tracking quality improvement over time (for example, measure selection criteria, data collection and reporting requirements)? What strategies (including those related to health information technology) could mitigate these challenges?

3. Describe current public reporting or transparency efforts that states and private entities use to display health care quality information.

4. How do health insurance issuers currently monitor the performance of hospitals and other providers with which they have relationships? Do health insurance issuers monitor patient safety statistics, such as hospital acquired conditions and mortality outcomes, and if so, how? Do health insurance issuers monitor care coordination activities, such as hospital discharge planning activities, and outcomes of care coordination activities, and if so, how?

Applicability to the Health Insurance Exchange Marketplace

5. What opportunities exist to further the goals of the National Quality Strategy through quality reporting requirements in the Exchange marketplace?

6. What quality measures or measure sets currently required or recognized by states, accrediting entities, or CMS are most relevant to the Exchange marketplace?

7. Are there any gaps in current clinical measure sets that may create challenges for capturing experience in the Exchange?

8. What are some issues to consider in establishing requirements for an issuer’s quality improvement strategy? How might an Exchange evaluate the effectiveness of quality improvement strategies across plans and issuers?

What is the value in narrative reports to assess quality improvement strategies?

9. What methods should be used to capture and display quality improvement activities? Which publicly and privately funded activities to promote data collection and transparency could be leveraged (for example, Meaningful Use Incentive Program) to inform these methods?

10. What are the priority areas for the quality rating in the Exchange marketplace? (for example, delivery of specific preventive services, health plan performance and customer service)? Should these be similar to or different from the Medicare Advantage five-star quality rating system (for example, staying healthy: screenings, tests and vaccines; managing chronic (long-term) conditions; ratings of health plan responsiveness and care; health plan members’ complaints and appeals; and health plan telephone customer service)?

11. What are effective ways to display quality ratings that would be meaningful for Exchange consumers and small employers, especially drawing on lessons learned from public reporting and transparency efforts that states and private entities use to display health care quality information?

12. What types of methodological challenges may exist with public reporting of quality data in an Exchange? What suggested strategies would facilitate addressing these issues?

13. Describe any strategies that states are considering to align quality reporting requirements inside and outside the Exchange marketplace, such as creating a quality rating for commercial plans offered in the non-Exchange individual market.

14. Are there methods or strategies that should be used to track the quality, impact and performance of services for those with accessibility and communication barriers, such as persons with disabilities or limited English proficiency?

15. What factors should HHS consider in designing an approach to calculate health plan value that would be meaningful to consumers? What are potential benefits and limitations of these factors? How should Exchanges align their programs with value-based purchasing and other new payment models (for example, Accountable Care Organizations) being implemented by payers?

Dated: November 6, 2012.

Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: November 16, 2012.

Kathleen Sebelius,
Secretary.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Council on Migrant Health; Cancellation of Meeting

Name: National Advisory Council on Migrant Health.

Dates and Times: December 4, 2012, 8:30 a.m. to 5:00 p.m. December 5, 2012, 8:00 a.m. to 12:00 p.m.

STATUS: The meeting of the National Advisory Council on Migrant Health, scheduled for December 4 and 5, 2012, is cancelled. This cancellation applies to all sessions of the meeting. The meeting was announced in the Federal Register of November 8, 2012 (77 FR 67014).

FOR FURTHER INFORMATION CONTACT:
Gladys Cate, Office of Special Population Health, Bureau of Primary Health Care, Health Resources and Services Administration, 5600 Fishers Lane, Room 15–74, Rockville, Maryland 20857; telephone (301) 594–0367.


Bahar Niakan,
Director, Division of Policy and Information Coordination.

[FR Doc. 2012–28699 Filed 11–26–12; 8:45 am] BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. 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,
Axon Regeneration After Brain or Spinal Cord Injury

Description of Technology: The invention is directed to modification of a particular sugar by the enzyme arylsulfatase B (ARSB), which results in axon regeneration.

Following traumatic brain or spinal cord injury, glial scars prevent regeneration of axons. Chondroitin sulfate proteoglycans (CSPGs) are major components of glial scars. CSPGs are made of a protein core containing glycosaminoglycan (GAG) sugar side chains, which, when sulfated, are responsible for the inhibitory activity of glial scars. Specifically, NIH researchers have shown that the 4-sulfate unit on a certain sugar on GAG is responsible for inhibiting axon regrowth and, when the 4-sulfate unit is reduced, axon regrowth is observed. Moreover, removal of this 4-sulfate unit by the ARSB enzyme promotes axon regrowth.

As a potential therapy for spinal cord injuries, researchers developed a vector expressing ARSB and demonstrated that this vector promotes axon regeneration when injected into the spinal cord of a mouse.

Potential Commercial Applications:
- Treatment of brain and spinal cord injury.
- Treatment of other CNS injuries, including stroke.
- Treatment of heart attack.

Competitive Advantages:
- There are no existing products for treatment of traumatic spinal cord injury.
- ARSB is already approved for treatment of Mucopolysaccharidosis VI, a lysosomal storage disease.

Development Stage:
- Early-stage.
- In vitro data available.
- In vivo data available (animal).

Inventors: Joseph A. Hrabie and Larry K. Keefer (NCI).

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

Nitric Oxide-Releasing Polynivylpyrrolidone-Based Polymers for Wound Healing and Related Applications

Description of Technology: Novel nitric oxide-releasing polynivylpyrrolidone-based polymers, their compositions, and use in treating wounds. The disclosed polymers appear to be stable, bio-compatible and bio-absorbable, while providing for extended nitric oxide release at therapeutic levels. The invention also encompasses medical devices, such as wound dressings and bandages, which include the polymers and are capable of releasing nitric oxide when in use. These devices may be used to treat a wound, various infections, and dermatological conditions.

The therapeutic efficacy of nitric oxide has been demonstrated for many indications, including wound healing. As wounds are deficient in nitric oxide, its application has been shown to have beneficial effects on wound healing by promoting angiogenesis and tissue remodeling.

Potential Commercial Applications:
- Wound healing, infections, and dermatological conditions.

Competitive Advantages: The claimed nitric oxide-releasing polymers are bio-absorbable and release greater amounts of nitric oxide over a greater period of time than other NO-releasing polymers.

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

Inventors: Joseph A. Hrabie and Larry K. Keefer (NCI).

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

Gag-Based DNA Vaccines Against HIV

Description of Technology: Novel DNA vaccine constructs against HIV that express highly conserved elements (CE) within the HIV Gag protein and elicit strong, cross-clade cellular and humoral responses. The DNA vaccine vectors were engineered to express CEs for protection against different clades of HIV and prevention of immunodominance, two issues associated with current HIV vaccine candidates.

In vivo studies of Rhesus macaques vaccinated with variants of these constructs expressing seven highly CEs covering >99 of all known Gag sequences elicited strong, cellular T-cell and humoral antibody immune responses. The Gag-specific antibody responses were high titer and cross-clade. Cross-clade protection is important given the sequence diversity of HIV as is the absence of immunodominant epitopes that generate antibodies which are not protective against HIV.

Potential Commercial Applications:
- HIV vaccines.

Competitive Advantages: Addresses two key hurdles faced by current HIV vaccines: sequence diversity of HIV and immunodominance.

Development Stage:
- Early-stage.
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

Inventors: George N. Pavlakis (NCI), Barbara K. Felber (NCI), James Mullins (University of Washington).

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; changke@mail.nih.gov.

Diagnostic Test and Therapeutic Target for Sjogren's Syndrome

Description of Technology: Sjogren's syndrome is an autoimmune disease that attacks salivary glands resulting in chronic dry mouth and dry eyes. Currently, there is no single diagnostic test to confirm the presence of Sjogren's. Physicians presently reach diagnosis after conducting a series of blood and functional tests for tear and salivary production. Diagnosis is further complicated as Sjogren's symptoms frequently mimic those of other autoimmune diseases (e.g., lupus, rheumatoid arthritis, etc.) and is often overlooked as dryness associated with medications being taken by the patient.

Researchers at NIDCR have identified overexpression of a growth factor, bone morphogenetic protein 6 (BMP6), in patients with Sjogren’s. By detecting BMP6 expression and/or activity, this invention potentially presents a singular confirmation to diagnose those suffering
and those at risk for developing Sjögren’s. BMP6 also presents a potential therapeutic target for Sjögren’s, a disease for which there is presently no cure.

Researchers have also discovered unique expression profiles for two other genes (XIST and MECP2) in male Sjögren’s patients. Detecting aberrant expression and/or activity of these genes also offer a potential singular test for diagnosing Sjögren’s in male subjects.

**Potential Applications:**
- Singular diagnostic test to diagnose Sjögren’s.
- Therapeutic target to develop treatment for Sjögren’s.

**Competitive Advantages:**
- Currently no single test available to diagnose Sjögren’s.
- Currently there is no cure for Sjögren’s; present palliative treatments only reduce symptoms (e.g., moisture replacement therapy for eyes and mouth, and systemic anti-inflammatory or immunosuppressive agents for more advanced forms of disease).

**Development Stage:**
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

**Potential Commercial Applications:**
- Methods for diagnosis and treatment of Angiogenesis-Related Diseases.
- Methods for measuring AM accurately in vivo.

**Use of PAMP (Proadrenomedullin N-Terminal 20 Peptide) and PAMP Inhibitors for the Treatment of Cancer, Cardiovascular Disease, and Other Angiogenesis-Related Diseases**

**Description of Technology:**
The technology includes methods for utilizing purified adrenomedullin (AM)-binding proteins, or functional portions thereof, to diagnose, treat, and monitor AM-related diseases such as diabetes and cancer. Antibodies and small-molecule antagonists, which can down-regulate the function of AM, Complement Factor-H (CFH), and the AM–CFH complex, have also been isolated.

AM is a ubiquitously-expressed peptide that functions as a universal autocrine growth factor. AM drives cell proliferation, acts as a vasodilator, can protect cells against oxidative stress in hypoxic injury, and acts as a dose-dependent inhibitor of insulin secretion. Methods for measuring in vivo levels of AM accurately and regulating the activity of available AM may be critically important in diagnosis and treatment of many conditions, such as heart disease, pulmonary disease, cirrhosis, cancer, diabetes, sepsis, and inflammation.

This technology centers on the observation that AM binds to CFH in vivo. Without a means to determine the amount of AM that is bound to CFH, measurements of AM are inaccurate. Furthermore, therapies focused on the AM–CFH complex may have advantages over therapies focused on AM alone.

**Potential Commercial Applications:**
- Methods for diagnosis and treatment of conditions, such as cancer, diabetes, or other conditions influenced by AM levels.
- AM-specific antibodies could be used in a diagnostic assay to measure levels of AM.

**Competitive Advantages:**
- More accurate measurements of serum adrenomedullin than current tests.
- Targeting AM–CFH decreases bioavailable AM, provides an additional pathway for modulating angiogenesis.

**Development Stage:**
- Pre-clinical.
- In vitro data available.
- In vivo data available (animal).

**Use of PAMP (Proadrenomedullin N-Terminal 20 Peptide) and PAMP Inhibitors for the Treatment of Cancer, Cardiovascular Disease, and Other Angiogenesis-Related Diseases**

**Description of Technology:**
This technology details the use of PAMP or PAMP derivatives as a means to induce angiogenesis in tissue, as well as the use of PAMP inhibitors to inhibit angiogenesis.

**PAMP (Proadrenomedullin N-terminal 20 peptide) is a 20 amino-acid molecule originating from the post-translational processing of proproadrenomedullin. PAMP is known as a potent hypotensive and vasodilatory agent; however, in addition to these properties, the inventors have discovered that PAMP also functions as a potent angiogenic factor. The inventors have also shown that an inhibitory fragment of PAMP, PAMP (12–20), is able to delay tumor growth in xenograft models of tumor progression. The ability to promote angiogenesis can be used as a means to increase vascularization in specific tissue areas or to treat patients with ischemic diseases. In contrast, the ability to inhibit this process can be used to limit growth of solid tumors and as a therapy for retinopathies, endometriosis, or arthritis.

**Potential Commercial Applications:**
- PAMP and derivatives may be used as treatments for ischemic disease or coronary artery disease and to promote vascularization in graft tissues.
- PAMP inhibitors may be used as treatments to limit growth of solid tumors or other angiogenesis-related disease.

**Competitive Advantages:**
- PAMP exhibits a potent angiogenic potential at femtomolar concentrations, as opposed to nanomolar concentrations of other growth factors such as bFGF and VEGF.
- PAMP and PAMP inhibitors provide a new mechanism for modulation of angiogenesis and treatment of angiogenesis-related diseases.

**Development Stage:**
- Early-stage.
- In vitro data available.
- In vivo data available (animal).

**Licensing Contact:** Tara Kirby, Ph.D.; 301–435–4426; tara@mail.nih.gov.

**Use of PAMP (Proadrenomedullin N-Terminal 20 Peptide) and PAMP Inhibitors for the Treatment of Cancer, Cardiovascular Disease, and Other Angiogenesis-Related Diseases**

**Description of Technology:**
This technology details the use of PAMP or PAMP derivatives as a means to induce angiogenesis in tissue, as well as the use of PAMP inhibitors to inhibit angiogenesis.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning (R34) Grants and Implementation Cooperative Agreements (U01).

Date: December 12, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: James T. Snyder, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities/ NIAID, National Institutes of Health, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–451–2634, james.snyder@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 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 Neurological Disorders and Stroke Special Emphasis Panel; Translational SEP.

Date: November 30, 2012.

Time: 2:00 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: Shanta Rajaram, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS, MSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Bethesda, MD 20892–9529, (301) 435–6033, rajarams@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; NINDS T–32.

Date: December 12, 2012.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)