Centers for Public Health Preparedness (CPHP) Program. The purpose of the CPHP Program is to strengthen terrorism and emergency preparedness by linking academic expertise to state and local health agency needs. The program brings together colleges and universities with a common focus on public health preparedness to establish a national network of education and training resources. Of these institutions, 27 are accredited Schools of Public Health funded through a five-year Cooperative Agreement for years 2004–2009. This program addresses the public health goals described in ''A National Strategy for Terrorism Preparedness and Response: 2003–2008 Strategic Plan,'' specifically Imperative Five, a Competent and Sustainable Workforce. Critical objectives under this Imperative are to: (1) Increase the number and type of professionals that comprise a preparedness and response workforce; (2) deliver certification and competency-based training and education; (3) recruit and retain the highest quality workforce; and (4) evaluate the impact of training to ensure learning has occurred.

CDC requests OMB approval for a period of one year to collect information beginning in the fall of 2009. CDC is undertaking a summative evaluation of the CPHP Program encompassing the period of the current Cooperative Agreement. In order to complete this evaluation, CDC is proposing three data collection instruments to gather information describing the program's processes and outcomes. These are: (1) CPHP Interview Instrument; (2) CPHP Customer/Partner Survey Instrument; and (3) CPHP Customer/Partner Follow-Up Interview Instrument. Collectively, these instruments are needed in order to gather, process, aggregate, evaluate, and disseminate CPHP program information. The information will be used by CDC to document progress toward meeting established program goals and objectives, to evaluate outcomes generated by the collective work of the 27 Centers, to inform the development of a new public health preparedness education and training cooperative agreement program, and to respond to data inquiries made by CDC and other agencies of the federal government.

The CPHP Interview Instrument will be used to guide a telephone interview process with key CPHP staff. Questions will gather perceptions about the CPHP Program from the perspective of CPHP staff. It is estimated that there will be a total of 81 respondents with an estimated time for data collection of 90 minutes. The CPHP Customer/Partner Survey Instrument will be used to gather information from representatives of organizations that have received training or technical assistance from the CPHP Program. It will be administered electronically with an option for paper copy administration. It is estimated that there will be one request per respondent and a total of 171 respondents with an estimated time for data collection of 20 minutes. The CPHP Customer/Partner Follow-Up Interview Instrument will be used to gather more in-depth information on the same categories of questions from the Survey Instrument. It is estimated that there will be a total of 20 respondents with an estimated time for data collection of 45 minutes. The annualized estimated burden hours are 193.5.

There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
CPHP PIs, PCs, and Evaluators	CPHP Interview Instrument.	81	1	1.5	121.5
CPHP Customers and Partners	CPHP Customer/Partner Survey Instrument.	171	1	20/60	57
CPHP Customers and Partners	CPHP Customer/Partner Follow-Up Interview Instrument.	20	1	45/60	15

Dated: July 2, 2009.

Marilyn I. Radke,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–16225 Filed 7–8–09; 8:45 am]

BILLING CODE 4163–18–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.

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.

Immunogenic Peptide from NGEP Protein for Developing Prostate Cancer Vaccines

Description of Technology: The NGEP protein is only present in the prostate and is typically overexpressed on prostate cancer cells. Hence, as a novel prostate tumor-associated antigen (TAA) it is a good target for developing active immunotherapies to kill prostate cancer cells. For example, NGEP could be used in a vaccine to activate an individual's immune system to recognize and kill NGEP-expressing prostate cancer cells. However, TAAs typically are not very effective in inciting an immune response. This can be overcome by identifying portions (epitopes) of the

TAA that are more immunologically active.

Investigators at the NIH have identified a small peptide fragment of the NGEP protein (NGEP CTL peptide epitope) that is very effective in activating cytotoxic lymphocytes, causing them to destroy prostate cancer cells and has great potential for development of a variety of active immunotherapy strategies, such as vector-based cancer vaccines, to treat and prevent prostate cancer. In addition, it could be used for developing sensitive immunoassays for measuring the immune response of a prostate cancer patient during immunotherapy.

Applications:

- Peptide cancer vaccine.
- Vector-based cancer vaccine.
- Liposome-based cancer vaccine.
- Cellular cancer vaccine.
- In vitro diagnostic for monitoring the immune response of prostate cancer patients during cancer vaccine trials.

Advantages:

- Small biologic therapeutic.
- Can be chemically synthesized or produced recombinantly.
- DNA encoded peptide allows molecular engineering.
- Can be used as a tumor antigen with the clinically proven TRICOM-based vaccine technology.

Development Status: Early stage.

Market: Prostate cancer is the second-leading cause of cancer death in men. It is estimated that in the United States there will be 192,280 new cases of prostate cancer and 27,360 deaths due to prostate cancer in 2009.

Inventors: Jeffrey Schlom *et al.* (NCI).

Publications: No publications directly related to this technology.

Patent Status: U.S. Provisional Application No. 61/170,900 filed 20 Apr 2009 (HHS Reference No. E–042–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Sabarni Chatterjee, PhD; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Laboratory of Tumor Immunology and Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Kevin Brand, J.D. at 301–451–4566 or *brandk@mail.nih.gov* for more information.

Gene Expression Signature Predictive of Response to Chemotherapy

Description of Technology: Combination cisplatin and fluorouracil (CF) is a reference chemotherapy regimen for metastatic gastric cancer. However, to date, no genome-wide studies have identified distinctions in gene expression that predict which subjects with metastatic disease will benefit from this therapy and which subjects will not exhibit a therapeutic response to chemotherapy. Given the toxicity of chemotherapy, however, defining parameters that identify those subjects who will likely benefit from chemotherapy is of paramount importance. Early identification of non-responders would provide opportunities to explore alternate or novel therapeutic approaches. Thus, a need exists to identify methods of predicting a subject's response to chemotherapy prior to receiving the treatment.

Scientists at the National Institutes of Health have discovered a three-gene signature that can be used to determine the chemotherapy response in patients with cancer. By measuring the expression of three cancer-specific genes it can be determined if a patient with an epithelial cancer such as gastric, bladder, head and neck, esophageal or cervical cancers, will respond to CF treatment. The inventors have demonstrated that examining these expression levels has high fidelity in identifying CF treatment non-responders. Further, the invention describes a mechanism that can help patients identified as non-responders become responsive to treatment. Therefore these methods have the potential to reduce fatalities caused by metastatic gastric cancer by identifying patients early on who are non-responsive to standard CF treatment and customizing a new treatment plan which may be better suited to their individual needs.

Applications:

- Prognostic testing of epithelial cancer patients.
- Customized treatment for gastric cancer patients identified as CF treatment non-responders.

Advantages:

- Expression levels of cancer-specific genes can be used to determine if metastatic gastric cancer patients are responsive to combination cisplatin and fluorouracil (CF) treatment.
- Fatalities due to metastatic gastric cancer may be reduced by customizing the treatment of non-responders.

Market: In 2008, it is estimated that there will be 21,500 new cases and 10,880 deaths from gastric cancer in the United States.

Development Status: Patient tissue sample data available.

Inventors: Jeffrey E. Green and Hark Kyun Kim (NCI).

Patent Status: U.S. Provisional Application No. 61/195,123 filed 03 Oct 2008 (HHS Reference No. E–282–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research, Laboratory of Cancer Biology and Genetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Gene Expression Signature Predictive of Response to Chemotherapy. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Therapeutic Applications of a p53 Isoform in Regenerative Medicine, Aging, and Cancer

Description of Technology: p53 plays a critical role in carcinogenesis and aging as a key regulator of cell cycle progression, senescence and apoptosis. The inventors have discovered that a natural variant of p53 (Δ133p53) inhibits p53-dependent cell senescence. Utilizing Δ133p53 siRNAs, the inventors have data demonstrating that siRNA-treated human fibroblast undergo cell senescence, thereby indicating that Δ133p53 inhibition could be a novel approach for cell senescence-mediated anti-proliferative therapy, including anti-cancer treatments. Alternatively, enhanced expression with Δ133p53 can extend the replicative lifespan of normal human cells. This technology may provide a new method in the field of regenerative medicine for aging-related degenerative disease.

Also available for licensing are Δ133p53 siRNAs and shRNA vectors, as well as a Δ133p53 overexpression vector, which can be used for cancer and age-related degenerative therapeutics. The shRNA can be stably integrated into the cellular genome for long-term Δ133p53 inhibition.

The inventors have also discovered that another p53 variant (p53β) accelerates p53-dependent cell senescence, and developed a vector for overexpressing p53β, which could be used for cell senescence-mediated anti-proliferative therapy.

Applications:

- Method to treat cancer.
- Method to treat aging related disorders.
- Method to promote tissue regeneration.

• Pharmaceutical compositions to inhibit cancer or promote cell regeneration.

Advantages:

• Ability to treat a wide variety of cancers and age-related diseases as p53 is present in normal cells.

• shRNA therapeutics are stably integrated into genome for long-term treatment.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

• An estimated 1,479,350 new cancer diagnoses in the U.S. in 2009.

• Cancer is the second leading cause of death in United States.

• It is estimated that the cancer therapeutic market would double to $50 billion a year in 2010 from $25 billion in 2006.

Inventors: Curtis C. Harris (NCI) *et al.*

Relevant Publications:

1. K Fujita *et al.* p53 isoforms, Δ133p53 and p53β, are endogenous regulators of replicative cellular senescence. Nat Cell Biol., in press.

2. International Agency Research on Cancer Conference, Lyon, France, November 13, 2007.

Patent Status:

• U.S. Provisional Application No. 60/987,340 filed 12 Nov 2007 (HHS Reference No. E–033–2008/0–US–01).

• PCT Application No. PCT/US2008/080648 filed 21 Oct 2008 (HHS Reference No. E–033–2008/0–PCT–02).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact *Curtis_Harris@nih.gov* for more information.

Novel Compounds that Specifically Kill Multi-Drug Resistant Cancer Cells

Description of Invention: One of the major hindrances to successful cancer chemotherapy is the development of multi-drug resistance (MDR) in cancer cells. MDR is frequently caused by the increased expression or activity of ABC transporter proteins in response to the toxic agents used in chemotherapy. Research has generally been directed to overcoming MDR by inhibiting the activity of ABC transporters. However, compounds that inhibit ABC transporter activity often elicit strong and undesirable side-effects, restricting their usefulness as therapeutics.

Investigators at the NIH previously identified that the compound NSC73306 had the ability to specifically kill cancer cells that overexpressed an ABC transporter responsible for MDR. Importantly, this ''MDR-selective compound'' is not an inhibitor of ABC transporters, reducing the likelihood of undesirable side-effects if used as a therapeutic.

Using NSC 73306 as a model, new MDR-selective compounds have been created with improved solubility and selectivity. These new MDR-selective compounds can also selectively kill MDR cancer cells, with their efficacy correlating directly with the level of ABC transporter expression. Recent evidence also shows that these new MDR-selective compounds have the ability to decrease the expression of ABC transporters, potentially re-sensitizing the cancer cells to chemotherapeutic agents. Thus, MDR-selective compounds represent a powerful strategy for treating multi-drug resistant cancers as a direct chemotherapeutic and as agents that can re-sensitize MDR cancer cells for treatment with additional chemotherapeutic agents.

Applications:

• Treatment of cancers associated with multi-drug resistance, either alone or in combination with other therapeutics.

• Development of a pharmacophore for improved effectiveness in treating cancers associated with multi-drug resistance.

• Re-sensitization of multi-drug resistant cancer cells to chemotherapeutic agents.

Advantages:

• MDR-selective compounds capitalize on one of the most common drawbacks to cancer therapies (MDR) by using it as an advantage for treating cancer.

• The compositions do not inhibit the activity of ABC transporters, thereby reducing the chance of undesired side-effects during treatment.

• The effects of MDR-selective compounds correlate with the level of ABC transporter expression, allowing healthy cells which do not express high levels of ABC transporters to better survive treatments.

• Increased specificity allows the new MDR-selective compounds to be tailored to treating cancers associated with the overexpression and hyperactivity of particular ABC transporters.

• Increased solubility of the new MDR-selective compounds allows greater access to cancer cells, thereby increasing therapeutic effectiveness.

Development Status: Preclinical stage of development.

Patent Status: PCT Application No. PCT/US2009/000861 (HHS Reference No. E–017–2008/0–PCT–02).

Inventors: Matthew D. Hall *et al.* (NCI).

For more information, see:

• MD Hall *et al.* Synthesis, activity, and pharmacophore development for isatin-beta-thiosemicarbazones with selective activity toward multidrug-resistant cells. J Med Chem. 2009 May 28;52(10):3191–3204.

• US Patent Application Publication 20080214606 A1 (US Patent Application 11/629,233).

Licensing Status: Available for licensing.

Licensing Contact: David A. Lambertson, PhD; 301–435–4632; *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Cell Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the agents described here. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Methods for Treating Cancer in Humans Using IL–21

Description of Invention: The present invention discloses the use of IL–21 for cancer therapy, cancer prevention, and method to induce apoptosis. When compared to similar cytokines, IL–21 has shown substantial anticancer activity and reduced toxicity in murine models.

IL–21 belongs to the class I family of cytokines and is closely related to IL–2 and IL–15. Some cancer patients have shown significant response to administration of IL–2. However, IL–2 has also been associated with severe toxicity leading to a variety of undesirable side effects. This invention attempts to resolve the toxicity concerns and presents a new therapy for cancer prevention and treatment.

Applications: Method to treat and prevent cancer.

Advantages: Targeted therapy to minimize negative side effects of IL–2 cancer therapeutics.

Development Status: Pre-clinical.

Inventors: Patrick Hwu (formerly NCI), Gang Wang (formerly NCI), Warren J. Leonard (NHLBI), Rosanne Spolski (NHLBI), *et al.*

Related Publications:

1. R Spolsi and WJ Leonard. Interleukin-21: Basic biology and implications for cancer and

autoimmunity. Annu Rev Immunol. 2008;26:57–79.

2. WJ Leonard and R Spolski. Interleukin-21: A modulator of lymphoid proliferation, apoptosis and differentiation. Nat Rev Immunol. 2005 Sep;5(9):688–698.

3. G Wang et al. In vivo antitumor activity of interleukin 21 mediated by natural killer cells. Cancer Res. 2003 Dec15;63(24):9016–9022.

Patent Status: U.S. Patent Application No. 10/508,978 filed 19 Nov 2004 (HHS Reference No. E–137–2002/0–US–03).

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.

[FR Doc. E9–16300 Filed 7–8–09; 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, 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.

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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

1. ML Landry *et al.* False negative PCR despite high levels of JC virus DNA in spinal fluid: Implications for diagnostic testing. J Clin Virol. 2008 Oct;43(2):247–249.

2. C Ryschkewitsch *et al.* Comparison of PCR-southern hybridization and quantitative real-time PCR for the detection of JC and BK viral nucleotide sequences in urine and cerebrospinal fluid. J Virol Methods. 2004 Nov;121(2):217–221.

3. T Yousry *et al.* Evaluation of patients treated with natalizumab for progressive multifocal leukoencephalopathy. N Engl J Med. 2006 Mar 2;354(9):924–933.

Patent Status: HHS Reference No. E–152–2009/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas, J.D.; 301–435–4646; *soukasp@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 (NHLBI).

Patent Status: U.S. Provisional Application No. 61/157,267 filed 04 Mar 2009 (HHS Reference No. E–048–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; *jeffreyja@mail.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