

limitations imposed by the review and funding cycle.  
(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 13, 2012.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; 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:* Center for Scientific Review Special Emphasis Panel; Member Conflict: CMIP and MEDI Continuous Submission Review Panel.

*Date:* July 27, 2012.

*Time:* 1:00 p.m. to 3:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

*Contact Person:* Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301-237-9870, [xuguofen@csr.nih.gov](mailto:xuguofen@csr.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. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 13, 2012.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Prospective Grant of Exclusive License: Development of a Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions

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

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in PCT Patent Application No. PCT/US2005/12289, U.S. Patent No. 7,901,881, U.S. Patent Application No. 13/024,845 and foreign equivalents thereof entitled "Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions" (HHS Ref. No. E-124-2004/0,1,2) and PCT Patent Application No. PCT/US2008/010139 and U.S. Patent Application No. 12/675,209 entitled "Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions" (HHS Ref. No. E-326-2007/0) to Veracyte, Inc., which is located in San Francisco, California. The patent rights in these inventions have been assigned to the United States of America.

Other than license applications submitted as objections to this Notice of Intent to Grant an Exclusive License, no further license applications will be considered for the exclusive field of use set forth below if Veracyte, Inc. is granted an exclusive license pursuant to this Notice of Intent to Grant an Exclusive License. The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the diagnosis and prognosis of thyroid cancer.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 20, 2012 will be considered, in addition to the current non-exclusive applications under consideration, for the prospective license territory and

field of use to be granted under the contemplated exclusive patent license.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; Email: [hastingw@mail.nih.gov](mailto:hastingw@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** 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 6 gene and 10 gene models that distinguish benign vs. malignant papillary thyroid tumors. Subsequently, a 72 gene model has been developed for diagnosing less common forms of thyroid cancer such as follicular carcinoma. 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. 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 in changes of DET gene and protein levels prior to and after treatment.

The prospective exclusive license and any further license applications received as objections to this Notice of Intent to Grant an Exclusive License, will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Any additional applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license.