

amounts. For calendar year 2002, section 1833(h) of the Act requires the national limitation amount for each test to be established at 74 percent of the median of all local laboratories' fee schedule amounts, or 100 percent of the median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established.

### Payment Codes

The codes used on the Clinical Laboratory Fee Schedule are largely the CPT codes that are developed and published by the American Medical Association (AMA). The codes are a listing of descriptive terms for reporting clinical laboratory tests. The AMA publishes the updated codes (through books and magnetic tape) every year in October for use by payers and providers for the upcoming calendar year. Approximately 1,000 separate clinical laboratory codes are currently listed in the 80000–89399 CPT code series. In addition, the Clinical Laboratory Fee Schedule contains a small number (less than 50) of HCFA's Common Procedure Coding System (HCPCS) alpha-numeric codes that are developed by the Blue Cross and Blue Shield Association (BCBSA), the Health Insurance Association of America (HIAA), and HCFA. These codes were created to include clinical laboratory codes that are unique to the Medicare payment system. An example of this type of code is G0103, prostate cancer screening; prostate specific antigen blood test. This alphanumeric code was introduced effective January 1, 2000, to implement section 4103 of the Balanced Budget Act of 1997 that mandates additional coverage and tracking of expenditures for this type of test for Medicare beneficiaries.

The AMA's CPT Editorial Panel has procedures for receiving requests to change codes and conducts meetings to review the requests. The CPT codes are updated annually to reflect changes in the practice of medicine and provision of health care. A request for a code change may be submitted by any interested party. The CPT meetings occur several times a year and result in annual additions, deletions, and modifications of codes. By June of each year, the CPT Editorial Panel has largely completed its coding decisions for the upcoming calendar year. In the past, to accord with the AMA CPT publication schedule, we have not been able to make the new codes publicly available until October. This constraint did not permit us sufficient time to seek public

input on the determination of pricing of new codes before we had to transmit the new fee schedule to our contractors. However, this year the AMA has agreed to make the codes available in draft during the summer so that we can proceed with this meeting to obtain public input.

Two methods for determining the payment rates for new codes are available, which may be summarized as follows:

- In the first method, called "cross walking," we determine a new test to be similar to an existing test, multiple existing test codes, or a portion of an existing test code. The new test code is then assigned the related existing local fee schedule amounts and resulting national limitation amount. In some instances, we determine that a test may only equate to a portion of an existing test, and, in those instances, we specify payment at an appropriate percentage of the payment for the existing test.

- The second method, called "gap filling," is used when no comparable, existing test is available. We then instruct each Medicare carrier to determine a payment amount for its area for use in the first year. Then, we use the carrier-specific amounts to establish a national limitation amount for the following year.

For each new code, we must determine whether it is appropriate to cross walk or to gap fill, and, if cross walking is appropriate, we need to know what tests to which to cross walk. These are the decisions on which we will seek public input at this meeting.

**Authority:** Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh)

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 22, 2001.

**Thomas A. Scully,**

*Administrator, Health Care Financing Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, DHHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by agencies 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.

#### Structure Determination of Materials Using Electron Microscopy

Sriram Subramaniam (NCI)

[DHHS Reference No. E-187-01/0 filed 23 Apr 2001]

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a method for automating the acquisition of electron microscopic images from a desktop computer interface to provide for data collection by any user from any location. Automated low-dose image acquisition procedures are used to record high-resolution images on either film or CCD, at desired defocus values, and under conditions that satisfy user-specified limits for drift rates of the specimen stage. In a fully automated procedure of the invention, the determination of regions suitable for imaging are carried out automatically using spiral search algorithms. All steps subsequent to insertion of the specimen in the microscope can be carried out on a remote personal computer connected to the microscope computer via the Internet.

#### Lever Coil Sensor for Respiratory and Cardiac Motion

Kenneth W. Fishbein (NIA)

DHHS Reference No. E-134-01/0 filed 30 Mar 2001]

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a device that generates a signal for synchronizing an MRI scanner with a subject's respiratory and cardiac motion to prevent blurring of the image during the scan. This device uses a small electromagnetic pickup coil to simultaneously sense

respiratory and cardiac motion and provide a synchronization signal. The invention uses a mechanical linkage to keep the pickup coil far from the center of the scanner's radio frequency and gradient coils, thereby eliminating artifacts in the sensor signal and magnetic resonance images caused by mutual inductance. The signal generated by this device is proportional to chest velocity rather than chest height and is, therefore, free of any offset voltages, permitting peak location with a simple threshold detector, and is large in amplitude even for small animal subjects. The invention operates without the need for any electrical leads inside the magnet and thus eliminates any burn hazards for the patient. This device provides an inexpensive alternative to commercially available bellows sensors and fiber optically coupled units. Unlike competing sensors, this invention can be inserted, removed, or adjusted without removing the subject from the magnet and can operate with the subject in a prone or supine position. This invention has applications in both animal and human imaging studies.

#### **Vessel Surface Reconstruction With a Tubular Deformable Model**

Yim et al. (CC)

[DHHS Reference No. E-239-01/0 filed 15 Feb 2001]

*Licensing Contact:* Dale Berkley; 301/496-7735 ext. 223; e-mail: berkleyd@od.nih.gov

The invention is a method for modeling a carotid or renal artery to measure stenosis from 3D angiographic data that may otherwise exhibit limited image resolution and contrast. The method reconstructs vessel surfaces from 3D angiographic data using a deformable model that employs a tubular coordinate system. Vertex merging is incorporated into the coordinate system to maintain even vertex spacing and to avoid problems of self-intersection of the surface. This method produces reconstructed surfaces that have a realistic smooth appearance and accurately represent vessel shape. The method allows for an objective evaluation of vessel shape and may improve the precision of shape measurements from 3D angiography.

This abstract revises one published in the **Federal Register** on Tuesday, May 20, 2001 (66 FR 29154) as DHHS Reference No. E-202-00/1.

#### **Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses**

Stephen S. Whitehead, Brian R. Murphy, Kathryn A. Hanley, Joseph E. Blaney Jr. (NIAID)

[DHHS Reference No. E-120-01/0 filed 22 May 2001]

*Licensing Contact:* Carol Salata; 301/496-7735 ext. 232; e-mail: salatac@od.nih.gov

Although flaviviruses cause a great deal of human suffering and economic loss, there is a shortage of effective vaccines. This invention relates to dengue virus mutations that may contribute to the development of improved dengue vaccines. Site directed and random mutagenesis techniques were used to introduce mutations into the dengue virus genome and to assemble a collection of useful mutations for incorporation in recombinant live attenuated dengue virus vaccines. The resulting mutant viruses were screened for several valuable phenotypes, including temperature sensitivity in Vero cells or human liver cells, host cell restriction in mosquito cells or human liver cells, host cell adaptation for improved replication in Vero cells, and attenuation in mice or in mosquitoes. The genetic basis for each observed phenotype was determined by direct sequence analysis of the genome of the mutant virus. Mutations identified through these sequencing efforts have been further evaluated by re-introduction of the identified mutations, singly, or in combination, into recombinant dengue virus and characterization of the resulting recombinant virus for phenotypes. In this manner, a menu of attenuating and growth promoting mutations was developed that is useful in fine-tuning the attenuation and growth characteristics of dengue virus vaccine candidates. The mutations promoting growth in Vero cells have usefulness for the production of live or inactivated dengue virus vaccines.

#### **Subgenomic Replicons of the Flavivirus Dengue**

Xiaowu Pang (CBER/FDA)

[DHHS Reference No. E-228-00/0 filed 09 Mar 2001]

*Licensing Contact:* Carol Salata; 301/496-7735 ext. 232; e-mail: salatac@od.nih.gov

Dengue virus, with its four serotypes Den-1 to Den-4, is the most important member of the Flavivirus genus with respect to infection of human producing diseases that range from flu-like symptoms of dengue fever (DF) to severe or fatal illness of dengue hemorrhagic

fever (DHF) and dengue shock syndrome (DSS). Dengue outbreaks continue to be a major public health problem in densely populated areas of the tropical and subtropical regions, where mosquito vectors are abundant. This invention relates to the construction of all four types of dengue subgenomic replicons (chromosome and plasmid which contain genetic information necessary for their own replication) containing large deletions in the structural region (C-preM-E) of the genome. Immunization using these replicons should be effective in eliciting not only a humoral-mediated immune response but also a cell-mediated immune response. These replicons should be safer than a live attenuated vaccine because they cannot cause disease in the host and they should be better than subunit vaccines because they can replicate in the host.

Dated: June 22, 2001.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **National Institutes of Health**

##### **National Cancer Institute; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors, National Cancer Institute.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Board of Scientific Counselors, National Cancer Institute, Subcommittee A-Clinical Sciences and Epidemiology.

*Date:* July 23, 2001.

*Time:* 9 am to 3:30 p.m.

*Agenda:* To review and evaluate personal qualifications and performance, and competence of individual investigators.