

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]

BILLING CODE 4140-01-P

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 may be 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:

Step 1: Profile population needs, resources, and readiness to address needs and gaps.

Step 2: Mobilize and/or build capacity to address needs.

Step 3: Develop a comprehensive strategic plan.

Step 4: Implement evidence-based prevention programs, policies, and practices.

Step 5: Monitor, evaluate, sustain, and improve or replace those that fail.

An evaluation team is currently implementing a multi-method, quasi-experimental evaluation of the first two Office of Management and Budget (OMB) approved SPF SIG cohorts receiving their first year grant awards in FY 2004 and FY 2005. This is known as the Cohort 1 and 2 Cross-Site Evaluation Study, OMB-0930-0279. This 60-Day Notice invites comment on grantee-level, community-level, and participant-level data collection instruments designed for the cross-site evaluation of 16 Cohort 3 grantees receiving grants in FY 2006 and a yet-undetermined number of Cohort 4 grantees to be

funded in the near future. Since the ultimate goal is to fund all eligible jurisdictions, there are no control groups at the grantee level. The purpose of cross-site evaluation is to measure the impact of community-funded grantees versus non-funded communities on SAMHSA's NOMs.

Data collected at the grantee, community, and participant levels using the three instruments will be combined in an analysis that investigates the relationship, if any, between the SPF process and substance use outcomes at individual and community levels. The instruments will be included in an OMB review package submitted immediately after the expiration of the comment period.

Grantee-Level Data Collection

Two instruments were developed for assessing grantee-level effects. Both instruments are guides for interviews that will be conducted by the grantees' evaluators twice over the life of the SPF SIG award. These instruments are

modified versions of those used in the SPF SIG Cohort 1 and 2 Cross-Site Evaluation Study (OMB-0930-0279). The total burden of the original instruments has been reduced by deleting several questions and replacing the majority of open-ended questions with multiple-choice questions. The *Strategic Prevention Framework Implementation Interview Protocol* will be used to assess the relationship between SPF implementation and change in the NOMs. The *Infrastructure Instrument* will capture data to assess infrastructure change and to test the relationship of this change to outcomes.

Prevention infrastructure refers to the organizational features of the system that delivers prevention services, including all procedures related to planning, data management, workforce development, intervention implementation, evaluation and monitoring, financial management, and sustainability. The estimated annual burden for grantee-level data collection is outlined below:

GRANTEE LEVEL INSTRUMENT BURDEN ESTIMATE

Interview guide	Content description	Number of respondents	Number of responses per respondent	Burden per respondent (hrs.)	Total burden (hrs.)
SPF Implementation	SEW activities, indicators for each SPF step, including cultural competence, throughout all five steps.	32	3	2	192
State Infrastructure	Assessment of a State's progress over time toward the implementation of these best practices.	32	3	3	288
Total Burden	15	480
Average Annual Burden Over Three Years.	5	160

Community-Level Data Collection (Revision)

The Community-Level Instrument is a two-part, Web-based survey for capturing information about SPF SIG implementation at the subrecipient community level. The instrument is a modified version of the one in use in the SPF SIG Cohorts 1 and 2 Cross-Site Evaluation Study (OMB-0930-0279). The total burden of the original instrument was reduced by deleting several questions.

Part 1 of the instrument focuses on the five SPF SIG steps and efforts to ensure cultural competency throughout the SPF SIG process. Part 2 will capture data on the specific intervention(s) implemented at the community level,

including both individually-focused and environmental prevention strategies. Part 2 is a modular instrument that includes separate subforms for each of the eight different intervention types. This part will be completed for each intervention implemented during the reporting period, selecting only those subforms that apply to the interventions being reported. Community partners receiving SPF SIG awards will be required to complete the entire online survey once and enter updates every six months, using a secure password system. The estimated annual burden for community-level data collection is displayed in the next table. Note that the total burden assumes an average of 15 community-level subrecipients per

grantee (a total of 480 respondents), an average of three distinct interventions implemented by each community, and two survey updates per year. Additionally, some questions will be addressed only once during the data collection process and these prior responses will populate subsequent updates. As community partners work through the SPF steps, they will report only on step-related activities. For example, needs assessment activities will likely precede monitoring and evaluation activities. Thus, respondents will answer questions related to needs assessment in the first few reports but will not address monitoring and evaluation items until later in the implementation process.

COMMUNITY LEVEL INSTRUMENT BURDEN ESTIMATE

Survey section	Content description	Average burden per response (hrs.)	Number of respondents	Number of responses per respondent	Total burden (hrs.)
Reporting Period 1					
Part I, 1–235	Community Partner Activities	39.5	480	1	1896
Part II, 1–44	Prevention Intervention Information.	1.3	480	3	1872
Part II, 45–280	Intervention-Type-Specific Information.	12.6	480	3	604.8
Reporting Periods 2–6 (updates)					
Part I, 1–235	Community Partner Activities	0.91	480	5	2184
Part II, 1–44	Prevention Intervention Information.	0.2	480	15	1440
Part II, 45–280	Intervention-Type-Specific Information.	0.15	480	15	1080
Total Burden Over Six Reporting Periods.	9076.8
Average Annual Burden Over Three Years.	3025.6

Participant-Level Data Collection (New Section)

Participant-level data will be collected from all participants in direct service programs which last 30 days or more. Two instruments will be used for this purpose, one for participants aged

12–17 (youth instrument) and another for participants aged 18 or older (adult instrument). The core sections of the two instruments will be the CSAP NOMs Adult and Youth Programs Survey Forms (OMB–0930–0230).

The participant-level instruments will be administered to each participant at

program entry, program exit, and six months after program exit. The following burden estimation is based on the assumption that each subrecipient community will serve 50 participants per year in direct-service interventions lasting 30 days or more, amounting to 12,000 participants per year.

PARTICIPANT LEVEL INSTRUMENT BURDEN ESTIMATE

Survey type	Number of respondents per year	Burden per respondent (hrs.)	Total annual burden (hrs.)
Baseline	12,000	0.83	9,960
Exit	10,800	0.83	8,964
Followup	8,400	0.83	6,972
Total	2.49	25,896
Average Annual Burden over Three Years	8,632

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at summer.king@samhsa.hhs.gov. Written comments should be received within 60 days of this notice.

Dated: August 14, 2008.

Elaine Parry,

Acting Director, Office of Program Services.
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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2008–0086]

Homeland Security Advisory Council

AGENCY: Policy Directorate, DHS.

ACTION: Notice of Open Teleconference Federal Advisory Committee Meeting.

SUMMARY: The Homeland Security Advisory Council (HSAC) will meet via teleconference for purposes of reviewing and reporting to the Secretary of the Department of Homeland Security the ten most pressing strategic-level challenges that will confront the next Secretary of Homeland Security.

DATES: The HSAC conference call will take place from 3 p.m. to 4 p.m. EST on Thursday, September 11, 2008. Please

be advised that the meeting is scheduled for one hour and we encourage all participating members of the public to call-in at the beginning of the call.

ADDRESSES: The HSAC meeting will be held via teleconference. The dial in number is 1–800–860–2442 with a PIN code of 82242#. Members of the public interested in participating in this teleconference meeting may do so by following the process outlined below (see “Public Attendance”).

If you desire to submit written comments, they must be submitted by September 5, 2008. Comments must be identified by DHS–2008–0086 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.