

Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 15, 2008.

**Jennifer Spaeth,**

*Director, 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**

**National Institute of Mental Health; Notice of Workgroup Meeting; Notice Is Hereby Given of a Meeting of the Strategic Planning Implementation Workgroup (SPIWG) Organized by the Interagency Autism Coordinating Committee (IACC)**

The purpose of the workgroup meeting is to discuss future budgetary requirements for the IACC Strategic Plan for Autism Spectrum Disorder (ASD) Research. The workgroup findings will be forwarded to the IACC for consideration and discussion at the next committee meeting on November 21, 2008.

Audio of this workgroup meeting will be accessible to the public via a teleconference phone link, and there will be Web-based access to information displayed at the meeting via computer/projector. Attendance at the meeting will be limited due to space available.

*Name of Committee:* Interagency Autism Coordinating Committee (IACC).

*Type of Meeting:* Strategic Planning Implementation Working Group.

*Date:* September 10, 2008.

*Time:* 11 a.m. to 3 p.m. EDT.

*Agenda:* To discuss future budgetary requirements for the IACC Strategic Plan for Autism Spectrum Disorder (ASD) Research.

*Place:* National Institutes of Health, Building 1, Wilson Hall, Bethesda, MD 20892.

*Access Information:* Conference Call and Webinar, Webinar Registration and Access Information: <https://www1.gotomeeting.com/register/550445924>. To Access the Conference Call: Dial: Number: 888-455-2920. Access Code: 3857872.

*Contact Person:* Azik Schwachter, Ph.D., Office of Autism Research Coordination, Office of the Director, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC Room 8203a, Bethesda, MD 20892-9669, 301-443-7163, [IACCPublicInquiries@mail.nih.gov](mailto:IACCPublicInquiries@mail.nih.gov).

**Please Note:** The workgroup meeting will be open to the public through a conference call phone number and a web presentation tool on the Internet. Individuals who participate using these electronic services and who need special assistance, such as captioning of the conference call or other

reasonable accommodations, should submit a request at least 2 weeks prior to the meeting.

Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. There may be an opportunity for members of the public to submit written comments during the workgroup meeting through the web presentation tool. Submitted comments will be reviewed after the meeting. If you experience any technical problems with the web presentation tool, please contact GoToWebinar at (800) 263-6317. To access the web presentation tool on the Internet the following computer capabilities are required:

A. Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later;

B. Windows® 2000, XP Home, XP Pro, 2003 Server or Vista;

C. Stable 56k, cable modem, ISDN, DSL or better Internet connection;

D. Minimum of Pentium 400 with 256 MB of RAM (Recommended);

E. Java Virtual Machine enabled (Recommended).

Information about the IACC is available on the Web site: <http://www.nimh.nih.gov/research-funding/scientific-meetings/recurring-meetings/iacc/index.shtml>.

Dated: August 15, 2008.

**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 an Exclusive License: Diagnostics Based on Immune Reactions to Brother of the Regulator of Imprinted Sites (BORIS)**

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

**ACTION:** Notice.

**SUMMARY:** This notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), announces that the Department of Health and Human Services is contemplating the grant of an exclusive license to practice the inventions embodied in PCT Application No. PCT/US2007/77281, entitled "BORIS Isoforms and Methods of Detecting and Treating Disease" filed August 30, 2007 (E-117-2006/0-PCT-02); EP Application No. 05799643.1, entitled "Method of Detecting Cancer Based On Immune Reaction To BORIS" filed September 21, 2005 (E-241-2004/0-EP-03); U.S. Application Serial No. 11/575,732, entitled "Method of Detecting Cancer Based On Immune Reaction To BORIS" filed March 21,

2007 (E-241-2004/0-US-04); U.S. Patent No. 7,375,206, entitled "Brother of The Regulator of Imprinted Sites (BORIS)" issued May 28, 2008 (E-227-2001/0-US-03); and EP Patent Application No. 03743179.8, entitled "Brother of The Regulator of Imprinted Sites (BORIS)" filed September 17, 2004 (E-227-2001/0-EP-04) to Wellstat Diagnostics, Inc.

The prospective exclusive territory may be worldwide, and the field of use may be limited to manufacture and sale of diagnostics for cancer and cancer predisposition.

**DATES:** Only written comments and/or license applications which are received by the National Institutes of Health on or before October 21, 2008 will be considered.

**ADDRESSES:** Requests for copies of the patent and/or patent applications, inquiries, comments and other materials relating to the contemplated exclusive license should be directed to: Mojdeh Bahar, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804. Telephone: (301) 435-2950; Facsimile: (301) 402-0220; E-mail: [baharm@od.nih.gov](mailto:baharm@od.nih.gov).

**SUPPLEMENTARY INFORMATION:** The above-mentioned patent applications describe the human protein Brother of Regulator of Imprinted Sites ("BORIS"), and a method of detecting cancer by monitoring BORIS expression or by detecting anti-BORIS antibodies. Dr. Victor V. Lobanekov and colleagues at the National Institute of Allergy and Infectious Diseases discovered BORIS and its potential application as a cancer diagnostic. BORIS is a paralog of CCCTC-binding factor ("CTCF"), a transcription factor that also functions in chromatin insulation. The amino acid sequences of BORIS and CTCF contain eleven conserved zinc fingers each of which binds to DNA. BORIS protein can be detected in cancer cells, and importantly, it is one of a few cancer-testis antigens that are immunogenic in humans.

BORIS resides in 20q13.2, a region that is commonly amplified in many human cancers. Normally, BORIS mRNA can be detected in testis, but not in other human tissues. However, BORIS mRNA is detectable in over one hundred cancer cell lines representing most of the major forms of human tumors and is also detectable in primary breast cancer tumor samples, but not in controls. BORIS protein is mis-expressed in cancer cell lines, and antibodies against BORIS have been detected in serum from patients with