

Information Collection: Intermediate Care Facility (ICF) for the Mentally Retarded (MR) or Persons with Related Conditions Survey Report Form and Supporting Regulations at 42 CFR 442.30, 483.410, 483.420, 483.440, 483.450 and 483.460; **Use:** This survey form is needed to ensure ICF/MR provider and client characteristics are available and updated annually for the Federal government's Online Survey Certification and Reporting (OSCAR) system. It is required for the provider to fill out at the time of the annual recertification or initial certification survey conducted by the State Medicaid agency. The team leader for the State survey team must review and approve the completed form before completion of the survey. The State Medicaid survey agency is responsible for transferring the 3070 information into OSCAR. **Form Number:** CMS-3070 (OMB#: 0938-0062); **Frequency:** Reporting—Yearly; **Affected Public:** Private Sector: Business or other for-profits and Not-for-profit institutions; **Number of Respondents:** 6,437; **Total Annual Responses:** 6,437; **Total Annual Hours:** 19,311. (For policy questions regarding this collection contact Kelley Tinsley at 410-786-6664. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services Participation Report; **Form Number:** CMS-416 (OMB#: 0938-0354); **Use:** States are required to submit an annual report on the provision of EPSDT services pursuant to section 1902(a)(43)(D) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs, to determine a State's results in achieving its participation goal and to respond to inquiries. Respondents are State Medicaid Agencies. The data is due April 1 of every year so States need to have the form and instructions as soon as possible in order to report timely. **Frequency:** Yearly; **Affected Public:** State, Tribal and Local governments; **Number of Respondents:** 56; **Total Annual Responses:** 56; **Total Annual Hours:** 504. (For policy questions regarding this collection contact Cindy Ruff at 410-786-5916. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-

mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *April 5, 2010*.

OMB, Office of Information and Regulatory Affairs.

Attention: CMS Desk Officer.

Fax Number: (202) 395-6974.

E-mail:

OIRA_submission@omb.eop.gov.

Dated: February 24, 2010.

Michelle Shortt,

Director, Regulations Development Group,
Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2010-4313 Filed 3-4-10; 8:45 am]

BILLING CODE 4120-01-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.

Monoclonal Antibody to Mouse Toll-Like Receptor 3 (TLR3) Extracellular Domain

Description of Invention: The best available antibody for labeling cells

expressing mouse TLR3 is now available for licensing. It is a rat IgG2a monoclonal antibody that was generated to the extracellular domain of mouse TLR3 and specifically binds mouse TLR3 in permeabilized cells. TLR3 is located in endosomes and recognizes double-stranded RNA, a molecular signature of many viruses. This antibody would be of interest to anyone studying TLR3 distribution and localization in studies related to innate immunity and dendritic cell function.

Applications:

- Fluorescence-Activated Cell Sorting (FACS).

- Immunofluorescence.

- Immunocytochemistry.

Inventors: David M. Segal, Yan Wang, Ivett Jelinek (NCI).

Related Publication: Unpublished.

Patent Status: HHS Reference No. E-038-2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: This technology is available as a research tool (hybridoma) under a Biological Materials License.

Licensing Contact: Steve Standley, Ph.D.; 301-435-4074; sstand@od.nih.gov.

Haptoglobin for Control of the Blood Pressure Response to Plasma Free Hemoglobin

Description of Invention: Release of hemoglobin into the blood is a central pathophysiologic event contributing to morbidity and mortality in chronic and acute hemolytic anemias and severe malaria. These toxicities arise from hemoglobin-related scavenging of nitric oxide, a blood vessel vasodilator, and peroxidative chain reactions that lead to damage of the surrounding tissues. Animal models have demonstrated both an attenuation of the hypertensive response due to nitric oxide scavenging and a prevention of peroxidative toxicity. Compartmentalization of hemoglobin, rather than short-lived nitric oxide-based drugs, may represent a new therapeutic paradigm in countering the pathophysiological side effects associated with free hemoglobin.

This technology identifies haptoglobin and haptoglobin mimetics as potential therapeutics for high blood pressure and intravascular toxicity due to release of hemoglobin from red blood cells. It provides a novel process in which free hemoglobin is compartmentalized within the haptoglobin molecule. Therapeutic proof-of-principle has been demonstrated for this technology in dog and guinea pig models.

Potential Applications and Advantages:

- A therapeutic for high blood pressure and intravascular toxicity resulting from free hemoglobin in the blood (as associated with hemolytic anemias such as sickle cell disease, paroxysmal nocturnal hemoglobinuria, and thalassemia, as well as cerebral malaria).

- Compartmentalization of hemoglobin may minimize toxicities associated with cell-free hemoglobin, in contrast to currently available nitric oxide-based drugs which seek to counterbalance but not minimize these toxicities.

Development Status: Pre-clinical stage.

Inventors: Abdu I. Alayash (FDA) *et al.*

Publication: FS Boretti *et al.* Sequestration of extracellular hemoglobin within a haptoglobin complex decreases its hypertensive and oxidative effects in dogs and guinea pigs. *J Clin Invest.* 2009 Aug;119(8):2271–2280. [PubMed: 19620788]

Patent Status: U.S. Provisional Application No. 61/226,602 filed 17 Jul 2009 (HHS Reference No. E–256–2009/0–US–01)

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301–435–4521; Fatima.Sayyid@nih.hhs.gov.

A Biomarker and Therapeutic Target for Ovarian Cancer

Description of Invention: This technology provides methods of diagnosing or treating certain ovarian cancers using STAMP, a steroid cofactor.

According to the American Cancer Society, ovarian cancer is the ninth most common cancer in the United States, but is the fifth most deadly, with an estimated 14,600 deaths in 2009; the 10-year survival rate for this cancer is less than 40 percent. The majority of ovarian cancer cases are diagnosed at late-stage disease, due to the difficulty in detecting this cancer in its early stages, when symptoms are subtle.

There are currently no effective methods for early-stage diagnosis of ovarian cancer. Diagnosis is usually made through a combination of physical examination, ultrasound imaging, and a blood test for the tumor marker CA–125. The CA–125 test only returns a true positive result for about 50% of early-stage ovarian cancers, and may be elevated in other conditions not related to cancer, so it is not an adequate early detection tool when used alone.

The inventors previously discovered STAMP, a steroid cofactor that

modulates glucocorticoid receptor-mediated gene induction and repression. The inventors have now shown that STAMP mRNA levels are elevated in ovarian cancer samples, including early-stage cancers. They have also found that in a subset of ovarian cancer cell lines, introduction of STAMP siRNAs slows cell proliferation. These findings suggest that STAMP may be useful as a biomarker to detect early stage cancer in ovarian tissues, and is also promising as a therapeutic target for a subset of ovarian cancers.

Applications:

- Development of an early-stage diagnostic test for ovarian cancer.
- Development of an siRNA-based therapy for ovarian cancer.

Development Status: Discovery stage.

Market: Ovarian cancer is the fifth most-deadly cancer in the United States, and over 21,000 new U.S. cases were diagnosed in 2009.

Inventors: S. Stoney Simons *et al.* (NIDDK).

Related Publications: In preparation.

Patent Status: U.S. Provisional Application No. 61/185,503 filed 09 Jun 2009 (HHS Reference No. E–226–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Tara Kirby, PhD; 301–435–4426; tarak@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Disease Steroid Hormones Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize STAMP, a steroid cofactor. Please contact S. Stoney Simons at steroids@helix.nih.gov for more information.

Conditional V2 Vasopressin Receptor Mutant Mice as a Model To Study X-linked Nephrogenic Diabetes Insipidus (XNDI)

Description of Invention: X-linked nephrogenic diabetes insipidus (XNDI) is a severe kidney disease caused by inactivating mutations in the V2 vasopressin receptor (V2R) gene that result in the loss of renal urine-concentrating ability. At present, no specific pharmacological therapy has been developed for XNDI, primarily due to the lack of suitable animal models. This technology provides a unique and viable animal model of XNDI. NIH investigators have generated mice in which the V2R gene could be conditionally deleted during adulthood by administration of 4–OH-tamoxifen. Radioligand-binding studies confirmed the lack of V2R-binding sites in kidneys

following 4–OH-tamoxifen treatment, and further analysis indicated that upon V2R deletion, adult mice displayed all characteristic symptoms of XNDI, including polyuria, polydipsia, and resistance to the antidiuretic actions of vasopressin.

Gene expression analysis suggested that activation of renal EP4 PGE2 receptors might compensate for the lack of renal V2R activity in XNDI mice. Strikingly, both acute and chronic treatment of the mutant mice with a selective EP4 receptor agonist greatly reduced all major manifestations of XNDI, including changes in renal morphology. These physiological improvements were most likely due to a direct action on EP4 receptors expressed on collecting duct cells. These findings illustrate the usefulness of V2R mutant mice for elucidating and testing new strategies for the potential treatment of humans with XNDI.

Inventors: Jürgen Wess *et al.* (NIDDK)

Publication: Li JH, Chou CL, Li B, Gavrilova O, Eisner C, Schnermann J, Anderson SA, Deng CX, Knepper MA, Wess J. A selective EP4 PGE2 receptor agonist alleviates disease in a new mouse model of X-linked nephrogenic diabetes insipidus. *J Clin Invest.* 2009 Oct 1;119(10):3115–3126. [PubMed: 19729836]

Patent Status: HHS Reference Nos. E–174–2009/0 & E–175–2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301–435–5020; vepas@mail.nih.gov.

Collaborative Research Opportunity: The National Institute of Diabetes and Digestive and Kidney Diseases, Laboratory of Bioorganic Chemistry, Molecular Signalling Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Dr. Jürgen Wess at jwess@helix.nih.gov for more information.

Dated: March 1, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–4758 Filed 3–4–10; 8:45 am]

BILLING CODE 4140–01–P