2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 19, 2015.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Philip Bautista at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10022 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–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. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel T Cell Therapy Against Patient-Specific Cancer Mutations

Description of Technology: This invention is a novel T cell therapy against cancer mutations that are patient specific. Scientists at the National Institutes of Health have developed a method to identify T cells that specifically recognize immunogenic mutations expressed only by cancer cells. Human cancers contain genetic mutations that are unique to each patient. Some of the mutated peptides are immunogenic, can be recognized by T cells, and therefore, may serve as therapeutic targets. The inventors identified cancer-specific mutations from a patient with widely metastatic cholangiocarcinoma by sequencing tumor samples and comparing with normal cells. Using tandem minigene constructs encoding all of the mutations expressed by a patient's tumor, the inventors identified T cells that recognized the immunogenic mutations from the same patient. These mutation-reactive T cells have the potential to eliminate the cancer cells while sparing normal tissues since normal tissues do not express the mutations. The inventors expanded these mutation-reactive T cells in vitro, and infused a highly pure population of these T cells back into the same patient. The patient experienced tumor regression when she was treated with this approach.

Potential Commercial Applications

- Personalized immunotherapy with mutation-reactive T cells for mediating tumor regression in patients with immunogenic mutations.
- Mutation-reactive T cell therapy especially beneficial for cancer patients refractory to other therapies.
- A research tool to identify patient-specific immunogenic mutations in the tumor.

Competitive Advantages

- This patient-specific therapy has the potential application to most epithelial cancers, which account for about 90% of cancer deaths in the United States.
- Personalized mutation-specific T cells recognize mutations harboring tumor cells only and spare normal tissues. This therapy has no tissue toxicities comparing to traditional chemotherapy and radiotherapy.
- The infusion of a highly pure population of these mutation-specific T cells may maximize therapy and result in regression of all target lesions.

Development Stage

- Early-stage
- *In vitro* data available
- *In vivo* data available (human)
- *Ex vivo* data available

Inventors: Eric Tran, Yong-Chen W. Lu, Paul F. Robbins, Steven A. Rosenberg (all of NCI).

Publications

1. Tran E, et al. Cancer immunotherapy based on mutation-specific CD4+ T cells in a patient with epithelial cancer. Science. 2014 May 9; 344(6184):641–5. [PMID 24812403]

2. Robbins P, et al. Mining exomic sequencing data to identify mutated antigens recognized by adoptively transferred tumor-reactive T cells. Nat Med. 2013 Jun;19(6):747–52. [PMID 23644516]

3. Tran E, et al. T-cell therapy against cancer mutations. Oncotarget. 2014 Jul 15;5(13):4579–80. [PMID 25046408]

Intellectual Property: HHS Reference No. E–229–2014/0—PCT Application No. PCT/US2014/058805 filed October 2, 2014.

Related Technology: HHS Reference No. E–233–2014/0—PCT Application No. PCT/US2014/058796 filed October 2, 2014.

Licensing Contact: Whitney A. Hastings, Ph.D.; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize T-cell therapy against cancer mutations. For collaboration opportunities, please contact Steven A. Rosenberg, M.D., Ph.D. at *sar@nih.gov.*

A Novel, Personalized T Cell Therapy: T-Cell Receptor Engineered T Cells Targeting Tumor Specific Mutations

Description of Technology: This invention is a novel T cell therapy against cancer mutations that are patient specific. Scientists at the National Institutes of Health have developed a method to identify and generate T-cell receptor (TCR) engineered T cells for personalized cancer therapy. The TCR is a complex of integral membrane proteins that recognizes antigens and activates T cells. Human cancers

contain genetic mutations that are unique in each patient. The inventors found cancer-specific mutations by sequencing tumors and comparing with normal cells. Using tandem minigene constructs encoding all of the patient's tumor mutations, they first identified T cells that were reactive with the unique mutated antigens expressed only in the patient's tumors. Next, they isolated the mutation-reactive TCRs and engineered peripheral blood T cells from the same patient to express these mutation-reactive TCRs. These personalized TCR engineered T cells can be expanded and infused back into the same patient with the potential to induce tumor regression.

Potential Commercial Applications

- Personalized immunotherapy to treat primary and recurrent epithelial cancer.
- A research tool to identify patient-specific immunogenic mutations in tumors.
- A research tool to identify and isolate mutation-specific T cell receptors.

Competitive Advantages

- This patient-specific therapy has the potential application to most epithelial cancers, which account for about 90% of cancer deaths in the United States.
- Personalized TCR engineered T cells target tumor cells and spare normal tissues. This therapy has no tissue toxicities comparing to traditional chemotherapy and radiotherapy.
- The infusion of a highly pure population of these T cells expressing mutation-specific TCRs may maximize therapy and result in regression of all target lesions.

Development Stage

- Early-stage
- *In vitro* data available
- *Ex vivo* data available

Inventors: Eric Tran, Yong-Chen W. Lu, Paul F. Robbins, Steven A. Rosenberg (all of NCI).

Publications

1. Tran E, et al. Cancer immunotherapy based on mutation-specific CD4+ T cells in a patient with epithelial cancer. Science. 2014 May 9;344 (6184):641–5. [PMID 24812403].

2. Robbins P, et al. Mining exomic sequencing data to identify mutated antigens recognized by adoptively transferred tumor-reactive T cells. Nat Med. 2013 Jun;19(6):747–52. [PMID 23644516].

3. Tran E, et al. T-cell therapy against cancer mutations. Oncotarget. 2014 Jul 15;5(13):4579–80. [PMID 25046408].

4. Gros A, et al. PD–1 identifies the patient-specific CD8+ tumor-reactive repertoire infiltrating human tumors. J Clin Invest. 2014 May 1;124(5):2246–59. [PMID 24667641].

Intellectual Property: HHS Reference No. E–233–2014/0—PCT Application No. PCT/US2014/058796 filed October 2, 2014.

Related Technology: HHS Reference No. E–229–2014/0—PCT Application No. PCT/US2014/058805 filed October 2, 2014.

Licensing Contact: Whitney A. Hastings, Ph.D.; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize TCRs reactive with tumor associated antigens. For collaboration opportunities, please contact Steven A. Rosenberg, M.D., Ph.D. at *sar@nih.gov.*

Recombinant Paramyxoviruses Expressing Optimized Heterologous Antigens

Description of Technology: The invention pertains to recombinant paramyxoviruses that express one or more heterologous antigens, such as the human respiratory syncytial virus (RSV) F protein, that have been optimized for increased expression and immunogenicity. The recombinant constructs induce a bivalent immune response to the paramyxovirus vectors and the heterologous antigen. Potential vectors include parainfluenza virus (PIV) serotype 1 and 3, Sendai virus, Newcastle disease virus, PIV2, and PIV5. An exemplary modified heterologous antigen includes the ectodomain of RSV F protein linked to the transmembrane and cytoplasmic domains of the F protein from the PIV vector, which results in efficient incorporation into the vector particle. The RSV F ectodomain can be engineered to be stabilized in an optimal conformation, such as the highly immunogenic prefusion conformation. Additionally, the exemplary heterologous RSV F ectodomain can include one or more amino acid substitutions to modify ectodomain expression, conformation, phenotype, or stability.

Potential Commercial Applications

- RSV vaccine
- Paramyxovirus vaccines
- Prophylactic vaccines

Competitive Advantages

- Multi-valence
- Immunogenicity

Development Stage

- Early-stage
- *In vitro* data available

Inventors: Peter Collins, Bo Liang Shirin Munir, Anne Schaap-Nutt, Ursula Buchholz, Natalie Mackow, Peter Kwong, Barney Graham, Jason McLellan (all of NIAID).

Intellectual Property: HHS Reference No. E–241–2014/0—US Provisional Patent Application 62/105,667 filed January 20, 2015.

Related Technologies: HHS Reference No. E–081–2013/0–/5—US Patent Application 14/207,372 filed March 12, 2014; International Patent Application PCT/US2014/026714 filed March 13, 2014. Priority documents as follows:

(1) US Provisional Application 61/780,910 filed March 13, 2013;

(2) US Provisional Application 61/798,389 filed March 15, 2013;

(3) US Provisional Application 61/857,613 filed July 23, 2013; and

(4) US Provisional Application 61/863,909 filed August 9, 2013.

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Jenish Patel at *jenish.patel@nih.gov.*

Adaptor for Suspending a Cryovial Over a Centrifuge Tube

Description of Technology: The invention pertains to a device and system for expediting the thawing of frozen specimens (*e.g.,* cryopreserved cells) contained in cryo-vials. An adaptor support suspends cryo-vials over a centrifuge tube containing culture medium in an inverted position. The adaptor has an elongated tubular body. While relatively basic, the adaptor dramatically expedites the process of recovering viable cells from frozen specimens. It reduces the labor time for thawing from several minutes to a few seconds. There is virtually no labor involved and enables a single person to load hundreds of samples within minutes. The cells, once thawed, spend essentially no time in liquid cryopreservative, since they are diluted instantly into growth medium contained in the centrifuge tubes. This process ensures the highest viability as well as recovery from each specimen while dramatically increasing throughput. Importantly, the elimination of multiple labor-intensive steps minimizes variation in viability and yield.

Potential Commercial Applications

- Sample preparation
- Cell culturing

Competitive Advantages

- High throughput
- Low labor
- Speed
- Reduced variability

Development Stage: Prototype.

Inventors: Mario Roederer, Margaret Beddall, Pratip Chattopadhyay (all of NIAID).

Intellectual Property: HHS Reference No. E–080–2015/0—US Patent Application No. 14/661,449 filed March 18, 2015.

Licensing Contact: Vince Contreras, Ph.D.; 301–435–4711; *contrerasv@mail.nih.gov*.

Collaborative Research Opportunity: The National Institutes of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Barry Buchbinder at *BBuchbinder@niaid.nih.gov* or 240–627–3678.

Dated: April 24, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–10013 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Biomedical Imaging and Bioengineering Special Emphasis Panel, NIBIB 2015–10 U01 Quantum Review.

Date: June 23, 2015.

Time: 10 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, Suite 920, 6707 Democracy Boulevard, Bethesda, MD 20892. (Virtual Meeting).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail.nih.gov*.

Dated: April 24, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10006 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App), 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Novel Treatment for Drug-Induced Respiratory Depression (2239).

Date: May 12, 2015.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, *lf33c.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.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, NIDA Blending Initiative (2244).

Date: June 4, 2015.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Lyle Furr, Scientific Review Officer, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 4227, MSC 9550, 6001 Executive Boulevard, Bethesda, MD 20892–9550, (301) 435–1439, *lf33c.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 24, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–10003 Filed 4–29–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Child Health and Human Development Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. A portion of this 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 for the review and discussion of grant applications. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the contact person listed below in advance of the meeting.

Name of Committee: National Advisory Child Health and Human Development Council.

Date: June 4, 2015.

Open: June 4, 2015, 8:00 a.m. to 12:10 p.m.

Agenda: Report of the Director, NICHD; Report of the Acting Director, Division of Extramural Research, NICHD; Division of Intramural Research, NICHD DIR Reorganization and Discussion; NIH BRAIN Initiative Update and New Business of the Council.

Closed: June 4, 2015, 1:00 p.m. to Adjournment.

Agenda: To review and evaluate grant applications.