safe from this disease, when those recommendations may run contrary to cultural norms. This delivery avenue will be more acceptable to the community, and will be more readily recognized for implementation within AI/AN communities.

This award is being made noncompetitively because there is no current, pending, or planned funding opportunity announcement under which this proposal could be competed. OCPS has identified two additional key reasons to support rationale for awarding this unsolicited proposal:

1. The JHU CAIH is well known in the AI/AN communities for robust

communication/messaging networks, research, training, and subject matter expertise. The dissemination of critical COVID-19 information for tribal communities builds trust, credibility, and integrity of promoting a culturally sensitive public health approach around the information.

2. The JHU CAIH is uniquely positioned to provide culturally specific subject matter expertise drawn from a direct care services or “boots on the ground” approach. The CAIH has nearly 40 years of collaboration with Native American tribes and supports public health interventions in more than 140 tribal communities in over 21 states. The breadth of knowledge and existing partnerships will enhance dissemination of information nationally.

Legislative Authority: The Snyder Act, 25 U.S.C. Section 13; the Indian Health Care Improvement Act, 25 U.S.C. Section 1621b; and Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136.

FOR FURTHER INFORMATION CONTACT:

Audrey Solimon at Audrey.Solimon@ih.gov or by telephone at 301–590–5421.

Michael D. Weahkee,

RADM, Assistant Surgeon General, U.S. Public Health Service, Director, Indian Health Service.

[FR Doc. 2020–17516 Filed 8–12–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public by videocast as indicated below. 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering.

Date: September 15, 2020.

Open: 12:00 p.m. to 3:00 p.m.

Agenda: Report from the Institute Director and other Institute Staff.

Place: National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy II, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: David T. George, Ph.D., Associate Director, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 920, Bethesda, MD 20892, georged@mail.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.nibib1.nih.gov/about/NACBIB/NACBIB.htm>, where an agenda and any additional information for the meeting will be posted when available.

Dated: August 7, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–17678 Filed 8–12–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Start-Up Patent License for Evaluation: Immunotherapy for Relapsed/Refractory Diffuse Large B Cell Lymphoma

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Heart, Lung, and Blood Institute, of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive start-up patent license for evaluation to ONK Therapeutics, a start-up company spun-off from the National University of Ireland Galway, and incorporated under the laws of the Republic of Ireland, to practice, for a limited time, the inventions covered by the patent estate

listed in the Supplementary Information section of this notice. Upon expiration of the evaluation period the granted licenses may be converted into a fully exclusive patent commercialization license for the term of the last to expire of the patent estate upon the company providing NHLBI with a commercial development plan supporting such a conversion. This notice is intended to apprise the public of a aforementioned license and provide a fifteen (15) day notice period for the objection.

DATES: Only written comments and/or applications for a license which are received by the National Heart, Lung, and Blood Institute on or before August 28, 2020 will be considered.

ADDRESSES: Requests for copies of patent applications (electronic only), inquiries, and comments relating to the contemplated an exclusive patent license should be emailed to: Michael Shmilovich, Esq., Senior Licensing and Patent Manager, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479, phone number 301–435–5019 shmilovm@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property (Patent Estate)

HHS Ref. No. E–036–2015–0 and –1, U.S. Provisional Patent Application 62/079,975 filed November 14, 2014 (expired), International Patent Application PCT/US2015/060646 filed November 13, 2015 (nationalized), U.S. Patent Application 15/525,921 having an effective filing date of November 13, 2015, and U.S. Divisional Patent Application 16/985,797 filed August 5, 2020, any and all continuation or divisional applications claiming priority to any of the above.

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in field of use that may be limited to *Immunotherapy against relapsed or refractory diffuse large B cell lymphoma*, and where the “Licensed Products” may be defined to be limited to transgenically modified allogeneic natural killer cells within the scope of the Licensed Patent Rights that transiently express one or more of a (1) CCR7 receptor, (2) CD16a (HA–CD16), (3) a DR5 specific TRAIL, or (4) CD19 chimeric antigen receptor.

The aforementioned patent estates cover methods of treating a subject with a tumor by administering transgenically modified adoptive NK (natural killer cells), methods of generating transgenic NK cells, and transgenic NK cells per se.