

applications and foreign counterparts, to NeuroMark, Inc., which has offices in Boulder, CO. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide, licensees will need to address the medical usefulness of multi-gene test formats should data be developed to support such approaches and the term of the agreement may be commensurate with commercial incentives and public health needs. The field of use may be limited to:

FDA approved diagnostic test kits for predicting the emergence of suicidal ideation subsequent to anti-depressant treatment and for screening patients to identify those patients more likely to exhibit an increased risk of treatment-emergent suicidal ideation by assaying for the presence of a genotype in the patients which is associated with an increased risk of treatment-emergent suicidal ideation.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 27, 2009 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Norbert Pontzer, Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5502; Facsimile: (301) 402-0220; E-mail: pontzern@mail.nih.gov.

SUPPLEMENTARY INFORMATION: Suicidal ideation is an uncommon symptom than can emerge during antidepressant treatment. The Food and Drug Administration (FDA) requires a black box warning of worsening depression and/or emergence of suicidality (i.e., development of suicidal thoughts or behavior) for both adult and pediatric patients taking antidepressant medications. While use of antidepressants fell after to the black box warning, studies suggest that pediatric suicides may actually be rising. This has led to concerns that the black box warning led to a decrease in treatment and resulted in an overall increase in suicides. The Sequenced Treatment Alternatives for Depression (STAR*D) trial at NIH found that versions of genes coding for components of the brain's chemical messenger system may be linked to suicidal thinking associated with antidepressant use. If links between genes and suicidal

thinking are validated under a license, depressed individuals at higher risk for suicide could benefit from closer monitoring, alternative treatments, or specialty care while allowing more aggressive treatment in individuals without the increased risk.

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 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 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.

February 18, 2009.

Richard U. Rodriguez,

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

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BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

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 SPF SIG cohorts receiving grants in FY 2004 and FY 2005. This 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 20 Cohort 4 grantees. Since the ultimate goal is to fund all eligible jurisdictions, there are no control groups at the grantee level. The primary evaluation objective is to determine the impact of SPF SIG on the SAMHSA National Outcomes Measures (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 and are the main focus of this announcement.

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 No. 09300279). 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-response 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 systems, 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

Survey type	Content description	Respondent	Burden per respondent (hrs.)	Number of respondents	Number of responses per respondent	Total burden (hrs.)
Grantee-Level Instrument (GLI)						
Grantee SPF implementation.	SEW activities; SPF activities, including cultural competence through all 5 steps.	Grantee	3.5	36	2	252
Grantee Infrastructure	Grantee progress over time toward implementation of these best practices.	Grantee	1.25	36	2	90
Total burden	342
Average annual burden over 4 Years.	85.5

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 No. 09300279). 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 individual-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 540 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 and the responses will be used to pre-fill 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 need to address monitoring and evaluation items until later in the implementation process.

COMMUNITY LEVEL INSTRUMENT BURDEN ESTIMATE

Survey type	Content description	Respondent	Burden per respondent (hrs.)	Number of respondents	Number of responses per respondent	Total burden (hrs.)
Community-Level Instrument (CLI)						
Reporting Period 1						
Part I, 1–20	Community Contact Information.	Grantee	1.5	36	1	54
Part I, 21–172	Community SPF Activities Prevention Intervention Information.	Community ..	3.0	540	1	1,620
Part II, 1–33		Community ..	.67	540	3	1,085.4
Part II, 34–138	Intervention Type-Specific Information.	Community ..	.33	540	3	534.6

COMMUNITY LEVEL INSTRUMENT BURDEN ESTIMATE—Continued

Survey type	Content description	Respondent	Burden per respondent (hrs.)	Number of respondents	Number of responses per respondent	Total burden (hrs.)
		Community ..				3,240
CLI Part I Reporting Period 2–4 (Annual Updates)						
Part I, 1–20	Community Contact Information.	Grantee25	36	3	27
Part I, 21–172	Community SPF Activities	Community ..	.75	540	3	1,215
Community-Level Instrument (CLI) Burden						
CLI Part II Reporting Periods 2–8 (Bi-Annual Updates)						
Part II, 1–33	Prevention Intervention Information.	Community ..	.33	540	21	3,742.2
Part II, 34–138	Intervention Type-Specific Information.	Community ..	.17	540	21	1,927.8
Total burden and cost: Period 2–8.		Grantee				27
		Community ..				6,885
Total burden and cost over 8 reporting periods.		Grantee				81
		Community ..				10,125
Average annual burden and cost over 4 years.		Grantee				20.3
		Community ..				2,531.3

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 the other 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 No. 09300230). Local evaluators will have the option of selecting one or more additional survey items from a standard menu of validated questions not included in the NOMs Instruments, based on site-specific targeted program outcomes. These optional questions will be added to the NOMs Instruments to create site-specific instruments. No site-specific instrument created in this fashion will exceed an average completion time of 50 minutes.

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 of the 540 community subrecipients will serve 50 participants per year in direct-service interventions lasting 30 days or more, amounting to 27,000 participants per year.

PARTICIPANT LEVEL INSTRUMENT BURDEN ESTIMATE

Survey type	Content description	Respondent	Burden per respondent (hrs.)	Number of respondents	Number of responses per respondent	Total burden (hrs.)
Participant-Level Instrument (PLI)						
Baseline		Participant83	27,000	4	89,640
Intervention completion		Participant83	22,500	4	74,700
Follow-up		Participant83	18,900	4	62,748
Total			2.5	68,400		
Total burden over 4 Years.						227,088
Average annual burden over 4 Years.						56,772

Overall SPF-SIG Data Collection

Across the three instruments, it is estimated that the average number of annual respondents will be 36 grantee-level directors, 540 community-level

directors, and 68,400 intervention-level participants. The average annual hour burden will be 685.2 hours for the 36 grantee-level directors (19 hours per grantee director); 2,531.3 hours for the

540 community-level directors (4.69 hours per community director); and 56,772 hours for 68,400 intervention-level participants (0.83 hours per intervention participant).

ALL THREE INSTRUMENT BURDEN ESTIMATE

Survey type	Respondent	Burden per respondent (hrs.)	Number of respondents	Total burden (hrs.)
GLI	Grantee	19.00	36	685.2
CLI	Community	4.69	540	2531.3
PLI	Participant83	68,400	56,772
Average Annual burden	68,976	59,988.5
Total burden over 4 Years	275,904	239,954

Written comments and recommendations concerning the proposed information collection should be sent by March 27, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: February 19, 2009.

Elaine Parry,

Acting Director, Office of Program Services.
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BILLING CODE 4162-20-P

comment period. USCIS did not receive any comments for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until March 27, 2009. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, Suite 3008, Washington, DC 20529-2210. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at rfs.regs@dhs.gov, and to the OMB USCIS Desk Officer via facsimile at 202-395-6974 or via e-mail at oir_submission@omb.eop.gov.

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0045 in the subject box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of an existing information collection.

(2) *Title of the Form/Collection:* Petition by Entrepreneur to Remove Conditions.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I-829. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals and households. This form is used by a conditional resident alien entrepreneur who obtained such status through a qualifying investment, to apply to remove conditions on his or her conditional residence, and on the conditional residence for his or her spouse and children(s).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 200 responses at 2 hours and 5 minutes (2.083) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 416 annual burden hours.

If you have additional comments, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please visit the USCIS Web site at: <http://www.regulations.gov/search/index.jsp>.

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I-829, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 30-Day Notice of Information Collection Under Review: Form I-829, Petition by Entrepreneur to Remove Conditions; OMB Control No. 1615-0045.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on December 15, 2008, at 73 FR 76038, allowing for a 60-day public