

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.

[FR Doc. E8-19450 Filed 8-21-08; 8:45 am]

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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 Schwechter, 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.

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.

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. Lobanenko 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

gliomas, lung, breast or prostate cancers but not in serum from controls.

The correlation between cancer and BORIS expression indicates that detection of aberrantly expressed BORIS and/or anti-BORIS antibodies could serve as a method of screening or diagnosing cancer. In patients already known to have cancer, expression of BORIS could be monitored to measure a patient's response to a particular therapeutic regimen.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establish that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

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. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 14, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8-19454 Filed 8-21-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Immunotoxins as Therapeutics for Focal Muscle Spasms

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 part 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 invention embodied in issued U.S. Patent 6,780,413 entitled "Immunotoxin (MAB-Ricin) for the Treatment of Focal Movement Disorders" [HHS Ref. E-132-1996/0-US-04] to Aphrodite Therapeutics, Inc.,

which has offices in Vancouver, Canada. This patent has been assigned to the Government of the United States of America. There are no foreign patents or patent applications associated with this technology. There are no other U.S. Patents or Patent Applications associated with this technology.

The prospective exclusive license territory may be worldwide, and the field of use maybe limited to the development and sale of antibody conjugated toxins targeting the nicotinic acetylcholine receptors for therapeutic treatment of focal muscle spasms, as claimed in the Licensed Patent Rights.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before October 21, 2008 will be considered.

ADDRESSES: Requests for copy of the patent, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Betty B. Tong, PhD, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 594-6565; Facsimile: (301) 402-0220; E-mail: tongb@mail.nih.gov.

SUPPLEMENTARY INFORMATION: The invention describes immunotoxins and methods of using the immunotoxins for the treatment of focal muscle spasms. A specific immunotoxin covered by this technology is MAB-Ricin. The immunotoxins are targeted via an antibody that is specific to acetylcholine receptors present in large numbers on the muscle side of the neuromuscular junction, allowing the specific destruction of muscle cells.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) 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 part 404.7.

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. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 14, 2008.

Richard U. Rodriguez,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Strategic Prevention Framework State Incentive Grant (SPF SIG) Program (OMB No. 0930-0279) Revision

SAMHSA's Center for Substance Abuse Prevention (CSAP) is responsible for the evaluation instruments of the Strategic Prevention Framework State Incentive Grant (SPF SIG) Program. The program is a major national initiative designed to: (1) Prevent the onset and reduce the progression of substance abuse, including childhood and underage drinking; (2) reduce substance abuse related problems in communities; and, (3) build prevention capacity and infrastructure at the State/territory/Tribe and community levels.

Five steps comprise the SPF: