

development through collaborative research opportunities with the inventors.

A Knockout Mouse for Transcription Factor Nurr1

Dr. Vera Nikodem (NIDDK)
HHS Reference No. E-024-1999/0—
Research Tool
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Transcriptional factor Nurr1 is an obligatory factor for neurotransmitter dopamine biosynthesis only in ventral midbrain as demonstrated by the Nurr1 genomic locus inactivation using homologous recombination.

From a neurological and clinical perspective, it suggests an entirely new mechanism for dopamine depletion in a region where dopamine is known to be involved in Parkinson's disease. Clinically, our findings indicate that activation of Nurr1 may be therapeutically useful for Parkinson's disease patients; therefore, the mice would be useful in Parkinson's disease research.

Dated: January 3, 2006.

Steven M. Ferguson,

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

National Institutes of Health

Prospective Grant of Exclusive License: Anthrax Lethal Factor Is a MAPK Kinase Protease

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 (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Patent Nos. 6,485,925 B1, issued November 26, 2002, 6,893,835 B2, issued May 17, 2005, and 6,911,203 B1, issued June 28, 2005, and U.S. Patent App. No. 11/112,137, filed April 22, 2005 and published on September 8, 2005 as U.S. Pat. Pub. No. 2005/019682 A1, all titled "Lethal Factor is a MAPK Kinase Protease" (HHS Ref. Nos. E-066-1998/0-US-06, -07, -08, and -10) to Van Andel

Research Institute, of Grand Rapids, Michigan. The patent rights in these inventions have been assigned to the Government of the United States.

The prospective exclusive license territory will be worldwide. The field of use may be limited to the development and sale of Anthrax lethal factor, a MAPK kinase protease, as a therapeutic agent for the treatment of cancer.

DATES: Only license applications which are received by the National Institutes of Health on or before March 13, 2006 will be considered.

ADDRESSES: Requests for information, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Thomas P. Clouse, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: 301-435-4076; Facsimile: 301-402-0220; E-mail: clouset@mail.nih.gov. Copies of the U.S. patent publications can be obtained from <http://www.uspto.gov>.

SUPPLEMENTARY INFORMATION: The above-identified patents relates to the discovery that Mitogen Activated Protein Kinase (MAPK) signal transduction pathway is an evolutionarily conserved pathway for effecting gene regulation that controls cell proliferation and differentiation in response to extracellular signals and also plays a crucial role in regulating oocyte meiotic maturation. The above-identified patent discloses in vitro and in vivo methods of screening for modulators, homologues, and mimetics of LF mitogen activated protein kinase (MAPKK) protease activity. Mos (i.e., an oncogene first identified as the transforming determinant of Moloney Murine Sarcoma Virus) is a serine/threonine kinase which phosphorylates and activates MAPK1 kinase which in turn phosphorylates and activates MAPK. The patent also discloses that LF prevents activation of MAPK in oocytes of *Xenopus laevis* and tumor derived NIH3T3 (490) cells expressing an effector domain mutant form of the human V12HaRas oncogene. The tumor derived NIH3T3 cells reverted to a more normal morphology after LF treatment. Therefore, LF directly inhibits the Mos/MAPK pathway. Tumor cells utilize MAPK kinases in a different way than normal cells as in tumor cells there is a constitutive MAPK kinase activity. Additionally, MAPKK1 was found to be a proteolytic substrate for the metalloprotease LF. By analysis of MAPKK2, a consensus sequence for LF activity was found. The disclosure is claimed in the above-identified patent

and other patents in the same patent family.

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 establish 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.

Dated: January 3, 2006.

Steven M. Ferguson,

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 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—NEW

The Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Substance Abuse Prevention (CSAP) is responsible for the Evaluation 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 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.

Under a contract with CSAP, an evaluation team will implement a multi-method quasi-experimental evaluation at national, State, and community levels. Evaluation data will be collected from 26 states receiving grants in 2004 and 2005 and as many as 32 non-grantee states that will serve as a comparison group. The primary evaluation objective is to determine the impact of SPF SIG on the SAMHSA National Outcome Measures (NOMs).

This notice invites comment on state-level and community-level data collection instruments. The instruments for assessing state-level change 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. These instruments will be reviewed first by OMB to ensure that state-level data collection occurs as specified in the evaluation plan (on or before June 30, 2006). Because the states have not awarded community-level funding, the evaluators will not initiate community-level data collection until late in 2006. Thus, the community-level survey will be submitted as an addendum approximately one month

after the comment period expires. However, the instrument is described in this notice and comments on the instrument are invited.

State-Level Data Collection

Two instruments were developed for assessing state-level effects. Both instruments are guides for telephone interviews that will be conducted by trained interviewers three to four times over the life of the SPF SIG award. The *Strategic Prevention Framework Index* will be used to assess the relationship between SPF implementation and change in the national outcome measures. The *State Infrastructure Index* 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 state-level data collection is displayed below in the table.

STATE LEVEL BURDEN ESTIMATE

Interview guide	Content description	Number of respondents	Number of responses	Hourly burden per response	Total hourly burden
Year 1					
SPF Implementation Index	SEW activities, indicators for each SPF step, including cultural competence throughout all five steps.	26	1	3	78
State Infrastructure Index	Assessment of a state’s progress over time toward the implementation of these best practices.	26	1	6	156
Total State Level Year 1 Burden	2	9	234
Year 2					
SPF Implementation Index	SEW activities, indicators for each SPF step, including cultural competence throughout all five steps.	26	1	3	78
State Infrastructure Index	Assessment of a state’s progress over time toward the implementation of these best practices.	26	1	6	156
Total State Level Year 2 Burden	2	9	234
Year 3					
SPF Implementation Index	SEW activities, indicators for each SPF step, including cultural competence throughout all five steps.	26	1	3	78
State Infrastructure Index	Assessment of a state’s progress over time toward the implementation of these best practices.	26	1	6	156
Total State Level Year 3 Burden	2	9	234

STATE LEVEL BURDEN ESTIMATE—Continued

Interview guide	Content description	Number of respondents	Number of responses	Hourly burden per response	Total hourly burden
Average Annual State Burden.	2	9	234

Community-level Data Collection

The Community Level Index is a two-part, web-based survey for capturing information about SPF SIG implementation at the community level. Part 1 of the survey 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. Community partners receiving SPF SIG awards will be required to complete the survey every six months, using a secure

password system. The survey data will be analyzed in conjunction with state and community outcome data to determine the relationship, if any, between the SPF process and substance use outcomes. This survey will be submitted as an addendum to the forthcoming OMB package approximately one month after the expiration of the comment period. The estimated annual burden for community-level data collection is displayed below. Note that the total burden assumes an average of 15 community-level sub-grantees per state (a total of 390 respondents) and two

survey administrations per year. Note also that some questions will be addressed only once and the responses will be used to pre-fill subsequent surveys. In addition, 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 SURVEY BURDEN ESTIMATE

Survey section	Content description	Number of respondents	Number of responses	Hourly burden/response	Total hourly burden
Year 1					
Part I, 1–10	Contact Information and Reporting Period.	390	1	0.2	78
11–19	Organization Type and Funding	390	1	0.2	78
20–26	Cultural Competence, Sustainability and Framework Progress.	390	2	0.1	78
27–47	Needs and Resources Assessments	390	1	0.5	195
48–137	Capacity Building Activities	390	2	1.7	1,326
138–155	Strategic Plan Development	390	1	1.0	390
172–178	Contextual Factors and Closing Questions.	390	2	1.0	780
Sub-form 179–191	Coalition Organizational Information	390	1	1.0	390
Part II 1–52	Intervention Specific Information and Adaptations.	390	3	2.0	2,340
Review of past responses	390	2	1.0	780
Total Community Level Year 1 Burden.	16	8.6	6,435
Year 2					
Part I, 20–26	Cultural Competence, Sustainability and Framework Progress.	390	2	0.1	78
48–137	Capacity Building Activities	390	2	1.7	1,326
172–178	Contextual Factors and Closing Questions.	390	2	1.0	780
Part II 1–52	Intervention Specific Information and Adaptations.	390	3	2.0	2,340
53–60	Intervention Outcomes	390	6	1.0	2,340
Sub-forms	Intervention Component Information	390	6	1.0	2,340
Review of past responses	390	2	1.0	780
Total Community Level Year 2 Burden.	23	7.8	9,984
Year 3					
Part I, 20–26	Cultural Competence, Sustainability and Framework Progress.	390	2	0.1	78
48–137	Capacity Building Activities	390	1	1.7	1,326
156–160	Intervention Implementation	390	2	0.1	78

COMMUNITY LEVEL SURVEY BURDEN ESTIMATE—Continued

Survey section	Content description	Number of respondents	Number of responses	Hourly burden/response	Total hourly burden
172–178	Contextual Factors and Closing Questions.	390	2	1.0	780
Part II, 1–52	Intervention Specific Information and Adaptations.	390	3	2.0	2,340
53–60	Intervention Outcomes	390	6	1.0	2,340
Sub-forms	Intervention Component Information	390	6	1.0	2,340
Review of past responses	390	2	1.0	780
Total Community Level Year 3 Burden.	24	7.9	10,062
Average Annual Community Burden.	21	8.1	8,827

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 71–1044, One Choke Cherry Road, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: December 30, 2005.

Anna Marsh,

Director, Office of Program Services.

[FR Doc. E6–95 Filed 1–9–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full

certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>. **FOR FURTHER INFORMATION CONTACT:** Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, SAMHSA/CSAP, Room 2–1035, 1 Choke Cherry Road, Rockville, Maryland 20857; 240–276–2600 (voice), 240–276–2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A laboratory must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum

standards to conduct drug and specimen validity tests on urine specimens:

- ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227. 414–328–7840/800–877–7016. (Formerly: Bayshore Clinical Laboratory).
- ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624. 585–429–2264.
- Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118. 901–794–5770/888–290–1150.
- Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210. 615–255–2400.
- Baptist Medical Center-Toxicology Laboratory, 9601 I–630, Exit 7, Little Rock, AR 72205–7299. 501–202–2783. (Formerly: Forensic Toxicology Laboratory Baptist Medical Center).
- Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215–2802. 800–445–6917.
- Diagnostic Services, Inc., dba DSI, 12700 Westlinks Drive, Fort Myers, FL 33913. 239–561–8200/800–735–5416.
- Doctors Laboratory, Inc., 2906 Julia Drive, Valdosta, GA 31602. 229–671–2281.
- DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974. 215–674–9310.
- Dynacare Kasper Medical Laboratories,* 10150–102 St., Suite 200, Edmonton, Alberta, Canada T5J 5E2. 780–451–3702/800–661–9876.
- ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655. 662–236–2609.
- Express Analytical Labs, 3405 7th Ave., Suite 106, Marion, IA 52302. 319–377–0500.
- Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare, Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4. 519–679–1630.