

interests for a particular committee or device panel. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within the 60 days, the Commissioner of Food and Drugs will select the nonvoting member to represent industry interests.

#### IV. Qualifications

##### A. NMQAAC

Persons nominated for membership as an industry representative on the NMQAAC must meet the following criteria: (1) Demonstrate expertise in mammography equipment, and (2) be able to discuss equipment specifications and quality control procedures affecting mammography equipment. The industry representative must be able to represent the industry perspective on issues and actions before the advisory committee, serve as liaison between the committee and interested industry parties, and facilitate dialogue with the advisory committee on mammography equipment issues.

##### B. Medical Devices Advisory Committee

Persons nominated for the device panels should be full-time employees of firms that manufacture products that would come before the panel, or consulting firms that represent manufacturers, or have similar appropriate ties to industry.

#### V. Application Procedure

Individuals may self nominate and/or an organization may nominate one or more individuals to serve as a nonvoting industry representative. A current curriculum vitae and the name of the committee of interest should be sent to the FDA contact person (see **FOR FURTHER INFORMATION CONTACT**) within the 30 days. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. (Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process).

FDA has a special interest in ensuring that women, minority groups, individuals with physical disabilities, and small businesses are adequately represented on its advisory committees, and therefore, encourages, nominations for appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from the food production and manufacturing industry; the dietary supplement manufacturing industry;

and the agricultural biotechnology manufacturing industry.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14 relating to advisory committees.

Dated: July 16, 2007.

**Randall W. Lutter,**

*Deputy Commissioner for Policy.*

[FR Doc. E7-14206 Filed 7-23-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Proposed Collection: Comment Request; Revision of OMB; No. 0925-0001/exp. 09/30/07, "Research and Research Training Grant Applications and Related Forms"**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of Extramural Research, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection:* Title: Research and Research Training Grant Applications and Related Forms. Type of Information Collection Request: Revision, OMB 0925-0001, Expiration Date 9/30/07. *Form Numbers:* PHS 398, 2590, 2271, 3734 and HHS 568. *Need and Use of Information Collection:* The application is used by applicants to request Federal assistance for research and research-related training. The other related forms are used for trainee appointment, final invention reporting, and to relinquish rights to a research grant. *Frequency of response:* Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed. *Affected Public:* Individuals or Households; Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local or Tribal Government. *Type of Respondents:* Adult scientific professionals. *The annual reporting burden is as follows:* *Estimated Number of Respondents:* 158,820; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 15.8; and *Estimated Total Annual Burden Hours Requested:* 2,517,466. The estimated annualized cost to respondents is \$88,058,547.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Mikia Currie, Division of Grants Policy, Office of Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892-7974, or call non-toll-free number 301-435-0941, or e-mail your request, including your address to: [curriem@od.nih.gov](mailto:curriem@od.nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: July 16, 2007.

**Mikia Currie,**

*OPERA, Office of Extramural Research, National Institutes of Health.*

[FR Doc. E7-14214 Filed 7-23-07; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Government-Owned Inventions; Availability for Licensing**

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

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent

applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

### **Cytochrome P450 Inhibitors for Treatment of Cocaine-Induced Fetal Brain Injury**

*Description of Technology:* It is estimated that one percent of pregnant women use cocaine at some point in their pregnancies. In addition to increased risk for complications during pregnancy such as stillbirth, stroke, and low birth weight, cocaine appears to affect both short-term and long-term mental development. Animal studies indicate changes in brain development and behavior in response to prenatal cocaine exposure, and research has shown that children exposed to cocaine before birth are at risk of learning and behavioral problems. Children exposed to cocaine before birth are twice as likely to have significant delays in mental skills by age two. Treatment for pregnant women who use cocaine is typically directed to cocaine avoidance, but these treatments do not directly address the problem of cocaine-induced damage in the developing fetus, particularly in the fetal brain. Thus, there exists a critical need for drugs that can prevent or treat cocaine-induced damage to the fetal brain.

The inventors have demonstrated that N-oxidative metabolism of cocaine causes oxidative stress to the endoplasmic reticulum, which ultimately results in cell cycle arrest and abnormal development of the fetal cerebral cortex. They have also shown that cytochrome P450 inhibitors can block the inhibition of cell proliferation by cocaine. This invention discloses methods of using cytochrome P450 inhibitors to treat or prevent cocaine-induced fetal brain injury, as well as methods for screening for inhibitory drugs to treat or prevent cocaine-induced fetal brain injury.

*Applications:* Development of cytochrome P450-based therapeutics for fetal brain injury caused by cocaine exposure; Assay to screen for new drugs that prevent cocaine-induced fetal brain injury.

*Development Status:* The inventors plan to test cytochrome P450 inhibitors in animal models.

*Inventors:* Chun-Ting Lee and William Freed (NIDA).

*Publication:* In preparation.

*Patent Status:* U.S. Provisional Application No. 60/893,218 filed 06 Mar 2007 (HHS Reference No. E-025-2007/0-US-01).

*Licensing Status:* This technology is available for exclusive, co-exclusive, or nonexclusive licensing.

*Licensing Contact:* Tara L. Kirby, PhD; 301/435-4426; tarak@mail.nih.gov.

*Collaborative Research Opportunity:* The Cellular Neurobiology Research Branch of the National Institute on Drug Abuse is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the development of P450 inhibitors and related compounds for the prevention of cocaine-induced developmental brain damage. Please contact John D. Hewes, PhD at 301-435-3121 or hewesj@mail.nih.gov for more information.

### **Methods and Materials for Identifying Polymorphic Variants, Diagnosing Susceptibilities, and Treating Disease**

*Description of Technology:* This invention relates to materials and methods associated with polymorphic variants in two enzymes involved in folate-dependent and one-carbon metabolic pathways important in pregnancy-related complications and neural tube birth defects: MTHFD1 (5,10-methylenetetrahydrofolate dehydrogenase, 5,10-methylenetetrahydrofolate cyclohydrolase, 10-formyltetrahydrofolate synthase) and methylenetetrahydrofolate dehydrogenase (NADP + dependent) 1-like (MTHFD1L). These enzymes are extremely important in the promotion of DNA synthesis, a process that is critical for normal placental and fetal development.

Recently, the inventors have discovered that a MTHFD1 polymorphism is also a maternal genetic risk factor for placental abruption, premature separation of a normally implanted placenta. This polymorphism may also be a risk factor for first and second trimester miscarriages. Diagnostic and therapeutic methods are provided in this invention involving the correlation of polymorphic variants in MTHFD1 and MTHFD1L and other genes with relative susceptibility for various pregnancy-related and other complications such as cancer, cardiovascular disease, developmental

anomalies and psychiatric illnesses. Both nutrient status and genetic background are independent yet interacting risk factors for impaired folate metabolism. However, the mechanisms that lead to pathology or the mechanisms whereby folate prevents these disorders are unknown. Therefore, a diagnostic and therapeutic invention of this kind would significantly improve the detection and treatment of disorders associated with folate metabolism.

*Inventors:* Lawrence C. Brody (NHGRI) *et al.*

*Publications:*

1. A Parle-McDermott *et al.* MTHFD1 R653Q polymorphism is a maternal genetic risk factor for severe abruptio placentae. *Am J Med Genet A.* 2005 Feb 1;132(4):365-368.

2. A Parle-McDermott *et al.* A polymorphism in the MTHFD1 gene increases a mother's risk of having an unexplained second trimester pregnancy loss. *Mol Hum Reprod.* 2005 Jul;11(7):477-480.

3. A Parle-McDermott *et al.* Confirmation of the R653Q polymorphism of the trifunctional C1-synthase enzyme as a maternal risk for neural tube defects in the Irish population. *Eur J Hum Genet.* 2006 Jun;14(6):768-772.

4. B Kempisty *et al.* MTHFD 1958G>A and MTR 2756A>G polymorphisms are associated with bipolar disorder and schizophrenia. *Psychiatr Genet.* 2007 Jun;17(3):177-181.

*Patent Status:* International Application No. PCT/US2005/21288 filed 16 Jun 2005, which is published as WO 2007/001259 on 04 Jan 2007 (HHS Reference No. E-149-2005/0-PCT-01).

*Licensing Status:* Available for exclusive or non-exclusive licensing.

*Licensing Contact:* Tara L. Kirby, PhD; 301/435-4426; tarak@mail.nih.gov.

*Collaborative Research Opportunity:* The National Human Genome Research Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Claire Driscoll at 301-402-2537 or cdriscoll@mail.nih.gov for more information.

Dated: July 16, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-14204 Filed 7-23-07; 8:45 am]

**BILLING CODE 4140-01-P**