

*Contact Person:* William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, [Benzingw@mail.nih.gov](mailto:Benzingw@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.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Clinician Training Program R25 Application Review.

*Date:* August 17, 2016.

*Time:* 2:00 p.m. to 8:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd, Suite MSC 9529, Bethesda, MD 20892-9529, 301-496-0660, [Benzingw@mail.nih.gov](mailto:Benzingw@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.

*Name of Committee:* National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Biorepository Resource Access Committee (BRAC) X01 Meeting.

*Date:* August 18, 2016.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Joel A. Sayoff, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, 301-496-9223, [joel.sayoff@nih.gov](mailto:joel.sayoff@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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

*Dated:* August 3, 2016.

**Sylvia L. Neal,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2016-18863 Filed 8-8-16; 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 licensing and/or co-development 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 and/or co-development.

**ADDRESSES:** Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

#### FOR FURTHER INFORMATION CONTACT:

Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

#### SUPPLEMENTARY INFORMATION:

Technology description follows.

*Title of invention:* Methods of Treating or Preventing Demyelination Using Thrombin Inhibitors and Methods of Detecting Demyelination Using Neurofascin 155.

*Description of Technology:* Neurofascin 155 is a cell adhesion molecule that attaches myelin to axolemma. Contactin-associated protein (Caspr) is a major component of the perinodes. Perinodal astrocytes regulate nodal structure and myelin thickness by regulating thrombin-dependent cleavage of axo-glia junction attaching the outermost paranodal loops of myelin to the axon membrane. Agents which inhibit the cleavage of Neurofascin 155 or the cleavage of Caspr1 stabilize the node and may impede the immunological attack of myelin where the paranodes are attached to the axon.

The technology is directed to methods of treating diseases characterized by demyelination (such as Multiple sclerosis), white matter injury, or conditions associated with myelin remodeling by administering an agent that inhibits cleavage of Neurofascin 155 or Caspr1. The agent could be a thrombin inhibitor, an agent that inhibits thrombin expression, an anti-thrombin antibody that specifically inhibits thrombin mediated cleavage of Neurofascin 155, a mutated version or fragment of Neurofascin 155 or Caspr1, antibodies to Neurofascin 155 or Caspr1.

The technology also includes methods of detecting remodeling of myelin by detecting changes in levels of Neurofascin 125 and Neurofascin 30 in a biological sample, such as central spinal fluid or blood.

*Potential Commercial Applications:* Treatment of demyelinating diseases, such as Multiple sclerosis.

Treatment of diseases characterized by white matter injury or myelin remodeling.

Monitoring the amount of or rate of remodeling of myelin to determine the efficacy of agents used demyelinating diseases.

*Value Proposition:* Agents which inhibit cleavage of Neurofascin 155 or Caspr1 or inhibit thrombin activity are a novel approach to treating demyelinating diseases or diseases characterized by white matter injury.

The methods of detecting modification in the amount or rate of remodeling of myelin can be used to determine the efficacy of treatments of neurological disorders and are less expensive than other methods currently used.

*Development Stage:* Pre-clinical (in vivo validation).

*Inventor(s):* R. Douglas Fields <https://science.nichd.nih.gov/confluence/display/snsdp/Home>.

*Intellectual Property:* HHS Reference No. E-151-2015/0-PCT-02.

PCT application, PCT/US2016/027776, filed April 15, 2016 entitled "Methods of Treating or Preventing Demyelination Using Thrombin Inhibitors and Methods of Detecting Demyelination Using Neurofascin 155".

*Publications:* 1. In preparation.

*Collaboration Opportunity:* Researchers at the Eunice Kennedy Shriver National Institute of Child Health and Human Development ("NICHD"), seek CRADA partner or collaboration for development of agents to treat multiple sclerosis or other conditions associated with myelin remodeling by administering an agent that inhibits cleavage of Neurofascin 155 or Caspr1. The agent could be a

thrombin inhibitor, an agent that inhibits thrombin expression, an anti-thrombin antibody that specifically inhibits thrombin mediated cleavage of Neurofascin 155, a mutated version or fragment of Neurofascin 155 or Caspr1, or antibodies to Neurofascin 155 or Caspr1.

*Contact Information:* Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: [john.hewes@nih.gov](mailto:john.hewes@nih.gov).

Dated: August 2, 2016.

**John D. Hewes,**

*Technology Transfer Specialist, Technology Transfer Center, National Cancer Institute.*

[FR Doc. 2016-18862 Filed 8-8-16; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2016-0053]

### Privacy Act of 1974; Department of Homeland Security/ICE-015 LeadTrac System of Records

**AGENCY:** Privacy Office, Department of Homeland Security (DHS).

**ACTION:** Notice of Privacy Act system of records.

**SUMMARY:** In accordance with the Privacy Act of 1974, the Department of Homeland Security (DHS) proposes to establish a new DHS system of records titled, "DHS/ICE-015 LeadTrac System of Records." This new system of records is being created from a previously issued system of records, DHS/ICE 009-External Investigations SORN. 73 FR 75452 (Dec. 11, 2008). This system of records allows DHS to collect and maintain records gathered by and in the possession of U.S. Immigrations and Customs Enforcement (ICE), Homeland Security Investigations (HSI), Counterterrorism and Criminal Exploitation Unit (CTCEU) and ICE field offices for appropriate enforcement action, used in the course of their duties in identifying, investigating, and taking enforcement action against foreign students, exchange visitors, and other non-immigrant visitors to the United States who overstay their period of admission or otherwise violate the terms of their visa, immigrant, or non-immigrant status (collectively, status violators) through the LeadTrac system. This SORN also allows DHS to collect information in LeadTrac about

organizations such as schools, universities, and exchange visitor programs being investigated by CTCEU and information about individuals, including designated school officials (DSOs), and associates of suspected status violators.

Additionally, DHS/ICE is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act, elsewhere in the **Federal Register**. This newly established system will be included in the Department of Homeland Security's inventory of record systems.

**DATES:** Submit comments on or before September 8, 2016. This new system will be effective September 8, 2016.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2016-0053 by one of the following methods:

- *Federal e-Rulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *Fax:* 202-343-4010.

- *Mail:* Jonathan R. Cantor, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

*Instructions:* All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, please visit <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For general questions, please contact: Amber Smith, Privacy Officer, (202) 732-3300, U.S. Immigration and Customs Enforcement, 500 12th Street SW., Mail Stop 5004, Washington, DC 20536, email: [ICEPrivacy@dhs.gov](mailto:ICEPrivacy@dhs.gov). For privacy questions, please contact: Jonathan R. Cantor, (202) 343-1717, Acting Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528-0655.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with the Privacy Act of 1974, 5 U.S.C. 552a, the Department of Homeland Security (DHS)/U.S. Immigration and Customs Enforcement (ICE) proposes to establish a new DHS system of records titled, "DHS/ICE-015 LeadTrac System of Records."

This record system allows DHS to collect and maintain information about foreign students, exchange visitors, and other non-immigrant visitors to the

United States, as well as associated organizations and individuals, who overstay their period of admission or otherwise violate the terms of their visa, immigrant, or non-immigrant status (collectively, "status violators"). Using the LeadTrac information technology (IT) system, ICE Homeland Security Investigations (HSI), Counterterrorism and Criminal Exploitation Unit (CTCEU) collects PII from key DHS databases and analyzes it to identify suspected status violators. This system of records contains records from Arrival and Departure Information System (ADIS), Student and Exchange Visitor Information System (SEVIS), Enforcement Integrated Database (EID/ENFORCE), TECS, Consular Consolidated Database (CCD), Computer-Linked Application Information Management System (CLAIMS 3), Automated Biometric Identification System (IDENT), and from commercial databases and public sources. CTCEU will also use LeadTrac to collect information about organizations such as schools, universities, and exchange visitor programs being investigated by CTCEU, and information about individuals, including designated school officials (DSOs) and associates of suspected status violators.

ICE collects information in LeadTrac about suspected status violators and organizations to help enforce compliance with U.S. immigration laws. Specifically, the information is collected and used to support the following DHS activities: Investigating and determining immigration status of individuals; identifying fraudulent schools and/or organizations and the people affiliated with those schools or organizations; providing HSI and Enforcement and Removal Operations (ERO) with information to further investigate suspected status violators; and carrying out the required enforcement activity.

Some of the individuals about whom ICE collects information in LeadTrac, such as DSOs and associates of suspected status violators, may have lawful permanent resident (LPR) status or be U.S. citizens. CTCEU and Overstay Analysis Unit (OAU) personnel query a variety of DHS and non-DHS information systems and enter the results into LeadTrac to build a unified picture of an individual's entry/exit, visa, criminal, and immigration history, and will comparably process information about associated individuals and organizations. Using this assembled information, CTCEU personnel will determine which individuals and organizations warrant additional investigation for possible