DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email paperwork@hrsa.gov or call the HRSA Reports Clearance Office at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (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.

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Email comments to paperwork@hrsa.gov or mail the HRSA Reports Clearance Officer, Room 19–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 24, 2012.

Jennifer Riggle,
Deputy Director, Office of Management.
[FR Doc. 2012–18637 Filed 7–30–12; 8:45 a.m.]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHHS.

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. 207 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.

**Gliarial Cell Line-Derived Neurotrophic Factor Opposite Strand (GDNFOS) for Treatment of Neurodegenerative Diseases**

**Description of Technology:** Gliarial cell line-derived neurotrophic factor (GDNF) is a small human protein encoded by the GDNF gene. GDNF has been effective in therapy in laboratory animal models of Parkinson’s disease and protects several types of neurons in the brain and peripheral nervous system. The NIDA inventors have discovered primate-specific GDNFOS, encoded by the opposite strand of gial cell derived neurotrophic factor (GDNF) gene. The GDNFOS gene encodes for novel peptides that was found to be reduced in human middle temporal gyrus of Alzheimer’s disease brains. These secreted growth proteins have potential neurotrophic activity and they might play a synergistic role in neuroprotective effects of GDNF in human brain. The NIDA inventors have also developed antibody against GDNFOS3 and generated compounds that have potential pharmaceutical use. The compounds consist of GDNFOS nucleic acid transcripts, GDNFOS protein or a functional fragment for treatment of human neurodegenerative diseases.

**Potential Commercial Applications**

- Synergistic role in neuroprotective effects of GDNF.
- Alzheimer’s disease, Parkinson’s disease, Amyotrophic lateral sclerosis, multiple sclerosis and diseases of peripheral organs such as diabetes mellitus type 1.

**Competitive Advantages**

- Secreted novel growth peptides.
- An antibody against GDNFOS3 was developed.

**Development Stage**

- Early-stage.
- Pre-clinical.
- In vitro data available.

**Inventors:** Qing-Rong Liu, Mikko Airavaara, Barry Hoffer, Brandon K Harvey (all of NIDA).


**Licensing Contact:** Betty B. Tong, Ph.D.; 301–594–6565; tongb@mail.nih.gov.

**Collaborative Research Opportunity:** The National Institute on Drug Abuse is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize GDNFOS peptide and non-coding RNAs as therapeutic agents for neurodegenerative diseases. For collaboration opportunities, please contact Vio Conley at conleyv@mail.nih.gov.

**Increased Therapeutic Effectiveness of Immunotoxins That Use Toxin Domains Lacking Human B-cell Epitopes**

**Description of Technology:** Immunotoxins kill cancer cells while allowing healthy, essential cells to survive. As a result, patients receiving an immunotoxin are less likely to experience the deleterious side-effects associated with non-discriminate therapies such as chemotherapy or radiation therapy. Unfortunately, the continued administration of immunotoxins often leads to a reduced patient response due to the formation of neutralizing antibodies against immunogenic epitopes contained within Pseudomonas exotoxin A (PE). To improve the therapeutic effectiveness of PE-based immunotoxins through multiple rounds of drug administration, NIH inventors have sought to identify and remove the human B-cell epitopes within PE. Previous work demonstrated that the removal of the murine B-cell and T-cell epitopes from PE reduced the immunogenicity of PE and resulted in immunotoxins with improved therapeutic activity. This technology involves the identification and removal of major human B-cell epitopes on PE by mutation or deletion. Considering these immunotoxins will be administered to humans, the removal of human immunogenic epitopes is important. The resulting PE-based immunotoxins have increased resistance to the formation of neutralizing antibodies, and are expected to have improved therapeutic efficacy.

**Potential Commercial Applications**

- Essential component of immunotoxins.
- Treatment of any disease associated with increased or preferential expression a specific cell surface receptor.
- Specific diseases include hematological cancers, lung cancer, ovarian cancer, breast cancer, and head and neck cancers.

**Competitive Advantages**

- PE variants now include the removal of human B-cell epitopes, further reducing the formation of neutralizing antibodies against immunotoxins which contain the PE variants.
- Less immunogenic immunotoxins result in improved therapeutic efficacy by permitting multiple rounds of administration in humans.
- Targeted therapy decreases non-specific killing of healthy, essential cells, resulting in fewer non-specific side-effects and healthier patients.

**Development Stage:** Pre-clinical.

**Inventors:** Ira H. Fastan et al. (NCI).

**Publication:** Liu W, et al.

**Collaborative Research Opportunity:** The National Cancer Institute 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 John Hewes, Ph.D. at hewesj@mail.nih.gov.

**Novel Nitroxyl (HNO) Releasing Compounds and Their Use in Treating Diseases**

**Description of Technology:** Nitroxyl (HNO) is a chemical species that exhibits distinct biological properties in comparison to its oxidized product, nitric oxide (NO). Previous investigations have revealed that the
distinct properties of HNO make it a tempting species for wide therapeutic application as it has shown potential in the treatment of heart failure, cancer, and other diseases in various animal and in vitro models. Non-steroidal anti-inflammatory drugs (NSAIDs), such as aspirin and ibuprofen, are compounds that inhibit cyclooxygenase (COX)-mediated conversion of arachidonic acids to prostaglandins. NSAIDs are known for their analgesic properties and are therapeutically involved in many physiological functions, including the inhibition of chronic pain and inflammation inhibition, prevention of heart disease, renal function, and cancer. Prolonged use of NSAIDs can lead to serious gastrointestinal and renal side effects, including ulcer perforation, upper gastrointestinal bleeding, and death, which has limited NSAID therapies.

The instant invention described HNO-releasing NSAIDs, which combine the potential therapeutic benefits of HNO and NSAIDs without the toxicities associated with chronic NSAID use. These HNO-releasing NSAIDs provide a reliable controlled release of HNO making them desirable HNO produgs. The instant invention disclosed various HNO-releasing NSAIDs and methods of treating or preventing various disorders with these compositions, such as cardiovascular disorders, cancers, pain, inflammation, and alcoholism.

**Potential Commercial Applications**
- Treatment of cancer.
- Treatment of cardiovascular disease.
- Aversion therapy for alcoholism.

**Competitive Advantages**
- Combination of therapeutic benefits of HNO and NSAIDs.
- Alleviated toxicity associated with chronic NSAID use.
- Controlled release of HNO.

**Development Stage**
- Early-stage.
- Pre-clinical.

**Inventors:** David A. Wink and Larry K. Keefer (NCI).

**Publication**


**Licensing Contact:** Betty B. Tong, Ph.D.; 301-594-6565; tongb@mail.nih.gov.

**Polyclonal Antibodies for the Specialized Signaling G Protein, Gbeta5**

**Description of Technology:** Researchers at NIDDK have developed polyclonal antibodies against the G protein, Gbeta5. Gbeta5 is a unique and highly specialized G protein that exhibits much less homology than other Gbeta isoforms (~50%) and is preferentially expressed in brain and neuroendocrine tissue. It is expressed prominently in the neuronal cell membrane, as well as in the cytosol and nucleus. Although this distribution pattern suggests that Gbeta5 may shuttle information between classical G protein-signaling elements at the plasma membrane and the cell interior, its function in the brain is largely unknown.

The antibodies were separately generated in rabbits to KLH-conjugates of peptides from the N-terminus of Gbeta5 (antibody ATDG) and the C-terminus of Gbeta5 (antibody SGS). The antibodies can be used for immunoblotting (ATDG, SGS), and immunoprecipitation (ATDG). They can be used to facilitate our understanding of the unique biology and function of Gbeta5 in brain and neurons.

**Potential Commercial Applications:** These antibodies can be used for research purposes (immunoblotting, immunoprecipitation) by those studying the biology and function of Gbeta5.

**Competitive Advantages:** Very specific antibodies to study Gbeta5 and G protein signaling.

**Development Stage:** In vitro data available.

**Inventors:** William Simonds and Jianhua Zhang (NIDDK).

**Publications**


**Licensing Contact:** Jaime Greene, M.S.; 301-435-5559; greenejaime@mail.nih.gov.

**Polyclonal Antibodies for the Gbeta5-Associated Regulator of G Protein Signaling Protein, RGS7**

**Description of Technology:** Researchers at NIDDK have developed polyclonal antibodies against the Regulator of G Protein Signalling (RGS) protein, RGS7. RGS7 binds tightly to Gbeta5, a unique and highly specialized G protein that exhibits much less homology than other Gbeta isoforms (~50%). RGS7 is preferentially expressed in brain and neuroendocrine tissue. Like Gbeta5, RGS7 is expressed prominently in the cell membrane, as well as in the cytosol. Although this distribution pattern suggests that complexes containing Gbeta5 and RGS7 may shuttle information between classical G protein-signaling elements at the plasma membrane and the cell interior, the function of the complex in the brain is largely unknown.

The antibodies were generated in rabbits to glutathione S-transferase (GST) fusion protein with residues 312–469 of bovine RGS7 (antibody 7RC–1) and react with human and rodent RGS7. The antibodies (7RC–1) can be used for immunoblotting and immunoprecipitation. They can be used to facilitate our understanding of the function of Gbeta5/RGS7 complexes in brain and neurons.

**Potential Commercial Applications:** These antibodies can be used for research purposes (immunoblotting, immunoprecipitation) by those studying the biology and function of RGS7.

**Competitive Advantages:** High-titer, multi-epitope antibodies to study RGS7 and RGS7/Gbeta5 complexes and G protein signaling.

**Development Stage:** In vitro data available.

**Inventors:** William Simonds and Jianhua Zhang (NIDDK).

**Publications**
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel Member Conflict: Skeletal Pathobiology and Orthopedics.

Date: August 28, 2012.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301–435–1781, liuhy@csr.nih.gov.

(Docket No. 2012–18651 Filed 7–30–12; 8:45 am)

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[DOcket No. USCBP–2012–0027]

Advisory Committee on Commercial Operations of Customs and Border Protection (COAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Advisory Committee on Commercial Operations of Customs and Border Protection (COAC) will meet on August 15, 2012, in Seattle, WA. The meeting will be open to the public.

DATES: COAC will meet on Wednesday, August 15, 2012 from 1:00 p.m. to 5:30 p.m. PST. Please note that the meeting may close early if the committee has completed its business.

Registration: If you plan on attending, please register either online at https://apps.cbp.gov/te_registration/index.asp?w=80 or by email to tradeevents@dhs.gov, or by fax to 202–325–4290 by close-of-business on August 12, 2012.

If you have completed an online on-site registration and wish to cancel your registration, you may do so at https://apps.cbp.gov/te_registration/cancel.asp?w=80. Please feel free to share this information with interested members of your organizations or associations.

ADDITIONAL INFORMATION: The meeting will be held at Jackson Federal Building, 915 2nd Avenue, Seattle, WA 98174, in the South Auditorium—4th Floor. All visitors report to main lobby of the building. All visitors to the Jackson Federal Building must show a state-issued ID or Passport to proceed through the security checkpoint to be admitted to the building.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229; telephone 202–344–1440; facsimile 202–325–4290.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The COAC provides advice to the Secretary of Homeland Security, the Secretary of the Treasury, and the Commissioner of U.S. Customs and Border Protection (CBP) on matters pertaining to the commercial operations of CBP and related functions within DHS or the Department of the Treasury.

Agenda

The COAC will hear from the following subcommittees on the topics listed below and then will review, deliberate, and formulate issues to be considered by the committee as listed in the “Agenda” section below.

Comments must be submitted in writing no later than August 8, 2012, and must be identified by USCBP–2012–0027 and may be submitted by one of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
• Email: Tradeevents@dhs.gov. Include the docket number in the subject line of the message.
• Fax: 202–325–4290
• Mail: Ms. Wanda Tate, Office of Trade Relations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue NW., Room 3.5A, Washington, DC 20229.

Instructions: All submissions received must include the words “Department of Homeland Security” and the docket number for this action. Comments received will be posted without alteration at http://www.regulations.gov, including any personal information provided. Do not submit personal information to this docket.

Docket: For access to the docket to read background documents or comments received by the COAC, go to http://www.regulations.gov.

There will be two public comment periods held during the meeting on August 15, 2012. Speakers are requested to limit their comments to two (2) minutes or less to facilitate greater participation. Contact the individual listed below to register as a speaker. Please note that the public comment period for speakers may end before the time indicated on the schedule that is posted on the CBP web page at the time of the meeting.