

Dated: August 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-19806 Filed 8-3-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 76 FR 45584-45585 dated July 29, 2011).

This notice reflects organizational changes to the Health Resources and Services Administration. Specifically, this notice updates the Division of Vaccine Injury Compensation (RR4) functional statement to better align functional responsibility, improve the management and delivery of information technology services, improve management and administrative efficiencies, and optimize use of available staff resources within the Healthcare Systems Bureau (RR).

Chapter RR—Healthcare Systems Bureau

Section RR-10, Organization

Delete in its entirety and replace with the following:

The Healthcare Systems Bureau (RR) is headed by the Associate Administrator, who reports directly to the Administrator, Health Resources and Services Administration. The Healthcare Systems Bureau includes the following components:

- (1) Office of the Associate Administrator (RR);
- (2) Division of Transplantation (RR1);
- (3) Division of Health Facilities (RR9);
- (4) Division of Vaccine Injury Compensation (RR4); and
- (5) Office of Pharmacy Affairs (RR7).

Section RR-20, Functions

(1) Delete the functional statement for the Division of Vaccine Injury Compensation (RR4) and replace in its entirety.

Division of Vaccine Injury Compensation (RR4)

The Division of Vaccine Injury Compensation (DVIC), on behalf of the

Secretary of Health and Human Services (HHS), administers all statutory authorities related to the operation of the National Vaccine Injury Compensation Program (VICP) by: (1) Evaluating petitions for compensation filed under the VICP through medical review and assessment of compensability for all complete claims; (2) processing awards for compensations made under the VICP; (3) promulgating regulations to revise the Vaccine Injury Table; (4) providing professional and administrative support to the Advisory Commission on Childhood Vaccines (ACCV); (5) developing and maintaining all automated information systems necessary for program implementation; (6) providing and disseminating program information; (7) maintaining a working relationship with the Department of Justice (DOJ) and the U.S. Court of Federal Claims (the Court) in the administration and operation of the VICP; (8) providing management, direction, budgetary oversight, coordination, and logistical support for the Medical Expert Panel (MEP) contracts as well as Clinical Reviewer Contracts; (9) maintaining responsibility for activities related to the ACCV, the development of policy, regulations, budget formulation, and legislation, including the development and renewal of the ACCV charter and action memoranda to the Secretary, and the analysis of the findings and proposals of the ACCV; (10) developing, reviewing, and analyzing pending and new legislation relating to program changes, new initiatives, the ACCV, and changes to the Vaccine Injury Table, in coordination with the Office of the General Counsel (OGC); (11) providing programmatic outreach efforts to maximize public exposure to private and public constituencies; (12) providing submission of special reports to the Secretary of HHS, the Office of Management and Budget, the Congress, and other governmental bodies; and (13) providing the coordination of ACCV travel, personnel, meeting sites, and its agenda.

Section RR-30, Delegations of Authority

All delegations of authority and re-delegations of authority made to HRSA officials that were in effect immediately prior to this reorganization, and that are consistent with this reorganization, shall continue in effect pending further re-delegation.

This reorganization is effective upon date of signature.

Dated: July 29, 2011.

Mary K. Wakefield,
Administrator.

[FR Doc. 2011-19804 Filed 8-3-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Expediting Research Tools to NIH Licensees Through the Use of Pay.gov for Rapid Processing of Royalty Payments

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

ACTION: Notice.

SUMMARY: NIH licensees can now expedite the receipt of research tools through the use of Pay.gov for rapid processing of their royalty payments.

SUPPLEMENTARY INFORMATION: With its introduction earlier this year, NIH licensees have found that using the new royalty payment site within Pay.gov expedites processing times for shipment of their research tools licensed from the NIH and FDA intramural research programs. The value of such time savings to corporate R&D programs is not trivial since waiting too long to secure research materials or tools can delay or sink a critical drug development program or other business venture. By eliminating the need for bank checks, the bank-to-bank transfer system at Pay.gov has shortened the processing time for research tool and other license agreements from several months down to a day or less. For example, a recent transaction for baculovirus vectors at NIH was indeed processed in a single afternoon allowing for almost instantaneous release of the licensed materials from the inventors laboratory.

Informal comments that NIH has received to date from licensees who have started to use Pay.gov for their royalty payments include: "For Pay.gov, it's easy, convenient and fast, I guess that's what I experienced.", "It literally only took me about 5 minutes after reading the email/letter to process payment. Great service!" and "I just completed sending all the MAR payments and it was great! I am glad I decided to try the system."

Pay.gov itself is a multifaceted web-based application allowing anyone to make Automated Clearing House (ACH) payments to government agencies by debit from a checking or savings account. Pay.gov is open 24-7, and is

encouraged for use in all types of royalty payments with NIH.

FOR FURTHER INFORMATION CONTACT:

Companies looking to save time on their royalty transactions with NIH can easily pay royalties on Pay.gov by going to <https://www.pay.gov> and clicking on NIH in the agency list. Pay.gov is maintained by the U.S. Department of the Treasury. For more information about the Pay.gov system itself, visit <https://www.pay.gov/paygov/faqs.html>.

Dated: July 28, 2011.

Steven M. Ferguson,

Deputy Director, Licensing & Entrepreneurship, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2011-19821 Filed 8-3-11; 8:45 am]

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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.

CDK4-Transformed Mouse Podocytes Useful for Studying Glomerular Diseases

Description of Technology: Podocytes, cells of the visceral epithelium in the kidneys, are a key component of the glomerular filtration barrier. Podocyte damage and loss contribute to the initiation of glomerular diseases. Cyclin-dependent kinase 4 (CDK4), a catalytic subunit of the cyclin D-CDK4 serine/

threonine kinase complex, is a critical regulator of the cell cycle. Recent studies showed that cells immortalized with CDK4 are useful to study pathophysiology. NIH investigators have generated mouse podocytes transformed with CDK4 as a nonviral immortalizing gene. These transformed podocytes show podocyte characteristics and express podocyte markers. Furthermore, confluent CDK4-podocyte cultures show higher levels of gene expression for multiple podocyte differentiation genes compared with subconfluent or lower density culture.

Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.

Potential Commercial Applications:

- Model system for study of glomerular disorders.
- Useful tools to study podocyte biology.

Competitive Advantage: Better model system to study podocyte structure and function.

Inventors: Drs. Toru Sakairi and Jeffrey B. Kopp (NIDDK).

Publication: Sakairi T, *et al.* Cell-cell contact regulates gene expression in CDK4-transformed mouse podocytes. *Am J Physiol Renal Physiol.* 2010 Oct;299(4):F802-809. [PMID: 20668098].

Intellectual Property: HHS Reference No. E-287-2010/0—Research Tool (Materials available for licensing: CDK4 podocytes). Patent protection is not being pursued for this technology.

Related Technology: HHS Reference No. E-049-2007/0—Model for Study of Glomerular Disorders: Conditionally-Immortalized Mouse Podocyte Cell Line with Tet-on-Regulated Gene Expression (Dr. Jefferey B. Kopp, NIDDK).

Licensing Contact: Suryanarayana (Sury) Vepa, PhD; 301-435-5020; vepas@mail.nih.gov.

Conditionally Immortalized Human Podocyte Cell Lines

Description of Technology: Podocytes, cells of the visceral epithelium in the kidneys, are a key component of the glomerular filtration barrier. Podocyte damage and loss contribute to the initiation of glomerular diseases. NIH investigators recently established long-term urinary cell cultures from two patients with focal segmental glomerulosclerosis and two healthy volunteers, via transformation with the thermosensitive SV40 large T antigen (U19tsA58) together with human telomerase (hTERT). Characterization of randomly selected clonal cell lines from each human subject showed mRNA expression for the podocyte markers synaptopodin, nestin, and CD2AP in all

clones. Podocin mRNA was absent from all clones. The expression of nephrin, Wilms tumor 1 (WT1), and podocalyxin mRNA varied among the clones, which may be due to transformation and/or cloning. These novel human urine-derived podocyte-like epithelial cell lines (HUPECs) generated from urine of patients and healthy volunteers will be useful to study podocyte cell biology.

Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.

Potential Commercial Applications:

- Model system for study of glomerular disorders.
- Useful tools to study podocyte biology.

Competitive Advantage: These podocyte-like cells are unique and novel compared to the currently available podocyte cells because these are obtained from individuals with glomerular disease.

Inventors: Drs. Toru Sakairi and Jeffrey B. Kopp (NIDDK).

Publication: Sakairi T, *et al.*

Conditionally immortalized human podocyte cell lines established from urine. *Am J Physiol Renal Physiol.* 2010 Mar;298(3):F557-67. [PMID: 19955187]

Intellectual Property: HHS Reference No. E-252-2010/0—Research Tool. Patent protection is not being pursued for this technology.

Related Technologies:

- HHS Reference No. E-049-2007/0—Model for Study of Glomerular Disorders: Conditionally-Immortalized Mouse Podocyte Cell Line with Tet-on-Regulated Gene Expression (Dr. Jefferey B. Kopp, NIDDK).
- HHS Reference No. E-287-2010/0—CDK4-Transformed Mouse Podocytes Useful for Studying Glomerular Diseases (Drs. Toru Sakairi and Jeffrey B. Kopp, NIDDK)

Licensing Contact: Suryanarayana (Sury) Vepa, PhD; 301-435-5020; vepas@mail.nih.gov.

An In-Vitro Cell System Useful For Identification of ROR γ Antagonists

Description of Technology: The retinoid-related orphan receptors alpha, beta and gamma (ROR α , β and γ , also referred to as NR1F1, 2 and 3, respectively) comprise a distinct subfamily of nuclear receptors. Study of ROR-deficient mice has implicated RORs in the regulation of a number of biological processes and revealed potential roles for these proteins in several pathologies. NIH investigators have developed an *in-vitro* system using CHO cells stably expressing a TET-On expression vector regulating ROR γ and a RORE-Luciferase reporter. This system