cancer using fine needle aspiration (FNA) biopsy. It makes use of gene expression profiles and/or their proteins to distinguish accurately malignant thyroid nodules from benign nodules. This technique exhibits superior accuracy to current cytology-based FNA diagnosis. This improved diagnostic also has potential use for the staging and treatment of thyroid cancer, a disease that disproportionately afflicts women.

Competitive Advantage of Our Technology

The identification of markers that can determine a specific type of tumor, predict patient outcome or the tumor response to specific therapies is currently a major focus of cancer research. The use of gene profiles to detect thyroid malignancy has the advantage that it complements the current method of diagnosis using FNA, but greatly increases the accuracy of detecting malignant thyroid lesions.

Technology Description

This technology is based on the discovery of differentially expressed thyroid (DET) genes and their encoded proteins whose expression levels can be correlated to benign or malignant states in a thyroid cell. Specifically, this data arose from a microarray analysis of genes expressed in the eight subtypes of thyroid tumors that are typically difficult to diagnose by cytology of fine needle aspiration (FNA) biopsies. Analysis of the (DET) genes led to the development of a 6 gene and 10 gene model that distinguishes benign vs. malignant papillary thyroid tumors. Subsequently, a 72 gene model has been developed for diagnosing less common forms of thyroid cancer like follicular carcinoma and others. These results provide a molecular classification system for thyroid tumors and this in turn provides a more accurate diagnostic tool for the clinician managing patients with suspicious thyroid lesions.

The invention employs analysis of DET genes (C21orf4, Hs.145049, Hs.296031, KIT, LSM7, SYNGR2, C11orf8, CDH1, FAM13A1, IMPACT, and KIAA1128) using microarrays or quantitative RT–PCR (qRT–PCR) to distinguish between malignant and benign tumors. For qRT–PCR, primer and probe sequences were designed to amplify the six genes or ten genes that constitute the model. Other means of detection may also be used such as in situ hybridization, Northern blot, Western blot, and immunocytochemistry. In addition to diagnostics, this invention can be used in the staging of thyroid malignancies by measuring changes in DET gene and protein expression relative to reference cells. Finally, this invention can also be used in the discovery of therapeutic agents through the detection of changes in DET gene and protein levels prior to and after treatment.

Market

In 2008, it is expected that about 37,340 new cases of thyroid cancer will be diagnosed in the United States. Women will be disproportionately affected constituting 76% of these new cases. In contrast to other adult cancers, thyroid cancer mainly affects younger people with nearly 2 out of 3 cases found in patients between the ages of 20 and 55. Fortunately, this is one of the least deadly cancers; the percentage of people living at least 5 years after being diagnosed is about 97%.

Although thyroid cancer is one of the most curable cancers, current methods of diagnosis are inaccurate. Thyroid cancer usually presents itself as nodules or lumps on the lobes of the gland. The development of nodules is common with increasing age; however, most nodules are usually benign. To distinguish benign from malignant nodules, a biopsy is performed using fine-needle aspiration biopsy (FNA). Then this sample is examined for cytological features associated with cancer. However, cancer is clearly diagnosed in only 5% of FNA biopsies. Many biopsy results are inconclusive and labeled as suspicious or indeterminate because of difficulties in distinguishing benign and malignant thyroid tumors solely on cellular features. This result greatly impacts treatment decisions because patients with benign nodules may be subjected to unnecessary surgery that will impact their lives considerably. Thus, there is a compelling need to develop more accurate diagnostic tests to detect thyroid cancer.

Patent Estate

This technology consists of the following patent applications:

I. United States Patent Application No. 11/547,995 entitled ''Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions'' filed October 10, 2004 (HHS Ref. No. E–124–2004/2–US–03); Pre-Grant Publication No. 2008–0145841.

II. European Patent Application No. 05735973.9 entitled ''Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions'' filed April 11, 2005 (HHS Ref. No. E–124–2004/2–PCT–01); WO publication No. WO/2005/100608.

III. PCT Application No. PCT/US2008/10139 entitled ''Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions'' filed August 27, 2008 (HHS Ref. No. E–326–2007/0–PCT–01).

Next Step: Teleconference

There will be a teleconference where the principal investigator will explain this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference please call or e-mail Mojdeh Bahar; (301) 435–2950; *baharm@mail.nih.gov*. OTT will then e-mail you the date, time and number for the teleconference.

Dated: October 23, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–26334 Filed 11–4–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Center for Research Resources Special Emphasis Panel, STRB SEP.

Date: November 12, 2008.

Time: 3 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Martha F. Matocha, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm. 1070, Bethesda, MD 20892, 301–435–0810, *matocham@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 Center for Research Resources Special Emphasis Panel, SEPA 09 Review.

Date: December 15–16, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Michael L. Bloom, PhD, Scientific Review Administrator, Office of Review, National Center for Research Resources, 6701 Democracy Blvd., Room 1090, Bethesda, MD 20892, 301–435–0965, *bloomm2@mail.nih.gov*.

Name of Committee: National Center for Research Resources Special Emphasis Panel, The BIRN-Community Service Award.

Date: February 3, 2009.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Maratha F. Matocha, PhD, Scientific Review Officer, Office of Review, National Center for Research Resources, National Institutes of Health, 6701 Democracy Blvd., 1 Democracy Plaza, Rm. 1070, Bethesda, MD 20892, 301–435–0810, *matocham@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research; 93.371, Biomedical Technology; 93.389, Research Infrastructure, 93.306, 93.333, National Institutes of Health, HHS)

Dated: October 28, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26340 Filed 11–4–08; 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; Diabetes Mellitus Interagency Coordinating Committee; Notice of Meeting

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) will hold a meeting on Tuesday, December 2, 2008, on the NIH campus, Building 31, C-wing, Conference Room 6, Bethesda, Maryland 20892 from 12:30 p.m. to approximately 4:30 p.m. The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 10 days in advance of the meeting.

The DMICC facilitates cooperation, communication, and collaboration on diabetes among government entities. DMICC meetings, held several times annually, provide an opportunity for members to learn about and discuss current and future diabetes programs in DMICC member organizations and to identify opportunities for collaboration. The topic of the December meeting will be ''Using Data from Managed Care Systems to Drive Improved Therapy of Diabetes.''

Please Note: The NIH has instituted security measures to ensure the safety of NIH employees and property. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport). All visitors should be prepared to have their personal belongings inspected and to go through metal detection inspection. Visitors are strongly encouraged to take public transportation to the NIH campus as there are very few visitor parking spaces available. Building 31 is a 10-minute walk from the Medical Center Station on the Red Line of the Metro.

A registration link and information about the DMICC meeting will be available on the DMICC Web site: *http://www2.niddk.nih.gov/AboutNIDDK/CommitteesAndWorkingGroups/DMICC/Default.htm*.

For further information concerning this meeting contact Dr. Sanford Garfield, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 654, MSC 5460, Bethesda, MD 20892–5460, *Telephone:* 301–594–8803 FAX: 301–402–6271, *E-mail: garfields@mail.nih.gov*.

Dated: October 28, 2008.

Sanford Garfield,

Executive Secretary, DMICC, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, National Institutes of Health.

[FR Doc. E8–26333 Filed 11–4–08; 8:45 am]

BILLING CODE 4140–01–P

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. Appendix 2), 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, ITMA/ITSP Conflicts.

Date: November 14, 2008.

Time: 1:30 p.m. to 4:30 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: Christopher S. Sarampote, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 9608, Bethesda, MD 20892, 301–443–1959, *csarampo@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: October 29, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–26335 Filed 11–4–08; 8:45 am]

BILLING CODE 4140–01–P