DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin 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: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group, Arthritis and Musculoskeletal and Skin Diseases Special Grants Review Committee.

Date: November 8–9, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton Washington, DC, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Helen Lin, Ph.D., Scientific Review Officer, NIH/NIAMS, 6701 Democracy Blvd., Suite 800, Plaza One, Bethesda, MD 20817, 301–594–4952, *linh1@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: October 9, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–22310 Filed 10–12–18; 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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Antibody Targeting Cell Surface Deposited Complement Protein C3d

Available for licensing and commercial development is a patent estate covering anti-C3d antibodies, antibody fragments, and their methods of use for killing cancer cells expressing C3d complement protein on their surface, and more particularly for the treatment of patients with Chronic Lymphocytic Leukemia (CLL); a malignancy of mature B-cells and the most common leukemia in the US. The most commonly used monoclonal antibodies (mAbs) are of mouse origin that have been chimerized or humanized to carry human constant regions (typically the human lgG1 isotype), required for the recruitment of human effector mechanisms. The complement system consists of soluble plasma proteins and is activated upon binding of a mAb to target cells resulting in the deposition of complement components on the cell surface and formation of the membrane attack complex (MAC), which can kill cells inducing lysis. The invention originated from an observation during CLL patient treatment with chemotherapy in combination with an anti CD20 mAb (*e.g.,* rituximab or ofatumumab). Upon infusion complement is deposited on the cell surface of CLL cells, a subset of cells is killed, and other cells escape having lost CD20 expression due to a process called trogocytosis by which antibody-CD20 complexes are pulled of the CLL cell surface by immune cells that bind the Fc-portion of the mAb. It has been noted that C3d is stably attached to the CLL cells that escape from further rituximab or ofatumumab targeting and remains detectable for weeks on these cells. C3d, thus, could serve as a neoantigen that could be targeted with anti C3d specific mAbs to kill off escaped tumor cells.

Potential Commercial Applications:

Development Stage:

• Mouse data available.

Inventors: Adrian Wiestner, Martin Skarzynski, Christoph Rader (all of NHLBI), and Margaret A. Lindorfer, Ronald P. Taylor, and Berengere Vire (all of the University of Virginia School of Medicine).

Relevant Publications:

• Robinson, et al. Blood. 2018 Aug 2;132(5):521–532. doi: 10.1182/blood–2018–02–830992.

Intellectual Property: HHS Reference No. E–758–2013–0 and –1; U.S. Provisional Patent Application 61/924,967 filed January 8, 2014 (converted), International Patent Application PCT/US2015/010620 filed January 8, 2015 (nationalized), U.S. Patent Application 15/110, 557 filed January 8, 2015, Canadian Patent Application 2936346 filed January 8, 2015, European Patent Application 15701442.4 filed January 8, 2015, and U.S. Divisional Patent Application 16/047,929 filed January 8, 2015.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Dated: October 4, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018–22359 Filed 10–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Center for Inherited Disease Research Access Committee.

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: Center for Inherited Disease Research Access Committee.

Date: November 9, 2018.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge 6700, Room 3185, MSC 6908, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Barbara J Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635 Fishers Lane, Ste. 4076, MSC 9306, Bethesda, MD 20892–9306, 301–402–0838, *barbara.thomas@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: October 5, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–22315 Filed 10–12–18; 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 inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by emailing the indicated licensing contact at the National Heart, Lung, and Blood, Office of Technology Transfer and Development Office of Technology Transfer, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–402–5579. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Lentiviral Protein Delivery System for RNA-Guided Genome Editing

Available for licensing and commercial development is an HIV–1-based lentiviral vector system for gene correction strategies involving a homologous recombination with a variation of the CRISPR/Cas9 system. Other such lentivirus-based vectors encode a guide RNA, which contains a specific sequence that recognizes a target gene, and a Cas9 endonuclease, which cuts at the specific site. Such systems are being explored as potential therapies for certain hereditary diseases (*e.g.,* sickle-cell disease). However, such systems present some problems due to constitutive expression of Cas9 endonuclease in lentiviral vector-transduced cells and the large size of the Cas9 gene. The variation of this invention delivers the Cas9 endonuclease directly, instead of the gene encoding the protein. This system comprises (a) a lentivirus vector particle comprising a lentiviral genome which encodes at least one guide RNA sequence that is complementary to a first DNA sequence in a host cell genome, (b) a Cas9 protein, and optionally (c) a donor nucleic acid molecule comprising a second DNA sequence. In addition, the invention provides a host cell comprising the foregoing system, as well as a method of altering a DNA sequence in a host cell comprising contacting a host cell with the foregoing system. Alternatively, the invention also provides a fusion protein comprising a Cas9 protein and a cyclophilin A (CypA) protein, wherein the fusion protein binds to the lentivirus vector particle, as well as a lentiviral vector particle comprising such a fusion protein. Gene correction using the disclosed lentiviral vector systems are being tested with respect to the beta-globin gene and the BCL11A gene (to treat sickle-cell disease) and will be used for induced pluripotent stem cell (iPS) generation.

Potential Commercial Applications:

- Sickle cell disease
- gene therapy

Development Stage:

- Early stage

Inventors: Naoya Uchida, Juan J. Haro Mora, John F. Tisdale (all of NHLBI)

Relevant Publications: Demirci et al., Cytotherapy. 2018 Jul;20(7):899–910. doi: 10.1016/j.jcyt.2018.04.003. Epub 2018 May 30.

Intellectual Property: HHS Reference No. E–165–2015; U.S Provisional Patent Application 62/236,223 filed October 2, 2015; International Patent Application PCT/US2016/054759 filed September 30, 2016, U.S. Continuation-in-Part Application 15/942,673 filed April 2, 2018 and European Patent Application 16782163.6 having an international filing date of September 30, 2016.

Licensing Contact: Michael Shmilovich, Esq, CLP; 301–435–5019; *shmilovm@mail.nih.gov.*

Dated: October 4, 2018.

Michael A. Shmilovich,

Senior Licensing and Patenting Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2018–22360 Filed 10–12–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Technology Transfer Centers (TTC) Network Program Monitoring—NEW

The Substance Abuse and Mental Health Administration's (SAMHSA) will monitor program performance of its Technology Transfer Centers (TTCs). The TTCs disseminate current behavioral health and HIV services research from the National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, National Institute of Mental Health, Agency for Healthcare Research and Quality National Institute of Justice, and other sources, as well as other SAMHSA programs. To accomplish this, the TTCs develop and update state-of-the-art,