Medical Applications Draft Guidance.'' The document was published with an outdated address in the section entitled ''Will there be transcripts of the meeting?'' This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3208, Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2011–20574, appearing on page 50231 in the **Federal Register** of Friday, August 12, 2011, the following correction is made:

1. On page 50233, in the second column, under the section entitled ''Will there be transcripts of the meeting?'' the address for the Division of Freedom of Information is corrected to read ''Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.''

Dated: August 31, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–22674 Filed 9–2–11; 8:45 am]

BILLING CODE 4160–01–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.

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.

Fully Automated Bone Mineral Densitometry on Routine CT Scans

Description of Technology: The invention relates to an improved system for measuring bone mineral density (BMD). BMD measurement is an important tool for the diagnosis of osteopenia- and osteoporosis-related fractures, a significant national health problem primarily affecting the elderly and women after menopause. More specifically, the invention relates to an algorithm and software for fully automating BMD measurement, using routine CT data and eliminating the need for a reference phantom or a specialized imaging protocol. The current standard methods not only require reference phantom to be placed underneath the patient and a specialized imaging protocol, but they also require manually placed regions of interest (ROI) to identify the appropriate bone structures. The benefit of the automated method provided in the invention is that with this system BMD measurement will be available for every patient with chest/abdominal CT scan (millions are done every year) so that the potential low bone mineral density can be discovered.

Potential Commercial Applications:

• The technique can be integrated to a CT scanner to provide automated measurement of BMD for every CT scan.

• The technique can be integrated into PACS (Picture Archiving and Communication Systems) to report BMD at the time of image interpretation by the radiologist or clinician.

Competitive Advantages: The technique can be readily integrated to existing medical imaging systems such as CT scanners (to provide BMD measurement with every CT scan) or PACS (to report BMD at the time of image interpretation).

Development Stage:

• Prototype

• In vivo data available (human)

Inventors: Ronald M. Summers *et al.* (NIH–CC)

Publication: Summers RM, et al. Feasibility of simultaneous computed tomographic colonography and fully automated bone mineral densitometry in a single examination. J Comput Assist Tomogr. 2011 Mar–Apr;35(2):212–216. [PMID 21412092]

Intellectual Property: HHS Reference No. E–218–2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Filovirus Vaccines and Diagnostics Based on Glycoprotein-Fc Fusion Proteins

Description of Technology: Ebola virus is a member of the Filoviridae, a family of viruses classified as ''Category A'' bioterrorism agents that cause severe hemorrhagic fever in humans and nonhuman primates with high morbidity and mortality rates up to 90%. This invention provides an efficacious Filovirus subunit vaccine based on a recombinant protein consisting of the extracellular domain of the Filovirus glycoprotein fused to an Fc Fragment of human immunoglobulin (FiloGP-Fc). Vaccination with FiloGP-Fc elicited humoral and cellular immunity against Filoviruses. The FiloGP-Fc vaccine induced antibodies that bound and neutralized replication-competent recombinant G-deleted Vesicular Stomatitis Virus containing the Filovirus GP (rVSV-FiloGP), and protected animals against Filovirus lethal challenge. Also described are cellular and humoral immunity tests as well as rVSV-FiloGP neutralization tests to evaluate anti-Filovirus immune responses in individuals.

Potential Commercial Applications:

• Vaccines for protection against infections by Ebola Virus and other Filoviruses.

• Diagnostic tests for cellular and humoral immunity based on FiloGP-Fc and rVSV-FiloGP to evaluate anti-Filovirus immune responses in vaccinated and infected animals and individuals.

Competitive Advantages: Filovirus vaccine candidates based on virus-like particles and virus vectors are currently under development by others. However, efficacious subunit vaccines have not yet been developed. The FiloGP-Fc fusion protein described in this invention has the advantage of resembling the native glycoprotein expressed at the surface of cells and viral particles. Thus, in addition to vaccines, the soluble FiloGP-Fc fusion proteins are ideal substrates to evaluate immune responses in animals and vaccinees.

Development Stage:

• Early-stage

• Pre-clinical

• In vitro data available

• In vivo data available (animal)

Inventors: Geraldo Kaplan (FDA), Krishnamurthy Konduru (FDA), *et al.*

Publication: Konduru K, *et al.* Ebola virus glycoprotein Fc fusion protein confers protection against lethal challenge in vaccinated mice. Vaccine 2011 Apr 5;29(16):2968–2977. [PMID 21329775]

Intellectual Property: HHS Reference No. E–222–2010/0—U.S. Patent Application No. 61/407,842 filed 28 October 2010.

Licensing Contact: Cristina Thalhammer-Reyero, PhD, MBA; 301–435–4507; *thalhamc@mail.nih.gov.*

Richard U. Rodriguez,

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

[FR Doc. 2011–22688 Filed 9–2–11; 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.

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Vaccine To Prevent BK Polyomavirus-associated Kidney and Bladder Infections in Organ Transplant Recipients

Description of Technology: Nearly all adults have chronic urinary tract infections with one or more strains of BK polyomavirus (BKV). In healthy persons, the infection is controlled by the immune system and no symptoms are apparent. However, immunosuppressed persons, such as organ transplant recipients, can suffer from bladder disease or kidney disease caused by uncontrolled BKV growth. BKV causes cancer in animals; it is unknown if the same is true in humans. A significant need remains for a means of preventing BKV infection and associated pathologies.

Researchers at the National Cancer Institute, NIH, have developed compositions and therapeutic methods for pre-vaccination of organ transplant recipients against BKV and prognostic methods to identify patients that may benefit from the vaccination. Methods for producing a BKV vaccine against all four known BKV serotypes are in development.

Potential Commercial Applications:

- An effective multivalent BKV vaccine to prevent BKV-associated pathologies of the urinary tract and bladder.
- A prognostic kit to determine clinical benefit.
- Tests for identifying renal transplant donors and recipients.

Competitive Advantages:

- A successful proof-of-principle study in mice has been conducted.
- The inventors have identified the major virulent BKV serotype.
- No vaccine for BKV infection currently exists.
- If BKV is linked to cancer, the technology might be relevant to vaccines applicable to the general public.

Development Stage:

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

Inventors: Christopher Buck and Diana Pastrana (NCI).

Publication: In preparation.

Intellectual Property: HHS Reference No. E–168–2011/0—U.S. Patent Application No. 61/508,897 filed 18 July 2011.

Licensing Contact: Patrick McCue, PhD; 301–435–5560; *mccuepat@mail.nih.gov.*

Collaborative Research Opportunity: The NCI Center for Cancer Research, Laboratory of Cellular Oncology, 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, PhD at *hewesj@mail.nih.gov.*

Gas Permeable Flasks To Grow Tumor Infiltrating Lymphocytes (TIL) for More Effective Anti-Cancer Immunotherapy

Description of Technology: Scientists at NIH have developed a strategy to obtain large quantities of highly reactive tumor infiltrating lymphocytes (TIL) from patient tumor samples for anti-cancer immunotherapy by making use of gas permeable (GP) flasks. This advancement in personalized anti-cancer immunotherapy involves culturing a tumor sample in a series of GP containers to isolate and rapidly expand TIL. The process provides suitable quantities of TIL for adoptive transfer into the cancer patient more reliably than previous approaches.

Culturing and growing TIL in the GP containers permits efficient gas exchange between TIL cells and the air to promote optimal respiration, growth, and viability of the patient's TIL throughout the process. Using GP flasks in the TIL expansion process provides for better circulation of the growth media and larger surface area so more TIL can grow per unit volume. Therefore, less reagents and fewer numbers of culture containers are need to generate the required number of TIL for adoptive immunotherapy protocols to treat cancer patients. NIH researchers have demonstrated the advantages of this GP TIL growth process in comparison to their more established TIL expansion protocols using human patient tumor samples. This new TIL production method should enable TIL therapy to become more GMP compliant and allow it to become more standardized for widespread utilization as a cancer treatment option outside of NIH.

Potential Commercial Applications:

- Adoptive cell transfer therapy (immunotherapy) for a variety of human cancers.
- Growing TIL in gas permeable cultureware has the potential to become the new standard for obtaining suitable quantities of TIL for use in adoptive immunotherapy.
- GMP grade TIL manufacture process to allow for regulatory approval of TIL therapy so that it can become a more widely available personalized cancer treatment option.

Competitive Advantages:

- Simpler, faster, less laborious, less reagent intensive, and less equipment intensive TIL growth process compared to methods of obtaining TIL without gas permeable cultureware.
- Reduces risks of microbial contamination versus comparable methodologies.
- More GMP-compliant than other TIL growing processes.
- Capable of producing larger quantities of TIL more reliably than other TIL methodologies.
- Potential to expand the number of patients and types of cancers treatable by TIL.

Development Stage:

- Pre-clinical.
- In vitro data available.
- In vivo data available (human).