


Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; wongje@mail.nih.gov.

Dated: July 1, 2009.

Richard U. Rodriguez,
Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

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.

ADDRESSES: 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.

qPCR Assay for Detection of JC Virus

Description of Invention: JC Virus causes a fatal disease in the brain called progressive multifocal leukoencephalopathy (PML) that occurs in many patients with immunocompromised conditions. For example, more than five percent (5%) of AIDS patients develop PML. Additionally, these conditions include, but are not limited to, cancers such as leukemias and lymphomas, organ transplants such as kidney, heart and autoimmune conditions with treatment that modulates the immune system such as Multiple Sclerosis (MS), rheumatoid arthritis, psoriasis, and systemic lupus erythematosus. The finding of JCV DNA in the patients with neurological symptoms of PML is a diagnostic criterion and is needed to confirm the diagnosis of PML to rule out other neurological conditions.

This technology describes a qPCR assay that utilizes viral DNA standards and testing samples to detect the presence of the JC viral genome in patients’ cerebrospinal fluid and blood, blood products, and tissue samples from biopsy or autopsy.

Application: Development of JC Virus (JCV) diagnostics, calibration of existing JCV assays.

Advantages: Assay is sensitive, reproducible and highly specific because the amount of JCV DNA in cerebrospinal fluid or blood or blood product samples may be very small.

Development Status: Materials and assay have been developed and tested.

Inventors: Eugene O. Major and Caroline Ryschkewitsch (NINDS).

Publications


Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; soukaspa@mail.nih.gov.

A Locking Device for Permanently Securing Surgical Suture Loops

Description of Invention: This technology relates to a device that can be used to non-invasively secure surgical suture loops when combined with a percutaneous delivery system. It has been shown to be effective in correcting mitral valve regurgitation (MVR) in an animal model. During the procedure, a guidewire is percutaneously conveyed to the atrium of the heart and is used to secure the “cerclage” suture encircling the mitral valve annulus, which is delivered using a delivery catheter. The locking device is advanced over the suture by the delivery catheter and it permanently secures the suture and maintains the tension on the annulus once the delivery system is removed. This locking device, in combination with the percutaneous procedure, allows for more complete coaptation of the valve leaflets and correction of MVR without the need for open heart surgery and its associated risks. The locking device is also adjustable, allowing the user to vary the tension on the suture if further tightening or loosening is required. It is also MRI compatible and all follow-up studies can be performed under MRI.

This invention has demonstrated its ability to correct MVR in animals where the locking device was observed to maintain the correct position and tension after implantation. This device has the potential to replace the traditional loop and knot method used for surgical correction of MVR, and may also be useful for other conditions that require permanently secured suture loops.

Applications: Non-invasive and effective correction of MVR and other conditions; Tensioning device for securing suture loops.

Advantages: Technology amenable to a non-invasive technique; Control of tension on surgical sutures.

Development Status: Early stage.

Inventor: Ozgur Kocaturk (NHBLI).


Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; jeffreyj@mai1.nih.gov.

Collaborative Research Opportunity: The National Heart, Lung and Blood Institute Cardiac Catheterization Lab is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the
tension fixation device. Please contact Peg Koeble at 301–594–4095 or koeblep@nhlbi.nih.gov for more information.

Modulators of Pregnane X Receptor (PXR) as Therapeutics for Bowel Disorders (BD)

Description of Invention: This technology is based on the novel findings that susceptibility to BD is strongly associated with genetic variation in the PXR gene, a member of the nuclear receptor family, and rifaximin is a specific activator of human PXR. PXR is an integral component of the body’s defense mechanism involved in endogenous and xenobiotic detoxication. Based on these novel findings, the present technology provides (a) methods of screening for compositions that modulate inflammatory bowel disease (IBD), (b) methods of inhibiting inflammation of the bowel and related tissues and organs, and (c) methods of treatment of inflammatory bowel disease.

Applications: Therapeutics for bowel disorders; Screening assays for candidate drugs to treat bowel disorders.

Development Status: Early stage.

Market: It is estimated that as many as one (1) million Americans have IBD, with that number evenly split between Crohn’s disease and Ulcerative Colitis (UC). Further, it is estimated that the IBD therapeutic market will grow to $1.8 billion by 2020. “Promising microbicides” Frontline (Volume 21—Issue 14, Jul. 03–16, 2004).

For influenza market, based on Report Buyer which is a UK-based independent online store supplying business information on major industry sectors: By 2010, the worldwide influenza market is likely to reach $7.1 billion, with average annual growth estimated at 19.8%.

Inventors: Michael R. Boyd (NCI), Barry R. O’Keefe (NCI), et al.

Publications

Patent Status
• E–117–1995/1—US Patent Numbers 5,821,081; 5,998,587; 6,987,096; and 5,962,668.

The Protein Cyanovirin Inactivates HIV and Influenza

Description of Invention: Cyanovirin-N (CV–N) potently and irreversibly inactivates diverse primary strains of HIV–1, including M-tropic forms involved in sexual transmission of HIV, as well as T-tropic and dual-tropic forms. CV–N also blocks cell-to-cell transmission of HIV infection. CV–N interacts in an unusual manner with the viral envelope, binding with extremely high affinity to poorly immunogenic epitopes on gp120. Further, CV–N and homologous proteins and peptides potently inhibit diverse isolates of influenza viruses A and B, the two major types of influenza virus that infect humans.

The described technology includes glycysolation-resistant mutants, which code sequences to enable ultra large-scale recombinant production of functional CV–Ns in non-bacterial (yeast or insect) host cells or in transgenic animals or plants. Therefore, these glycysolation-resistant mutants may allow industry to produce CV–Ns on a large scale and make CV–Ns cheap enough for developing countries to benefit from this invention.

CV–N was benign in vivo when tested in the rabbit/monkey vaginal toxicity/irritancy model and was not cytotoxic in vitro against human immune cells and lactobacilli. CV–N is readily soluble in aqueous media, is remarkably resistant to physicochemical degradation and is amenable to very large-scale production by a variety of genetic engineering approaches.

Applications
• Therapeutics and prevention of HIV and influenza infection.
• Topical microbicide to protect HIV infection.
• Ex vivo devices incorporating CV–N to remove or inactivate HIV from fluid samples.

Advantages
• Potent anti-HIV and anti-influenza activity.
• Can be applied both systematically or locally.
• Can be applied both in vivo and ex vivo.
• Inexpensive and large scale manufacturing.

Development Status
• Preclinical (rabbit/monkey) data in micobiocide field are available at this time.
• Initial animal efficacy studies (both mouse and ferret) against influenza (H1N1) have been completed and published.

Market: For HIV therapeutics market, a published report by the financial services firm Griffin Securities suggested that sales of HIV/AIDS drugs reached $13 billion annually in 2007 (http://www.hivandhepatitis.com). For microbicide market, it has been estimated that the global market size of microbicide will reach to $900 million by 2011 and will reach the sales of over $1.8 billion by 2020. “Promising microbicides” Frontline (Volume 21—Issue 14, Jul. 03–16, 2004).

For influenza market, based on Report Buyer which is a UK-based independent online store supplying business information on major industry sectors: By 2010, the worldwide influenza market is likely to reach $7.1 billion, with average annual growth estimated at 19.8%.

Inventors: Frank J. Gonzalez (NCI), Xiaochao Ma (NCI), et al.


Licensing Status: Available for licensing.

Licensing Contact: Suryanarayana (Sury) Vepa, PhD, J.D.; 301–435–5020; vepas@mail.nih.gov.

Collaborative Research Opportunity: The Laboratory of Metabolism, Center for Cancer Research, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize compounds that ameliorate bowel disorders through the PXR pathway. Please contact Lisa Finkelstein, PhD at 301–451–7458 or lfinkel@mail.nih.gov for more information.

Under the European Community’s Framework Programme 7, NCI is offering the opportunity for European researchers and industry to collaborate with the laboratories involved in these projects. Interested researchers or companies should contact Xiaochao Ma (NCI), koeblep@nhlbi.nih.gov.

Licensing Status: Available for licensing.

Licensing Contact: Sally Hu, PhD, 301–435–5606, HuS@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Molecular Targets Development Program, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, PhD at 301–435–3121 or hewesj@mail.nih.gov for more information.

Novel Osteobiologic Proteins for Treatment of Osteoporosis, Rheumatoid and Neurologic Diseases

Description of Invention: In an effort to find effective strategies for treatment of body tissue and structural damage as the result of trauma, cancer and other diseases, scientists at the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) have identified proteins and associated pathways instrumental in replacing or regenerating damaged tissue. The identified proteins include Cartilage-Derived Morphogenetic Proteins (CDMP), Bone Morphogenetic Proteins (BMPs) and a tissue fate modifying FRZB Protein. Each has unique activities likely to be useful as stand alone agents or in construction of engineered tissues.

CDMPs appear helpful in the healing of bone and joint surface lesions, and also for the repair or reconstruction of cartilaginous tissues, tendons and ligaments. BMP antagonists will be useful in the study of stem cell differentiation. FRZB Protein, a tissue fate modifying secretable antagonist of Wnt signaling, is involved in the formation of cartilage, bone, neural and muscle tissue.

Potential Areas of Application
- Rheumatic diseases of the bone.
- Osteoporosis and osteoarthritis.
- Wound healing.
- Neurodegenerative disorders.
- Growth and repair of musculoskeletal tissues.
- Tissue engineering.

- Useful in the therapeutic induction, repair, and maintenance of skeletal tissues and cartilage growth.
- Polynucleotides encoding these proteins are useful as diagnostic reagents for detecting genetic abnormalities associated with poor skeletal development.

Tissue Fate Modifying FRZB Protein (HHS Reference Nos. E–127–1995/0/1/2)
- Involved in the formation of cartilage, bone, neural and muscle tissue.
- Regenerative agent to treat degenerative disorders (i.e., Huntington’s, Alzheimer’s or spinal cord injuries), myodegenerative disorders (i.e., muscular dystrophy, myasthenia gravis or myotonic myopathies) and osteodegenerative disorders (i.e., osteoporosis or osteoarthritis)
- Selectively blocks diseases associated with Wnt family of signaling molecules including neoplasias.

Bone Morphogenetic Protein Variants (HHS Reference No. E–196–2004/0)
- Promote repair of menisci, cruciate and collateral ligaments of the knee, and rotator cuff or other tendons and/or ligaments.
- Induce the proliferation and differentiation of progenitor cells into functional bone, cartilage, tendon, or ligament tissue.

Advantages: Osteobiologics, such as BMPs, have the ability to stimulate musculo-skeletal repair instead of using donated human tissue allografts and synthetic materials.

Market Size: Ankylosing spondylitis afflicts least half a million people in the United States. Currently, there remains a need for the development of effective therapeutics for treating spondyloarthopathies that could overcome the disadvantages of current drugs.

Osteoarthritis overall affects an estimated 30 million US adults. Direct medical expenses for arthritis and other rheumatic conditions are estimated at $80.8 billion. In the United States, 10 million people have Osteoporosis. Osteoporosis related fractures attributed for $21 billion with the number expected to rise to $26 billion in 2025.

Inventors: Malcolm C. Moos Jr. (FDA), Frank P. Luyten (NIDCR), et al.

Related Publications

Patent Status

Tissue Growth-Inducing FRZB Protein (HHS Reference Nos. E–127–1995/0/1/2)
- U.S. Patent Application No. 11/184,005 (allowed).

Bone Morphogenetic Variants (HHS Reference No. E–196–2004/0)

Licensing Status: Available for licensing.

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; vathyams@mail.nih.gov.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; Time Sensitive Applications.

Date: July 16, 2009.

Time: 1:30 p.m. to 2:30 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: Aileen Schulte, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd, Room 6140, MSC 9608, Bethesda, MD 20892–9608, 301–443–1225, asculte@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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: July 1, 2009.

Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–16092 Filed 7–8–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Ancillary Studies.

Date: July 29, 2009.

Time: 1:30 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dan E. Matsumoto, Ph.D., Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8094, matsumoto@extra.niddk.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. 93.847, 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)

Dated: July 1, 2009.

Jennifer Spaeth, Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–16902 Filed 7–8–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee on Procedures Reviews, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting for the aforementioned subcommittee:

Time and Date: 10 a.m.–5 p.m., August 13, 2009.

Place: Cincinnati Airport Marriott, 2395 Progress Drive, Hebron, Kentucky 41018, Telephone (859) 334–4611, Fax (859) 334–4619.

Status: Open to the public, but without a public comment period. To access by teleconference dial the following information 1(866)659–0537, Participant Pass Code 9933701.

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC).

In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, renewed at appropriate intervals, and will expire on August 3, 2009.

Purpose: The Advisory Board is charged with (a) Providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The Subcommittee on Procedures Reviews, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)