

postulates that passively transferred anti-leukocyte antibodies from blood donors are responsible for TRALI. The donor antibodies implicated in TRALI include antibodies directed towards HLA class I and class II antigens, and anti-neutrophil antibodies. The LAP Study is a cross-sectional multi-center study to measure the prevalence of HLA and neutrophil antibodies in blood donors with or without a history of blood transfusion or pregnancy, and the development of a repository of blood samples obtained from these donors. Specifically, 7,900 adult blood donors across six blood centers participating in the Retrovirus Epidemiology Donor Study II (REDS-II) will be enrolled in the study. Eligible donors will be asked to complete a short questionnaire on their transfusion history (ever, and date of last transfusion) and, for female donors, questions on pregnancy history (ever, number and outcome of pregnancies, last pregnancy). Each donor will also be asked to provide a sample of blood which will be tested for

the presence of HLA class I and class II antibodies. This data will help us evaluate variations in HLA antibody prevalence based on blood transfusion and pregnancy history and time since the last immunizing event. Further, neutrophil specific antibodies will be measured in those blood donors who have HLA antibodies. Also, donors with neutrophil antibodies will be tested to determine their neutrophil phenotype using routine serologic and DNA methods, since individuals homozygous for certain neutrophil antigens are more prone to develop certain neutrophil antibodies. The results from testing HLA positive donors for neutrophil antibodies in this primary study could be used to develop an optimal testing strategy for large number of donors using the stored repository samples. These data will provide the basis for calculating donor loss in the event that a TRALI prevention strategy is implemented that includes deferring donors with a history of transfusion or pregnancy or those with HLA or

neutrophil antibodies. The second major goal of this study is to develop a repository of blood samples from well characterized blood donors whose detailed transfusion and pregnancy histories are known. Repository samples will be stored indefinitely. Although future research on repository samples is yet to be determined, they may be tested for studies designed to help transfusion safety and transfusion biology.

Frequency of Response: Once. *Affected Public:* Individuals. *Type of Respondents:* Adult Blood Donors. The annual reporting burden is as follows: *Estimated Number of Respondents:* 7,900; *Estimated Number of Responses per Respondent:* 1; *Average Burden of Hours per Response:* 0.17; and *Estimated Total Annual Burden Hours Requested:* 1343. The annualized cost to respondents is estimated at: \$24,174 (based on \$18 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adult Blood Donors	7,900	1	0.17	1343

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address 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 the assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information 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 Dr. George Nemo, Project Officer, NHLBI, Two Rockledge Center, Room 10142, 6701 Rockledge Drive, MSC 7950, Bethesda, MD 20892-7950, or call 301-435-0075, or e-mail your request to nemog@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: January 20, 2006.

Charles M. Peterson,
Director, DBDR, National Institutes of Health.
[FR Doc. E6-1269 Filed 1-31-06; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: FDA Approvable Human DNA Diagnostic Test for Endometriosis

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 worldwide to practice the invention embodied in U.S. Patent

Application Number 60/654,331 filed February 18, 2005, entitled "Identification of Molecular Markers for Endometriosis in Blood Lymphocytes Using DNA Microarrays," to Ortho-Clinical Diagnostics, having a place of business in Raritan, NJ 08869. The contemplated exclusive license may be limited to an FDA approvable human DNA diagnostic test for endometriosis. The United States of America is the assignee of the patent rights in this invention.

DATES: Only written comments and/or application for a license which are received by the National Institutes of Health on or before April 3, 2006 will be considered.

ADDRESSES: Requests for a copy of the patent, inquires, comments, and other materials relating to the contemplated license should be directed to: Marlene Astor, Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: 301-435-4426; Facsimile: 301-402-0220; e-mail: ms482m@nih.gov.

SUPPLEMENTARY INFORMATION:

Endometriosis is a common, non-malignant gynecological disease that

affects up to twenty percent (20%) of women during their reproductive years. Endometriosis is characterized by the growth of endometrial tissue outside the uterus. This growth of tissue causes recurring severe pain and can lead to infertility. As the current procedure used for diagnosis is invasive and not entirely accurate, there is a need for a fast, accurate, and minimally invasive test to test for endometriosis.

Using DNA microarray analysis of blood lymphocytes, the inventors have identified two gene markers expressed in blood that are able to discriminate between those women who have endometriosis and those that don't. This new technology would be minimally invasive and quick using a blood sample from a patient.

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 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.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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 23, 2006.

Steven M. Ferguson,

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

[FR Doc. E6-1277 Filed 1-31-06; 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.

Rapid Anti-Depressant Response Produced by Low Dose Treatment with Anti-Muscarinic Drugs

Maura Furey and Wayne Drevets (NIMH).

U.S. Patent Application No. 11/137,114 filed 25 May 2005 (HHS Reference No. E-175-2004/0-US-01).

Licensing Contact: Norbert Pontzer; 301/435-5502; pontzern@mail.nih.gov.

Available for licensing are new methods of rapidly treating depression. The drugs currently used to treat depression work by increasing the activity at serotonin, norepinephrine and perhaps dopamine receptors in the CNS. However these drugs are effective in only 60-70% of patients, require 3-4 weeks of treatment before clinical improvement and have many side effects. These inventors have shown that in human patients, the administration of anti-muscarinic agents produces a rapid, prolonged alleviation of depressive symptoms. Beginning the day following administration of the anti-muscarinic agent, a majority of patients show significant improvements in mood, anxiety, sleep and other depressive symptoms that last days or weeks. The very slow dissociation of some muscarinic agents from their receptors may account for the prolonged therapeutic effects.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: January 23, 2006.

Steven M. Ferguson,

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

[FR Doc. E6-1286 Filed 1-31-06; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

State-of-the-Science Conference: Cesarean Delivery on Maternal Request; Notice

Notice is hereby given of the National Institutes of Health (NIH) "State-of-the-Science Conference: Cesarean Delivery on Maternal Request" to be held March 27-29, 2006, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on March 27 and 28, and at 9 a.m. on March 29, and will be open to the public.

Despite the national goal of reducing rates of cesarean delivery to 15 percent of births established as part of Healthy People 2010, cesarean delivery rates have continued to increase. In 2003, 1.1 million or 27.5 percent of births in the U.S. were by cesarean delivery. An estimated 2.5 percent of births that year were cesarean deliveries performed on request, in the absence of medical necessity, and the rate of cesareans on request appears to be growing rapidly over time.

The potential benefits of elective cesarean delivery as compared to vaginal delivery are not fully understood but are thought to include decreased risk of urinary incontinence, pelvic organ prolapse, anal sphincter damage and fecal incontinence. Elective cesarean delivery also has the benefit of flexible timing for mother and physician. However, like any major surgical procedure, there are risks associated with cesarean delivery. Risks that are known to be higher for cesarean deliveries than for vaginal delivery include adverse reactions to anesthesia, breathing problems, bleeding, infection, urinary tract injury, and injury to the baby. In addition, recovery time following cesarean delivery is typically longer than for vaginal delivery.

Given these risks, any decision to deliver by cesarean delivery when vaginal delivery is also available should be informed by the best possible information regarding potential health outcomes, good and bad, for both mother and baby. Toward that end, the National Institute of Child Health and Human Development and the Office of Medical Applications of Research of the National Institutes of Health will convene a State-of-the-Science Conference from March 27 to 29, 2006, to assess the available scientific evidence relevant to the following questions: